The Future of Prescription Drug Promotion and Digital Marketing

Virtual Public Workshop

September 14, 2023

Speaker Biographies

Nancy M. Allen LaPointe is an Adjunct Associate Professor in Medicine at Duke University and Faculty Fellow at the Duke-Margolis Center for Health Policy. She is a researcher and cardiovascular clinical pharmacist with extensive experience in health outcomes research, health services research, evidence synthesis, medication management, and the protection of human research subjects. Her clinical and research work has been focused on patient safety, predominately in patients with cardiovascular disease. This includes work in reducing medication errors, improving medication adherence, safely and effectively translating evidence into clinical practice, comparing safety and effectiveness of therapeutics, evaluating risk communication and mitigation strategies, and exploring the interface between health policy and patient safety. Prior to working with Duke-Margolis, she was an Associate Professor in Medicine at Duke University and the Duke Clinical Research Institute, Director of the Duke Heart Center Distinguished Research Center Program, Chair in the Duke University Health System IRB, Program Director of the Duke Center for Education and Research on Therapeutics, Principal in Applied Research and Analytics at Premier Inc, and Cardiovascular Clinical Pharmacist with the Duke Heart Center. She was also a Clinical Associate Professor at UNC School of Pharmacy and Adjunct Professor of Pharmacy Practice at Campbell University School of Pharmacy and Health Sciences. Dr. Allen LaPointe received her BS in Pharmacy and Doctor of Pharmacy degrees at Purdue University and completed her pharmacy residency at the Duke University Medical Center, Department of Pharmacy, and her clinical pharmacy fellowship in cardiology at the Duke University Medical Center, Division of Cardiology. She then received a MHS with focus on comparative effectiveness research at Duke University.

Janelle Applequist (Ph.D/M.A. Penn State University) is an associate professor of advertising and public relations in the Zimmerman School of Advertising & Mass Communications at the University of South Florida. Her research focuses on mixed-methods approaches in advertising and health communication, primarily involving the pharmaceutical industry and its coordinated message design. She serves on the Patient Engagement Advisory Committee for the Food and Drug Administration (FDA), where she provides her research expertise on the following topics: agency guidance and policies, clinical trial design, device labeling, and patient reported outcomes related to mass communications. Dr. Applequist is the author of Broadcast pharmaceutical advertising in the United States: Primetime pill pushers and co-author of CTE, media, and the NFL: Framing a public health crisis as a football epidemic (2016 and 2019, Lexington Books). As a researcher focused on health communication and advertising, Dr. Applequist's expertise in the pharmaceutical advertising industry is focused on the development of normative frameworks for supporting patient education. Her research explores the

content of pharmaceutical advertisements, legal compliance with Food and Drug Administration (FDA) requirements, and issues of representation related to patients and health care pharmaceutical ads. More broadly, Dr. Applequist has also been able to successfully navigate the intersectionality of applying mass communications principles with physician-centric stakeholder adoption of innovative policy-based health infrastructure changes. Most recently, she led the research phases for the message design, testing, and dissemination for the recruitment of six international clinical trials for patients with rare diseases. She has been published in Annals of Family Medicine, Journal of the American Pharmacists Association, Journal of Medical Internet Research, BMC Medical Research Methodology, Journal of Health Communication, Qualitative Health Research, Journal of Interactive Advertising, and others. Dr. Applequist has been fortunate to bridge her research with policy, presenting her research to the FDA on multiple occasions.

Dale Cooke is the president of PhillyCooke Consulting, which helps companies communicate about FDA-regulated products using 21st century tools, while remaining compliant with regulations written in the 1960s. Dale has worked with more than 50 pharmaceutical and medical device clients and more than 30 advertising agencies around the world. His insights have been features in Politico, The Pink Sheet, Stat News, Law360, and other publications. Dale is an active member of the Regulatory Affairs Professionals Society (RAPS), Drug Information Association (DIA), Food and Drug Institute (FDLI), the Alliance for a Stronger FDA, and the Digital Health Coalition. Dale teaches in the Temple University School of Pharmacy RAQA program.

Dale is the author of *Effective Review and Approval of Digital Promotional Tactics,* which is now in its second edition in FDLI's Topics in Food and Drug Law series. He is regularly invited to speak at industry conferences on topics including FDA enforcement trends, best practices for review processes, global review practices, and life sciences use of social media.

Dale earned his B.A. in Philosophy from Southern Methodist University, an M.A. in Philosophy from the University of Arizona, studied Epidemiology and Biostatistics at Drexel University's School of Public Health, received a graduate certificate in Healthcare Compliance from Seton Hall University's School of Law, and his J.D. at Drexel University's Kline School of Law.

Anthony D. Cox, Ph.D. is a health behavior research and consultant, and Professor Emeritus at Indiana University. His work uses consumer research insights to promote healthy behaviors, improve patient health outcomes, and enhance patients' healthcare experiences. During his career he has been a co-investigator on three major NIH-funded projects; has published research in top journals in both business and health (including Journal of Marketing, Journal of Marketing Research, Journal of Consumer Research, Health Psychology and Journal of Adolescent Health); has been the recipient of multiple teaching awards, including the MBA Teaching Excellence Award, and the Schuyler F. Ottesen Undergraduate Teaching Award, and the Trustees Teaching Award; has

served as Chair of the Indiana University Physician MBA Program; and has extensive experience providing consulting and executive education in the health care industry.

Sneha Dave graduated from Indiana University in May 2020 where she majored in chronic illness advocacy as well as journalism. She created Generation Patient and its program the Crohn's and Colitis Young Adults Network (CCYAN) to develop support systems for adolescents and young adults with chronic conditions across the U.S. and internationally. She is proud to work with a team composed entirely of young adults with chronic conditions and also to keep Generation Patient and CCYAN independent from the pharmaceutical and insurance industries. Sneha has completed an undergraduate research fellowship in health policy at Harvard T.H. Chan School of Public Health. She has also interned at numerous places such as Pfizer in health economics and outcomes research for Inflammation and Immunology. Sneha has spoken on Capitol Hill, featured nationally on C-SPAN, and is a past contributor for U.S. News and World Report. She has served on the Democratic National Committee Disability Policy Subcommittee and recently joined the Midwest Comparative Effectiveness Public Advisory Council, an independent appraisal committee of the Institute for Clinical and Economic Review. She also serves on the FDA Patient Engagement Collaborative and in a grantmaking committee with the Robert Wood Johnson Foundation. Sneha was awarded two academic fellowships with the Association of Health Care Journalists. For her work, she was selected as one of the most influential teenagers in 2018 by the We Are Family Foundation and was recognized as an American Association of People with Disabilities Emerging Leader in 2020.

Andrea Downing is a BRCA Community Organizer and a security researcher. In 2022, her proof-of-concept study on cross-site trackers catalyzed follow-up investigations, and a ban on surveillance trackers by HHS and the FTC.

Her work has been featured on CNN, Fortune, and The Verge, and has catalyzed an urgent dialogue on national health privacy policy and the need for protections outside of HIPAA. Andrea has co-founded a nonprofit called The Light Collective to work with vulnerable patient groups seeking digital rights and safe spaces for patient support communities on social media.

Catherine Gray leads the Office of Prescription Drug Promotion (OPDP) in the Office of Medical Policy (OMP) at the FDA. Her diverse team of professionals focuses on the challenging and evolving policy and operational issues pertaining to prescription drug promotion. She oversees policy development, social science research, regulatory counseling, compliance activities, labeling development, stakeholder engagement, and operational support to the office as it realizes its mission to protect the public health. She previously worked in clinical pharmacy and the pharmaceutical industry. Dr. Gray's education includes a B.S. from the University of Notre Dame, a Doctor of Pharmacy from Campbell University, and fellowships through Rutgers University and the Partnership for Public Service.

Evelyn R. Hermes-DeSantis, PharmD, BCPS, is the Director for Research and Publications for phactMI and Professor Emerita at the Ernest Mario School of Pharmacy at Rutgers, the State University of New Jersey. She is dedicated to advancing and elevating the practice of medical information.

phactMI, a non-profit consortium of medical information leaders of 30+ pharmaceutical companies, focuses on increasing the awareness, credibility, and access to medical information. At phactMI, Evelyn has overseen and conducted numerous projects that have resulted in presentations and publications; precepted and mentored fellows; and has provided continuing education programs focused on medical information.

Prior to joining phactMI, Evelyn was a Clinical Professor at the Ernest Mario School of Pharmacy at Rutgers, the State University of New Jersey and Director of Drug Information Services at Robert Wood Johnson University Hospital. In her role she was dedicated to training student pharmacists, residents, and fellows in medical information skills including medical literature evaluation and application. Her research focused in the area of provision of drug information services within in institutions, the relationship between hospital and industrial pharmacy practice, and education of pharmacists. She also has expertise in research study procedure design. She worked with the Rutgers Industry Pharmacy Fellowship program and mentored numerous fellows on their research project over the years.

Evelyn received both a bachelor's degree (BS) in Pharmacy and a doctorate in pharmacy (PharmD) from Rutgers, The State University of New Jersey. She then completed a Drug Information specialty residency at the Medical College of Virginia Hospital in Richmond, Virginia prior to working at the University of Utah Hospital Drug Information Service for a few years.

Jennifer Hessler is an Assistant Professor in Film and Media Studies at North Carolina State University. Her research expertise is on the relationships between media industries, technology, and audiences, with a current focus on how the television industry collects and uses audience data. Her book on the history of audience measurement technologies, which examines the coalescence of the consumer information and cybernetics industries throughout the 20th Century, is under contract with MIT Press. Jennifer's research appears in numerous academic journals, including the Journal of Cinema and Media Studies, Television & New Media, The Velvet Light Trap, Participations: Journal of Audience Reception Research, as well as multiple book collections.

Brittne Kakulla is a senior research advisor, consumer insights in AARP Research and the research lead for the cross-enterprise Technology/Digital Connections Impact area. In these roles, Brittne engages with partners around issues related to AgeTech, with a focus on social connections and technology. This work supports AARP, the marketplace, and policy and decision-makers in understanding, engaging with, and innovating for the 50+ consumer and their families.

Brittne's work involves digging into behavior and emotions through a variety of qualitative and quantitative research studies using survey, exploratory, generative, participatory, and evaluative research methods.

Brittne also serves as an advisor for the Cornell University, Product Studio Age and Accessibility Tech cohort. In this role, Brittne advises and mentors graduate students enrolled in the Product Studio course as they develop a tech product or service in response to a "How Might We" challenge related to AgeTech and accessibility.

She holds a doctorate in social psychology from Howard University.

Michael Kubin is a 30-year veteran of the media industry, Michael Kubin began as a member of INVIDI's Board of Directors and joined the operating side three years later as Executive Vice President, Media. He acts as the evangelist for addressable television to agencies and advertisers to get them to adopt addressable television as part of their media plans, and is involved in the company's global expansion, in particular to Latin America and Europe. He also leads the Global Communications Group whose responsibilities include marketing, learning and training, and technology communications. Michael has managed a significant string of successful entrepreneurial ventures. At his first media buying company, Corinthian Media Buying, Michael was integral to the creation and growth of it

direct response subsidiary, Corinthian Direct, which grew to over $100 million in billings in just three years. After Corinthian, Michael became president of Club Med Inc., the travel company's U.S. subsidiary. Michael then co-founded Media Incorporated which, along with its direct response subsidiary, Media Direct Partners, was sold to IPG (The Interpublic Group) in 1996. Michael then went on to co-found Evaliant Media Resources, a web-based advertising tracking firm, which was sold to CMR (Taylor Nelson Sofres) in 2002. A member of several corporate boards of directors, Michael has a B.S. in operations research from Cornell, an M.B.A from Harvard Business School, and an M.S. in journalism from Columbia. His articles have been published in the New York Observer, The New York Times, and The New Yorker.

John Paul Marcus is currently the Sr. Director, Commercial Regulatory at Travere Therapeutics, a San Diego-based biopharmaceutical company focused on rare diseases. Prior to Travere, he had increasing responsibilities starting at Hospira, Takeda, AbbVie and most recently, Horizon Therapeutics. Throughout his career, he has focused on educating students at all levels via internships or pharmacy school rotations. He earned his Pharm.D. from Howard University and B.A. in Microbiology from The University of Texas at Austin.

Mark McClellan is the Robert J. Margolis, M.D., Professor of Business, Medicine and Policy and Director of the Duke-Margolis Center for Health Policy. A physician-economist focused on advancing quality and value in health care, his COVID-19 response work spans virus containment and testing strategies, resilient care delivery, and accelerating therapeutics and vaccine development. Dr. McClellan is a former leader of the Centers for Medicare & Medicaid Services and the U.S. Food and Drug Administration. An independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ, Dr. McClellan co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network and serves as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

Reshma Ramachandran, MD, MPP, MHS is a board-certified family physician and health services researcher. Her research focuses on the realignment of incentives for healthcare stakeholders including pharmaceutical companies, hospitals, and universities towards prioritizing equitable patient access to safe, effective health technologies. She co-directs the Yale Collaboration for Regulatory Rigor, Integrity, and Transparency, an interdisciplinary initiative that researches medical product evaluation, approval, and coverage towards advancing policies that improve patient outcomes. Prior to this role, Reshma worked as research faculty as part of the Innovation + Design Enabling Access (IDEA) Initiative at the Johns Hopkins Bloomberg School of Public Health, where she focused on policies to address the global challenge of antimicrobial resistance and unaffordable access to prescription drugs. Dr. Ramachandran trained in both medicine at the Alpert Medical School at Brown

University and in public policy at the Harvard Kennedy School of Government. She completed her family medicine residency at Kaiser Permanente Los Angeles Medical Center and health services research and policy fellowship at the National Clinician Scholars Program at Yale. Previously, she served as the first PharmFree Fellow with the American Medical Student Association focused on removing the undue influence of pharmaceutical companies on prescribing behavior and medical education. She currently chairs the Doctors for America FDA Task Force. She also is the Board President of Universities Allied for Essential Medicines (UAEM) North America.

Christina Silcox is the Research Director for Digital Health at the Duke-Margolis Center for Health Policy, working on policy solutions to advance innovation in health and health care and improve regulation, reimbursement, and long-term evaluation of medical products, with a focus on digital health. Dr. Silcox's portfolio includes multiple areas in digital health policy and real-world evidence, with an emphasis on medical devices. Currently, she is concentrating on challenges to regulating and adopting of artificial intelligence-enabled software as a medical device, using mHealth to collect real-world data, and characterizing real-world data quality and relevancy. Her projects have included the use of patient-generated health data in medical device evaluations, the exploration of value-based payments for medical devices, and the convening the National Evaluation System for health Technology (NEST) Planning Board.

Before she joined Duke-Margolis, Dr. Silcox was a senior fellow at the National Center for Health Research, focused on federal regulation of and policies for medical products. She earned a M.S. from the Massachusetts Institute of Technology (MIT) in Electrical Engineering and a Ph.D. in Medical Engineering and Medical Physics from the Harvard-MIT Division of Health Sciences and Technology (HST).

Amanda Starc, Ph.D., is an Associate Professor of Strategy at the Kellogg School of Management and a Faculty Research Fellow at the National Bureau of Economic Research (NBER). She received her BA in Economics from Case Western Reserve University, and her PhD in Business Economics from Harvard University. Dr. Starc's research interests include industrial organization and health economics.

Her research examines the Medicare Advantage, Medicare Part D, and Medicare Supplement ("Medigap") markets, as well as consumer behavior in insurance exchanges. Recent work measures the effectiveness of direct-to-consumer advertising of pharmaceuticals. Her work links models of consumer choice and supply side incentives, and uses a range of econometric techniques to analyze data.

Erin Willis is an associate professor at the University of Colorado Boulder in the Department of Advertising, Public Relations, and Media Design. She earned a doctorate from the University of Missouri School of Journalism, and a master's of public health from the University of Memphis. Willis's research examines the ways in which health messages influence people's behaviors. She is particularly interested in the processes by which health behavior is shaped by the information and technology that people use every day. The goal of her research is to explore how message design can influence people's understanding about health and health promotion, which is central to public health. Willis's work has appeared in notable journals such as Health Communication, Health Psychology, Health Informatics and Journal of Medical Internet Research.

Bartosz Wojdynski (Ph.D., University of North Carolina, 2011) is a behavioral social scientist studying the effects of digital message design on attention and understanding. He serves as Jim Kennedy New Media Professor at the University of Georgia, where he directs the Digital Media Attention and Cognition (DMAC) Lab which he founded in 2014. His research focuses on using eye-tracking measures to study the role visual attention plays in media message process and categorization, with a focus on consumer deception in news, advertising, and social media.

Steven Woloshin, MD, MS is a general internist, Professor of Medicine and Community & Family Medicine and Director of the Center for Medicine and the Media at the Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth (Lebanon, NH, USA). His research addresses the excessive fear and hope created by exaggerations, and selective reporting in medical journals, advertising, and the health news. He has worked to improve communication of medical evidence to physicians, journalists, policy makers and the public. He is co-author of 2 books: Know Your Chances and Overdiagnosed, his essays have appeared in the New York Times, Washington Post and Los Angeles Times and he is a founding-organizer of the international Preventing Overdiagnosis meeting sponsored by BMJ, Dartmouth, Consumers Union and Oxford and Bond Universities, and founded the Lisa Schwartz Foundation for Truth in Medicine. He serves on the editorial boards of JAMA Internal Medicine and the Cochrane Library, and the advisory board of the International Congress on Peer Review and Scientific Publication.

This project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award U01FD006807 totaling $2,975,023 with 100 percent funded by FDA/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.