The Nonprescription Drug Facts Label in a Changing Consumer Marketplace 2021

Virtual Public Workshop

Date: June 9th, 2021
Time: 8:30 am – 4:30 pm EST

Speaker Biographical Summaries

Julie Aker is a licensed clinical scientist and currently the President and CEO at Concentrics Research, a novel CRO that designs and conducts late state research including clinical trials, patient and healthcare provider research, real-world research, and most notably Rx-to-OTC Switch studies.

Julie provides consultation to pharmaceutical and device companies for regulatory and program strategy for new OTC and Rx development programs. Julie has been involved in over 1,500 consumer behavior studies and has been invited to speak with regulatory authorities in the US and ROW, in industry meetings (e.g., CHPA, RAPS, DIA, Brookings Institution, Consumer Health Products Canada) and with key agencies such as FDA, CDC, NIH, Health Canada, and MHRA.

She has been involved in creating novel research methods, teaching and contributing to manuscripts. She has over 20 years of clinical healthcare experience in large healthcare systems and over 20 years' experience in clinical research, including consumer behavior research. Ms. Aker has been invited to participate in key FDA meetings such as a Part 15 Hearing for NSURE and various Advisory Committees including those for Consumer Behavior Methods (which included input about label comprehension, self-selection and actual use studies that led to Guidances for Label Comprehension and Self-Selection), Risk Communications, Approaches Using Antivirals for Pandemics and various Advisory Committees for new drugs and devices and Microbiology Devices Panel at FDA for in vitro diagnostic devices. Julie and her colleagues also worked directly with FDA to research and publish the results of the novel OTC Naloxone labeling.

Most recently Ms. Aker has been sought to discuss the future of healthcare and how innovative technology and virtual approaches can facilitate broader access to drugs and devices for patients and consumers, areas in which Concentrics has been progressive.

Mark W. Becker, PhD, is a Professor and the Associate Chair and Director of Undergraduate Education in the Department of Psychology at Michigan State University. He leads the Attention and Perception Lab in the Cognition and Cognitive Neuroscience Program within the Department. The lab performs basic research on the allocation of visual attention and how attention influences information processing. The lab also engages in applied work, working with an interdisciplinary group that applies methods and theory from basic research in visual cognition to the design and evaluation of product labels that garner attention to critical information. The lab also investigates how basic research can be leveraged to improve the detection of rare targets in real-world visual search contexts such a baggage screening and radiology. His work has been published in in numerous outlets including: *Psychological Science, Scientific Reports, Attention, Perception, and Psychophysics, the Journal of Experimental Psychology: Human Perception and Performance, and Cognitive Research: Principles and Implications.*

Laura Bix, PhD, is the Assistant Dean for Teaching, Learning and Academic Analytics for the College of Agriculture and Natural Resources and a Professor at the School of Packaging at Michigan State University. At MSU, she has received awards for both teaching and her approach to interdisciplinary research. One of her proudest accomplishments was being named as one of the 100 most influential people in the medical device industry by Medical Device and Diagnostics Magazine (2008). At MSU, she leads a group called the Packaging HUB (Healthcare, Universal Design and Biomechanics). HUB researchers quantify the interface between people and packaging (perceptually, cognitively and physically) with the goal of improving health outcomes. Generally, HUB researchers investigate packaging issues associated with healthcare products, although they occasionally research food packaging as well. Dr. Bix has served on international and national panels convened by ISO, the US Food and Drug Administration (FDA), the US Centers for Disease Control and Prevention (CDC), the Consumer Healthcare Products Association (CHPA) and the Gerontological Society of America (GSA). Work from her group has been published or highlighted in numerous outlets, including: *PLoS One, The Proceedings of the National Academy of Sciences of the US, Consumer Reports and Men's Health.*

Cindy Brach is a Senior Health Care Researcher at the Agency for Healthcare Research and Quality (AHRQ), part of the U.S. Department of Health and Human Services (HHS). Cindy is the Co-Chair of the HHS Health Literacy Work Groups and served on the HHS Language Access Steering Committee. As the lead for AHRQ's health literacy activities, Cindy's projects have included the development of the AHRQ Health Literacy Universal Precautions Toolkit, CAHPS® Item Sets for Addressing Health Literacy, AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research, Making Informed Consent an Informed Choice: Training Modules for Health Care Leaders and Professionals, and the Patient Education Materials Assessment Tool (PEMAT).

Cindy is also AHRQ's point person for cultural and linguistic competence and served on the National Project Advisory Committee to enhance the National Standards for

Culturally and Linguistically Appropriate Services. In addition to overseeing the development of the TeamSTEPPS Limited English Proficiency (LEP) Module, Cindy commissioned and co-authored the Re-engineered Discharge Toolkit to address the needs of diverse patients. Cindy served on the National Academy of Medicine's Roundtable on Health Literacy, where she led an effort to define the ten attributes of a health literate organization. Cindy is a founding Editorial Board member of the journal HLRP: Health Literacy Research and Practice. She is a frequent speaker at national conferences and on webinars, and has published book chapters, blogs, and in journals such as Health Affairs, Journal of General Internal Medicine, Journal for Healthcare Quality, Journal of Health Communication, and Medical Care.

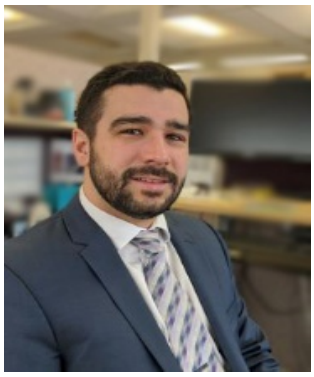
Dr. Eric Brass received his M.D. and Ph.D. (Pharmacology) degrees from Case Western Reserve University. He completed an internal medicine residency and clinical pharmacology fellowship at the University of Washington. After holding faculty positions at the University of Colorado and Case Western Reserve 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. Dr. Brass has authored over 180 scientific papers.

Jesse Catlin is an Associate Professor of Marketing at California State University, Sacramento. His research focuses on consumer behavior, with an emphasis on pharmaceutical marketing and health decision-making, including how consumers process and interpret over-the-counter drug information. He holds a Ph.D. in Management with an emphasis in Marketing from the University of California, Irvine in addition to M.A. and B.A. degrees in Economics from California State University, Sacramento.

Terry C. Davis, PhD, is a Professor of Medicine and Pediatrics and the Feist Weiller Cancer Center at the LSU Health Science Center at Shreveport, Louisiana. For the past 40 years, she has investigated the impact of patient literacy on health and health care, and has more than 160 publications related to health disparities and health communication. Her achievements include the development of the Rapid Estimate of Adult Literacy in Medicine (REALM), the most widely used test for literacy in medical settings, and user-friendly patient education and provider training materials that are used nationally.

Dr. Davis has served on health literacy advisory boards for the American Medical Association and the American College of Physicians as well as on the FDA's Center for Drug Evaluation and Research. She is a member of the National Academies' Roundtable on Health Literacy, serves on the U.S. Pharmacopeia Convention Expert Panel on Health Literacy and the National Institute of Nursing Research Strategic Plan Working Group. On a state level, she is the Health Literacy Director on a NIH-sponsored IDeAS grant, where she trains investigators in 11 academic institutions across Louisiana and co-leads the North Louisiana Community Advisory Board.

Dr. Davis has a productive record of federally funded research developing and implementing literacy and culturally appropriate interventions to improve the health outcomes of vulnerable populations. Her wide-ranging work focuses on improving cancer screening in rural federally qualified health centers, the self-management of diabetes in safety net settings, the use of health coaches to facilitate weight loss in community clinics, and improving prescription medication adherence and labeling. Recently her research has investigated racial and rural disparities in access and acceptance of clinical trials, COVID -19 testing and vaccinations. She was appointed to serve on the Governor's COVID -19 Health Equity Task Force.



Jason DiMuzio is the Manager of Label Review in the Non-prescription Drugs Evaluation Division, Natural and Non-prescription Health Products Directorate (NNHPD), Health Canada. In his current role, Jason applies expertise in the implementation of plain language labeling during the pre-market assessment of non-prescription drugs. Prior to this role, he worked in submission coordination for both non-prescription drugs and natural health products, and in risk communication evaluation. Jason holds a Master of Science in Health: Science, Technology and Policy from Carleton University and an Honours Bachelor's Degree with Specialization in Chemistry from the University of Ottawa.

Barbara A. Kochanowski, PhD, is Sr. Vice President, Regulatory and Scientific Affairs at the Consumer Healthcare Products Association (CHPA), the national trade association representing manufacturers and marketers of consumer healthcare products, including over-the-counter medicines, dietary supplements and consumer medical devices. Prior to joining CHPA in 2009, Dr. Kochanowski worked for more than 23 years in Research and Development at The Procter & Gamble Company (P&G), before retiring in December 2008 as director of global personal health care, oral care, and feminine care product safety and regulatory affairs and corporate microbiology. While at P&G, Dr. Kochanowski was very active in CHPA activities, serving as chair of the Scientific Affairs Committee from 2007-2008.

Kochanowski is a member of the American Society of Nutrition. She also serves on the board of directors of the American Foundation for Pharmaceutical Education. She received her M.S. and Ph.D. degrees from the University of Illinois, Division of Nutritional Sciences.

Stephen Konya serves as the Senior Advisor to the Deputy National Coordinator, and Innovation Portfolio Lead for the Office of the National Coordinator for Health IT (ONC), U.S. Department of Health and Human Services (HHS). In addition to his role in helping shape the Agency's long-term strategy, he also serves as the Agency's primary liaison for innovation related projects and challenges, specifically targeting engagement opportunities with the healthcare startup and investor communities. Prior to his position with the Federal Government, he served concurrently as Chief of Staff, Chief Operating Officer, and Chief Results Officer for the Illinois Department of Public Health, and Chief of Staff for the IL Department of Commerce and Economic Opportunity. He holds a BBA in Finance and International Business from Loyola University of Chicago, and was both a Fellow and Mentor of the Mid-America Regional Public Health Leadership Institute (MARPHLI) program, at the University of Illinois-Chicago (UIC), School of Public Health.

Dr. Kevin Lorick received a Bachelor of Science degree in Biological Chemistry from the University of Chicago and a Ph.D. in Molecular and Cellular Biology from Tulane University.

He moved to the National Cancer Institute where he conducted research in protein degradation, discovering the Ubiquitin ligase potential of RING finger proteins. He spent time in industry as a synthetic chemist and later, as a cell biologist.

He came to FDA's Center for Devices and Radiologic Health (CDRH) in 2009 as a premarket reviewer and consumer safety officer; primarily for Pathology devices in the Office of In Vitro Diagnostics.

He came to CDER and what is now the Office of Nonprescription Drug products in 2016 and serves as a Lead Interdisciplinary Scientist, specializing in labeling for analgesic, gastrointestinal, and smoking cessation drug products for the OTC market.

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Dr. Ruth Parker is Professor of Medicine, Pediatrics and Public Health, and a Sr. Fellow in Ethics at Emory University in Atlanta, Georgia. She attended Davidson College and the University of North Carolina at Chapel Hill School of Medicine, completed residencies in Internal Medicine and Pediatrics at the University of Rochester, and was a Clinical Scholar at the University of Pennsylvania. For three decades, she has advanced research, education, and policy efforts to improve our nation's health literacy. Her focus is on using the best available evidence to make demands and complexities of health and healthcare align with the skills and abilities of people to navigate, understand and use what is needed for health. She is an author of the Test of Functional Health Literacy in Adults (TOFHLA) and co-author of a widely used definition of health literacy. She is a National Associate of the National Research Council of the National Academy of Sciences, and serves on Advisories to the FDA and PCORI.

Dr. Parker served in leadership roles for professional societies and consulted with numerous federal and state agencies, professional organizations and members of industry regarding their health literacy efforts. She received the Silver Achievement Award from the AAMC, the Richard and Hinda Rosenthal Award from the ACP, the Walter C. Alvarez Award from the American Medical Writers Association, the Cecilia and Lenard Doak National Health Literacy Award, and an FDA Advisory Committee Service Award. At Emory University, she received the Thomas Jefferson award and is founding Co-Director of TRACE (The Renaissance Academy at the Center for Ethics), where her efforts support cross-disciplinary work to integrate health and the humanities.

Amanda Pike-McCrudden is a Social Science Analyst in the Division of Nonprescription Drug Products 1 (DNDP1), a division within the Office of Nonprescription Drugs (ONPD) of FDA's Center for Drug Evaluation and Research (CDER) charged with reviewing over the counter products. Pike-McCrudden joined FDA in 2015 as a Fellow before transitioning to her current role in 2016. She previously worked in program evaluation and implementation for a variety of nonprofit, museum, and government organizations. Trained as a Medical Anthropologist, she is interested in the intersections of culture and health, and has conducted extensive fieldwork in the areas of health education, maternal health, immigration and migration.

Clark Richardson is the President & CEO of PEGUS Research, an entity focused almost entirely on developing and testing new over-the-counter Drug Facts Labels. Clark routinely assists pharmaceutical clients in program development and interactions with the US FDA, is a frequent speaker and presenter, and advocates for new tools and technologies to enhance communication of critical drug-related, consumer-oriented information. After nearly 24 years of consumer behavior research at PEGUS, Clark brings a wealth of practical knowledge and experience to timely dialogue about re-envisioning and re-defining the Drug Facts Label.

Dr. Betsy Scroggs is Associate Director for Labeling in the Office of Nonprescription Drugs under FDA's Office of New Drugs (OND)/Center for Drug Evaluation and Research (CDER).

She is a pharmacist by training and received her Doctor of Pharmacy degree from the University of Maryland College of Pharmacy and BS Pharm from the University of Arkansas for Medical Sciences College of Pharmacy.

Since 2002, she has served in a variety of FDA positions, all within CDER. Prior to her current position, she was an Interdisciplinary Science team leader and review scientist. Other roles at FDA have included pharmacovigilance review within the Office of Surveillance and Epidemiology. Earlier in her FDA career she served as a Regulatory Health Project Manager in the Division of Gastrointestinal Products.

Dr. Jovonni Spinner is an award-winning public health strategist and thought leader with a deep passion for advancing health equity across the lifespan through research, communication, multi-sector partnerships, and leadership coaching. She creates culturally-competent and inclusive public health programming, but also shines at telling public health stories, giving voice to those rarely heard, and sharing outcomes with key influencers to provide programmatic strategic direction. She believes in building systems where health is a priority and supports people to make the best-informed health decisions.

In her current role at FDA, she serves as the Associate Director for Outreach and Communications in the Office of Minority Health and Health Equity. In this role, she oversees the strategic direction of the outreach and communications team, advises senior leadership on minority health, health disparities and health equity, and is recognized as an expert leader in meaningfully engaging minority stakeholders and implementing health education and promotion programs.

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Over the course of her career, she has led state and national health equity driven programs like FDA's Diversity in Clinical Trials Initiative, NIH's Community Health Worker Health Disparities Initiative, and the Virginia Vaccines for Children Program which have reached millions of consumers to help them make better informed health decisions, obtain the services they need, and advocate for healthier communities.

Dr. Spinner is an adjunct professor teaching courses on public health programing and social determinants of health. She serves on non-profit boards, writes women's health articles, and is active in her community by delivering programs to build the public health workforce and mentoring early-career professionals.

She is an alum of Virginia Commonwealth University, Emory University, and Morgan State University.

Elisabeth Walther, PharmD, JD, is the Acting Associate Director for Strategic Initiatives in the Office of Nonprescription Drug Products at FDA. She currently leads regulatory policy development programs and initiatives related to nonprescription drug products. She also continues to practice as a community pharmacist.

Michael Wolf, PhD, MPH, MA, is the James R. Webster, Jr. Professor of Medicine, Associate Division Chief for General Internal Medicine and Geriatrics, and Associate Vice Chair of Medicine at the Feinberg School of Medicine at Northwestern University. In addition, he is the Director of the Center for Applied Health Research on Aging (CAHRA), as well as a National Institute on Aging Claude D. Pepper Older Americans Independence Center. Dr. Wolf is a health services researcher and cognitive/behavioral scientist who studies health literacy, cognitive aging, and self-management of chronic conditions, with specific interests in medication safety and adherence. He led the first clinical trials, funded by AHRQ, testing patient-centered drug labeling strategies that included a Universal Medication Schedule to promote safe use of prescription regimens.

H. Shonna Yin, MD, MSc, is a general pediatrician and an Associate Professor of Pediatrics and Population Health at the NYU School of Medicine. A large focus of her research involves examining the intersection between health literacy and medication safety, including the development and evaluation of low literacy strategies to improve parent understanding of medication instructions. Dr. Yin has served as PI of several NIH/NICHD grants, including an R01 study to identify best practices in the labeling/dosing of pediatric prescription medication labels and dosing tools, and an R21 to examine a web app to support safe medication dosing by parents after their baby is discharged from the neonatal intensive care unit. She served as PI of an FDA Safe Use-funded project focused on improving OTC pediatric cough/cold product labeling, and is currently PI of another FDA project to use an EHR eRx-based intervention to support pharmacy adoption of best practices with respect to dosing instructions and dosing tool provision. Her RWJ Foundation and NIH/NICHD-supported research focused on improving the labeling/dosing of pediatric medications using a health literacy perspective was extensively cited in an American Academy of Pediatrics (AAP) Policy Statement, and led her to be awarded the Institute for Safe Medication Practices (ISMP) Cheers Award in 2017. Dr. Yin has been a key member of the CDC's PrOTECT initiative to reduce medication overdoses in children since it was formed in 2008, and serves as an Executive Committee Member of the AAP's Council on Quality Improvement and Patient Safety. 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.