Tobacco Science Symposium
March 30, 2023
Speaker Biographies

JASJIT SINGH AHLUWALIA is a physician and public health scientist at Brown University's School of Public Health and Medicine and is the Associate Director of the Legoretta Cancer Center. He has been in academic medicine since 1992 and has been a practicing physician, faculty member, department chair, associate dean and center director in medical schools, and dean of the School of Public Health. His primary research areas are smoking cessation and nicotine addiction in African American smokers. He has been continuously funded by the National Institutes of Health for 25 years and has published more than 350 manuscripts. Ahluwalia has served on the U.S. government's National Advisory Council on Minority Health and Health Disparities, on the SRNT board of directors and just completed a 3-year term on the federal government's Interagency Committee on Smoking and Health chaired by the U.S. Surgeon General. Ahluwalia trained at New York University, received a Doctor of Medicine degree and a Master of Public Health degree at Tulane University, a medical residency at the University of North Carolina at Chapel Hill and a clinical epidemiology fellowship at Harvard Medical School, where he received a master's degree in health policy.

ELIZABETH BECKER serves as Senior Director, Population Science within the Regulatory Sciences organization of Altria Client Services (ALCS) in Richmond, VA. In this role, she leads a team of scientists who develop and execute perception and behavior research and narrative strategies to support product applications and regulatory submissions. Elizabeth oversees research to understand the impact of new products, claims and marketing on tobacco user and nonuser perceptions, intentions, and behaviors. Since 2005, Elizabeth has held a variety of positions across Altria. Elizabeth started her career supporting underage tobacco prevention and cessation support research and has since held roles in Corporate Communications and Innovation. Prior to joining Regulatory Sciences in 2018, Elizabeth led Altria's Corporate Responsibility efforts. Elizabeth received her Master Business Administration from University of Massachusetts Amherst, Amherst in 2010, and her B.S. Psychology from Virginia Commonwealth University in 2004.

ARUNI BHATNAGAR is Professor of Medicine and Distinguished University Scholar at the University of Louisville. He is the Director of the Christina Lee Brown Envirome Institute and Co-Director of the American Heart Association Tobacco Regulation Center. He is a leading expert on the mechanisms by which environmental exposures such as air pollution affect cardiovascular disease risk. Dr. Bhatnagar's initial work involved the purification and characterization of aldose reductase and its role in diabetic complications. To this end, he established the identity of this enzyme in several tissues and investigated its structural, kinetic, and inhibitory properties. His work has shown that increasing NO availability prevents aldose reductase activation and sorbitol accumulation in diabetic tissues. Additionally, his recent studies show that glucose activates

multiple protein kinases and that the activation of these kinases is required for the inflammatory effects of glucose in vascular tissues. At UofL, Dr. Bhatnagar's work also led to elucidation of the mechanisms by which free radicals and lipid peroxidation products affect the function of individual ion channels. He was the leader of a Program Project Grant from the NIEHS to study the cardiovascular toxicity of environmental aldehydes. In this program-project he directed a large multi-disciplinary team of investigators studying the molecular and cellular mechanisms of aldehyde toxicity. His studies at UofL have led to the development of the new field of Environmental Cardiology. He was the Deputy Editor of Circulation Research for 10 years. He has participated in over 50 NIH review panels and chaired several review panels. He was the recipient of the President's Award for Outstanding Scholarship, Research and Creative Activity, University of Louisville, and Partner in Healthcare Award – Contributing to Greater Louisville Healthcare Community, in 2007. In 2007, he also received the first Outstanding Faculty Mentor of Graduate Students, and the Outstanding Mentor Award from the Conference of Southern Graduate Schools. In 2017, he was designated Research Exemplar by Washington University. Dr. Bhatnagar has published 378 peer-reviewed manuscripts, 25 book chapters and reviews and over 200 abstracts. He has mentored 61 graduate students and post-doctoral fellows in his laboratory and has served on the dissertation committee of 18 PhD students.

CHRISSIE CAI is a Data Quality Management Team Supervisor at the Division of Regulatory Science Informatics, Office of Science at the Center for Tobacco Products of FDA. Her passion lies in data standards, and she strongly believes that they play an essential role in ensuring that data is both usable and meaningful. As a new member of the Tobacco Implementation Guide (TIG) project, Chrissie is currently overseeing the development of TIG v1.0 standards in collaboration with CDISC. Furthermore, she is leading the Data Governance and Data Management initiatives at CTP, constantly seeking ways to improve the data management processes within her organization. While Chrissie was at NIH, she had a track record of successfully leading numerous international clinical trials, implementing CDISC data standards to enhance data quality.

TODD CECIL is currently the Deputy Director of Regulatory Management in the Office of Science of CTP. He has served as the Acting Director of the Office of Science during portions of the past 9 months. Todd joined CTP in 2015 and has served in many roles within the Office of Science from a chemistry reviewer, through several leadership roles. He has also served in the Technical Project Lead role for SE, EX, and PMTA programs. Prior to joining FDA, Todd spent over 23 years at the United States Pharmacopeia (USP), were he served as the Vice-president of Compendial Science. Todd also served as the USP member of the International Council on Harmonization (ICH) and as the representative of the Pharmacopeial Discussion Group (PDG). Both of these organizations focused on developing globally harmonized standards for the pharmaceutical industry and regulatory partners. He received his Bachelor's degree in Chemistry from the University of Iowa and Ph.D. in Analytical Chemistry from Virginia Commonwealth University.

CHRISTINE CONNOLLY

GAL COHEN

GEOFFREY T. FONG is Professor of Psychology and Public Health Sciences at the University of Waterloo and Senior Investigator at the Ontario Institute for Cancer Research. Professor Fong leads the International Tobacco Control Policy Evaluation Project (the ITC Project), the first-ever international cohort study of tobacco use and tobacco control policy impact in 31 countries covering over half of the world's population and over two-thirds of the world's tobacco users. Over two decades, the ITC Project has conducted landmark evaluation studies of graphic warnings, smoke-free laws, changes in tobacco tax rates and tax structure, restrictions on tobacco advertising and marketing, plain packaging, and more recently key product regulations, including menthol cigarette bans in Canada, Netherlands, and England. Since 2016, the ITC Project has engaged in a 7-country longitudinal comparison of the interaction between cigarettes and non-combustible tobacco/nicotine products such as e-cigarettes and heated tobacco products, and the impact of policies on both cigarettes and these other nicotine products on that interaction. These include ongoing longitudinal cohort studies in Japan and the Republic of Korea. Professor Fong contributed to the creation of the FDA/NIDA Population Assessment of Tobacco and Health (PATH) Study, and he is a member of the PATH Scientific Leadership Group. Professor Fong was Technical Coordinator of the WHO FCTC Impact Assessment Expert Group, which conducted the official evaluation of the WHO Framework Convention on Tobacco Control—the global tobacco control treaty—in its first decade. He has served as an expert consultant for WHO, the FCTC Secretariat, and many countries, including Uruguay and Australia whose policies were successfully defended in legal challenges brought via trade treaties. Among Professor Fong's awards are the WHO World No Tobacco Day Award, Luther Terry Award for Outstanding Research Contribution, Health Research Foundation Medal of Honour, Alton Ochsner Award Relating Smoking and Disease, SRNT John Slade Award, AAPOR Policy Impact Award, CIHR Knowledge Translation Award, and the Governor General's Innovation Award. In 2021, Professor Fong was appointed an Officer of the Order of Canada.

JONATHAN FOULDS is a Professor of Public Health Sciences and Psychiatry at Penn State University, College of Medicine. His recent research has focused on the effects of switching to reduced nicotine cigarettes and the effects of electronic cigarettes. He has published over 150 papers in peer-reviewed scientific journals and continues to treat addicted smokers, teach on smoking cessation and conduct research on tobacco and health at Penn State College of Medicine in Hershey, PA.

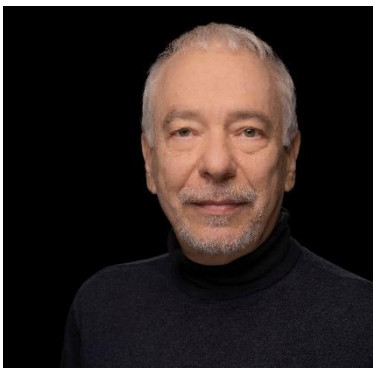
J. BENNEVILLE (BEN) HAAS is a partner at the law firm of Latham & Watkins LLP in Washington, DC, and a corporate partner in the firm's Health Care and Life Sciences Practice Group. Mr. Haas focuses his practice on

regulatory, transactional, and legislative matters involving the medical device, pharmaceutical, biotechnology, tobacco, food, cosmetic, and dietary supplement industries. He has counseled clients on a wide variety of regulatory matters involving FDA, including, among others, premarket product development and clinical and pre-clinical testing; FDA submissions; product promotion and labeling; compliance with good manufacturing practice requirements; agency inspections, and recalls. Mr. Haas recently co-authored FDLI's "Tobacco and Nicotine Delivery Regulation and Compliance" reference book. He has also authored and co-authored articles on FDA regulatory matters, including articles in the Food and Drug Law Institute's Update Magazine and the Pharmaceutical Law & Industry Report, and has been a featured speaker and lecturer on FDA regulatory and policy matters at industry-sponsored events. He also served as a member of the firm's Global Training and Career Enhancement Committee. Mr. Haas received a BS from Georgetown University and a JD from the University of Virginia School of Law.

DOROTHY K. HATSUKAMI is the Associate Director of Cancer Prevention and Control and also Director of the Tobacco Research Programs. She also holds adjunct appointments in the Departments of Psychology and Division of Epidemiology in the School of Public Health. Dr. Hatsukami is an expert in the areas of nicotine addiction and treatment of nicotine addiction among the general population of adult smokers, as well as adolescents. She has also conducted extensive research in the area of smokeless tobacco. Most of her efforts have been focused on development or testing of medications, including a nicotine vaccine and combination medications, in these populations. Additionally, she has expertise in tobacco product evaluation and methods to reduce tobacco harm. She was the Principal Investigator of a Transdisciplinary Tobacco Use Research Center. Dr. Hatsukami has authored or co-authored about 300 journal articles, monographs, book chapters, and other publications. Dr. Hatsukami has served on numerous national committees, is a past president of the Society on Research on Nicotine and Tobacco, and a past president of the College on Problems of Drug Dependence.

CHRISTOPHER JUNKER serves as Vice President, Scientific & Regulatory Affairs for RAI Services Company in Winston-Salem, NC. In this role, he is responsible for regulatory strategy and engagement, leading a multidisciplinary team of scientists and regulatory experts in the synthesis of premarket regulatory submissions for RAI's electronic nicotine delivery systems (ENDS) and oral tobacco product portfolios. Dr. Junker has held successive leadership roles within Scientific & Regulatory Affairs. Most recently, he served as Vice President, Regulatory Sciences, where he led a team of scientists and regulatory specialists across preclinical toxicology, clinical studies, population health research, statistics, and electronic publishing, developing the scientific substantiation for the company's Premarket Tobacco Product Applications and supporting external science engagement. Previously, Chris led teams within Submissions & Engagement focused on RAI's smokeless tobacco and cigarette portfolios and a team within Analytical Research. Before joining Reynolds American in 2011, Dr. Junker received his PhD in Synthetic Organic Chemistry from Wake Forest University (2011) and BS in Chemistry from Catawba College (2007).

DAVID LEVY



SAUL SHIFFMAN, PhD is Research Professor of Psychology (Clinical and Health Psychology), Psychiatry, Pharmaceutical Sciences, and Clinical Translational Science at the University of Pittsburgh. He also serves as Senior Scientific Advisor at Pinney Associates, which consults exclusively to JUUL Laboratories on e-cigarettes and tobacco harm reduction. Dr. Shiffman has published over 450 scientific papers on topics including smoking patterns, nicotine dependence, smoking cessation and relapse, smoking cessation treatment, e-cigarette use, and tobacco harm reduction. His papers have received over 50,000 citations in the scientific literature. Dr. Shiffman has worked on research in support of several product applications submitted to the FDA Center for Tobacco Products.

JIM SOLYST is Principal with JMS Scientific Engagement. He previously worked for Swedish Match where he contributed to the preparation of the General Snus PMTA and MRTP. He is a frequent contributor to FDLI journals and speaker at FDLI conferences.

ANGELA VAN DER PLAS M.D, Ph.D, is the Manager of Real-World Evidence and Epidemiology at Philip Morris International (PMI), with at least 20 years of experience in the field. She holds an M.D from the Universidad de San Martin de Porres, an MSc and DSc in Genetic Epidemiology, and a PhD in Medicine (Epidemiology and Biostatistics) from Erasmus MC, The Netherlands. Angela currently supervises multiple cohort, cross sectional, and ecological studies, amongst others. Prior to joining PMI in 2012, she worked as a Global Epidemiologist at Novartis Pharma, and at Astellas Pharma Europe, where she oversaw the epidemiological support for the oncology, dermatology, and transplantation franchises. Angela has published numerous articles in international scientific peer-reviewed journals around the topic of real-world evidence and epidemiology.

BRIAN YAGI is an Assistant Professor of Internal Medicine at Johns Hopkins Medical School where he practices as a Hospitalist specializing in inpatient care. Trained as an MD, JD, his academic work focuses on areas of regulatory law and biomedical research policy. He has experience working in the Office of Policy and Planning at the FDA as well as the Office of the Director at the NIH. By

incorporating experience in these federal regulatory agencies with input from diverse stakeholders in public health and industry, he aims to craft policy proposals that will increase the timeliness and transparency of health product regulation. He is particularly interested in areas of emerging technologies with rapid innovation cycles whose regulation requires careful consideration of clinical trial and public health data, of which Electronic Nicotine Delivery Systems are a key example.