FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)

Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products
February 10, 2026

PARTICIPANTS

Moderator
Matthew C. Farrelly, Ph.D. has a Ph.D. in economics and is the Director of the OS-CTP-FDA. As director, he is responsible for the overall strategic direction of the Office, including a tobacco regulatory science research portfolio. Prior to FDA, Dr. Farrelly spent 26 years at RTI International focusing on evaluating the effectiveness of multi-faceted tobacco control programs and policies at the federal, state and local level. Dr. Farrelly has over 120 peer-reviewed publications that have been cited nearly 12,000 times. Dr. Farrelly received his Ph.D. in Economics from the University of Maryland at College Park.

Product Characterization

Presenters & Panelists
Mark Anton is the CEO of What A Smoke, LLC, an inventor of patented vaping hardware, and a long-time participant in product development, retail, and regulatory advocacy. He has been active in the vaping and ENDS industry since 2008. He has contributed hardware to the NIDA Standardized Research E-Cigarette (SREC) project, served as Executive Director of SFATA (a national vaping trade association), acted as Federal liaison for the New Jersey Vapors Rights Coalition, presented before FDA leadership and engaged in governmental relations, industry panel organization, manufacturing standards development, and coalition building.

Karen Coyne, Ph.D. is the Associate Director for the DPS-OS-CTP-FDA. In this role, she serves as the engineering subject matter expert for scientific application review and research, while overseeing high-priority, cross-cutting scientific and policy initiatives. Dr. Coyne has been with CTP since 2017, where she supported the development and implementation of tobacco product application rules and guidance, served as an engineering reviewer and technical project lead, and oversaw engineering research to inform product application review. Prior to joining FDA, Dr. Coyne was a research engineer for the U.S. Army. Dr. Coyne's academic background includes an ORISE post-doctoral research fellowship at the U.S. Army, a Ph.D. and M.S. from the University of Maryland, College Park, and a B.S. from Drexel University.

Geoff Habicht, B.S.E. is the President & Co-Founder of Mi-One Brands. He has over 25-years' experience in consumer products and is one of the pioneers in the ENDS category. His expertise includes Product Development, Marketing & Sales.

Ryan Muckenthaler is the Regulatory Compliance Officer for Lotus Vaping Technologies. He has worked in the vapor and ENDS industry for 14 years, managing day-to-day warehouse

operations for the company's nationally distributed e-liquid brand and overseeing the company's chain of 28 retail locations. For the past 10 years, he has led Lotus Vaping Technologies' PMTA submissions, overseeing regulatory strategy and compliance with FDA requirements.

Colleen Rogers, Ph.D. serves as Director of the DPS-OS-CTP-FDA. In this leadership role, she oversees the development and implementation of premarket application review programs. She provides scientific oversight for application reviews and policy development, serves as the division's microbiology subject matter expert, and leads cross-cutting scientific and policy initiatives. Dr. Rogers brings over 20 years of regulatory science experience to her position. She joined CTP in 2015 and previously worked in FDA's CDER, where she wrote drug monographs and led a team in reviewing new drug applications. Her academic background includes postdoctoral research at Uniformed Services University, a Ph.D. from the University of Wisconsin-Madison, and a B.S. from the University of Illinois.

William Tang (Tang Hai), M.E. is the Compliance Officer at ZOVOO(Shenzhen) Technology Co., Ltd. in Shenzhen, China. He holds a master's degree in engineering and has over 15-years of experience in product compliance within the medical device and novel tobacco industries. He led and coordinated the submission of PMTAs for multiple novel tobacco products.

CDR Matthew Walters, Ph.D. serves as the Deputy Director in the DPS-OS-CTP-FDA. Concurrently, he is an officer in the U.S. Public Health Service Commissioned Corps. In his FDA role, CDR Walters oversees the functional operation of the chemistry discipline, supporting PMTA reviews and providing direction for chemistry-related regulatory decision-making. CDR Walters has more than 15 years of experience in tobacco regulation and has been with CTP since 2010. During his tenure, CDR Walters has contributed to policy development for the PMTA program among others, in which he played a key role in efforts related to the testing, reporting, and validation of HPHCs. Prior to joining FDA, CDR Walters completed a fellowship in biochemistry at Vanderbilt University. He earned a B.S. degree from the College of Charleston, a Ph.D. from Duke University, and an M.P.H. degree from Johns Hopkins University.

Bill Wikstrom is the Owner and President for Vaporized Inc. and Savant Industries DBA Paradigm Distribution. He is an honorably retired U.S. Army combat veteran with 35 years of leadership experience in operational planning, logistics, and financial management, and is a recipient of the Combat Action Badge. Mr. Wikstrom graduated with Highest Honors from The University of Southern Mississippi College of Business and has over 13 years of experience in the vapor industry, where he has focused on regulatory compliance, responsible manufacturing

and retail operations, and providing harm-reduction alternatives intended for adult smokers seeking to transition away from combustible tobacco products.

Panel Moderator
Todd L. Cecil, Ph.D. is currently the Deputy Director of Regulatory Management in the OS-CTP-FDA. Dr. Cecil joined CTP in 2015. Prior to joining FDA, Dr. Cecil spent over 23 years at the United States Pharmacopeia (USP), where he served as the Vice-president of Compendial Science. He earned his Ph.D. in Analytical Chemistry from Virginia Commonwealth University.

Manufacturing Controls

Presenters & Panelists
Bryan Burd, COO is the Scientific Advisor for Nepa Wholesale Inc. Mr. Burd has been providing regulatory support to the tobacco industry for the past 11 years. He specializes in new tobacco products.

Karen Coyne, Ph.D.

George Jawlakian, J.D. is the Corporate Counsel and Regulatory and Compliance director for Fumizer. He has over 15 years of experience in the tobacco industry particularly related to FDA compliance.

Chuck Melander, B.S., M.B.A. is the Chief Strategy Officer for Streamline Group. He was with Swedish Match for 22 years as VP of R&D and Quality Assurance where he served on the Global Scientific Advisory Panel and played a key role in their harm reduction scientific strategy. Chuck spent 16 years with Turning Point Brands as Senior VP of Operations, overseeing all Science, R&D, Product Development, Manufacturing, and Logistics. Chuck currently serves as Chief Strategy Officer at Streamline Group, supporting the company's future growth strategy with an emphasis on growth in the FDA regulatory environment.

Steven Przybyla, Esq. is a Board Member and Secretary for IKE Tech LLC. Steven has over 10 years of tobacco and regulated product experience, his expertise is in legal and regulatory matters. He was part of the regulatory team that received PMTA and MRTP approval for a 95% reduced nicotine cigarette at 22nd Century Group, Inc.

Colleen Rogers, Ph.D.

CDR Matthew Walters, Ph.D.

Panel Moderator
Todd L. Cecil, Ph.D.

Pharmacological Profile

Presenters & Panelists

Ed Carmines, Ph.D. is an independent director for Charlie's Holdings, Inc. He has over 30 years' experience in the tobacco industry specializing in regulatory submissions and product safety.

Steven Haddad, J.D. is the Managing Member of Breeze Smoke, LLC. He has over 17 years of experience across the convenience store, tobacco, and vapor industries. His expertise is in business operations, marketing, and compliance strategy.

Eric N. Heyer, J.D. is a partner at Thompson Hine LLP in Washington, D.C. and serves as regulatory counsel for Maduro Distributors Inc. In addition to Maduro, Eric has counseled and represented a broad range of clients from the vaping industry, including many domestic and foreign manufacturers, regarding the PMTA process and agency actions on PMTAs.

Willie J. McKinney, Ph.D., D.A.B.T. is the CEO of McKinney Regulatory Science Advisors, LLC. Dr. McKinney represents Custom Technologies Inc. and brings over 25 years of experience in the tobacco and nicotine industry, with expertise in toxicology and business.

Char Owen is the Chief Executive Officer of Matrix Minds LLC. She is an independent researcher and a Senior Engineer with 25 years of experience working with government agencies and contract enterprises including FEMA and Accenture. She has worked extensively on PMTA submissions since 2019.

Carolina Ramôa, Ph.D. serves as a Supervisory Pharmacologist in DIHS-OS-CTP-FDA. In this capacity, she leads a team of PhD-level scientists in evaluating tobacco product applications and conducting regulatory science research. Her scientific expertise is in addiction, and behavioral and clinical pharmacology of tobacco, with extensive experience in regulatory science. Prior to FDA, she gained international experience at the WHO's Tobacco Free Initiative in Geneva, Switzerland. She completed her postdoctoral research at Virginia Commonwealth University, and has a Ph.D. in Neuroscience, an M.S. in Biological and

Physical Sciences, and a B.A. in Biology and Cognitive Sciences from the University of Virginia.

Megan J. Schroeder, Ph.D. is the BCP Branch Chief for the DIHS-OS-CTP-FDA. Dr. Schroeder joined CTP as a pharmacology reviewer in 2012, and her expertise in tobacco product abuse liability is particularly relevant for research and premarket product review. In addition, she co-leads the TPLs who make marketing recommendations for PMTAs. Dr. Schroeder received her Ph.D. in Pharmacology from Georgetown University and completed a postdoctoral fellowship at the NIH.

Panel Moderator
Lynn C. Hull, Ph.D. is currently the Acting Senior Advisor in the OS-CTP-FDA and has been with CTP since 2014. She is a pharmacologist with expertise in behavioral and clinical pharmacology and regulatory science. Dr. Hull received her Ph.D. in Pharmacology and Toxicology from Virginia Commonwealth University (VCU) in 2009. She completed a Postdoctoral Fellowship at VCU and was then an AAAS Science and Technology Policy Fellow at the NIH National Cancer Institute's (NCI) Office of Nanotechnology Cancer Research from 2012-2014 prior to joining the FDA.

Studies of Adult Benefit

Presenters & Panelists
Dino Baccari is the CEO and founder of White Horse Vapor with more than fifteen years of experience in the ENDS industry. He has direct experience overseeing product development, customer engagement, and long-term data collection, including analysis of real-world adult use patterns relevant to studies of adult benefit.

Amy L. Gross, Ph.D., M.H.S. serves as the Epidemiologist for the DPHS-OS-CTP-FDA. In this capacity, she focuses on epidemiologic review of PMTA, development of OS guidance for such reviews, and research on epidemiologic aspects of tobacco regulatory science. Dr. Gross has five years of regulatory experience at FDA and has been with CTP since 2021. Within her time at CTP, Dr. Gross has served as primary reviewer on large PMTA bundles, worked on the development of memos and reviewer resources related to PMTA review from a behavioral perspective, and co-authored eight tobacco regulatory science research papers, as Health Scientist and Epidemiologist. Prior to FDA she worked as an Epidemiologist for the Maryland Department of Health, and Senior Staff Scientist at Vanderbilt University Medical Center. Dr. Gross received her B.A. from Johns Hopkins University, and her M.H.S. in

Biochemistry and Molecular Biology and Ph.D. in Epidemiology from Johns Hopkins Bloomberg School of Public Health.

Eric Heyer, J.D.

Sarah E. Johnson, Ph.D. serves as a Senior Science Advisor in the OS-CTP-FDA. In this role, she works closely with the senior leadership to provide expert guidance on scientific and policy issues related to application review and has contributed to the development of both the premarket and modified risk tobacco product application review pathways. In her prior role in the social science branch, she conducted research related to consumer perceptions and understanding and led the development of an FDA Guidance related to tobacco product perception and intention studies. Prior to joining CTP, Dr. Johnson served as an APA/AAAS Science and Technology Policy Fellow at the NIH. Dr. Johnson received her B.A. from Emory University and her M.S. and Ph.D. from Northwestern University.

Mollie Miller, Ph.D. is a Senior Health Scientist in the DIHS-OS-CTP-FDA. Dr. Miller joined CTP as a pharmacology reviewer in 2018. Dr. Miller's focus is on evaluating the abuse liability of tobacco products, particularly as it relates to PMTA product review. In addition, Dr. Miller is a scientific expert in the fields of addiction and behavioral pharmacology of tobacco and is a primary investigator on multiple clinical studies designed to fill gaps in tobacco regulatory knowledge. Dr. Miller was trained in behavioral pharmacology at the University of Vermont and completed a postdoctoral fellowship at Brown University's Center for Alcohol and Addiction Studies.

Ryan Muckenthaler

David B. Portnoy, Ph.D., M.P.H. serves as Acting Division Director for the DPHS-OS-CTP-FDA. In this capacity, he leads a division with expertise spanning psychology, communication science, epidemiology, statistics, and public health. Dr. Portnoy has over 13 years of experience within the DPHS at CTP. Throughout his career at CTP, Dr. Portnoy has led transformative initiatives including a complex research program to develop and test new cigarette health warnings and spearheaded development of a streamlined Division PMTA review process to enhance review efficiency. Dr. Portnoy has authored over 30 peer-reviewed scientific publications, numerous guidance documents, and rules. Prior to joining FDA, he completed The Cancer Prevention Fellowship Program at the National Cancer Institute. He received his B.A. in Psychology and Anthropology from George Washington University, his

Ph.D. in Social Psychology from the University of Connecticut, and his M.P.H. from Johns Hopkins University Bloomberg School of Public Health.

Bill Wikstrom

Jessica Zdinak, Ph.D. is the Founder and Chief Research Officer for ARAC - Applied Research and Analysis Company. She has two decades of experience using her expertise in psychology, human behavior, and statistics in a variety of research settings, including federal government, federal government consulting, academia, and most recently tobacco harm reduction. She has 11 years of experience working within the tobacco harm reduction industry.

Panel Moderator
Benjamin Apelberg, Ph.D. is currently the Deputy Director for Regulatory Science in the OS-CTP-FDA. Dr. Apelberg has held numerous roles since joining CTP in 2010, including as the Director of the DPHS and Chief of the Epidemiology Branch. Prior to joining FDA, Dr. Apelberg was a faculty member at the Johns Hopkins Bloomberg School of Public Health, where he also received his Ph.D. in Epidemiology.

Toxicological Profile

Presenters & Panelists
Steven Haddad, J.D.

Mary Irwin, Ph.D. serves as a Supervisory Pharmacologist in the DNCS-OS-CTP-FDA. In this capacity, she supervises and mentors a team of nine scientists in tobacco product regulatory science, including tobacco product application review and research project development. Dr. Irwin has nearly a decade of regulatory experience at CTP. During her time at CTP, Dr. Irwin has performed toxicological assessments of tobacco products submitted for every marketing pathway, including PMTA. She has also guided and drafted regulatory policy memoranda, such as the most recent DNCS Genotoxicity Hazard Identification and ELCR memoranda. Prior to joining CTP, Dr. Irwin earned a B.S. in Biochemistry from the University of Michigan, and a Ph.D. in Pharmacology and Cancer Biology from Wayne State University. She then completed an F32 funded postdoctoral fellowship at M.D. Anderson Cancer Center.

Willie J. McKinney, Ph.D., D.A.B.T

PARTICIPANTS continued

Manoj Misra, Ph.D. is a consultant representing ECS Global LLC, a manufacturer and distributor of ENDS products (PHIX Brand). He has been consulting with industry for 6 years and his expertise is in Chemistry and Toxicology.

Char Owen

Hans Rosenfeldt, Ph.D. is the Director of the DNCS-OS-CTP-FDA. In this capacity, he focuses on leading the toxicology and environmental science aspects of application review, scientific research designed to support application review, and development of scientific approaches for the assessment of tobacco product toxicity. Dr. Rosenfeldt has eighteen years of regulatory experience at FDA and has been with CTP since 2012. Prior to CTP he worked in CDER, conducting primary toxicology reviews of drugs indicated for rheumatoid diseases. Prior to FDA, Dr. Rosenfeldt did his postdoctoral work in the Oral and Pharyngeal Cancer Branch of the NIDCR and in the Department of Biochemistry at Georgetown University. Dr. Rosenfeldt received his B.A. from the University of Texas at Austin, and his Ph.D. from UT Southwestern Medical Center.

Panel Moderator
Todd L. Cecil, Ph.D.