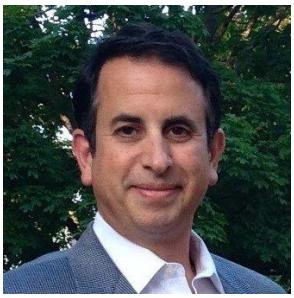
Tobacco Products Regulation and Policy Conference

October 26-27, 2017
W Hotel Washington, DC | 515 15th Street, NW | Washington, DC

Speaker Biographies



TONY ABBOUD is Executive Director of the Vapor Technology Association. Tony is a government relations expert and litigator with 25 years' experience in grassroots organizing, politics, state lobbying, and the courtroom. Tony has spent the past decade defending vapor companies and companies in other heavily regulated industries against government over-reach. Tony brings his unique set of lobbying, legal, political, and governmental experience to developing the strategic solutions that will enable vapor companies to succeed in a regulated world.

DAVID ABRAMS, PhD, is a professor of behavioral and social sciences at New York University College of Global Public Health. Dr. Abrams holds a BSc (Hons.) in Psychology and Computer Science, University of the Witwatersrand, South Africa and a Doctorate, Clinical Health Psychology, Rutgers University, United States. Professor and founding Director of the Centers for Behavioral and Preventive Medicine at Brown University, he then directed the Office of Behavioral and Social Sciences Research (OBSSR), National Institutes of Health. Principal Investigator on numerous NIH grants, Dr. Abrams has published over 270 peer-reviewed articles, served on the Board of Scientific Advisors of the National Cancer Institute, been President of the Society for Behavioral Medicine, and is a recipient of their Distinguished Scientist Award. He received the Cullen Memorial Award, American Society for Preventive Oncology for lifetime contributions to tobacco control. Dr. Abram's focuses on tobacco and nicotine use research to inform practice, policy, and regulation to reduce the harms overwhelmingly caused by the deadly smoke from combusting tobacco products and not nicotine.

SCOTT BALLIN is a tobacco and health policy consultant in Washington, DC, and has spent more than 30 years involved in issues related to tobacco and health. He was the Vice President for Public Policy and Legislative Counsel at the American Heart Association and Chairman of the Coalition on Smoking OR Health (ASC, ALA, AHA). More recently, he served on the Steering Committee of the Alliance for Health Economic and Agriculture Development (AHEAD), an informal organization committed to bringing parties together in order to discuss controversial issues, remove barriers, foster constructive dialogue, and look for new opportunities to find common ground. He continues to advocate for dialogue and is currently serving as an advisor to the Institute for Environmental Negotiation at the University of Virginia in putting together a series of dialogues on harm reduction.

GERMANA BARBA is Vice President, Regulatory Affairs at Philip Morris International (PMI). Previously at PMI, she held various positions in the areas of regulatory, government, and EU affairs in various countries. She has been involved in a number of legislative and regulatory dossiers at national and international level, including the EU Tobacco Products Directive. In her current position, she is responsible for regulatory and government affairs for PMI's reduced-risk products and conventional tobacco products. Before joining PMI, she worked in journalism and politics. She is a member of the Italian Association of Journalists, a former Rotary Ambassadorial Scholar, and an Aspen Junior Fellow. She holds a Master of Science in international relations and a Master of Science in EU studies from the London School of Economics and Political Science.

CLIVE BATES is the Director of Counterfactual Consulting Limited. Mr. Bates has had a diverse career in the public, private, and not-for-profit sectors. He started out in IT marketing for IBM then switched careers to work in the environment movement, including for Greenpeace. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. In 2003, he joined Prime Minister Blair's Strategy Unit as a civil servant and worked in senior roles in the public sector in the UK and for the United Nations in Sudan. At the start of 2013, he opened a new venture, Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy, and public health.

CYNTHIA CABRERA has been an integral part of the vapor space: beginning in 2011 as VP of Compliance & Logistics for VMR Products, then Executive Director of the Smoke-Free Alternatives Trade Association, and now as founder and president of the Cating Group. She is a frequent speaker on business trends, regulatory and legislative issues, and the future of the vapor industry. An avid supporter of harm-reducing technologies like alternative nicotine products, Cynthia has presented for the Tobacco Merchants Association (TMA), the Global Tobacco Nicotine Forum (GTNF), the Global Forum on Nicotine (GFN), the Food & Drug Law Institute (FDLI), the Responsible Retailers Forum (RRF), ECIG USA, the Morven Dialogues, and at a wide variety of vapor shows and exhibits. Cynthia has appeared on Fox Business, CNN Español, NBC, CBS, AP News, and has been quoted in The Washington Post, The New York Times, The Wall Street Journal, and various industry publications.

JEANNIE CAMERON is Founder and Managing Director of JCIC International, a UK-based strategic advocacy and public affairs consultancy specializing in tobacco harm reduction and anti-illicit trade. She is most well known for being a specialist on the FCTC (Framework Convention on Tobacco Control) and its Protocol. Jeannie has an LLM in International Law from Kings College, University of London having received a Distinction for her Masters in Law (LLM) dissertation: *Emerging International Public Health Issues – Human Rights, Harm Reduction and the Framework Convention on Tobacco Control (FCTC*) in 2007. Between 2001 and 2011 Jeannie was International Regulatory Affairs Manager and Head of International Advocacy responsible for advice to the BAT group worldwide on all aspects of the FCTC. Jeannie spent many years in the Australian Parliament and two years as Assistant Director of the International Legal Section

of the Department of Prime Minister & Cabinet. Jeannie is also International Law & Regulatory Fellow of the Washington Democracy Institute and has co-chaired an OECD Taskforce on Charting Illicit Trade.

AZIM CHOWDHURY is a partner at the law firm of Keller and Heckman LLP in Washington, DC. In this role, he advises domestic and foreign corporations in matters of FDA and international regulatory compliance. In particular, he assists corporations in establishing clearances for food and drug additives in the US, Canada, and European Union, with an emphasis on indirect additives used in food-contact materials. Chowdhury has also developed expertise in tobacco product regulation and has experience representing drug, dietary supplement, medical device, and tobacco companies in FDA regulatory matters. He is also a frequent contributor to the Food and Drug Law Institute's (FDLI) *Update Magazine*, and is Editor of FDLI's publication, *Tobacco Regulation and Compliance: An Essential Resource*. Chowdhury received a BA and BS from Johns Hopkins University; an MBA from the University of Maryland Robert H. Smith School of Business; and a JD, cum laude, from the University of Maryland School of Law.

KATHERINE CIAMBRONE is the Senior Vice President of Product Integrity and Compliance and Chief Compliance Officer with ITG Brands in Greensboro, NC. Katherine worked for 23 years in the pharmaceutical industry in various clinical and preclinical risk management, quality and operations roles. She holds a Master's degree in quality assurance and regulatory affairs from Temple University in Philadelphia, PA, as well as a Master's degree in organizational development from the University of Pennsylvania in Philadelphia, PA. She was previously employed as Vice President, Global Ethics and Compliance and Chief of Staff with GlaxoSmithKline in London and Philadelphia where she led their global ethics and compliance strategy.

DEAN CIROTTA is the President and Chief Operating Officer for EAS Consulting Group where he is responsible for the day-to-day management of the technical aspects of the company with responsibility for client relations and personnel management. Mr. Cirotta has 29 years of experience in the pharmaceutical and dietary supplement industries, including executive management roles with responsibility for regulatory affairs, compliance, quality assurance, laboratory operations, and overall corporate management. In addition, Mr. Cirotta regularly speaks on GMP compliance and initiatives and is a lead trainer for EAS. He often performs audits of manufacturers and works with clients in responding to FDA 483 observations and warning letters. He also assists the tobacco industry in complying with the Deeming Rule requirements and ensuring compliance with the Family Smoking Prevention and Tobacco Control Act. Mr. Cirotta has a Bachelor of Science degree in chemistry from the University of North Carolina at Greensboro and a Master's degree in business administration from the University of North Carolina at Chapel Hill.

DAVID CLISSOLD is a partner and the Director in the Washington, DC law firm Hyman, Phelps & McNamara, PC. He advises pharmaceutical, biotechnology, medical device, and food/dietary supplement industry clients on regulatory and legislative matters. He has also advised health care professionals, major universities, and medical schools on regulatory compliance, as well as provided pro bono counsel to state healthcare agencies and patient groups. Mr. Clissold has represented clients in the development of lifecycle management strategies for prescription and over-the-counter drugs, medical devices, and biologics. Additionally, he advises on strategies for FDA approval including clinical, preclinical, and toxicology protocol development and data presentation. He has authored several scientific papers in journals such as The New England Journal of Medicine; Journal of Pharmacology and Experimental Therapeutics; and Pharmacology, Biochemistry and Behavior. Before joining the firm, he conducted clinical and pre-clinical research at Nova Pharmaceutical Corporation and the Johns Hopkins University School of Medicine. Mr. Clissold received his BS in psychobiology from the University of California, Los Angeles; his MA in experimental psychology from Indiana University; and his JD from the University of Maryland School of Law.

GREGORY CONLEY is the President of the American Vaping Association (AVA), a nonprofit organization that champions regulatory policies toward vapor products designed to maximize the effectiveness of vaping for quitting smoking. He is one of the most prominent defenders of vaping in the United States, and has appeared on CNN, Fox News, and MSNBC. In addition to his work with the AVA, Mr. Conley is an attorney and a consultant on vaping legislative and regulatory issues. He began working on vaping issues in 2010 after quitting smoking with a vapor product while in law school. He served as the pro bono legislative director for the Consumer Advocates for Smoke-Free Alternatives Association from 2011 to 2014.

BRITTANI CUSHMAN is the Vice President of External Affairs for Turning Point Brands, parent company of National Tobacco Company, VaporBeast, Vapor Shark, and Intrepid Brands, of Louisville, Kentucky. Ms. Cushman is responsible for the management of regulatory and legislative issues at both the federal and state levels. Ms. Cushman provides industry leadership among like-sized manufacturers, advising on regulatory issues as they emerge and placing those issues in the context of both the current science and complex landscape of the vaping and tobacco industries. Ms. Cushman currently serves on the National Association of Tobacco Outlets (NATO) Board of Directors, the Vapor Technology Association (VTA) Board of Directors, and the Pipe Tobacco Council Board of Directors. She also participates in the Cigar Association of America and the Coalition of Independent Tobacco Manufacturers of America (CITMA). Ms. Cushman has a BSBA in Business Management from The University of Tulsa and a JD from Washington & Lee University School of Law. She previously served as General Counsel for a privately-held tobacco product manufacturer.

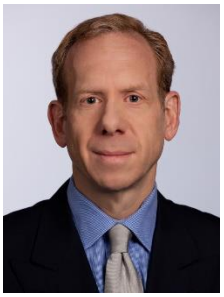
JIM DILLARD serves as Altria Group's Senior Vice President, Research, Development and Sciences, and Chief Innovation Officer. He leads the Product Development, Regulatory Sciences, and Engineering departments in the creation of products and technologies for Altria's tobacco operating companies. He also leads the execution of Altria's innovation framework and strategies, along with the work related to building our companies' innovation capabilities. Prior to his current position, Jim was Senior Vice President, Regulatory Affairs, for Altria Client Services. Jim also served as Senior Vice

President, Manufacturing, Science and Technology, for U.S. Smokeless Tobacco Company (USSTC), an Altria Group operating company. He joined USSTC in December 2001. Between 1987 and 2001, Jim worked for the FDA, where he last served as Director of the Division of Cardiovascular and Respiratory Devices. During his 14 years at the FDA, he held various leadership roles in the Center for Devices and Radiological Health and the Office of Device Evaluation, based in Rockville, Maryland. Jim received his undergraduate and graduate degrees in Biomedical Engineering from Tulane University in New Orleans, where he also served as a board member for the Biomedical Engineering Department from 2000 to 2002. He serves on the Board of the Richmond Forum and is a past Board Member of the CenterStage Foundation of Richmond.

DAVE DOBBINS is Chief Operating Officer at Truth Initiative. As Truth Initiative's Chief Operating Officer since 2007, Dave Dobbins has provided operational and strategic leadership for the organization. Over the years, he has helped to develop the organization's reputation as a leader both in tobacco regulatory practice and as a steadfast advocate for policies that increase health equity in tobacco control. He frequently represents the organization's policy positions at conferences and in the press. Dave began working for Truth Initiative in 2002 as its Associate General Counsel. In this role, he helped with the successful defense of the organization against the Lorillard Tobacco Company's effort to shut down the truth® youth smoking prevention campaign by claiming the ads "vilified" cigarette makers. Before joining Truth Initiative, he was part of the team that defended high-profile tobacco industry whistleblower Dr. Jeffrey Wigand from claims brought against him by the Brown & Williamson tobacco company.

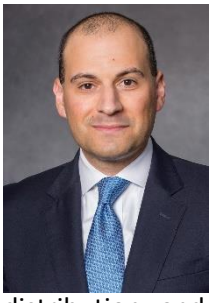
ERIC C. DONNY is a Professor of Psychology (primary), Psychiatry, and Behavioral & Community Health Sciences at the University of Pittsburgh. His expertise includes behavioral pharmacology, biological and health psychology, addiction, and regulatory science. His research has included a wide range of topics and techniques including animal models of self-administration, human abuse liability of cocaine and heroin, functional neuroimaging, population-based surveys, and clinical trials of tobacco products. His current interests focus on regulatory approaches to reducing the health burden of tobacco. He co-directs the Center for the Evaluation of Nicotine in Cigarettes (CENIC), an NIDA/FDA-funded cooperative agreement involving 12 institutions that aims to increase understanding of how behavior and health might be affected in the vast majority of smokers who are either unable or unwilling to quit, if the nicotine content of combustible tobacco products is reduced.

STACY EHRLICH is a partner at Kleinfeld Kaplan & Becker LLP in Washington, DC. Her practice focuses on counseling and advocating on behalf of pharmaceutical, food, dietary supplement, tobacco, cosmetic, and medical device companies on a variety of matters involving FDA, USDA, and FTC, as well as state agencies. Ms. Ehrlich regularly speaks and writes on various food and drug law topics, including drug and cosmetic labeling and advertising, dietary supplement marketing, and nicotine and tobacco product regulation. She has authored chapters in the FDLI publications, *Food and Drug Law & Regulation*, *How to Work with the FDA,* and *Top 20 Food and Drug Cases & Cases to Watch*. Ms. Ehrlich currently serves on the Board of Directors of FDLI and has been named to Best Lawyers in America for FDA Law. She received her JD from Harvard Law School, cum laude, and her BA in English, magna cum laude, from Emory University.



MARC FIRESTONE is Senior Vice President and General Counsel at Philip Morris International. Before joining Philip Morris in 2012, Mr. Firestone was Executive Vice President, Corporate and Legal Affairs and General Counsel of Kraft Foods Inc., where he served since 2003. From 1988 to 2003, Mr. Firestone held numerous positions in the law departments of Philip Morris Companies Inc. and Philip Morris International Inc., lastly as Senior Vice President & General Counsel of PMI. Mr. Firestone started his legal career as an attorney at Arnold & Porter in Washington, DC. He received a BA, magna cum laude, in Romance Languages and Philosophy from Washington & Lee University and a JD, magna cum laude, from Tulane University School of Law. Mr. Firestone is a co-founder and the chairman of the Institute for Inclusion in the Legal Profession; Adjunct Professor of Law at New York Law School; a frequent speaker on international antitrust law, diversity, and in-house legal practice; and a recipient of the Director's Roundtable Distinguished General Counsel award.

CHARLES GARNER, PhD, DABT, CIH, is Vice President of the Next Generation Products-Submissions and Engagement group in Scientific and Regulatory Affairs for RAI Services Company. Over his 35+ year career he has worked in cancer research, occupational and environmental health, and product stewardship and regulatory affairs for both traditional tobacco products and novel products derived from tobacco. He is a frequent speaker in industry forums, scientific meetings, and other venues. Dr. Garner received his PhD in Pharmaceutical Sciences (specialization in toxicology/pharmacology) from Wayne State University and is board certified by both the American Board of Toxicology and the American Board of Industrial Hygiene.



JONATHAN A. HAVENS, an associate at Saul Ewing Arnstein & Lehr LLP, counsels clients on regulatory, compliance, enforcement, and transactional matters related to products regulated by the U.S. Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and the U.S. Consumer Product Safety Commission (CPSC). Companies in the consumer health care products, life sciences, food and beverage, cosmetics, tobacco, and medical cannabis industries turn to Jonathan for advice on how to get and keep their products on the market. He advises companies throughout the product life cycle, including product development, formulation, manufacture, distribution, and promotion. Jonathan's deep understanding of the complex regulatory and statutory requirements that govern a wide range of products and services is enhanced by his experience working in government and on Capitol Hill. Before entering private practice, Jonathan served as a regulatory counsel with FDA, where he focused on compliance and enforcement related to promotion, advertising, and labeling. Jonathan serves on FDLI's Tobacco Committee.

BRYAN HAYNES is a partner at the law firm Troutman Sanders, where he devotes his practice to representing businesses in disputes and regulatory compliance matters initiated by governmental agencies, including by state Attorneys General, and in other commercial litigation. Bryan is an accomplished trial lawyer who has served as lead counsel in state and federal courts across the country. Bryan is a member of the firm's Tobacco Law practice and is focused on representing tobacco manufacturers, distributors, retailers and suppliers in all aspects of their businesses, including regulatory compliance, Food and Drug Administration (FDA) requirements, administrative disputes involving a federal or state governmental entity, commercial agreements, and tobacco taxation matters.

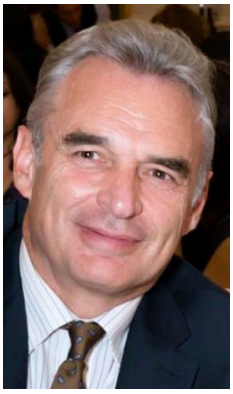
DENNIS HENIGAN is Director, Legal and Regulatory Affairs at the Campaign for Tobacco-Free Kids. He focuses on issues involving FDA regulation of the tobacco industry and related litigation, as well as providing legal guidance on federal, state, and local tobacco control legislation. Prior to joining the Campaign in September 2012, he worked for over two decades at the Brady Center to Prevent Gun Violence, first as Director of the Center's Legal Action Project, and then as the Center's Vice President. Before his tenure at the Brady Center, Denny was a partner in the law firm Foley & Lardner.

KATHLEEN HOKE, JD, is a law school professor, Director of the Legal Resource Center for Public Health Policy, and Director of the Network for Public Health Law, Eastern Region, at the University of Maryland Carey School of Law. Through the Center and Network, Kathleen provides technical legal assistance to state and local health officials, legislators, researchers, and organizations working to use law and policy change to improve public health. Hoke graduated as a member of the Order of the Coif from the University of Maryland School of Law in 1992, completed a clerkship with the Honorable Lawrence Rodowsky of the Maryland Court of Appeals, and served with distinction as an Assistant Attorney General and Special Assistant to the Attorney General of Maryland prior to joining the School of Law in 2002.

MICHAEL HUFFORD, PhD, is Vice President of Regulatory Affairs, Behavioral Science and Innovation at PinneyAssociates. He is an entrepreneur and drug developer with experience developing small molecules (Cypress Bioscience), biologics (Amylin Pharmaceuticals), organ regeneration (LyGenesis), and drug delivery technologies (e-Nicotine Technology). He has consulted to drug development programs in a wide variety of therapeutic areas, spanning clinical trial design, patient-reported outcomes (invivodata), neuropsychological outcomes (NeuroCog Trials), and Rx-to-OTC switches (PinneyAssociates). His philanthropic work includes co-founding and serving as the CEO of Harm Reduction Therapeutics, Inc., a nonprofit pharmaceutical company developing low-cost OTC naloxone. Michael earned his undergraduate degree with distinction from Purdue University, and his master's and doctoral degrees in clinical psychology from the University of Pittsburgh before completing a Research and Clinical Fellowship in the Department of Psychiatry at Harvard Medical School.

JOHN HUGHES, MD is Professor of Psychiatry, Psychology, and Family Practice at the University of Vermont. Dr. Hughes is board certified in Psychiatry and Addiction Psychiatry. His major focus has been clinical research on tobacco use. He is a co-founder and past president of the Society for Research on Nicotine and Tobacco and the Association for the Treatment of Tobacco Use and Dependence. Dr. Hughes received the Ove Ferno, Alton Ochsner, and the John R. Hughes ATTUD Excellence in Tobacco Treatment, Training and Advocacy Award. Dr. Hughes has been Chair of the Vermont Tobacco Evaluation and Review Board, which oversees VT's multi-million dollar tobacco control program. He has over 450 publications on nicotine and other drug dependencies and is one of the world's most cited tobacco scientists. Dr. Hughes has been a consultant on tobacco policy to the World Health Organization, the US Food and Drug Administration, the US Office on Smoking and Health, and the White House. Dr. Hughes has received fees from companies that develop smoking cessation devices, medications, and services; from governmental

and academic institutions; and from public and private organizations that promote tobacco education or control and serves as a consultant to Swedish Match for their snus product.



DELON HUMAN, MBChB, MPraxMed, MFGP, DCH, MBA, is President of Health Diplomats, a specialized health, nutrition, and wellness consulting group operating worldwide. He has acted as adviser to the WHO Director-General and to former UN Secretary-General Ban Ki Moon. Up to 2014 he served as Secretary-General and Special Envoy to WHO/UN of the International Food and Beverage Alliance, a group of leading food and non-alcoholic beverage companies with a global presence (including Unilever, Nestlé, McDonald's, Coca-Cola, PepsiCo, Ferrero, Mars, General Mills, Mondeléz, and the Bel Group). From 1997 to 2005, Dr. Human served as Secretary-General of the World Medical Association (WMA), the global representative body for physicians. He was instrumental in the establishment of the World Health Professions Alliance, an alliance of the global representative bodies of physicians, nurses, pharmacists, dentists, and physical therapists. During 2006 he was elected to serve as the Secretary-General of the Africa Medical Association (AfMA). Dr. Human qualified as a physician in South Africa and completed his postgraduate studies in family medicine and child health in South Africa and Oxford, England. He was a clinician for two decades, part of the pediatric endocrinology research unit at the John Radcliffe Hospital and was involved in the establishment of several medical centers, a hospital, and an emergency clinic in South Africa. His business studies (MBA) were completed at the Edinburgh Business School.

NATHAN HURLEY is the Ombudsman for the Center for Tobacco Products (CTP). Nathan began his federal career as a Park Ranger in the National Park Service after graduating from Shepherd University with a degree in Environmental Science. He came to CTP's Office of Science in 2010 as a Staff Assistant and worked his way to Lead Regulatory Health Project Manager. In his over six years of experience in CTP, Nathan has observed, contributed to, and developed a solid foundation in the growing processes and procedures shaping the Center.

NILESH JAIN is the Founder of www.ivape.in and is a very passionate social entrepreneur One of the goals with which he founded www.ivape.in was to help provide safer alternatives to 100 million people in India. He strongly believes that vaping can save lives and help Indians get access to better and safer alternatives for improving their lifestyle and health. Nilesh has a background in technology and life sciences from Carnegie Mellon University, and owns businesses in medical devices and medical implants manufacturing in India.

DESMOND JENSON is a staff attorney at the Tobacco Control Legal Consortium. His focus is federal tobacco control policy, primarily the FDA's regulation of tobacco products. Mr. Jenson leads the public health community in identifying opportunities to strengthen federal tobacco regulation. He coordinates with local, state, tribal, national, and global public health leaders, keeping them apprised of regulatory changes and litigation impacting federal tobacco control. Mr. Jenson drafts many of the Consortium's comments to the FDA, coordinates the filing of *amicus curiae* briefs in important litigation, develops educational materials explaining federal law, and speaks to public health audiences about tobacco control. Mr. Jenson also works closely with scientists, consulting on the development of research as well as writing manuscripts, to build an evidence base for legally-

defensible tobacco control policies. Mr. Jenson received his JD from William Mitchell College of Law and his BA from Augsburg College.

IAN JONES is the Reduced-Risk Products Vice President at Japan Tobacco International (JTI), based in Geneva, Switzerland. He joined JTI in 2006 from the University of Bath, UK, where he was a lecturer in Developmental Neuroscience at the Department of Biology and Biochemistry. Prior to this, he held post-doctoral research positions at the Universities of Bath, Oxford, and London, specializing in the anatomical neuropharmacology of nicotinic acetylcholine receptors. He holds a PhD in cell physiology, completed at Imperial College, London (1995).

PATRICIA KOVACEVIC is the General Counsel and Chief Compliance Officer of Nicopure Labs LLC, the leading e-liquid and vaping device manufacturer of –US-made Halo and eVo e-liquids and Triton, Reactor, and G6 devices. With extensive US and international industry experience, Kovacevic held senior legal and compliance positions at, among others, Philip Morris International and Lorillard. Prior to joining Lorillard, she was a partner at Patton Boggs. Her expertise includes global e-cigarette and tobacco regulation, compliance and all regulatory aspects of marketing/media communications, corporate affairs, criminal investigations, FCPA, trade sanctions, privacy, product development, and launch. Kovacevic serves on the board of the Vapor Technology Association and on the advisory board of the Global Tobacco and Nicotine Forum. In the past she was a United Nations staff member, served on UN's Public-Private Partnership Commission, and was also an advisor to the Council for Burley Tobacco. Kovacevic is admitted to practice in New York and before the Supreme Court of the United States. She holds a JD from Columbia Law School (NY) and has graduated from the Harvard Business School "Corporate Leader" course. She is fluent in seven European languages.

LYNN T. KOZLOWSKI, PhD, is professor of Community Health and Health Behavior and former dean of the School of Public Health and Health Professions at the University at Buffalo. Kozlowski holds a Bachelor's degree from Wesleyan University and a Doctorate in psychology from Columbia University. His research focuses on addictions, tobacco use, tobacco epidemiology, ethics, and tobacco policy. He has held faculty positions at the Wesleyan University, the University of Toronto, and Penn State. Kozlowski is a senior editor of the journal, *Addiction* and associate editor of *Tobacco Control*.

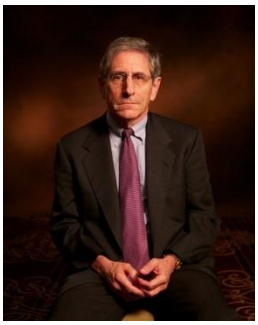
SCOTT J. LEISCHOW, PhD, joined Arizona State University in June 2017 as Professor and Associate Director for Public Health. Prior to that, Dr. Leischow held academic positions at the Mayo Clinic and the University of Arizona, and served as Chief of the Tobacco Control Research Branch at the National Cancer Institute and Senior Advisor for Tobacco Policy in the US Department of Health and Human Services. Dr. Leischow completed his Doctorate in Health Education from the University of Maryland and a postdoctoral fellowship in Behavioral Pharmacology from Johns Hopkins University. Dr. Leischow has received several awards, including the NIH Director's Award. Most of Dr. Leischow's research and publications focus on tobacco treatment, tobacco control policy, and systems and network approaches to

public health. Dr. Leischow is past President of the Society for Research on Nicotine and Tobacco (SRNT), and is Editor-in-Chief of the journal *Tobacco Regulatory Science*.

DAVID LEVY is a professor at Georgetown University. David Levy has a PhD from UCLA in Economics. He is currently a Professor of Oncology at Georgetown University. He has published over 250 papers, including articles in the American Economic Review, BMJ, AJPH, *JAMA*, Lancet, Medical Care, AJPM, Tobacco Control, Nicotine and Tobacco Research, PLOS Medicine, and Review of Economics and Statistics. He has been principal investigator of grants from the CDC, WHO, NCI, NIDA, Bloomberg/Gates Foundation, European Union, and the Robert Wood Johnson Foundation. He is currently Principal Investigator of a 5-year grant from NCI's CISNET program, a 4-year grant from NIDA, and a 5-year P-50 with the ITC group. Dr. Levy is currently overseeing the design and development of the *SimSmoke* tobacco policy simulation model, with models for the US and 10 states, and for over 40 countries covering 90% of the world population. He is now developing models of smokeless tobacco and e-cigarette use.

ERIC LINDBLOM is Director for Tobacco Control and Food & Drug Law at Georgetown Law's O'Neill Institute for National and Global Health Law. He works on a range of law and policy projects relating to U.S. and global tobacco control efforts, FDA regulation, the First Amendment, legalized cannabis, and other domestic and international regulatory matters. Before joining the O'Neill Institute, Mr. Lindblom was Director of the Office of Policy at the FDA Center for Tobacco Products. Prior to that, Mr. Lindblom served as General Counsel and Director for Policy Research at the Campaign for Tobacco-Free Kids, and previously held positions with the federal government, a member of Congress, political campaigns, a law firm, and nonprofit advocacy organizations. Mr. Lindblom has a JD from Harvard Law School and a BA in Political Science from Yale University.

JOE MURILLO serves as Vice President, Regulatory Affairs, Altria Client Services. Joe leads FDA-related regulatory strategy, engagement, communications, and advocacy for Altria's tobacco operating companies. Joe also develops regulatory and research strategies related to Altria's pursuit of tobacco harm reduction and FDA authorization of modified risk tobacco products. Before being appointed to his current position, Joe served as President and General Manager of Nu Mark, LLC. In that role, Joe led the company's development and marketing of innovative tobacco products for adult tobacco consumers. Previously, Joe was Vice President and Associate General Counsel of Altria Client Services, where he led the company's Brand Integrity efforts and provided legal support to a number of different areas at Altria. During the course of his career, Joe has developed extensive knowledge of the marketing, sales, distribution, regulatory, and communications aspects of bringing tobacco products to market. Joe is a 1986 graduate of Columbia Law School and a 1983 graduate of the University of Miami, where he was elected to Phi Beta Kappa.



MATTHEW MYERS is President and CEO of the Campaign for Tobacco-Free Kids, a privately funded organization established to reduce tobacco use and its devastating consequences in the United States and around the world. Over the last 25 years, Mr. Myers has participated in virtually every major national tobacco-related legislative effort and has worked with state tobacco prevention advocates and officials around the country. In 1999, Mr. Myers was asked to serve on the first advisory committee established to advise the Director General of the World Health Organization on tobacco issues. The following year, Mr. Myers was named by President Clinton to co-chair a Presidential Commission to examine the economic problems being experienced by tobacco farmers and their communities and recommend possible solutions. In October 2004, the Harvard School of Public Health bestowed its highest honor, the prestigious Julius B. Richmond award, on Mr. Myers for his work as an advocate in preventing tobacco industry marketing to children.

MITCH NEUHAUSER is Vice President and Assistant General Counsel – Regulatory at RAI Services Company. In this role, he provides legal advice and direction to Reynolds American Inc.'s tobacco operating companies on a variety of regulatory issues, including FDA compliance. Mr. Neuhauser has over 20 years of experience as both outside counsel and in-house counsel to tobacco companies on regulatory and litigation matters. This includes in-house roles at British American Tobacco in London, and Brown & Williamson Tobacco Corporation in Louisville, Kentucky, as well as outside counsel to Brown & Williamson while at King & Spalding's Atlanta office. Mr. Neuhauser received his BA from Duke University and his JD from the University of Virginia School of Law.

RAYMOND NIAURA is Professor of Social and Behavioral Sciences at the College of Global Public Health, New York University. He also holds adjunct faculty appointments at the Johns Hopkins Bloomberg School of Public Health and the Department of Oncology and Lombardi Comprehensive Cancer Center at Georgetown University. From 2009-2017, he was Director of Research at the Schroeder Institute, Truth Initiative (formerly the American Legacy Foundation). He has extensive expertise in tobacco dependence and treatment, and he has published over 340 peer-reviewed articles and several book chapters in this area. His interests include studying the biobehavioral substrates of tobacco dependence, evaluating behavioral and pharmacological treatments for cessation, and understanding and addressing public health disparities in tobacco-related burdens of illness and disability. He has been Principal Investigator (PI) or co-Investigator of over 30 NIH-funded grants, and he is the former President of the Society of Nicotine and Tobacco Research. He also has a background and interest in factors that influence adolescent/early adult tobacco use trajectories. He was also PI of one of the Transdisciplinary Tobacco Use Research Centers (TTURC), and is currently a co-I and co-PI, respectively, on two large, multicenter initiatives: (1) the Population Assessment of Tobacco and Health (PATH, funded by National Institute on Drug Abuse/Center for Tobacco Products, FDA), a national, longitudinal cohort study of more than 40,000 users and non-users of tobacco products ages 12+, including adolescents and young adults; and (2) The Center for Evaluation and Coordination of Training and Research (CECTR) in Tobacco Regulatory Science (U54), which coordinates the 14 Tobacco Centers of Regulatory Science (TCORs) for the FDA/NIH. He is also a member of the Julius B. Richmond Center of Excellence Tobacco Consortium, American Academy of Pediatrics (AAP).

FEDRIK PEYRON is the Senior Vice President Regulatory Affairs and Group Communication for Swedish Match. He has previously held positions as General Counsel of Autoliv Inc. and Swedish Match.

BARRY SCHAEVITZ is a partner at Fox Rothschild. Barry represents clients on a range of issues involving federal regulation and federal agencies, including the Food and Drug Administration, working closely with clients on various compliance matters. He similarly works with clients on a wide variety of regulatory matters before state agencies and departments. A former Assistant Attorney General for the State of New York, Barry also represents product manufacturers and industry trade associations in litigation matters. He has defended clients in complex product liability matters involving medical, scientific, and other technical issues in courts throughout the country. His experience includes representing clients in cases involving the constitutionality of federal, state, and local laws, as well as questions of disease causation and addiction. Drawing on experience working as a congressional aide, Barry also engages on federal and state legislative matters. In doing so, he counsels clients on policy questions and meets with legislators, staff, and other public officials on matters of concern to clients.

MARC J. SCHEINESON is a partner in the Washington, DC office of Alston & Bird. He heads the firm's food and drug law practice. He has practiced food and drug law, health care law, and administrative law for over 30 years in national law firms and at the Food and Drug Administration (FDA). His practice focuses on determining the "regulatory course of least resistance" to market medical products and assisting clients with legal and regulatory issues, drug and medical device applications, marketing, compliance, and enforcement matters. He also represents small businesses engaged in tobacco and e-product manufacture and sale. Mr. Scheineson provides legal, regulatory, and legislative counsel to a variety of marketers, research institutions, professional associations, and manufacturers of pharmaceutical and biological drug products, medical devices, cosmetics, dietary supplements, tobacco, and traditional foods. He is a frequent speaker in industry forums. He is also experienced with the application of the Office of Inspector General (OIG) anti-kickback statute, HIPAA privacy rules, clinical trial regulation, human research protection, scientific misconduct, technology transfer and licensing, advertising and promotion law, and advises on the FDA regulatory aspects of health care transactions. He previously served as Associate Commissioner for Legislative Affairs at FDA. He received his BA and JD from the University of Cincinnati and its College of Law, and his LLM from the Georgetown University Law Center.

HENRY SICIGNANO, III, is President and Chief Executive Officer of 22nd Century Group, Inc. (NYSE American: XXII). 22nd Century is a plant biotechnology company focused on genetic engineering and plant breeding, which facilitates the growing of tobacco plants with 95% less nicotine than conventional plants. Mr. Sicignano has served as Chief Executive Officer of 22nd Century Group since March 2015, prior to which time he served as the company's President since August 2010. From February 1997 through July 2002, he served as Vice President and Marketing Director of Santa Fe Natural Tobacco Company, parent to the Natural American Spirit cigarette brand. In 2002, Mr. Sicignano was instrumental in the $356 million sale of Santa Fe Natural Tobacco to R.J. Reynolds Tobacco Company. Mr. Sicignano holds a Bachelors of Arts degree in Government from Harvard College and a Master of Business Administration degree from Harvard University.

VALERIE BRIGGS SOLOMON is Managing Counsel, R&D and Regulatory, at RAI Services Company, a subsidiary of Reynolds American Inc. (RAI). Among other responsibilities, she supports the Research & Development and Scientific & Regulatory Affairs functions and advises RAI's subsidiaries on state, federal, and international regulatory compliance. Prior to joining RAI Services Company in 2010, Ms. Solomon was in private practice in Washington, DC, where she counseled clients in the food, medical device, and pharmaceutical industries on various regulatory, litigation, policy, and business matters. Ms. Solomon previously served as Vice President for Healthcare Research at a New York-based investment, advisory, and consulting firm. She is a member of the FDLI Tobacco Planning Committee and serves on the board of two nonprofit organizations in Winston-Salem, North Carolina. Ms. Solomon received her BA in history from Yale University and her JD, *cum laude*, from Washington College of Law, American University.

JAMES M. SOLYST is the Vice President of Federal Regulatory Affairs for Swedish Match, where he directs the company's preparation of a modified risk tobacco product application. He has participated in numerous science and policy forums related to tobacco harm reduction, including making presentations at national conferences and writing articles for regulatory science journals. Mr. Solyst has held senior positions in Washington, DC-based companies and associations, including the National Governors' Association, American Chemistry Council, and the consulting firm ENVIRON International Corporation. In these positions he worked closely with federal agencies, including the Food and Drug Administration, the Environmental Protection Agency, and the White House Office of Management and Budget. Mr. Solyst is currently a member of the National Academy of Sciences (NAS) Chemical Sciences Roundtable, has served on a NAS committee regarding chemical safety, is an external affiliate with the Johns Hopkins School of Public Health Risk Science and Public Policy Institute, and is a member of the American Chemical Society's Committee on Environmental Improvement.

KATHLEEN STRATTON began her career at the National Academies of Sciences, Engineering, and Medicine in 1990 in the Institute of Medicine. She has spent most of her time with the Board on Population Health and Public Health Practice. She has staffed committees addressing vaccine safety and development, pandemic preparedness, environmental and occupational health, drug safety, and tobacco control. She was given the IOM Cecil Research Award for sustained contributions to vaccine safety and was made a staff Scholar in 2005. After two years at The Pew Charitable Trusts working on FDA reform, she returned to IOM in fall 2013 to direct the Roundtable on Environmental Health Sciences, Research, and Medicine and the Committee on the Health Implications of Raising the Minimum Purchase Age for Tobacco. She most recently directed a study on accounting for socioeconomic status in Medicare payment programs and is currently directing a study on the health effects of electronic cigarettes. She received a BA in Natural Sciences from The Johns Hopkins University and a PhD in Pharmacology and Toxicology at the University of Maryland at Baltimore. She conducted post-doctoral research in the Department of Neuroscience at the Johns Hopkins School of Medicine.

DAVID SWEANOR is an adjunct professor of law with the Centre for Health Law, Policy and Ethics at the University of Ottawa and an Honorary (Consultant) Assistant Professor, University of Nottingham. He has worked on national and global tobacco and health issues for more than a third of a century and played a key role in a wide range of Canadian and global tobacco control policies. His primary area of work has been the interaction of law and economics as a determinant of public health, and recently much of his time has been focused on appropriate policy measures for reduced risk products capable of replacing lethal cigarettes. His interests extend to a wide range of issues, and in addition to his personal work, he funds numerous initiatives in a sometimes-Quixotic effort to create a better world. He was the recipient of the Outstanding Individual Philanthropist award for Ottawa in 2016.

DONNA VALLONE serves as the Chief Research Officer at Truth Initiative's Schroeder Institute and holds an Associate Professor (adjunct) appointment at the College for Global Public Health, New York University. Dr. Vallone leads a multidisciplinary team of over 30 research staff focused on examining the influence of health communication and tobacco policy initiatives to reduce tobacco use among youth and young adults. Most notably, Dr. Vallone leads the evaluation of the national youth smoking prevention truth® campaign. Her research interests focus on examining the influence of media messages to reduce tobacco use, particularly among lower socioeconomic status (SES) and racial/ethnic minority groups. As a leader in advancing our knowledge of tobacco-related disparities, Dr. Vallone serves as an editor of the National Cancer Institute Tobacco Control Monograph: A Social Ecological Approach to Addressing Tobacco-Related Health Disparities (released September 2017). She also helped establish and lead the Tobacco Research Network on Disparities (TReND) and the Diversity Network, a special interest group within the Society for Research on Nicotine and Tobacco (SRNT). Dr. Vallone serves on numerous expert panels, editorial teams, and evaluation advisory committees, and is the author of over 80 peer-reviewed academic manuscripts. Dr. Vallone holds a doctoral degree in Sociomedical Sciences from Columbia University and Masters' degree in public health from New York University.

DEREK YACH, a global health expert and anti-smoking advocate for more than 30 years, is the founder and president-designate of the Foundation for a Smoke-Free World. Throughout his career, he has supported and led smoking cessation research and policy development and has been a strong proponent of harm-reduction policies, calling for a greater emphasis on harm reduction as early as 2005. He is also a passionate advocate of health promotion and disease prevention, and is advancing his career's work at the Foundation for a Smoke-Free World. Dr. Yach is a former World Health Organization (WHO) cabinet director and executive director for noncommunicable diseases and mental health where he was deeply involved with the development of the world's treaty on tobacco control, the Framework Convention on Tobacco Control. He is also the former chief health officer of the Vitality Group, executive director of the Vitality Institute, senior vice president of global health and agriculture policy at PepsiCo, director of global health at the Rockefeller Foundation, and a professor of global health at Yale University. He has authored or co-authored more than 250 peer-reviewed articles on global health and has served on several advisory boards, including the World Economic Forum, Cornerstone Capital, and the Wellcome Trust. From 2007 to 2016, he served on the program advisory committee of the Clinton Global Initiative.

MITCH ZELLER, JD, became director of the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) in March 2013. The mission of CTP—established by enactment of the 2009 Family Smoking Prevention and Tobacco Control Act—is "to make tobacco-related death and disease part of America's past, not America's future, and, by doing so, ensure a healthier life for every American family." "Today, FDA has an unprecedented opportunity to use the new tools in the Tobacco Control Act," Zeller said. "Product regulation is a powerful component of a comprehensive strategy to reduce the death and disease from tobacco use. We will marshal the science to support new policies to help combat the leading cause of preventable disease and death in the United States," he added. Mr. Zeller, a graduate of Dartmouth College and the American University Washington College of Law, has been working on FDA issues for more than 30 years. He began his career as a public interest attorney in 1982 at the Center for Science in the Public Interest (CSPI). In 1988, Mr. Zeller left CSPI to become counsel to the Human Resources and Intergovernmental Relations Subcommittee of the House of Representatives Government Operations Committee where he conducted oversight of enforcement of federal health and safety laws. Mr. Zeller joined the staff of then FDA Commissioner David Kessler, M.D., in 1993. What began as a two-week assignment by Kessler to examine the practices of the tobacco industry led to his serving as associate commissioner and director of FDA's first Office of Tobacco Programs. Instrumental in crafting the agency's 1996 tobacco regulations, Mr. Zeller also represented FDA before Congress, federal, and state agencies. Mr. Zeller also served as an official U.S. delegate to the World Health Organization (WHO) Working Group for the Framework Convention on Tobacco Control. In 2000, Mr. Zeller left the FDA to continue his work for tobacco control as executive vice president of the American Legacy Foundation. His responsibilities there included marketing, communications, strategic partnerships, and, in 2002, creating the foundation's first Office of Policy and Government Relations. That year, Mr. Zeller joined Pinney Associates where, as senior vice president, he provided strategic planning and communications advice on domestic and global public health policy issues involving the treatment of tobacco dependence and the regulation of tobacco products and pharmaceuticals. Mr. Zeller, who is also a professorial lecturer at American University School of Law, lives with his family in Montgomery County, Maryland.