THE E-CIGARETTE SUMMIT
Science, Regulation & Public Health
The Marriott, Georgetown · Washington D.C. · May 17, 2022

07.45 - 08.15	**REGISTRATION & REFRESHMENTS**
	Evidence Update – Use Patterns & Health
08.15 - 08.20	**Welcome & Introductions Summit Chair - Prof Robin J. Mermelstein, PhD – Professor of Psychology and Director Institute for Health Research and Policy (IHRP) University of Illinois, Chicago**
08.20 – 08.40	**OPENING KEYNOTE: Thinking Outside the Box on E-cigarettes:** *Substantially reducing the number of people smoking combusted tobacco products and minimizing the initiation of their use by non-smokers, especially youth, presents an objective that would have a profound impact on reducing the preventable disease and premature death from tobacco product use. Because their use mimics smoking, delivers substantial amounts of nicotine quickly, and delivers significantly less harmful and potentially harmful constituents during exclusive use compared to smoking, e-cigarettes are a tool that could make a major impact on overall population health. However, to date, e-cigarettes have not met their potential with too many adolescents starting their use and too many smokers either becoming dual users or rejecting e-cigarettes and relapsing to smoking. This presentation will discuss some of the current approaches and propose some out-of-the-box ideas for consideration that are intended to encourage the conversation of how to maximize the potential benefits of e-cigarettes for reducing morbidity and mortality of tobacco smoking while minimizing the unintended consequences.* **David L. Ashley, Ph.D. - RADM (retired) US Public Health Service: Research Professor, Department of Population Health Sciences, School of Public Health, Georgia State University**
08.40 – 08.55	**The Risk Continuum:** *The continuum of risk is a cornerstone of a nicotine-based framework for public health proposed by the FDA in 2016. The idea is that products that deliver nicotine fall on a spectrum of risk based on toxicity and addictiveness. Combusted tobacco products such as cigarettes pose the highest risk, both in toxicity and addictiveness. An exception is the very low nicotine content cigarette, which is has high toxicity, but low addictiveness, and if mandated by regulation would be expected to promote smoking cessation or switching to less harmful nicotine products. Non-combusted nicotine products are less toxic, and if smokers cannot or do not want to quit smoking, switching to these products would benefit their health. This presentation will review the risks as well as potential benefits of nicotine delivered from sources other than combusted tobacco. It will also consider how risks of nicotine compare to other widely used drugs, such as alcohol and cannabis.* **Prof Neal L. Benowitz MD – Professor of Medicine Emeritus (Active), University of California San Francisco,**
08.55– 09.10	**Does nicotine harm the developing brain?** *The close links between smoking and social disadvantage and poor mental health were traditionally considered to be primarily due to smoking having a stronger appeal for people whose lives are more stressful, but with the rise of vaping, claims increased that the association shows adverse effects of nicotine on the developing brain, either during pregnancy, or via smoking in adolescence. In animal studies, very large and stressful nicotine dosing of developing foetus and during early adolescence generated a range of pathological outcomes, but it is not clear whether this is relevant for nicotine self-administration in humans. This presentation will review human studies that examine whether the associations between smoking and lower IQ and educational achievement, and between smoking and increased risk of ADHD, anti-social behaviour, autism and use of illegal drugs is due to smoking or due to genetic, familial and environmental factors. The talk will also consider the causality of the association between starting smoking at a younger age and higher cigarette dependence. It will then consider to what extent any adverse behavioural effects of smoking may apply to nicotine on its own, when not combined with other tobacco chemicals.* **Prof Peter Hajek – Professor of Clinical Psychology, Wolfson Institute of Public Health, Queen Mary University of London**
09.10 – 09.25	**The latest Cochrane evidence on e-cigarettes for smoking cessation – living with and addressing uncertainty** • *The most recent Cochrane evidence on the effectiveness and safety of e-cigarettes for quitting smoking* • *Findings from new analyses of longer-term e-cigarette use, the role of flavours in cessation, and biomarkers of harm* • *How we conceptualise, communicate, and address uncertainties in the evidence base* **Dr Jamie Hartmann-Boyce – Associate Professor and Editor, Cochrane Tobacco Addiction Group, Nuffield Department of Primary Care Health Sciences, University of Oxford**
09.25 – 09.40	**PATH Study Data on Cigarette Smokers with no plans to ever quit smoking:** *Cigarette smokers not planning to quit are often overlooked in population studies. This session will examine the methods and findings from a cohort study of 1600 adult daily cigarette smokers who did not initially use e-cigarettes and had no plans to ever quit smoking. The main outcomes were discontinuation of cigarette smoking (i.e., no cigarette smoking) and discontinuation of daily cigarette smoking (i.e., no daily cigarette smoking) at follow-up interview. These findings call for consideration of smokers who are not planning to quit when evaluating the risk-benefit potential of e-cigarettes for smoking cessation in the population.* **Andy Hyland - Roswell Park Comprehensive Cancer Center, Scientific Principal Investigator, NIH/FDA PATH**

09.40 – 10.10	**Panel Discussion and Q&A: What would a "Comprehensive Tobacco Control Plan" look like and is it possible in the US?** • *Has the US lost sight of the harm continuum, are we following the science?* • *Can the US still implement a comprehensive tobacco control plan?* • *Is dual use a failure of public health, the product or both?* • *Is the current strategy either protecting children or helping adults, is anyone happy?* **Chair - Prof Robin J. Mermelstein, PhD – Professor of Psychology and Director Institute for Health Research and Policy (IHRP) University of Illinois, Chicago** **Session Responder: Prof Scott Sherman – Professor of Population Health, Medicine and Psychiatry- NYU Grossman School of Medicine**
10.10 -10.30	**MORNING REFRESHMENT BREAK**
	Youth & Scientific Communication
10.30- 10.45	**Tobacco Harm Reduction: Sorting Truth:** *We live in a saturated information environment (infosphere) that has both positive and negative consequences for parsing facts from fiction. This is also true for scientific endeavors, including so-called tobacco regulatory science and tobacco harm reduction science. Unfortunately, the tobacco science infosphere distorts and obscures scientific realities, and it is not clear that conventional scientific processes and procedures are up to the task of sorting truth from falsehoods. I will discuss strengths and weaknesses of scientific peer review (publications and grant proposals), evidence reviews (quantitative, qualitative, authoritative), funding of research, and the role of science networks (e.g., societies). I will also speculate about ways to strengthen existing information systems as they continue to evolve* **Ray Niaura – Interim Chair of Department of Epidemiology, Professor of Social & Behavioural Sciences NYU School of Global Public Health**
10.45 -11.00	**Reconceptualizing Where E-Cigarettes and Harm Reduction Fit in the Full Developmental Trajectory of Use** *Comprehensive tobacco control approaches, the continuum of risk, and chronic care models of treatment for tobacco dependence are all considered important foundational elements of a public health approach to tobacco control. However, how e-cigarettes fit within each of these elements and blend these "pillars" together, as well as across the full developmental life cycle of tobacco use, has been less considered. This presentation will focus on how "harm reduction" approaches can help fit across the continuum of youth to adults and across products, with an emphasis on key risk communication principles.* **Prof Robin J. Mermelstein, Ph.D. – Professor of Psychology and Director Institute for Health Research and Policy (IHRP) University of Illinois, Chicago**
11.00 -11.15	**Effective Science Based Communication - Kids and the tobacco risk continuum** *The priority remains to prevent teens from becoming part of the tobacco risk continuum but what should be done for kids that are already addicted? This session will explore:* • *FDA's understanding of the mindset of susceptible teens* • *What factors contribute to making them so vulnerable* • *For addicted teens, why FDA encourages complete cessation while still noting that smoking combustibles is the most harmful way to get nicotine* • *What federal resources can help roughly 2M addicted teens* **Kathleen Crosby – Director, Center for Tobacco Products Office of Health Communication & Education, US Food and Drug Administration**
11.15 - 11.30	**A Child and Adolescent Psychiatrist's Perspective:** *Dr. Gray will offer insights based on clinical practice and research focused on understanding and addressing adolescent substance use. Amid a critical developmental window, adolescents are particularly prone to substance initiation and progression to problematic use. Clinical messaging to minimize substance-related harms in this age group presents several challenges. Overly simplistic messaging may be perceived as stilted and condescending, whereas overly complicated messaging may muddle critical information. Messaging specific to nicotine vaping requires nuance, especially when delivered in the context of general substance-related information. Dr. Gray will share perspectives on "planting seeds" of salient information in clinical contexts with adolescents, emphasizing thoughtful approaches to constructively inform adolescent decision-making.* **Prof Kevin M. Gray, M.D. - Professor of Psychiatry and Behavioral Sciences, Medical University of South Carolina**
11.30- 12.00	**Extended Discussion: Kids & Vaping – Working in the Field:** *Communicating the harms of nicotine to kids has been a core strategy to prevent youth uptake of vaping. Jennifer Pearson will guide a discussion on the challenges public health professionals face public health professionals face when communicating the harms of vaping to youth in the real world. From government health messaging to working with kids in schools, this session will*

	explore how to optimize youth education and communication to reach the right kids with the right message at the right time. ***Discussion topics will include:*** • *Personal experiences working in youth vaping prevention and treatment – what's it like out there?* • *The real-world concerns that youth and parents have about vaping.* • *Thinking through the "on the ground" concern that a relative harm message will encourage vaping.* • *Deciding what to tell youth about nicotine vaping and to whom to deliver that message.* • *People's experiences as to how nicotine vaping intersects with mental distress, adverse childhood events, and other substance use.* • *How to target adolescents at highest risk for negative health outcomes.* **Moderator: Associate Prof Jennifer Pearson – Health Administration and Policy, University of Nevada, Reno** • **Jeff Lynch – Facilitator Prevention/Intervention Education, CHOICES Prevention Programs, Tulare County Office of Education** • **Prof Kevin M. Gray, M.D. – Professor of Psychiatry and Behavioral Sciences, Medical University of South Carolina** • **Kathleen Crosby – Director, Center for Tobacco Products Office of Health Communication & Education, US Food and Drug Administration**
12.00-12.30	**Panel Discussion and Q&A: Does harm reduction have a role in youth communication?** • *E-cigarettes and health research – what are the barriers & priorities for delivering better quality research.* • *Has the focus on nicotine over the harms of combustibles made accurate health communication harder?* • *Does current health communication reflect the real world and lived experiences of kids* • *Does THR compliment or contradict the 3 pillars of the CDC tobacco control – Prevention, cessation and smoke free environment* **Chair - Cliff Douglas, JD - Director, Tobacco Research Network, Adjunct Professor, Department of Health Management and Policy, University of Michigan School of Public Health**
12.30 -13.15	**LUNCH**
Regulation and Tobacco Control	
13.15 – 13.45	**Extended Session with Q&A: FDA – Regulatory Update:** *FDA has taken action on millions of e-cigarette PMTAs over the past year. I will provide any update on those actions and discuss some of the major issues that FDA encountered when evaluating these PMTAs. I will also look forward to what the future holds for e-cigarette regulation in the United States.* **Matthew R. Holman, Ph.D. – Director, Office of Science (OS), Center for Tobacco Products (CTP) U.S. Food and Drug Administration**
13.45 – 14.00	**An Applicants Perspective – PMTA:** *The preparation of a PMTA that will be sufficient to establish, to FDA's satisfaction, that the marketing of a product is "appropriate for the protection of public health" requires careful consideration of multiple sources of FDA's expectations and requirements for such a filing. These include guidance's, proposed rules, formal scientific advice, PMTA workshop presentations, and other sources. I will discuss my perspective on the challenges and opportunities that characterized my participation, on behalf of an applicant, in this important and historic process.* **David Graham – Chief Impact Officer, NJOY**
14.00 - 14.15	**The Vape Shop Experience:** *In this session Marc Slis will describe how his independent vapor industry shop such has evolved and its unique role within his community. The session will explore how the regulatory environment has impacted his ability to operate and most importantly his ability to help current smokers move towards becoming smokefree. The foundation of the services is recognizing that each potential client is a unique individual, determining their specific needs and unique circumstances as they relate to tobacco use and cessation. Marc Slis was a smoker for 41 years, unable to quit he intimately knew the futility of trying to force a round peg into a square hole. His method is to individually carve the best fitting hole for each client that walks in to his shop and treat them as a human being throughout the process. No matter how long it takes. No lies. No Shame, judgement, penalties or exclusion. There are no rules and no limits, only guidelines suggestions and encouragement.* **Marc Slis – Independent vape shop owner - Onboard Seismic QC**
14.15 – 14.30	**Why is FDA tobacco regulation such a mess?** *This presentation will look at underlying flaws in the FDA's understanding of key regulatory issues such as youth vaping, e-liquid flavours and tobacco product risks, raising its vulnerability to unintended consequences. We will briefly consider how the agency could better serve the American public and public health.* **Clive Bates – Director, Counterfactual**

14.30 – 14.45	**State and Local Governments: The Original Tobacco "Regulators" are Still in the Game:** *Kathi Hoke will take us on a short tour down memory lane when there was no FDA Center for Tobacco Regulation yet over decades state and local governments and public health advocacy organizations methodically worked to reduce smoking and tobacco use and the related health harms. In the shadow of intense focus on what the FDA can and should do, what a comprehensive plan looks like, what the PMTA process should accomplish, state and local governments continue to innovate in tobacco regulation. In many areas of the country, adult tobacco use is in the single digits. In other areas, public health agencies are earnestly developing programs, policies, and laws to reduce health inequities cause by the tobacco industry's targeting of Black communities, LGBTQ populations, and other marginalized people. What are the innovative approaches state and local governments are taking or considering? How does federal law or the CTP support this work and how do they get in the way? Kathi will address how the CTP could enhance its collaborations with state and local government and provide resources to support these laboratories of innovation.* **Kathleen Hoke J.D – Director of the Network for Public Health Law-Eastern Region, at the University of Maryland Carey School of Law**
14.45 – 15.15	**Panel Discussion and Q&A: What are the likely impacts of a "regulated" product category?** • *Has the lack of federal regulation led to a "wild west" for lawmakers and industry?* • *"Big Tobacco" v Vape Stores –what are the regulatory implications for both, what significance will this have* • *Will there be enough PMTA approved products to meet adult demand?* • *Will the PMTA process create a 2-tier product category and a black market?* • *Do people working in public health know enough smokers* **Session Responder: Prof David Levy – Professor of Oncology, Lombardi Comprehensive Cancer Center, Georgetown University** **Chair - David L. Ashley, Ph.D. - RADM (retired) US Public Health Service: Research Professor, Department of Population Health Sciences, School of Public Health, Georgia State University**
15.15 – 15.35	**AFTERNOON REFRESHMENT BREAK**
Public Health & Policy	
15.35 – 15.50	**Nicotine product standard for combusted tobacco: support and barriers:** *With cigarettes killing more than 480,000 smokers each year in the U.S. alone, innovative and aggressive measures to facilitate quitting smoking among the almost 70% of smokers who want to quit is urgently needed. These methods include eliminating or reducing the attractiveness of a product, such as banning characterizing menthol flavor. However, the approach that will lead to the greatest reduction in the prevalence of smoking is likely to be reducing the addictiveness of cigarettes. Recently, researchers have been systematically and comprehensively examining the potential effects of a nicotine product standard for cigarettes. To date, results from randomized clinical trials indicate that, compared to smokers assigned to smoking normal nicotine content cigarettes, those who are assigned to very low nicotine content (VLNC) cigarettes experience reduced number of cigarettes per day, exposure to toxicants, and cigarette dependence and higher number of quit attempts and cessation rates. These results are found among smokers who experience the greatest prevalence of smoking and experience the greatest health disparities. The results also suggest that reducing the reinforcing value of cigarettes facilitates the uptake of alternative nicotine delivery systems, such as e-cigarettes. This uptake augments the beneficial effects of VLNC cigarettes. Modeling population impact showed that 8 million tobacco-related deaths would be averted by the turn of the century. However, despite these promising findings, several barriers against a nicotine product standard exist such as: 1) a sentiment that reducing nicotine in cigarettes is a draconian measure and smacks of prohibition and that access to alternative products under the right circumstances should be sufficient; 2) similarly, the belief that such a standard would be an infringement on a person's freedom to choose whether to smoke or not; 3) the potential for a flourishing illegal market; 4) misperceptions about nicotine (e.g., nicotine causes cancer so reducing nicotine will reduce cancer risk); and 5) inadequate resources for those who need or want to continue to use nicotine. This presentation will describe what would be necessary to implement a nicotine product standard while minimizing unintended consequences.* **Prof Dorothy Hatsukami – Professor, Department of Psychiatry Associate Director of Cancer Prevention and Control for the Masonic Cancer Center, University of Minnesota**
15.50 – 16.05	**"Smokefree" means smokefree, not vapefree – New Zealand's harm proportionate plans to end smoking** *Vaping has had a profound impact on reducing smoking rates in New Zealand in recent years. Even though this has been accompanied by youth uptake, the Government has not been deterred from seeing vaping as an important tool for reducing the disproportionate toll of smoking on public health. In late 2021, the New Zealand Government published their smokefree plan to get adult smoking rates under 5% by 2025. The plan is notable in that it considers harm reduction and vaping a perquisite for success, declaring: "We will not achieve our goal of Smokefree 2025, however, until our current regulatory settings reflect a more risk-proportionate framework. We can ensure this by making smoked tobacco products more regulated and less available than vaping products".*

	Plans to dramatically reduce nicotine content, additives, flavourings and severely limit access will focus exclusively on combustibles, with the deliberate intention to ensure vaping products remain more affordable, accessible, and ultimately the main source of non-pharmacological nicotine for adult users. This presentation will unpack New Zealand's approach to vaping and smoking, the evidence, experiences and ideologies that have informed it, and how harm reduction has become a cornerstone of our plans for a smokefree nation. **Ben Youdan – Director, Youdan Consulting (Consultant - ASH NZ)**
16.05 – 16.20	**Latest developments on vaping from England:** *England's current tobacco control plan ends in 2022 and plans and consultations are underway to inform the next one which is due to be published in the spring. Last autumn the Medicines and Healthcare products Regulatory Agency published updated guidance on e-cigarettes with an intent of facilitating and expediting progress on making licensed e-cigarettes available. Also, the last evidence update of e-cigarettes commissioned by the Office for Health Improvement and Disparities is underway and will be the largest ever, covering health effects of e-cigarettes as well as the usual chapters on current use among adults and youth, and health perceptions. This talk will update on these new developments and their implications.* **Prof Ann McNeill – Professor of Tobacco Addiction, Institute of Psychiatry, Psychology & Neuroscience, Kings College London**
16.20 – 16.35	**Let's not forget the smokers: a clinician's call to find common ground to save lives now** *In the often-contentious debate about the potential risks and benefits of e-cigarettes, the smokers, who are dying now of their combustible tobacco use, tend to be forgotten. Speaking on their behalf and from a clinician's perspective, Dr. Rigotti will offer her perspective on newer evidence and policy proposals, including information covered in today's symposium, about the balance of health risks and benefits of e-cigarettes and how we can use our imperfect but advancing knowledge to reduce toll of combustible tobacco use.* **Prof Nancy Rigotti – Professor of Medicine, Harvard Medical School Director, Tobacco Research & Treatment Center, Massachusetts General Hospital, Boston**
16.35 – 16.55	**Closing Keynote: Tobacco Harm Reduction in a Global Context: Strategies for the 21st Century** *In the closing keynote Dr Vaughan Rees will explore the success and failures of global tobacco control over the last 5 decades and discuss the impact of policies and current evidence-based interventions. Examining both adult and youth trajectories from different countries, using systematic reviews, Dr Rees will consider the impact of smoking cessation interventions on population prevalence and health disparities. The session will look at the challenge, opportunities and urgent need to chart a future path to change the trajectory of tobacco-related harm in the 21st century.* **Dr Vaughan Rees – Director of the Center for Global Tobacco Control, Harvard T.H. Chan School of Public Health**
16.55 – 17.25	**Panel Discussion and Q&A: Framing the future** • *Why has smoking cessation been so ineffective for disadvantaged communities?* • *Is devaluing combustible products essential to deliver the full potential of reduced risk products or vice-versa?* • *Is a medicinal pathway alongside the consumer pathway preferable or possible in the US?* • *Could VLNC be the beginning of the end for big tobacco?* • *Why has a consensus in the US been so hard to achieve?* • *If it's not helpful to frame the public health conversation as "Supporters/Opponents" then what can we agree on?* **Chair - David L. Ashley, Ph.D. - RADM (retired) US Public Health Service: Research Professor, Department of Population Health Sciences, School of Public Health, Georgia State University** **Session Responder: Cliff Douglas, JD - Director, Tobacco Research Network, Adjunct Professor, Department of Health Management and Policy, University of Michigan School of Public Health**
17.25 – 17.30	**Summary and Closing Remarks from the Chair**
17.30 – 18.15	**End of Summit – Networking Drinks**