07.45 - 08.15	**REGISTRATION & REFRESHMENTS**
NICOTINE, TOBACCO & GOVERNMENT POLICY	
08.15 - 08.20	**Welcome & Introductions Summit AM Chair 2024:** **Prof Robin J. Mermelstein, PhD – Distinguished Professor of Psychology and IHRP Director, University of Illinois, Chicago**
08.20 – 08.35	**OPENING KEYNOTE: Trends in cigarette and e-cigarette use and transitions, a tale of two (or more) populations.** *Use patterns of e-cigarettes and cigarettes have changed dramatically in the US during the past 10 years. During this time, newer e-cigarette products have emerged, public perceptions have shifted, and both policies and regulations have evolved. In this opening keynote session, Dr. Meza will review recent US trends of cigarette and e-cigarette prevalence and transitions between products highlighting differences by age, sex, and socioeconomic status. Finally, Dr Meza will discuss the implications of recent changes in the rates of initiation, cessation and switching between products on projections of future prevalence.* **Dr. Rafael Meza, PhD – Distinguished Senior Scientist, Integrative Oncology, BC Cancer Research Institute**
08.35 – 08.50	**A personal take on the harm reduction debate:** *Mitch Zeller, J.D., was the director of the FDA's Center for Tobacco Products from March 2013 through April 2022. 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." As Center Director, Zeller led the FDA's efforts to use the tools of product regulation to reduce disease and death from tobacco use and bring previously unavailable information about its dangers to light. In this session, Mitch will outline a brief descriptive overview of the competing positions in the harm reduction debate. He will offer some observations on the reality of how the debate is playing out in the U.S. given the statutory and regulatory regime created by the U.S. Congress. Mitch will then contrast the state of play in the U.S. with the UK approach and offer a suggested approach to reframe the debate.* **Mitch Zeller, J.D. – Director (Retired) Center for Tobacco Products Food and Drug Administration (FDA)**
08.50– 09.05	**What is the UK's policy on smoking and vaping in 2024:** *In February 2024 the UK government tabled legislation to create a smoke-free generation and tackle youth vaping. With the support of the Prime Minister and the Official Opposition, the legislation is expected to pass into law before the next general election. It is not expected to change significantly during the passage of the Bill. The government's policy aim on vaping is to balance curbing the rise in youth use, with continuing to support adult smokers to quit. This presentation will set out the measures being proposed to achieve this policy aim.* **Deborah Arnott – Chief Executive, Action on Smoking & Health (ASH UK)**
09.05 – 09.20	**Pathways to Smokefree New Zealand and Australia:** *New Zealand and Australia both have a goal to reduce adult smoking to under 5%. New Zealand by 2025, Australia by 2030. Other than vaping laws, the two countries also have almost identical tobacco control policies. New Zealand has some of the most liberal vaping laws in the world with products widely available. Australia, by contrast, has among the most stringent vape laws, banning nicotine vapes without a medical prescription whilst cigarettes remain widely available. Daily smoking prevalence is falling at record rates in New Zealand, almost halving in the last 5 years to 6.8%, mirrored with a rise in vaping. Smoking rates in Australia have stagnated at around 12%, but youth and adult vaping are still increasing. This talk will examine the impact and policy learnings of New Zealand and Australia's contrasting approaches to harm reduction. This will include the role and relevance of New Zealand's planned 'endgame' laws of mandatory de-nicotinization of all tobacco cigarettes, 90% reduction in tobacco sales and a smokefree generation law. These yet to be implemented laws are to be repealed in 2024 following a change in government. Why did these world first policies fail to survive a change in politics? Should we give up hope, or can we still achieve our goals?* **Ben Youdan – Director, ASH New Zealand**
09.20 – 09.50	**The Center for Tobacco Products' comprehensive 5-year strategic plan:** *In December 2023, the CTP released a new comprehensive 5-year strategic plan. The plan defines five goals, 10 outcomes, and several corresponding objectives, to advance the CTP mission to protect public health from tobacco-related death and disease. The report's goals state commitments to issuing impactful regulations, using robust science to inform application reviews, pursuing timely and impactful compliance and enforcement strategies, and educating the public about the risks of tobacco products. Through the development of the strategic plan, CTP aims to reduce the negative health effects caused by tobacco use by ensuring a well-regulated marketplace, preventing people from starting to use tobacco products, encouraging people who use tobacco products to quit, and reducing the harm caused by tobacco product use. In implementing this plan, CTP will utilize data and analytics to regularly track and monitor progress and make necessary adjustments to key activities to reflect challenges and maximize opportunities.* **Dr Brian King – Director, Center for Tobacco Products (CTP), Food and Drug Administration (FDA)**
09.50 – 10.15	**Session Responder** **Alex Clark –Chief Executive Officer, The Consumer Advocates for Smoke-free Alternatives Association (CASAA)**

	Panel Discussion and Q&A: Nicotine, Tobacco & Government Policy • *Has generic language on "tobacco" products undermined understanding of the "nicotine harm continuum"* • *How can high-risk adolescents be considered in the drive to reduce youth* • *Has a more liberal approach to vaping in other countries reduced smoking* • *Will there be enough PMTA-approved products to meet adult demand* • *Are the voices of people who smoke being heard and considered in health equity discussions?*
10.15 -10.35	**MORNING REFRESHMENT BREAK**
	INDUSTRY, SOCIETY & NICOTINE
10.35- 10.50	**Cannabis and Public Health: Informing a future role of nicotine in society:** *In this presentation, Prof Benowitz will consider the commonalities and differences between cannabis and nicotine use including safety and health impacts and the implications for potential societal acceptance. The use of cannabis products has become normalized in the U.S. over the past 75 years, including the legalization of recreational cannabis use in many states and Canada. The transition from an illicit drug to a socially acceptable drug was driven by evidence of possible medicinal benefit and a marked change in public perception about its harm. Combusted tobacco use has had a devastating effect on public health in the U.S. for more than 100 years. Many former smokers would like not to smoke for health reasons but would like to use nicotine in a less harmful form. In recent years a number of non-combustible nicotine products, both inhaled and oral, have been marketed. However, these products have not gained public acceptance. This appears to relate in part to the tobacco industry's role in promoting cigarettes, raising public skepticism of industry marketing of nicotine as a legitimate drug, and due to concerns about youth adoption of nicotine use. While nicotine drives combusted tobacco use, most of the harm from smoking is caused by products of combustion of tobacco leaf, not from nicotine. However, public perception strongly links nicotine to the harms of smoking. The experience with cannabis normalization suggests that the public perception of nicotine will need to change before non-combusted nicotine products are accepted as appropriate for public health. Part of this education might include a comparison of the benefits vs risks of cannabis v nicotine.* **Prof Neal L. Benowitz MD – Professor Emeritus of Medicine, University of California San Francisco**
10.50 -11.05	**Recent Trends in US Nicotine Delivery Product Markets:** *While US cigarette use among youth and young adults has plummeted, cigarette use has stayed relatively constant among older adults. At the same time, e-cigarette use continues to grow in the US, with much of the growth in disposables, such as Elf bar. Oral nicotine pouch use has also increased, and heated tobacco products are poised to take off. For each of these nicotine delivery product submarkets, this talk will present sales growth, the composition of firms selling the products (focusing on cigarette vs independent companies), and obstacles faced by firms in each of these markets. Special attention will be focused on the role of FDA regulations and other tobacco control policies.* **Prof David Levy – Professor of Oncology, Lombardi Comprehensive Cancer Center, Georgetown University**
11.05 -11.20	**Modern nicotine and tobacco policy: where is the public health frontier?** *Over the past decade, governments worldwide have introduced an array of policies to reduce the health burden of tobacco and nicotine use. Typically targeting product characteristics, prices, or access, these regulations range from taxes to limits on nicotine concentration, to packaging requirements and marketing restrictions, to prohibitions on flavors or even complete sales prohibitions for certain products. Evidence suggests that consumers often substitute between various nicotine and tobacco products when policies make one less accessible or more expensive, while firms respond with new products or marketing to evade restrictions. Given these dynamics, determining which combination of policies will best reduce the harm from tobacco and nicotine use is exceedingly complex, but also vital for public health. This talk will give an overview of modern nicotine and tobacco regulations, including what the evidence suggests about their intended and unintended effects, in order to clarify regulatory opportunities with the greatest potential to promote public health.* **Assoc Prof Abigail Friedman – Associate Professor, Dept of Health Policy & Management, Yale School of Public Health**
11.20 - 11.35	**Taming the Nicotine Industrial Complex - Tobacco Control 2.0:** *"Insight must precede application", said great German physicist Max Planck. The first challenge of exerting control over the market for nicotine is to understand it. That means understanding the complex adaptive system of the demand and supply for nicotine before attempting to regulate it. Is it possible that modern technologies and commerce are beginning to render this market ungovernable? What can and should be done, and are we in need of a reboot of tobacco control? What will Tobacco Control 2.0 look like?* **Clive Bates – Director, Counterfactual Consulting Ltd**
11.35 - 11.50	**Keeping up with the science on vaping: lessons from Surgeon General Reports on smoking and health** *As this E-Cigarette Summit commemorates the 60th anniversary of the historic 1964 Advisory Committee Report on Smoking and Health to the US Surgeon General (SG), my talk will focus on the lessons learned from that report and those that followed in terms of the implications for tracking the evolving science on vaping. The 1964 report was certainly ground-breaking in establishing the basis for defining the causal relationship between cigarette smoking and disease. However, the 1964 report did not end the debate on smoking and health it only marked the*

	beginning of the modern era of tobacco control that relied on continuous updating of the science to alert the public about the dangers of smoking and guide public policies to curb the harms from smoking. Science based tobacco product regulation as it relates to vaping requires a process that ensures the continuous review and updating of scientific evidence much like what was done for smoking and health with reports issued annually as was done following the 1964 SG report. In a regulated market, we need to find ways for industry to share their science more widely so that public health authorities can critically review and update evidence available about products so consumers can rely on the information coming from government authorities. **Prof Kenneth Michael Cummings – Professor, Department of Psychiatry & Behavioral Sciences, MUSC**
11.50 -12.05	**The FDA's legal choices and the federal court's response:** *This session will focus on the FDA's struggles with the PMTA review process. Those struggles were first seen with the Agency's initial scheduling of the PMTA deadline – with a federal court ultimately requiring the Agency to pull the deadline forward by two years. They have continued with FDA's review decisions, where the Agency has chosen to institute what appears to be a de facto product standard (i.e., a flavor ban) by simply denying every application for an e-cigarette product in a flavor other than tobacco. FDA is increasingly encountering setbacks from the federal bench for these PMTA decisions, including most notably in a recent, extremely critical, 5th Circuit en banc decision against the Agency. Brian Yagi will share his views on how the FDA can get the PMTA decision-making process on track and, thereby, increase the chances that regulated harm reduction can make a positive impact on American public health.* **Dr Brian Yagi, M.D., J.D. – Assistant Professor of Internal Medicine, John Hopkins School of Medicine**
12.05-12.35	**Panel Discussion and Q&A: Industry, Society & Nicotine** • *Is THR a public health principle or an industry strategy?* • *Is nicotine use in society inevitable and if so, should it ever be acceptable* • *How can the U.S. regulatory and policy process adapt to such a fast-evolving nicotine market* • *What are the costs of pursuing a policy for a smoke-free and nicotine-free future?*
12.35 -13.20	**LUNCH**
THR, CESSATION & HEALTH	
13-20– 13.25	**Welcome & Introductions Summit PM Chair: Prof Thomas J. Glynn, PhD – Adjunct Lecturer, Stanford Prevention Research Center, Stanford University School of Medicine**
13.25 – 13.40	**As e-cigarettes become the dominant form of tobacco use, how can we help e-cigarette users who want to quit?** *In this session, Prof Benjamin Toll will present recently published nationally representative data from the US FDA Population Assessment of Tobacco and Health (PATH) study showing that since 2013 in the key demographic of 18-24 year-olds, rates of combusted cigarette use have been falling and rates of e-cigarette use have been rising, such that now 14.5% use e-cigarettes, compared with only 6.1% who use combustible cigarettes. Moreover, more than half of these young adults who use e-cigarettes have never smoked. This age group of young adults (age 18-24) has historically been important to the tobacco industry as a time when tobacco users often transition to established use and brand loyalty, and these data may forecast a future in which e-cigarettes are the dominant tobacco product in the US. Importantly, we have shown in published papers that over 60% of all e-cigarette users in the US express (in responses reported in Waves 4 and 5 of the PATH study) that they plan to quit vaping. A recent systematic review from our group shows that there are almost no studies of e-cigarette treatment to assist the many e-cigarette users who plan to quit. We will present several pilot clinical trials investigating dual nicotine replacement therapy, high dose dual nicotine replacement therapy, and varenicline tartrate for the treatment of e-cigarette use.* **Prof Benjamin Toll – Professor and Vice Chair of Public Health Sciences, Medical University of South Carolina**
13.40 – 13.55	**Cigarette smoking relapse among recent former smokers who switched to e-cigarettes or other tobacco products:** *Electronic cigarettes (or e-cigarettes) have been studied as a cessation tool in clinical trials and longitudinal studies. Less well-studied is how e-cigarette use among former smokers affects smoking relapse, a concept that is not well-defined. A recent paper looked at this issue but only used any cigarette smoking in the past 12 months as their smoking relapse measure. We examine how the use of different definitions of relapse might affect findings. Using longitudinal data from three consecutive waves (waves 1-3 and 2-4) of the Population Assessment of Tobacco and Health (PATH) Study, we found that more than half of recent former smokers relapsed if we define relapse as any cigarette smoking in the past 12 months (Measure I), 40.3% relapsed if we use the definition of any past 30-day smoking (Measure II), and 30.1% relapsed if we use the definition of smoking on >=3 days in the past 30 days (Measure III). Compared with those who remained tobacco-free, recent former smokers who switched to current e-cigarette use or any non-cigarette tobacco use were marginally more likely to relapse using Measure I but showed no increased likelihood of relapse using measures II or III. Recent former smokers who switched to current e-cigarette use may be more likely to slip but reported no difference in the likelihood of cigarette smoking relapse, especially when not defining relapse as any lapse during the 12 months following quitting.* **Dr Ruoyan Sun – Assistant Professor, Department of Health Policy & Organization, School of Public Health, University of Alabama at Birmingham, USA**

13.55 - 14.10	**Vaping-smoking transitions: a focus on the evidence:** *Much of the debate around the potential public health benefits and harms of e-cigarettes focuses on their relationship to smoking. If – at a population level – e-cigarettes lead to more people smoking than would have otherwise, then their net impact on public health will undoubtedly be a negative one. If, however, vaping decreases smoking at a population level, there is the potential for public health benefit. In this talk, Jamie Hartman-Boyce will describe the current state of the evidence on the impact of vaping on smoking behaviors, including flagging some potential consequences of vaping restrictions. I'll touch on topical issues including the theories that vaping may act as a gateway into smoking, and the potential role e-liquid flavors may have on vaping-smoking transitions.* **Dr Jamie Hartmann-Boyce – Assistant Professor in Health Promotion and Policy, University of Massachusetts Amherst**
14.10 – 14.25	**England's national "Swap to Stop" program:** *In April 2023 England's Minister for Public Health announced an ambitious national Swap to Stop scheme through which 1 million smokers will be supported to quit smoking through the use of an E-Cigarette, this presentation will review the evidence and update on progress including highlighting the targeted way the scheme is seeking to reduce health inequalities by serving some of England's most disadvantaged smokers.* **Martin Dockrell -Tobacco Control Evidence Lead, Office for Health Improvement and Disparities in England's Department of Health and Social Care**
14.25 – 14.40	**Getting e-cigarettes into the tobacco treatment toolkit: Moving the medical community from "Should we?" to "How do we and for whom?":** *The accumulating evidence now supports a strong conclusion that e-cigarettes are tools that healthcare clinicians can—and should—use to help adults stop smoking, especially those who cannot quit another way or who want to reduce health harm without quitting. It is time for the medical community to add e-cigarettes to the tobacco treatment toolbox. The question is no longer "Should we?" but "How and for whom?" should we recommend them? Doing so will require addressing multiple barriers. Both patients and clinicians misunderstand the relative risk of nicotine vs. combustible tobacco products. Lack of a medically licensed product or guidance from medical organizations complicates making a specific recommendation for choosing a product or learning how to use it. This session will raise questions and highlight issues that are likely to arise for U.S. clinicians who add e-cigarettes to their tobacco treatment toolkit.* **Dr. Nancy A. Rigotti, MD – Professor of Medicine, Harvard Medical School, Director, Tobacco Research & Treatment Center, Massachusetts General Hospital, Boston**
14.40 – 14.55	**E-cigarettes for harm reduction: Starting with priority populations:** *This session will look at the role of e-cigarettes as a harm reduction strategy for high priority individuals, specifically those with high smoking prevalence or with the most immediate risk of particular health harm.* *Smoking cessation is the most effective means of slowing the decline of lung function associated with chronic obstructive pulmonary disease (COPD) but while effective smoking cessation treatments are available, they are underutilized and nearly half of people with COPD continue to smoke. In this session, Dr Sherman will present the findings from a recent pilot study that looked to identify barriers and facilitators to the use of and assess the preliminary effectiveness of e-cigarettes as a harm reduction strategy for people with COPD, CAD or PAD who currently smoke. Dr Sherman will incorporate findings from their ongoing studies for people with opioid use disorder, mental health diagnosis and HIV.* *Finally, Dr Sherman will talk about the launch of a new Center on vaping for both nicotine and cannabis products.* **Prof Scott E. Sherman, MD – Professor, Department of Population Health, NYU Grossman School of Medicine**
14.55– 15.25	**Panel Discussion and Q&A: THR, Cessation & Health** • *Has the controversy over e-cigarettes been a roadblock to advising current smokers about their choices? and, if so, how could this be corrected?* • *Does long-term e-cigarette use pose more of a public health challenge than a potential relapse to combustible products?* • *Who is responsible for communicating the evidence on the harms of smoking and vaping to clinicians* • *How can e-cigarettes be promoted to optimize smoking cessation in disadvantaged communities?* • *Why is harm reduction a recognized tool for many societal issues, but so controversial in tobacco control?* • *Are we targeting the right people with the right message?*
15.25 – 15.45	**AFTERNOON REFRESHMENT BREAK**
TOBACCO, NICOTINE & PUBLIC HEALTH	
15.45 – 16.00	**The future mortality implications of vaping for adolescents** *The most serious potential adverse consequence of vaping by adolescents would be future mortality associated with long-term vaping itself or with vaping-induced cigarette smoking – the gateway effect. Whether the gateway effect exists remains a contentious issue. For the purposes of this analysis, we will assume that it does. We assume, as well, that vaping by smokers increases their odds of quitting smoking. While simulation analyses have examined the net impact of vaping on population-level mortality, most finding a net reduction in premature mortality, no study to date has investigated how vaping would affect the future mortality associated with vaping within a single*

	birth cohort of adolescents. The present study employs a simulation model to evaluate the mortality impact, over their entire lifetimes, of vaping by members of the cohort of 12-year-olds in 2016. Findings indicate that, under some assumptions, vaping will reduce the cohort's lifetime premature mortality, while under others, it will increase premature mortality. In all cases, however, the impact of vaping on the cohort's lifetime mortality will be minuscule. **Prof Kenneth E. Warner – Avedis Donabedian Distinguished University Professor Emeritus and Dean Emeritus, School of Public Health, University of Michigan**
16.00 – 16.15	**The transition to harm-reduced nicotine products is inevitable:** *In this presentation, Professor Ron Borland will question if the conventional goal of many in public health to eliminate all nicotine use is achievable, and whether a transition to the use of harm-reduced nicotine products is inevitable. Furthermore, given the enormous cost of smoking, should governments look to facilitate this transition rather than inhibit it? Prof Borland will present data, specifically looking at levels of smoking in young adults in countries where they have been exposed to strong anti-smoking messages all of their lives, including countries such as Australia, where access to vaping products is technically illegal. Prof Borland will examine the potency of conventional tobacco control armoury tools, such as health warnings and price, both before and after vaping started to become popular. Finally, given the enormous costs of allowing people to continue to smoke, or effectively forcing them to because of a lack of access to viable alternatives, Prof Borland will consider the frameworks that will most rapidly achieve a transition away from smoked tobacco, while at the same time minimizing the inevitable use by adolescence.* **Prof Ron Borland PhD, FASSA – Professor of Psychology Health Behaviour, Melbourne School of Psychological Sciences, The University of Melbourne**
16.15 – 16.30	**Effectiveness of a vaping cessation text message program among a diverse and high-risk sample of adolescent e-cigarette users:** *E-cigarettes have been the most commonly used tobacco product among adolescents in the United States for nearly a decade. There is broad consensus that adolescents should not use any form of tobacco product, and yet there are no published studies of vaping cessation interventions for teens. This presentation will describe the results of a randomized, controlled clinical trial conducted from October 2021 to October 2023 that compared a text message intervention to an assessment-only control among a diverse and high-risk sample of 1,503 U.S. teens ages 13-17. Results from this trial will be placed in the context of ongoing national public education efforts to disseminate the intervention, which have yielded uptake among more than 700,000 teens and young adults since the program launched in January 2019.* **Dr Amanda L. Graham, PhD – Chief Health Officer, Truth Initiative**
16.30 – 16.45	**Changing nicotine beliefs: key to changing tobacco and nicotine use behaviors?** *Widespread misperceptions of the health risks of nicotine undermine use of nicotine replacement therapy for smoking cessation, and potentially, switching from combusted to non-combusted tobacco and nicotine products. They may also impact the public health benefits of FDA's actions, including modified risk tobacco product (MRTP) authorizations and a reduced nicotine product standard for cigarettes. Dr. Villanti will present findings from a national randomized controlled trial testing the effects of nicotine corrective messaging on beliefs about nicotine, nicotine replacement therapy (NRT), e-cigarettes, and reduced nicotine content (RNC) cigarettes.* **Assoc Prof Andrea Villanti – Associate Professor, Department of Health Behavior, Society, and Policy, Rutgers School of Public Health**
16.45 – 17.00	**Panel Discussion and Q&A: Tobacco, Nicotine & public health** • *Is ending smoking and nicotine use at the same time a realistic public health goal at the population level* • *How can THR be successfully incorporated into tobacco control* • *What are the influencing factors that impact public risk perceptions on both smoking and nicotine use and how can messages to promote vaping cessation encourage quitting without relapse to smoking?* • *What does the future look like for youth who currently vape?*
17.00 – 17.30	**Closing Keynote Conversation: A Tale of Two Cities** *"It was the best of times, it was the worst of times..." is the famous opening line of Charles Dickens' historical novel, set during a period of revolution and change. In this session, Tom Glynn will lead a conversation with Ann McNeill and Robin Mermelstein exploring the scientific, cultural, and policy questions that e-cigarettes and novel nicotine products pose for governments, scientists, and the public health community. Drawing on their experiences of working in countries with very different approaches, they will consider the challenges and opportunities that have emerged in the fight to end smoking.* **Prof Robin J. Mermelstein, PhD – Distinguished Professor of Psychology and IHRP Director, University of Illinois, Chicago** **AND** **Prof Ann McNeill – Professor of Tobacco Addiction Institute of Psychiatry, Psychology & Neuroscience, King's College London**
17.30**– 18.**30	**End of Summit – Networking Drinks**