

07.45 - 08.15	REGISTRATION & REFRESHMENTS
Regulatory Frameworks	
08.15 - 08.20	Welcome from the Chair- Thomas J. Glynn, PhD Adjunct Lecturer, Stanford Prevention Research Center, Stanford University School of Medicine
08.20 – 08.35	Opening Address: Why is Tobacco Harm Reduction so Divisive? <i>By objective standards this should be a good time for tobacco control in the United States. Adult smoking rates have fallen to a modern low of 14%, meaning that millions of premature deaths have been averted. And although youth smoking rates bumped up from 7.6% in 2016 to 8.1% in 2017, they are still far below the rate of 15.8% in 2011, and 35% in 1997. Yet, the situation today resembles the phrase Aaron Wildavsky used when describing health care in 1976: “Doing Better and Feeling Worse.” So, why is tobacco harm reduction so divisive?</i> Steven A. Schroeder, MD - Distinguished Professor of Health and Health Care, Department of Medicine. Director, Smoking Cessation Leadership Center UCSF
08.35 – 09.00	Trends in emerging tobacco product use in the United States: <i>This presentation will describe trends in tobacco product use in the United States, including the evolving landscape of e-cigarettes and other emerging products. Data will be presented on self-reported use among adults and youth from a variety of established national and state-specific surveillance systems. In addition, data on sub-annual and emerging trends in novel product use will be presented from web-panel surveys and retail sales datasets. The presentation will conclude with a discussion of existing gaps and future directions for monitoring emerging tobacco product use.</i> Dr Brian King, PhD, MPH - Centers for Disease Control and Prevention, Office on Smoking and Health
09.00 – 09.15	Tobacco harm reduction in a hostile regulatory environment: The Australian experience: <ul style="list-style-type: none"> • <i>What can we learn from a truly hostile environment?</i> • <i>Unintended consequences of the current strategy without tobacco harm reduction</i> • <i>Smoking rates in Australia</i> • <i>The unhelpful intervention of Big Tobacco in the debate</i> Colin Mendelsohn - Conjoint Associate Professor, University of New South Wales, Sydney
09.15 – 09.30	England’s answers to Mitch Zeller’s five questions: <i>Last October Mitch Zeller explained that the FDA wanted help answering a number of fundamental questions about how the principle of harm reduction should shape policy decisions on the future of nicotine regulation. This presentation sets out how the English Government and its arms-length bodies, such as the NHS and Public Health England, are answering these questions in practice.</i> 1) How comfortable are we with long-term, or possibly permanent, use of less harmful nicotine delivery mechanisms by adults, if they help keep currently addicted smokers from relapsing to combustible tobacco products? 2) How much weight should be placed on diminished interest in quitting nicotine altogether? 3. Given the potential health impacts of dual use of tobacco, how acceptable is a short period of dual use while transitioning to less harmful nicotine-containing products? What if many current smokers engage in dual use on a long-term or permanent basis? 4) Can we revise labeling and indications for medicinal nicotine to increase quitting? 5) How might youth initiation be affected by the availability of different nicotine-containing products and how should we account for youth uptake of these products? Deborah Arnott - Chief Executive, Action on Smoking and Health (ASH), UK
09.30 – 09.45	How is the increase in youth vaping impacting the Canadian approach to regulating e-cigarettes? <i>Canada’s new regulatory regime for e-cigarettes and other vaping products was established with the passage of the Tobacco and Vaping Products Act in May 2018. The Act balances the opportunities and risks associated with the use of these products to help Canadians quit smoking and prevent youth and non-smokers from developing a dependence on nicotine. Almost a year later and with emerging evidence of an increase in youth use in Canada, there is a need to re-examine the regulatory balance. Mr. Van Loon will outline the comprehensive activities that the Government of Canada is taking to address recent increases in youth vaping and look ahead to key issues and challenges.</i> James Van Loon - Director General, Tobacco Control Directorate, Health Canada
09.45 – 10.15	Panel Discussion and Q&A: What are the key considerations for prudent regulation of e-cigarettes? <ul style="list-style-type: none"> • <i>Can youth use of nicotine ever be acceptable to public health</i> • <i>Are we seeing a “gateway” effect to combustible products</i> • <i>Could youth use be a passing fad or a phenomenon that’s here to stay?</i> • <i>How to maximize benefits for smokers and minimize potential harms for youth.</i> Steven A. Schroeder, Dr Brian King, Colin Mendelsohn, Deborah Arnott, James Van Loon, Kenneth Warner
10.15 -10.35	MORNING REFRESHMENT BREAK

Youth Initiation and Smoking Cessation

10.35- 10.50	<p>Youth vaping and the emergence of nicotine salt products in Canada, England and the US: implications for vaping policy: <i>The vaping market has evolved over the past year, including changes to the regulatory status of vaping products in Canada and the emergence of nicotine salt products. The extent to which these developments have influenced youth vaping remains a topic of concern and debate within the public health community. The presentation will examine changes in vaping among youth between 2017 and 2018 in Canada, the US, and England using data from the International Tobacco Control (ITC) Youth Tobacco and Vaping Survey. The ITC youth survey was conducted with 23,928 youth aged 16 to 17 across the three countries, and provides detailed information on youth smoking, vaping, and product use. The presentation will examine changes patterns of vaping between 2017 and 2018, as well as the use of JUUL and other nicotine salt brands among youth. The presentation will consider the policy implications, including potential regulatory measures announced in Canada and the US that seek to minimize vaping among youth.</i></p> <p>Prof David Hammond PhD – Professor & CIHR/PHAC Applied Public Health Chair, University of Waterloo</p>
10.50 -11.05	<p>E-cigarette use and smoking among adolescents: are gateway concerns supported by the data? <i>Given recent changes in e-cigarette use and smoking rates seen among youths in the US, there are fears that novel nicotine delivery devices may undermine decades of tobacco control efforts to prevent smoking uptake in adolescents. This presentation will use latest data from UK and US cross-sectional and longitudinal population surveys as well as from a micro-simulation model to interrogate whether such concerns are justified and how trends in North America compare with those seen in the UK.</i></p> <p>Dr Lion Shahab – Associate Professor in Health Psychology, University College London</p>
11.05 -11.20	<p>The potential of reduced risk products to diminish the toll of cigarette smoking: <i>How much of the toll of cigarette smoking could reduced risk products (RRPs) like e-cigarettes eliminate? This paper will report findings from a new study, employing the Mendez-Warner U.S. cigarette smoking simulation model that addresses this question, specifically looking at the metric of life-years saved.</i></p> <p>Prof Kenneth Warner - Professor Emeritus and Dean Emeritus, School of Public Health, University of Michigan</p>
11.20 -11.35	<p>Do e-cigarettes help smokers quit? <i>The relevant evidence that can answer this question can be gathered from two different sources: Efficacy of e-cigarettes provided proactively by health professionals as a smoking cessation intervention; and effects of e-cigarettes that smokers purchase themselves. Regarding e-cigarettes as a clinical treatment, the presentation will review existing randomised controlled trials with a focus on a recently published large UK study. Re. e-cigarettes purchased as consumer products, population data and cohort studies are now starting to provide information on the proportion of ex-smokers who quit with e-cigarettes compared to other methods and on outcomes of quit attempts using different quit aids. The crucial evidence will emerge from studies of links between changes in cigarette and e-cigarette sales and between smoking and vaping prevalence.</i></p> <p>Prof Peter Hajek - Professor of Clinical Psychology, Queen Mary University of London</p>
11.35 -11.50	<p>Who are “dual users” who switch to using e-cigarettes only? <i>This presentation will highlight data from an observational study of dual cigarette and e-cigarette users, focusing on patterns and predictors of switching products or maintaining dual use. Characteristics of dual users who continue or desist use of one or both products will be discussed with implications for maximizing the potential to help combustible smokers switch completely.</i></p> <p>Prof Robin J. Mermelstein - Professor of Psychology and Director Institute for Health Research and Policy (IHRP), University of Illinois, Chicago</p>
11.50 -12.05	<p>The doctor’s dilemma: Providing guidance on e-cigarettes to adult smokers amid controversy and change. <i>In the 15 months since the U.S. NASEM report on e-cigarettes was released, much has changed. JUUL emerged as a dominant product and further data appeared about e-cigarettes’ potential impact on tobacco use initiation, cessation, and health risks. Health care providers caring for adult smokers are tasked with translating incomplete evidence into guidance that balances the individual patient’s best interest with public health concerns. This presentation will summarize areas of consensus and disagreement in the medical community, as illustrated by how professional medical societies have recently addressed the challenge.</i></p> <p>Prof Nancy Rigotti, MD - Professor of Medicine, Harvard Medical School; Director, Tobacco Research & Treatment Center, Massachusetts General Hospital, Boston, MA USA</p>
1205 -12.35	<p>Panel Discussion and Q&A:</p> <ul style="list-style-type: none"> • <i>E-cigarettes and health research – what are the barriers & priorities for delivering better quality research.</i> • <i>Is dual use an important step in cessation or a failing of harm reduction</i> • <i>Is health communication to youth and adults accurately reflecting the science</i> <p>Kenneth Warner, Lion Shahab, Nancy Rigotti , Robin J. Mermelstein, David Hammond, Peter Hajek</p>
12.35 -13.20	LUNCH

Tobacco Control, Industry & Regulation

13.20 – 13.35	<p>The role of electronic cigarettes within US regulatory strategy: <i>FDA-CTP has announced a comprehensive plan for tobacco and nicotine regulation that involves reducing the permissible nicotine content in cigarettes to minimally addictive levels, while allowing regulated non-combustible nicotine products to remain on the market. The major cigarette companies will oppose implementation of this strategy but they are aware that there is already an accelerating decline in US cigarette sales and a mirror-image increase in e-cig sales. In recent years the evidence-base demonstrating that the very low nicotine cigarette strategy is feasible has been strengthening. As this progresses there will come a tipping point at which it will no longer be necessary for some of the major cigarette companies to oppose reduced nicotine regulation for cigarettes. It remains critical for FDA to enhance and enforce regulations to minimize all tobacco sales to youth and for companies themselves to not indulge in reckless marketing to young people. Concerns about youth e-cig use are well founded, but the main concern of a gateway to cigarettes will not be an option once nicotine content in cigarettes is minimized.</i></p> <p>Prof Jonathan Foulds - Professor of Public Health Sciences and Psychiatry, Penn State Tobacco Center of Regulatory Science, Cancer Institute</p>
13.35 – 13.50	<p>How worried should e-cigarette manufacturers and tobacco harm reduction proponents be about FDA’s review of new product applications? <i>Every e-cigarette on the U.S. market is currently illegal and will ultimately need a permissive new-product order from FDA to stay on the market legitimately. And no new or substantially changed e-cigarettes can legally enter the market without a permissive new-product order. What standards must and could FDA apply to manufacturers’ applications for new-product orders? Will politics come into play? Is helpful product innovation being stalled? Can it be encouraged? So far, applications to get permissive orders have consisted of hundreds of thousands of pages and many months of back-and-forth revisions and review. Is there an easier way?</i></p> <p>Eric N. Lindblom - Director for Tobacco Control and Food and Drug Law at the O’Neill Institute for National and Global Health Law, Georgetown Law</p>
13.50 - 14.05	<p>FDA’s regulatory approach to addressing youth appeal and access: How should FDA close the on-ramp for youth while maintaining the off-ramp for adult smokers? <i>In its recent reevaluation of the compliance policy for deemed tobacco products that were on the market on August 8, 2016, FDA has focused primarily on flavors and convenience stores. Is this the right focus? Are flavors the main appeal of e-cigarettes to youth? Are convenience stores the primary source for youth purchases? How would FDA’s proposed changes to the compliance policy impact adult smokers? Are there other regulatory approaches that might strike a more appropriate balance? Does FDA have the legal authority to modify its compliance policy as it has proposed?</i></p> <p>Stacy L. Ehrlich - Partner, Kleinfeld, Kaplan & Becker LLP</p>
14.05 – 14.20	<p>Industry, flavors and tobacco harm reduction: <i>This presentation will discuss why the singular focus on flavors is misleading and will not address the core youth issues of appeal and access but undermine the efforts of adults trying to quit.</i></p> <ul style="list-style-type: none"> • <i>What is the flavored versus non-flavored ENDS dialectic and why does that old tobacco paradigm not apply to the modern ENDS market?</i> • <i>Why flavors are important to independent vape shop owners</i> • <i>How vape shops are important to the overall mission of promoting tobacco harm reduction</i> <p>Tony Abboud - Executive Director, Vapor Technology Association</p>
14.20 – 14.35	<p>Market competition in the e-cigarette industry and its impact on public health: <i>David Levy will discuss market competition in the e-cigarette market and how that relates to the cigarette industry. Market concentration, entry barriers and pricing behavior will be considered. The potential impact of Altria's purchase of 35% share of Juul will also be discussed.</i></p> <p>Prof David Levy, Professor of Oncology, Lombardi Comprehensive Cancer Center, Georgetown University</p>
14.35 – 15.05	<p><u>Panel Discussion and Q&A:</u></p> <ul style="list-style-type: none"> • <i>What direction should the FDA take with e-cigarettes and tobacco control?</i> • <i>“Big Tobacco” v Vape Stores –what are the regulatory implications for both, what significance will this have</i> • <i>Regulating flavors to maximize benefit (smoker uptake) and minimize harm (youth appeal)</i> • <i>Is the burden associated with the PMTA process too high, not high enough or about right?</i> <p>Prof Jonathan Foulds, Eric N. Lindblom, Stacy L. Ehrlich, Tony Abboud, Prof David Levy, Clive Bates</p>
15.05 – 15.25	<p>AFTERNOON REFRESHMENT BREAK</p>

Public Health & Policy

15.25 – 15.40	<p>The continuing complexity associated with regulating and setting policy in the context of evolving and imperfect information: <i>This presentation will highlight the points of substantial disagreement among researchers, sharply differing current and emergent policy approaches and lessons learned from other epidemics where the responses varied among and within countries and evolved over time. The potential “natural” experiment that is unfolding globally will likely yield a number of lessons learned and surprising results. Gathering and applying these lessons is crucial and can save many lives.</i></p> <p>Cheryl G. Heaton - Dr.PH, Dean and Professor, NYU College of Global Public Health</p>
15.40 – 15.55	<p>Sound Public Health Policy Requires Meaningful Regulation: <i>In the hope that E-Cigarettes would inevitably transform the battle to reduce the death and disease caused by tobacco, too often scientific standards have been lowered and fundamental public health lessons ignored. It is not a surprise that there are so few solid scientific answers because so much of the discussion has been characterized by broad bold overly simplistic statements that are guaranteed to generate conflict because there are examples where they are provably wrong. E-Cigarettes are not a single product and their impact on population health will vary based on a host of confounding factors. The same e-cigarette can also lead to significantly different results depending on a wide variety of factors, including, among others, how they are marketed, the laws governing marketing and product content, including nicotine content and delivery, the capacity of different governments to regulate and/or enforce whatever rules do exist, the effectiveness and potential of existing tobacco reduction measures, the behavior of different companies, requirements for companies to test and disclose how specific products are used, and many others. Under these circumstances, it is not surprising that the experience in different countries varies. The product matters, and we don't focus adequately on their differences, but so do other factors. Supporters of e-cigarettes argue that traditional regulation will kill innovation. History teaches that the absence of meaningful regulation undermines public health goals, innovation that maximizes public health, and the production of the kind of information that leads to consensus.</i></p> <p>Matthew L. Myers, President, Campaign for Tobacco-Free Kids</p>
15.55 – 16.10	<p>Are we asking the right questions? <i>Alternative nicotine products have created a paradigm shift which researchers, policy makers and the public are struggling to catch up with. As lead author of three Public Health England evidence updates with two more over the next two years, this presentation will discuss what their purpose is, what has been learned, and how that learning sits within the history of nicotine use in England. They also allow us to identify whether research is broadly asking the right questions, in particular for a) the billions of smokers who are not engaging with reduced harm products, b) the millions of smokers who have switched and c) adolescents who are experimenting and/or regular users?</i></p> <p>Prof Ann McNeill - Professor of Tobacco Addiction, UK Centre for Tobacco and Alcohol Studies, KCL, UK</p>
16.10 – 16.25	<p>Will there be anything left for the inevitable next generation of people who smoke? <i>Whether we are evangelical about our experience of switching to smoke-free alternatives or went into the business of selling them, people who vape all share compassion for people who continue to smoke and have a strong desire to protect legal, affordable access to safer alternatives to combustible tobacco. But, our long-term success with living smoke-free has a perceived expiration date in the U.S. The moving PMTA compliance deadline is drawing closer. Subsequently, consumer mistrust and disdain for regulators and public health organizations is growing. Where are our allies?</i></p> <p>Alex Clark – Vaper & Chief Executive Officer, CASAA</p>
16.25 – 16.40	<p>Credible public health communication and truth telling about tobacco and nicotine: <i>The effectiveness of public health institutions depends on developing and maintaining trust relationships with communities. To communicate credibly and ethically about tobacco and nicotine products, institutions must listen and be responsive to the people they serve. Regardless of whether public health gatekeepers believe that information about the relative risks of different tobacco and nicotine products is “good for” people, many people clearly want this information. When public health communication elides distinctions that people care about, public trust is eroded with far reaching consequences.</i></p> <p>Rachelle Annechino - Associate Research Scientist, Critical Public Health Research Group and the PIRE/Prevention Research Center</p>
16.40 – 16.55	<p>A public health perspective on combating youth e-cigarette use while aiming at the bull’s eye: the end of combustible tobacco use: <i>In February 2018, the American Cancer Society published its Position Statement on Electronic Cigarettes, which recognized that “Some smokers, despite firm clinician advice, will not attempt to quit smoking cigarettes and will not use FDA approved cessation medications.” It advised that “These individuals should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products,” and concluded that “these individuals should be regularly advised to completely quit using all tobacco products.” Since the release of that statement, the controversy surrounding alternative nicotine delivery products has grown even more fraught, due in great part to the rapid increase in consumption of e-cigarettes by youth in the US, heavily fueled by the popularity of JUUL. An additional consequence of the justified media focus on the youth e-cigarette epidemic is that the exponentially</i></p>

	<p><i>larger impact of combustible cigarette smoking on public health continues to receive inadequate attention. The public health community and others must continue to aggressively counter youth e-cigarette use while emphasizing the overarching need to end combustible tobacco use.</i></p> <p>Cliff Douglas JD - Vice President, Tobacco Control, Director, Center for Tobacco Control, American Cancer Society</p>
16.55 – 17.20	<p>Panel Discussion and Q&A:</p> <ul style="list-style-type: none"> • <i>What are the main priorities for current smokers</i> • <i>What are the main priorities for preventing youth initiation</i> • <i>Are these two priorities compatible</i> <p>Cheryl Heaton, Matthew L. Myers, Prof Ann McNeill, Alex Clark, Rachelle Annechino, Cliff Douglas JD;</p>
17.20 – 17.30	Summary and Closing Remarks from the Chair
17.30 – 18.15	End of Summit – Networking Drinks