

07.45 - 08.15	REGISTRATION & REFRESHMENTS
Regulatory Frameworks	
08.15- 08.20	<p>Welcome from the Chair- Thomas J. Glynn, PhD Adjunct Lecturer, Stanford Prevention Research Center, Stanford University School of Medicine</p>
08.20 – 09.00 (Q&A 10 Mins)	<p>Opening Address: An Update on FDA’s Comprehensive Plan on Nicotine and Tobacco <i>On July 28, 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation. The plan is a multi-year roadmap to significantly reduce tobacco-related disease and death. This approach places nicotine, and the issue of addiction, at the center of FDA’s regulatory efforts. FDA acknowledges that nicotine is delivered through products on a continuum of risk and cigarettes are the most harmful. Therefore, FDA must seek to strike an appropriate balance between smart regulation and encouraging the innovation of satisfying, less harmful products. This presentation will provide an update on the status of the core elements of the July 28th announcement.</i></p> <p>Mitch Zeller – Director, FDA Center for Tobacco Products, Silver Spring, Maryland</p>
09.00 – 09.15	<p>Nicotine Reduction: Harm Reduction not Prohibition <i>Reducing nicotine in cigarettes reduces smoking because it renders cigarettes less satisfying and less addictive. However, the impact and viability of such a policy will depend on the availability of appealing, satisfying and safer alternatives. A low nicotine product standard combined with policies that enable the use of less harmful alternatives, and proper messaging about nicotine and harm, has the potential to facilitate rapid changes in the products people prefer and the health consequences they will likely incur as a consequence of nicotine use.</i></p> <p>Prof Eric Donny – Professor of Physiology and Pharmacology, Wake Forest School of Medicine</p>
0915 – 09.30	<p>The New Zealand Experience with E-cigarettes <i>The sale of nicotine-containing e-cigarettes (EC) is currently illegal in NZ, although people can legal import EC for their personal use. In June 2016, the Cabinet Social Policy Committee decided, in principle, to legalise the sale of EC, but with appropriate controls. The potential of e-cigarettes to help improve public health depends on the extent to which they can act as a route out of smoking for New Zealand’s 550,000 daily smokers, without providing a route into smoking for children and non-smokers. In 2017 the Government proposed to change the law regulating e-cigarettes. These proposed changes included the legalisation of the sale and supply of nicotine e-cigarettes and e-liquid as consumer products, but with controls. This presentation will provide an overview of the journey to date and possible future direction.</i></p> <p>Prof Hayden McRobbie – Clinical Director of the Dragon Institute for Innovation (NZ), Professor in Public Health Interventions, Queen Mary University of London</p>
09.30 – 09.45	<p>Regulatory framework for e-cigarettes in the EU <i>From 2016 onwards the Tobacco Products Directive introduced regulations for e-cigarettes which provide a consistent regulatory framework across the whole of the EU, with 28 member states and a population of over 500 million. This session will explain how the regulatory framework establishes a notification system for consumer products which has allowed the independent e-cigarette sector to continue to flourish, with the option left open to apply for more stringent medicines licensing. It will go on to explain how the regulatory system in the UK, while conforming to the EU rules, is embedded within a strategy for driving down smoking prevalence which is the most advanced in Europe and what the implications of that have been. It will also point out the differences between the EU and the US systems, and what the implications of these differences are.</i></p> <p>Deborah Arnott – Chief Executive, Action on Smoking and Health (ASH), UK</p>
09.45 – 10.15	<p>Panel Discussion and Q&A: What are the Key Considerations for Prudent Regulation of E-Cigarettes?</p> <ul style="list-style-type: none"> • <i>What are the most effective strategies to divert smokers away from combustible tobacco products</i> • <i>How can regulation responsibly support innovation and product appeal to maximize public health benefits</i> • <i>Will very low nicotine cigarettes send a mixed message about the real harm of combustion over nicotine</i> • <i>How to maximize benefits for smokers and minimize potential harms for youth.</i> <p>Mitch Zeller, Eric Donny, Hayden McRobbie, Deborah Arnott, Matt Myers (Campaign for Tobacco Free Kids), Dr Cheryl Heulton (Dean, College of Global Public Health)</p>
10.15 -10.35	MORNING REFRESHMENT BREAK

Safety & Health Research

10.35- 10.55	<p>Exploring Five Common Claims About E-Cigarette Use: <i>This talk will cover published and unpublished data from the Smoking Toolkit Study, various national youth surveys, the Cochrane collaboration and other observational as well as experimental studies to look at five common statements relating to e-cigarette use. In particular, this presentation will address and critically dissect evidence relating to the claim that e-cigarettes 1) renormalize tobacco use; 2) are a youth gateway to smoking cigarettes; 3) are ineffective as a smoking cessation tool; 4) are as dangerous as conventional cigarettes and 5) that they are completely safe.</i></p> <p>Dr Lion Shahab – Senior Lecturer/Associate Professor in Health Psychology, University College London</p>
10.55 -11.10	<p>The NASEM Report on E-Cigarettes – Summary and Relevance to Clinicians: <i>Dr. Rigotti will summarize the conclusions of the recent NASEM report and the priorities that it identified for future research. Additionally, in the current state of incomplete organizations, she will discuss the challenges for individual clinicians and their professional organizations as they attempt to answer patient questions and create clinical guidance.</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>
11.10 -11.25	<p>Public Health England’s Independent Expert E-Cigarettes Evidence Review – Misinformation, Misreporting and Public Understanding: <i>The 2018 PHE report highlighted the pervasiveness of misunderstandings in the nicotine product field. Perceptions of the relative harmfulness of nicotine compared with smoking have changed little over the last 15 years and underpin misperceptions about relative risks, addictiveness and harm. Inadequate or inaccurate reporting of scientific studies regularly generate media attention which misleads the public and as a consequence smokers continue to smoke. Gateway scares are prevalent in the media, despite the fact that UK surveys provide no evidence that e-cigarettes are leading never smokers to take up smoking. The PHE 2015 report indicates that this theory is extremely difficult to test in humans and recommends gateway terminology be abandoned until the theory can be tested in the field</i></p> <p>Prof Ann McNeill – Professor of Tobacco Addiction, UK Centre for Tobacco and Alcohol Studies, KCL</p>
11.25 -11.40	<p>Relative Risks of Electronic Cigarettes: <i>Dr. Benowitz will discuss safety concerns with use of E-cigarettes, including toxicant exposure, nicotine addiction and cardiopulmonary disease. He will explore the relative risk values between different types of e-cigarettes for example higher powered devices versus products with higher nicotine content and comment on how safety should be considered within a broader context of smokers needs and regulation.</i></p> <p>Prof Neal Benowitz – Professor of Medicine and Bioengineering & Therapeutic Sciences, University of California, San Francisco, USA</p>
11.40 -11.55	<p>Prevention and Protection Policies for Youth Use of E-Cigarettes and Tobacco Products <i>Everyone in public health tries to prevent any tobacco/nicotine use by youth, but it is shortsighted to also neglect the different policy needs for those youth who are already using such products. Moral psychology informs the powerful desire to prevent any contamination of youth as well as a sometimes-opposing desire to protect youth product users from doing greater harm to themselves. Dominant messages that ‘no product is harmless’ or ‘a safe alternative to cigarettes’ can be of low relevance to the many low-risk youth; while they can mislead the fewer young product users by providing no information on major differences in harms and by leaving many with the belief that the product harms are equal.</i></p> <p>Prof Lynn T. Kozlowski – Professor of Community Health and Health Behavior, School of Public Health and Health Professions, University at Buffalo, SUNY</p>
11.55 -12.10	<p>Switching from Combustibles to E-Cigarettes - What We Need to Know and Strategies Moving Forward <i>This presentation will present data from an observational study of dual cigarette and E-cigarette users focusing on patterns and predictors of switching products, discuss gaps that need to be addressed in developing approaches to help combustible smokers switch, and suggest potential strategies for advancing our knowledge of what works to help smokers switch.</i></p> <p>Prof Robin J. Mermelstein – Professor of Psychology and Director Institute for Health Research and Policy (IHRP), University of Illinois, Chicago</p>
12.10 -12.40	<p>Panel Discussion and Q&A: How Can We Help the Public Understand Relative Risks?</p> <ul style="list-style-type: none"> • <i>E-cigarettes and Health Research – what are the priorities for delivering better quality research.</i> • <i>The clinical and regulatory significance of the NASEM and PHE reports</i> • <i>Is Dual use an important step in cessation or a failing of harm reduction</i> • <i>Understanding youth use – how should data be interpreted and presented</i> <p>Lion Shahab, Nancy Rigotti MD, Ann McNeill, Neal Benowitz, Lynn T. Kozlowski, Robin J. Mermelstein</p>
12.40 -13.25	LUNCH

Tobacco Control, Industry & Regulation

13.25 – 13.40	<p>Regulation & the Realization of a Positive Impact Potential of ENDS: <i>The National Academies of Science recent report on the Public Health Consequences of E-Cigarettes concluded that, under likely modeled scenarios, the use of e-cigarettes in the population will result in a net public health benefit. Also that, while the absolute numbers are important the overall health consequences of e-cigarettes, positive or negative, are likely to be very small compared to the overall toll of tobacco smoking. This is consistent with other reports & projections. FDA has indicated its intent to strike the right balance between fulfilling its vital consumer protection role while also fostering innovation when it comes to potentially less harmful forms of nicotine delivery. How might this positive impact potential be realized (and not undermined) both by balanced regulation of ENDS as “tobacco products” and by the modernization of the FDA’s approach to the development and regulation of nicotine replacement therapy products (potentially also including ENDS)</i></p> <p>David Graham – Chief Impact Officer, NJOY</p>
13.40 – 13.55	<p>The Tobacco Industry; Harm Reduction and the Unique Need for Regulation: <i>The debate around E-Cigarettes revolves around whether they are more effective at helping people quit smoking than existing products or whether they will enable more people who would not otherwise quit, to switch completely to products that will significantly reduce their risk of disease. However, the real debate is around whether a free market approach with only minimal government oversight or whether an approach that provides the government the opportunity to review products, verify claims and set standards to insure that consumer receive independently verified and reliable information is the best way to accomplish these goals. The “Trust me” approach has been tried in this field before and failed and is not working with e-cigarettes. Meaningful regulation is needed for products that claim to help those who suffer from a disease and are seeking cures that they can trust. Regulation would already be happening if the e-cigarette industry hadn’t resisted it at every step.</i></p> <p>Matthew L. Myers, President, Campaign for Tobacco-Free Kids</p>
13.55 - 14.10	<p>Examining Competition in the E-Cigarette Market and its Potential Impact on the Cigarette Market: <i>A framework will be provided for analyzing and maintaining competition in the e-cigarette market, focusing on industry concentration, entry barriers and market conduct. This session will explore the importance of competition in the e-cigarette market both toward discouraging cigarette manufacturers from marketing cigarettes (by reducing profit potential) and toward encouraging them to market heat-not-burn cigarettes as an alternative to cigarettes (as PMI has promised).</i></p> <p>Prof David Levy – Professor of Oncology, Lombardi Comprehensive Cancer Center, Georgetown University</p>
14.10 – 14.25	<p>iQOS, E-Cigarettes and Tobacco Control - Harm Reduction the Japanese Way: <i>Japan presents a unique case study for scientists and regulators interested in reducing the health harms caused by combustible tobacco products. From 1904 to 1985 the Ministry of Finance in Japan presided over a tobacco monopoly, and government continued to be a major shareholder of tobacco stock after the privatization of the tobacco industry. The government’s financial stake in the tobacco, which helps to explain Japan’s historically high rates of tobacco consumption and its lax tobacco control regulations, serves as the backdrop to the regulation of e-cigarettes and heat-not-burn products. This presentation will explain the Japanese government’s regulatory approach to e-cigarettes and heat-not-burn products, describe the reception of iQOS in Japan, and assess the relationship between the increase in iQOS use and the decline of smoking rates.</i></p> <p>Prof Eric A. Feldman – Professor of Law, Professor of Medical Ethics & Health Policy, University of Pennsylvania Law School</p>
14.25 – 14.40	<p>The Flavor Controversy - How to Make Sense of the Flavors Issue in 10 Questions: <i>Flavors remain the most controversial issue surrounding e-cigarettes. The concern is that “kiddie appealing” flavors are inadvertently or as part of a deliberate strategy attracting kids in to nicotine use and lifelong addiction. This session will ask if we can establish a framework for investigating the effect of flavors on vaping and smoking behaviors? What do we need to do show that flavors change behavior, and how do we establish whether these effects are harmful or beneficial? Through a sequence of 10 questions, we will interrogate these subtle issues.</i></p> <p>Clive Bates – Director, Counterfactual</p>
14.40 – 15.10	<p>Panel Discussion and Q&A: The Challenges of ENDS Regulation</p> <ul style="list-style-type: none"> • “Big Tobacco” v Vape Stores –what are the regulatory implications for both, what significance will this have • Regulating flavors to maximize benefit (smoker uptake) and minimize harm (youth appeal) • Achieving a regulatory balance that maintains product appeal and investment in non-combustible “tobacco products” <p>David Graham, David Levy, Eric A. Feldman, Clive Bates, Matthew L. Myers, Dr Cheryl Heaton (Dean, College of Global Public Health)</p>
15.10 – 15.30	<p>AFTERNOON REFRESHMENT BREAK</p>

Public Health & Policy

15.30 – 15.45	<p>Smokers, Children, and Bystanders: Evidence, E-Cigarettes, and the Politics of Harm Reduction <i>This session will look at the origins of the ethical debates surrounding e-cigarettes and the conflicts that they have highlighted between harm reduction and precaution principles. There has been a marked divide between those that focus on (UK PHE) smokers and (US) children and now bystanders. Where we land will depend on both ethics and evidence but what should the bottom line be in the face of disagreement?</i></p> <ul style="list-style-type: none"> • <i>The Continuum of Harm Reduction</i> • <i>Why have NASEM and PHE come to such different conclusions about the evidence on children & bystanders</i> <p>Prof Amy Fairchild – Associate Dean of Academic Affairs, Texas A&M School of Public Health</p>
15.45 – 16.00	<p>Finding the Sweet Spot - Science is Re-framing Nicotine Use to Save Lives More Rapidly: <i>Absent massive changes in behaviour, 7.2 million people worldwide will continue to die each year. An array of non-combustible nicotine products (NNPs) has emerged. For the first time in 120 years, evidence is mounting that NNPs can be the “sweet spot” to disrupt and displace the global dominance of cigarettes that persists despite tobacco control’s best efforts. Smoking control – not tobacco or nicotine control – embraces use of appealing and economically viable NNPs as part of the solution to the cause of health harms—smoke. NNPs can be smoking control’s valued ally to eliminate the smoking epidemic. We must address the false equivalence of promoting weak headline grabbing studies that exaggerate the harms of NNPs, undermining harm minimization efforts and perpetuating smoking behaviour. A synthesis of the stronger scientific evidence provides our guidance. Influential leaders must align and speak with one voice to reassure smokers and those who care about smokers that nicotine is not the major source of harm and that a switch to NNPs will improve their health.</i></p> <p>David B Abrams PhD – Professor Global College of Public Health, New York University</p>
16.00 – 16.15	<p>Honest Communication to Consumers: <i>The duty of an Attorney General is to act as gatekeeper and steward for consumer protection and ensure that information is accurately communicated to the public so that they can make informed decisions. AG Tom Miller historically held the tobacco industry to account for inaccurately communicating the harm and risks of their products. With the introduction of alternative nicotine delivery systems he will explore the new questions this has raised and how different and sometimes misleading perspectives on harm reduction are influencing consumers and ask what lessons can be learned.</i></p> <p>A.G Tom Miller – Attorney General of Iowa</p>
16.15 – 16.30	<p>A Crossroads for the Tobacco Control Movement: <i>Claims by cigarette companies that they want to transform their business and move towards a smoke free future, has raised the question if this is a public relations stunt that should be ignored or a legitimate strategy warranting efforts to accelerate that transformation. There are good reasons to be sceptical. But if one takes the view that profiting from an addictive but nonlethal product might be an ethically questionable abuse of corporate power on citizens but profiting from addictive and lethal products like cigarettes amounts to a human rights’ violation, then what should the response from the public health community be? Is there a way for the public health community to find common ground again and work towards a regulatory response that is proportional to the harm products cause?</i></p> <p>Laurent Huber – Executive Director ASH (US), FCA Ambassador, Framework Convention Alliance (FCA) for Tobacco Control</p>
16.30 – 16.45	<p>Smoking Harm Reduction - If Not Now When? <i>Dr. Cummings will discuss the urgent need to implementing new approaches to help cigarette smokers transition away from cigarettes. With ½ million deaths from smoking predicted this year in the US and over 6 million worldwide the time to act is now. Innovations in safer alternative nicotine products offer an opportunity to disrupt the cigarette marketplace in ways that can have a dramatic impact on preventing needless deaths from cigarette addiction. Public health and the vaping community need to work together to push the cigarette industry into the history books.</i></p> <p>Prof K. Michael Cummings, PhD, MPH – Professor, Department of Psychiatry & Behavioral Sciences, Medical University of South Carolina</p>
16.45 – 17.15	<p>Panel Discussion and Q&A: What Actions Will Achieve the Best Public Health Outcomes</p> <ul style="list-style-type: none"> • <i>Public Health communication – how can we responsibly communicate the continuum of harm</i> • <i>Regulator frameworks – striking the right balance to maximize public health benefits by enabling smoker choice along the harm continuum</i> • <i>How best can tobacco control and harm reduction policies support each other</i> <p>Prof Amy Fairchild, David B Abrams PhD, A.G Tom Miller, Prof K. Michael Cummings, Laurent Huber</p>
17.15– 17.25	<p>Summary and Closing Remarks from the Chair</p>
17.25 – 18.00	<p>End of Summit – Networking Drinks</p>