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Public Health Key Opinion Leaders’ and Scientists’
Submission of Comments Pertaining to Vaping Products (ENDS) as
being debated in the Senate of Canada, Bill S-5

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1. Introduction

The undersigned experts in European, African, and global public health wish to express their appreciation to the Committee for the opportunity to comment on the Senate of Canada’s current consideration of Bill S-5, “An act to amend the Tobacco Act and the Non-Smoker’s health Act and to make consequential amendments to other Acts”. We are regularly concerned in our professional lives with combatting the tremendous burden of disease and mortality borne by European and African citizens due to combustible tobacco products. We fully support the World Health Organization, the Government of Canada, the European Commission, and the many Member State public and private organizations engaged in smoking cessation and reducing the great harm to individual and public health caused by combustible tobacco products.

From this perspective, we regard vaping products (ENDS) as having a strong evidence-based potential benefit for tobacco cessation and harm reduction, for both individual and population health.

2. Recommendation to the Committee

Based on the regulatory issues being under consideration in the Senate of Canada, Bill S-5, we wish to state the following for the Senate’s consideration:

• The Canadian government makes a clear distinction between combustible tobacco-based products and vaping products, which are neither combustible, nor contain tobacco.

• It would be in the Canadian consumers’ best interests to develop proportionate, evidence-based regulation in a manner that would discourage the consumption of combustible tobacco products and encourage cessation programs, including the use of vaping products.

• Provisions should be made in regulation for regulatory pathways that are product appropriate: (e.g., vaping products / ENDS should be considered in different pathways than those for combustible tobacco products, taking into account proportionate risk and potential benefits).

• Health warnings should be appropriate to tobacco product classes and be based on science and evidence-based medicine, e.g., carefully and explicitly explaining the risk of combustible tobacco products while clearly informing consumers of tobacco products of the significantly lower risks of ENDS and their potential for harm reduction.

• The variety of e-liquid flavors is vital to helping adult smokers switch to low-risk products, and create a distancing effect from tobacco, and thus any decision to ban an ingredient should be based purely on its direct impact on human health.

If the Committee were to invite external speakers for hearings, and if appropriate, we would be delighted to make ourselves available to provide comments in person or via teleconference.
3. Rationale for the recommendation

3.1 Harm to Canadian public health

Smoking kills nearly 40,000 Canadians every year and costs the Canadian health-care system approximately $17 billion annually, or $3,071 per smoker. Although smoking rates have dropped in recent years, the most vulnerable communities continue to smoke at an alarming rate. For instance, in 2014, 62% of Nunavut residents and 244,682 youth ages 12 to 19 were smokers.

3.2 What are Vaping Products / Electronic Nicotine Delivery Systems (ENDS)?

ENDS (electronic nicotine-delivery devices, or e-cigarettes) generally consist of a battery, a heating coil and a liquid containing nicotine held in a tank or cartridge. Drawing on the device or pressing a switch activates the battery to heat the coil, which vaporises the liquid without burning it. This is then inhaled and the nicotine absorbed into the blood via mouth, throat and lungs. The liquids usually contain nicotine, water, a ‘diluent’ such as propylene glycol or glycerol, and flavouring, such as tobacco, mint, vanilla, or fruit.

There are now hundreds of flavours, and these are an intrinsic part of the appeal to smokers, help to break the link to, and the habit of, tobacco. The devices and the liquids can be sold as integrated units or with liquids sold separately. Some look like cigarettes (1st generation ‘cig-a-likes’), some look like pens (2nd generation ‘Ego’ type), and the larger ones with tanks can look very unusual (3rd generation ‘tanks’ or ‘mods’). There are also many designs for e-shisha, which use electrical heating and e-liquids instead of charcoal or wood and tobacco. It is possible to create e-cigarettes without nicotine, but this overlooks their main public health value – as a substitute for nicotine consumption via smoking and would make e-cigarettes largely ineffective as smoking substitutes.

3.3 Fundamental difference between Vaping Products and Combustible Products

Vaping Products / ENDS create aerosol by using electrical current to evaporate ‘e-liquid’, a mixture of nicotine and flavourings dissolved in an inert solvent. ENDS come in a huge variety of designs, and the liquids in thousands of flavour and nicotine strength combinations. While the nicotine in e-liquids is usually derived from tobacco, as is nicotine in pharmaceutical nicotine products, this is where any similarity to traditional tobacco products ends. Nicotine-free e-liquids are also available.

The tobacco and nicotine product market is varied and complex, and may be categorized in a number of ways, including in terms of product composition and potential for harm. What is clear is that ENDS are a new product category and do not resemble conventional combustible tobacco products.

Products may be categorized as containing tobacco or not. Nicotine patches (regulated as medicinal products), nicotine inhalers (prescribed or purchased over the counter), and ENDS (consumer goods / medicinal products) do not contain tobacco. Combustible cigarettes, loose tobacco, and tobacco heating products (reconstituted tobacco in pod or stick format) contain tobacco and thus constitute (a) category (ies) distinct from ENDS.

An additional alternative, and from a health perspective, more interesting way to categorize these products is to consider them in terms of risk as well as their potential benefit for serious harm reduction and a distinct lowering of one of society’s greatest public health
burden. The greatest harms from smoking come from the products of combustion; when the potential harms of tobacco and nicotine products are compared on a continuum, there is a clear distinction between combustible tobacco products (cigarettes, cigars etc.) and products not involving combustion.\textsuperscript{1} The difference between products is so great, that ENDS are considered to be at least 95\% safer than combustible cigarettes, a position held by Public Health England\textsuperscript{ii} and the UK’s Royal College of Physicians.\textsuperscript{iii} The health hazards associated with combustible cigarettes are well known, and for the sake of public health, governments worldwide have implemented measures to discourage smoking. The Framework Convention on Tobacco Control\textsuperscript{iv} promotes, amongst other things, the use of fiscal measures to discourage smoking of combustible tobacco and, consistent with this approach, the European Union levies excise duty on tobacco products. Smokers continue to smoke because of their dependence on nicotine, but they die from the tar\textsuperscript{v}. ENDS, therefore, have the potential to play an important public health role in harm reduction, as they are able to deliver nicotine to users with a dramatically lowering of the other risks associated with smoking.

3.4 Differences in Risk between Vaping Products and Combustible Tobacco Products

Third party research indicates that ENDS are significantly less hazardous to consumers than combustible tobacco. In a recent study, Nutt et al. modelled a risk continuum of different nicotine delivery products and located different products a scale of 0 to 100, with 100 being the most harmful and 0 the least (no harm). The study found that e-cigarettes (ENDS) earn a relative harm score of less than 5, whereas cigarettes have a score of 99.6.\textsuperscript{vi}


A number of other studies on the relative harm of ENDS compared to smoking tobacco have found that ENDS are significantly less hazardous than traditional tobacco products. For example, a Royal College of Physicians' 2016 report concluded that: "... ENDS are likely to be beneficial to UK public health. Smokers can therefore be reassured and encouraged to use them, and the public can be reassured that ENDSs are much safer than smoking". A systematic review by Public Health England concluded that ENDS were around “95% safer” compared to combustible tobacco. The authors commented: "... ENDS are not completely risk free but when compared to smoking, evidence shows they carry just a fraction of the harm.”

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**Figure 1 - the relative risk of different nicotine delivery products**

![Relative Risk Chart](image)

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There are concerns that e-cigarettes will increase tobacco smoking by renormalizing the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking. To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco.

A study by Goniewicz et al., found that ENDS vapour might contain traces of toxic metals such as cadmium, nickel and lead, which were similar to environmental levels, as well as potentially toxic aldehydes. However, the level of these substances were between 9 to 450 times lower than those in combustible cigarettes and, in many cases, the levels were comparable to trace amounts present in medicinal nicotine inhalers. They said that their findings were “...consistent with the idea that substituting tobacco cigarettes with e-cigarettes may substantially reduce exposure to selected tobacco-specific toxicants.” The authors also commented “We believe that e-cigarettes will prove to be much less harmful than smoking – so for a smoker to switch from tobacco to e-cigarettes will bring significant health benefits.”

Cancer Research UK has stated that: “...while nicotine is addictive and not entirely harmless, e-cigarettes do not contain the extensive cocktail of cancer-causing drugs found in tobacco.” They consider that while the long-term health consequences are uncertain, they are almost certainly safer than tobacco cigarettes. The World Health Organization (WHO) has acknowledged the lower risk of ENDS compared to smoking tobacco, but has expressed reservations about the benefits of ENDS out of a concern that their use sometimes reduces smoking rather than encouraging quitting.

In 2014, the Eurobarometer Survey, performed by the European Commission, identified that current ENDS use in the European Union was largely observed among current (4.2%) or former (2.7%) smokers, while prevalence of use was extremely low among never-smokers.

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Additionally, very high rates of smoking cessation and reduction were reported by current and, especially, current daily e-cigarette users. The health benefits from this are potentially huge. In its recent FCTC paper, the WHO conceded: “If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement.”

3.5 Potential Benefits

Vaping Products / ENDS work for health because they substitute for many aspects of the smoking experience (nicotine, taste, hand-to-mouth behavior, ritual etc.), but cause far less harm to the body: they are likely to be at least 95% less harmful than smoking. The key to understanding this reduction in harm is that nicotine itself is the reason why people smoke, but it is not what causes the harm – the harm is caused by the toxic particles of burning organic material and hot gases in cigarette smoke. ENDS deliver the nicotine without the smoke and without any products of combustion, and so the risks are greatly reduced.

Many smokers wish to quit but find it difficult because they are dependent on nicotine, others do not wish to quit because they like smoking and the impact it has on their mood. ENDS provide a solution: smokers can continue using nicotine, but without the disease, death and anti-social aspects of smoking that no one wants. Many smokers will find it easier to switch to vaping than to give up smoking, nicotine, and all the behavioural rituals in one big effort. The reward for health at both individual and population level is that it offers a new and potentially attractive way to stop smoking that will attract more people to quit.

3.4 Potential risks

Concerns have been raised about a potential 'gateway effect' in which low risk products such as ENDS cause people who would not have smoked to become cigarette smokers, however there is no evidence of this occurring. Generally there has been a decline in teenage smoking accompanying any rise in ENDS use, and ENDS use is highly concentrated among those who were already smokers. It is likely that ENDS use is an alternative to smoking in young people who would otherwise have started to smoke - and thus have a primary preventive (i.e. protective) effect. Longer-term data are needed, but there is no basis to draw any conclusion that use of ENDS leads to an increase in smoking. “Renormalization” of smoking is another issue that has been raised. Professor Linda Bauld, the leading expert in cancer prevention at the major research charity Cancer Research UK, summarised the evidence on renormalization in August 2015:

"Fears that ENDS have made smoking seem normal again or even led to people taking up tobacco smoking are not so far being realised based on the evidence assessed by this

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important independent review. In fact, the overall evidence points to ENDS actually helping people to give up smoking tobacco.”

There have been concerns raised about the levels of various toxins in e-cigarette vapour, however the concentrations of these substances are generally tens to thousands of times lower than in cigarette smoke. Many toxins are simply not present at detectable levels or are equivalent to the tolerances allowed in medical products.\textsuperscript{vii}

### 3.5 UK regulation

In the UK, ENDS are classified as consumer products and can be legally purchased online and from dedicated “vape” shops, pharmacies and other retail outlets. The most common reason for using ENDS is to reduce the health risks of smoking by stopping or reducing smoking. ENDS are currently used by 2.6 million “vapers” in the UK. More than 1 million vapers are ex-smokers who have switched to vaping as a safer alternative to smoking and to avoid relapsing into smoking.\textsuperscript{viii} Long-term use of safer nicotine products has been supported as a harm-reduction strategy in the UK since a landmark report of the Royal College of Physicians, which concluded that:

“Smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.”\textsuperscript{ix}

ENDS are now the most popular aid for quitting smoking in England, being used in 38% of quit attempts. It has been estimated that of 1 080 000 smokers who tried to quit using ENDS in 2014 in England, 20 340 additional smokers were able to achieve long-term (1-year) abstinence because of the availability of ENDS.\textsuperscript{x} A recent independent review of the evidence commissioned by PHE concluded that e-cigarettes are around 95% safer than smoking, and that their use could be encouraged for smokers who have failed to quit with other methods or as a harm-reduction strategy for smokers who are not willing or able to quit. In the view of PHE, there are sufficient data to endorse the use of ENDS while further research and monitoring continue.\textsuperscript{xi}

### 3.6 New Zealand regulation

The government of New Zealand has recently unveiled plans to make ENDS legal, as part of a strategy to make New Zealand smoke-free by 2025. Associate Health Minister Nicky Wagner stated that:

"Scientific evidence on the safety of e-cigarettes is still developing but there's a general consensus that vaping is much less harmful than smoking...this is an opportunity to see if restricted access to e-cigarettes and e-liquid can help lower our smoking rates, reduce harm and save lives."

### 4. Key concerns with potential S5 regulatory changes

#### 4.1 Proportionate regulation

Smoking is primarily driven by the consumption of nicotine, and there are many people who cannot or will not stop using nicotine. It has been known for 40 years that people "smoke for the nicotine and die from the tar".\textsuperscript{xii} This creates the prospect that providing nicotine without the tar and toxic gases in tobacco smoke could have significant health benefits. There is strong consensus among scientists that nicotine products that do not involve burning tobacco are far less risky than smoking. The main public health agency in England recently
published a comprehensive review of the published evidence on e-cigarette technologies and vaping behavior and concluded that:

“The current best estimate is that e-cigarettes are around 95% less harmful than smoking” and “there is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers”.

In fact this 95% estimate is cautious advice from a responsible public body designed not to imply that consumers should assume they are perfectly safe. The 95% reduction in risk is likely to be an over-estimate of the residual risk as it includes a large safety margin for unknown future effects. The main underlying assessments of toxic exposure from vapour compared to cigarette smoke suggest much lower levels of exposure and risk. Typically, the harmful constituents of cigarette smoke are not present in vapour at detectable levels, or present at levels 20-1000 times lower. The major reviews of e-cigarette safety should give confidence that risks are at least 95% lower than smoking.

As the Royal College of Physicians of London explained in its landmark report, Harm reduction in nicotine addiction:

“This report makes the case for harm reduction strategies to protect smokers. It demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.”

ENDS are not tobacco products, do not rely on combustion, and do not contain anything close to the level of toxicants contained in combustible cigarettes. Furthermore, this nascent product category has great public health potential as a quitting or harm reduction tool in combustible tobacco-related chronic disease and premature mortality. ENDS, therefore, should not be treated in a similar way to tobacco products in Bill S5, but rather regulated in a manner that makes them attractive to smokers who might use them as a way to quit smoking.

4.2 Product standards

ENDS are consumer products that compete with and displace cigarettes in the market for recreational nicotine use. The Canadian government needs to ensure that regulation is proportionate to risk, and does not favour the riskier products. To that end, a sound regulatory regime for ENDS would include the following:

- Standards for liquids, such as use of pharmaceutical grade ingredients and food grade flavours;
- Standards for devices – including electrical and thermal safety and material leaching;
- True and fair information about the product ingredients and sell by date;
- Proportionate warnings and consumer messages;
- Controls on marketing and retailing to ensure products are targeted at adult smokers,
- Child-resistant containers for liquids. and
- Stewardship requirements – for example, ‘responsible person’ and ‘means to recall’.
4.3 Health warnings

All of the scientific evidence today, across a wide range of sciences and carried out by leading government or university-funded researchers indicates that ENDS are far less harmful than combustible tobacco products. Bill S5, however, proposes the same health warnings for ENDS as for tobacco products. Such health warnings would be completely inaccurate, unsubstantiated and misleading, and would make ENDS relatively less attractive to smokers, discouraging switching to these lower risk alternatives. This would contribute to an ongoing high smoking rate, directly contributing to a greater incidence of serious diseases (including cancer) among Canadians. Regulating ENDS in the same, or even similar manner as combustible tobacco products, will not only condemn many present and future smokers to a much lower quality of life, real serious disease, and premature death; but also assist in continuing the enormous burden on public health expenditure shared by all Canadians. The use of accurate language in any health warning, explaining the risk relative to cigarettes as well as the (very low) absolute risk would result in potentially huge health benefits.

4.4 Product flavours are important to consumers

While we recognize the risk of, and need to regulate e-liquid flavors, these flavors are nonetheless vital to helping people switch to low-risk products and steering the away from the future use of combustibles. Professor Farsalinos reports that: “flavours are marketed in order to satisfy vapers’ demand. They appear to contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking.”

Bill S-5 would ban most of the popular flavors that are helping people stay smoke-free. This is contrary to, not only the opinions of medical doctors and university professors dedicated to smoking cessation, but also contrary to the existing scientific evidence. In deciding which flavorings to prohibit/permit, their particular role in ENDS must be properly understood and their chemical composition first studied. A wide range of flavors is very important to the consumer who wants to quit smoking because although people tend to start with tobacco flavors, which makes the transition from smoking to vaping smoother, many then move on to sweeter flavors, further distancing themselves from combustibles. Smokers have dulled olfactory capacity, and when they switch to ENDS they regain their sense of smell and taste. New, interesting flavors appeal to them, and so they become an important consumer demand by those wishing to stop smoking using ENDS. This is critically important, because the change in taste breaks the link to tobacco and cigarettes. The flavors are pleasant in and of themselves and are important in that they make smoked tobacco seem more unpleasant, thus creating a “distancing” effect from smoking. A wide choice of flavors means that vapers who move from tobacco flavors to sweeter flavors are far less likely to return to smoking traditional cigarettes and tobacco.

Concerns have been expressed over the role of flavors in ENDS, highlighting their potential to appeal to children and young people and to smokers, appealing to taste predilections while also suggesting safety. One of the few experiments conducted with both teenagers and adults on their interest in, and preferences for, ENDS flavors concluded that interest in

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ENDS flavors was very low among teenagers (0.41 on a 10-point scale). Those most affected by flavor were adult ENDS users. In the UK, over 60% of ENDS users choose a non-tobacco flavor, and recent qualitative data indicate that non-tobacco flavors\textsuperscript{xx} are also popular among ENDS users in the USA.\textsuperscript{xx} Important studies do not show that any interest amongst teenagers in ENDS flavors is resulting in regular use of ENDS in this age group. Flavors are important to many users of ENDS, and that while some appear attractive to children, it would be wrong to prohibit their use.\textsuperscript{xxi}

There are concerns about the safety of flavorings, but the magnitude of any risks is likely to be substantially lower than those of smoking, and extremely low in absolute terms. Many of the flavors used are known to be safe when ingested, but this is not necessarily the case when heated and inhaled. In vitro studies indicate that there is wide variation in the cellular toxicity of the various flavors, and that toxicity varies greatly by the product type used. However, the level of exposure in in vitro studies that would be relevant to realistic human effects has not been defined. The report also pointed out that these risks arise primarily from contaminants and components generated by vaporization, which should be amenable to reduction through technological and purity improvements.\textsuperscript{xxii}

4.5 The availability of scientific evidence

Freedom of information is a foundation of any free society, and in addition to this, given the weight of evidence in favour of the significantly reduced risk of ENDS when compared to smoking, it is incomprehensible that Bill S-5 implies that merely making Canadians visiting a vape shop aware of a peer-reviewed scientific journal article could result in a fine of up to $500,000 and a two year prison term. Rather, the Canadian Government should consider encouraging dissemination of evidence-based advice to the general public and positively encouraging smokers to take steps to switch to a vastly less harmful way of obtaining nicotine. There is now recognition among tobacco control professionals and public sector practitioners that ENDS can be used constructively to reduce harm. For example in Britain the National Centre for Smoking Cessation and Training and Public Health England, the government’s public health agency, have developed evidence-based guidance for health professionals. It provides a clear and measured assessment of the state of science and best practice, and this of value for Canada as it considers how to exploit the opportunities and minimize the risks.\textsuperscript{xxiii}

5. Conclusion

ENDS should not be regulated along the same regulatory pathways as tobacco products, but rather regulated in a manner that makes them attractive to smokers as an alternative to combustible tobacco. Bill S5 should include provisions for appropriate product standards for ENDS that ensure regulation that is proportionate to risk, that takes into account the enormous individual and public health benefits of tobacco reduction, and does not make them less attractive to smokers than more risky products. Any health warnings must be accurate and evidence-based, explaining the risk relative to cigarettes as well as the (very low) absolute risk of ENDS. The variety of e-liquid flavors is vital to helping people switch to low-risk products, and create a distancing effect from tobacco, and thus any decision to ban an ingredient should be based chemical composition and its direct impact on human health. Vape shops and other stakeholders should be permitted to disseminate evidence-based
information to the general public, and the Canadian government should consider positively encouraging smokers to take steps to switch from combustible cigarettes to ENDS.

Despite all the warnings, campaigns, and valiant efforts of researchers and the medical community over the past 20 years, in 2014 18% of the Canadian population continued to use combustible tobacco products, primarily cigarettes. Nearly all want to quit and have wanted to quit for a long time. Many have repeatedly failed smoking cessation programs, including those that use pharmaceutical products. ENDS are essential alternatives to combustible tobacco products, with the potential to replace them entirely, hence dramatically improving public health. In a 2016 FCTC report, the WHO stated:

“If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement.”

The Canadian Government has the responsibility to regulate these products responsibly, and hence we call for a reconsideration of the current amendments to Bill S5.

6. Background of authors

• **Delon Human** M.B.Ch.B., M.Prax.Med, MFGP, DCH, MBA is a French, South African citizen and physician qualified in family medicine and child health, with an MBA from the Edinburgh Business School. He is a published author and health care consultant specializing in global health strategy, harm reduction and health communication. He has been active in tobacco control for decades, including advocacy for taxes on combustible tobacco to drive down consumer demand.

  He has acted as adviser to WHO Director-Generals and UN Secretary-General Ban Ki Moon. Formerly, he was Secretary General of the World Medical Association (WMA), the global representative body for physicians and thereafter Secretary General of the International Food and Beverage Alliance (IFBA). He is a fellow of the Russian and Romanian Academies of Medical Sciences. Delon has been involved in harm reduction in tobacco and nicotine, alcohol and drugs for the last 25 years. In clinical medicine, his work focused on tobacco cessation programs, while in medical politics, the development of the FCTC. He was Chair of the coordinating committee for NGOs in preparation of World No Tobacco Day 1999. He authored the book “Wise Nicotine”.

• **Konstantinos E. Farsalinos** (Greece), M.D., recently published the book “Analytical Assessment of e-cigarettes” and is a research fellow at the Onassis Cardiac Surgery Center in Athens, Greece, and at the Department of Pharmacy, University of Patras, Greece. He has been conducting laboratory and clinical research on e-cigarettes as a principal investigator since 2011. Examples of his work include the first study on the cytotoxic effects of e-cigarette vapor on cultured cells and the immediate effects of e-cigarette use on cardiac function and coronary circulation. He ran a worldwide online
survey of almost 20,000 vapers (users of e-cigarettes) identifying patterns of use and experience with e-cigarettes among consumers, published in 2014. He has presented his research findings at major international scientific congresses and his research was used in preparing the regulatory framework on e-cigarettes by the European Union. As of early 2017, he has published more than 50 studies and articles in international peer-reviewed scientific journals about smoking, tobacco harm reduction, and e-cigarettes. He was also the handling editor and main author in a book titled “Analytical Assessment of e-Cigarettes”, published by Elsevier. Affiliations and Expertise: Onassis Cardiac Surgery Center, Athens, Greece; Department of Pharmacy, University of Patras, Patras, Greece

- **Riccardo Polosa** (Italy) is the Director of the Institute for Internal Medicine and Clinical Immunology of the University of Catania, Italy. He is co-author of the recently published book “Analytical Assessment of e-cigarettes”. He is also in charge of the University's Centre for Tobacco Research (CPCT) and is Honorary Professor of Medicine at University of Southampton, UK. An internationally recognized leader in the field of clinical bronchoprovocation (airway-challenge studies), he has published more than 250 peer-reviewed articles and books, mainly on respiratory medicine, clinical immunology, and tobacco addiction. After many years of service as President of the Italian Anti-Smoking League (LI: Lega Italiana Anti Fumo), he now serves as its Chief Scientific Advisor. Affiliations and Expertise: Institute for Internal Medicine and Clinical Immunology and Centre for Tobacco Research (CPCT), University of Catania, Catania, Italy; Faculty of Medicine, University of Southampton, Southampton, UK. He is currently the Chair for the Working Group on “Requirements and test methods for emissions of electronic cigarettes”, within the European Committee for Standardization (CEN/TC 437).

- **Francis P. Crawley** (Belgium, United States) is a philosopher specialized in the ethics and regulation of medicinal products. He has served as an expert for the WHO, CIOMS, UNESCO, the European Commission, the Council of Europe, the European Medicines Agency, the US NIH, and the US FDA as well as for governments in the EU, Eastern Europe, Asia, and Africa. He is the Executive Director of the Good Clinical Practice Alliance – Europe (Brussels).

- **Karl Fagerström** was born in Sweden 1946. He studied at the University of Uppsala and graduated as a licensed clinical psychologist 1975. At that time he started a smoking cessation clinic and invented the Fagerstrom Test for Cigarette Dependence. In 1981 he got his Ph.D. on a dissertation about nicotine dependence and smoking cessation. In the end of the seventies and early eighties he served as the editor – in – chief for the Scandinavian Journal for Behaviour Therapy. From 1983 through 1997 he worked for Pharmacia & Upjohn as Director of Scientific Information for Nicotine Replacement Products. He has worked with the nicotine gum Nicorette since 1975 and has been contributing to NRT developments such as patch, spray, pouch and inhaler. Ever since 1975 to 2010 he has been working clinically part-time. From 1997 to 2008 he worked with his private research clinic where he studied various drugs intended for treating nicotine dependence. Currently he works with his own private consultancy (Fagerstrom Consulting). He is a founding member of the Society for Research on Nicotine and Tobacco and currently a Deputy Editor of the Nicotine & Tobacco Research. He started
the European SRNT affiliate in 1999 of which he was been the president up to 2003. His main research contributions have been in the fields of Behaviour Medicine, Tobacco and Nicotine with 170 peer reviewed publications of which he is the first author of 100. The current main interests are on understanding the positive effects of nicotine and reducing harm and exposure to tobacco toxins among all those who cannot give up smoking. He was awarded the WHO medal 1999 for outstanding work in tobacco control. Recently he was announced to be the recipient of the 2013 Award on Clinical Science from the Society for Research on Tobacco and Nicotine.

• **Dr Jacques Le Houezec** (France), trained as a neuroscientist in Paris, has been working on nicotine and smoking cessation for more than 30 years. He is a Consultant in Public Health & Tobacco dependence, based in Rennes, France. He is also Director of www.treatobacco.net (a website dedicated to the treatment of tobacco dependence, available in 11 languages), Honorary Clinical Associate Professor, at the UK Centre for Tobacco Control Studies, University of Nottingham, England, and member of the Addiction research group at INSERM 1178 (Mental and Public Health), in Paris, France.

• **Dr Anders Milton** (Sweden) is a qualified nephrologist who completed his studies in Sweden before starting a distinguished career as an international health diplomat. He served as both CEO and President of the Swedish Medical Association, for more than a decade. During this time he was also elected as the Chair of Council of the World Medical Association. He held this position for 6 years and subsequently was elected as the President of the Swedish Red Cross. For many years Anders has been a senior adviser to the government delegation to the World Health Assembly and recently the Swedish government appointed Anders to head two commissions of enquiry. This first was to investigate the health care capacity in his country to treat mental health problems and the second to develop a strategy to combat HIV / AIDS. Other government appointments include:
  o Government appointed chairman of select committee to study how to increase organ donation and transplantation
  o Government appointed chairman of select committee to study how to make prevention against unwanted pregnancies more effective
  o Chairman of the Board of Uppsala Monitoring Centre, a WHO collaborating Centre working with pharmacology vigilance

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4. [http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/health74b-eng.htm](http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/health74b-eng.htm)
[xvii] https://vaping.com/blog/comment/tobacco-industry-and-ecig-flavors-the-truth/