

PUBLIC COMMENT

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To: Parliament of Australia, Select Committee on Tobacco Harm Reduction

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Honourable members of the Select Committee,

I am a scientist with an established work and publication record in the field of smoking and tobacco harm reduction. Based on this research, in November 2019, I was declared a Highly Cited Researcher 2019, a group of scientists with the highest impact in global scientific research during the past 10 years in 21 fields. With this letter I kindly present my views in relation to your inquiry on electronic cigarettes. Due to the limited length of the submissions (based on your guidelines), I will focus on 3 subjects.

1. Treatment of nicotine vaping products in developed countries and proposed regulatory principles

The European Union is currently one of the few regions that has an established regulatory framework on electronic cigarettes through the Tobacco Products Directive which was voted in 2014 and implemented in all member states since 2016 [1]. In general, this regulation represents a reasonable approach of establishing quality criteria, allowing the marketing of products based on consumer products regulatory principles and establishing specific restrictions such as ban on the sales to youth and warning messages about the dependence potential of nicotine. It should be emphasized that the Tobacco Products Directive regulates electronic cigarettes under a separate section that does not classify them as tobacco products. This is appropriate since electronic cigarettes do not contain any tobacco. Furthermore, it allows electronic cigarettes to be sold as consumer products, which is in agreement with the intended use by smokers. Electronic cigarettes are not used therapeutically but as smoking substitutes and in an effort by the

smokers to substitute the experience and effects of smoking with similar experience derived from a substantially less harmful product.

The principles that should be followed when creating a regulatory framework for electronic cigarettes are:

- A. Regulation should be risk-proportionate.** This represents the only proper approach to the regulation of any product. Evidence on risk determines the levels of restrictions that need to be implemented. Currently, there is compelling and undisputed evidence on the low risk of electronic cigarettes, especially when compared with the devastating effects of smoking.
- B. Regulation should be realistic and ensure product quality.** It would make little sense to create a regulation that would be expensive or difficult to comply. This would result in the elimination of electronic cigarettes and the creation of an uncontrolled black market. Both consequences will end-up protecting tobacco cigarette sales while no quality standards can be expected from black market products. Setting unreasonably high quality standards creates a competitive advantage for tobacco cigarettes, while the regulation should aim for the opposite.
- C. Regulation should ensure that electronic cigarettes do not target never-smokers and youth.** This can be ensured by introducing a ban on the sales of electronic cigarettes to people younger than 18 years old (with heavy fines for those violating this rule), specific regulatory restrictions (but not ban) on advertising and marketing, and proper education that electronic cigarettes should be used as smoking substitutes only.
- D. Regulation should create a competitive advantage for electronic cigarettes compared to tobacco cigarettes.** Unfortunately, tobacco cigarettes are very cheap to make and generate a lot of profits for the industry, despite heavy taxation. Electronic cigarettes are technology products; thus, they are by definition more expensive to produce than tobacco products. Regulation should ensure that smokers are motivated to switch to electronic cigarette use and completely quit smoking. Therefore, taxation policy should ensure that they are cheaper than tobacco cigarettes. Additionally, smokers should have easier access to electronic cigarette products than to tobacco cigarettes. The current situation almost everywhere in the world is the opposite: tobacco cigarettes are easily accessible by smokers while limited access exists for electronic cigarettes. Marketing and advertising bans should be implemented for tobacco cigarettes while regulated and carefully controlled marketing for electronic cigarettes is essential in order to target, inform and educate smokers about the existence and value of electronic cigarettes in improving their health. Products should contain enough nicotine; otherwise, smokers will continue to smoke in order to obtain the nicotine they need.
- E. Regulation should classify electronic cigarettes as consumer products with specific rules and restrictions.** The success of electronic cigarettes as smoking substitutes is based on their use as consumer products. They are used according to smokers' preferences and needs, while product choice also depends on personal taste and preference. This can only be ensured through a regulatory framework of characterizing electronic cigarettes as consumer products with the restrictions mentioned above.
- F. Regulation should allow innovation and development of better and even safer electronic cigarette products.** Being technology products, electronic cigarettes have evolved at a rapid pace in recent years. Currently available products are safer and more effective as smoking substitutes than the products available a few years ago because

of using better materials, providing a better experience for smokers and being more effective in alleviating smoking cravings.

2. *Impact of nicotine vaping products on smoking cessation*

Unlike commonly heard arguments that electronic cigarettes are not proven to help smokers quit, there is compelling evidence on their smoking cessation potential based on reported reasons for regular, frequent and sustained use, association between electronic cigarette use and smoking status in population studies as well as clinical trials.

- A. The vast majority of regular electronic cigarette users are current or former smokers.** This is clear evidence that electronic cigarettes are appealing predominantly to people with a positive smoking history. In the US, data from the CDC National Health Interview Survey show that 90.9% of daily electronic cigarette users are current or former smokers [2]. In Greece, 98.5% of current electronic cigarette users were current or former smokers [3]. In the UK, 93.9% of current electronic cigarette users are current or former smokers [4]. In the European Union, 92.7% of current electronic cigarette users are current or former smokers [5].
- B. Population studies have found strong associations between electronic cigarette use and having quit smoking.** In the US, current daily electronic cigarette users had > 3 times higher odds of having quit smoking compared to never electronic cigarette users [6]. In Greece, current daily electronic cigarette users had almost 11 times higher odds of having quit smoking compared to never electronic cigarette users [7]. In the European Union, current daily electronic cigarette users had almost 5 times higher odds of having quit smoking compared to never electronic cigarette users [8]. In the US, it was found that the substantial increase in electronic cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level [9]. The authors emphasized that this was the first statistically significant increase observed in population smoking cessation among US adults in nearly a quarter of a century.
- C. A randomized controlled trial showed that electronic cigarettes are more effective than approved nicotine replacement therapies.** The study examined smoking cessation at 1 year, and identified that electronic cigarettes were two times more effective in smoking cessation than pharmaceutical nicotine products [10].

3. *Uptake by non-smokers and youth – gateway issue*

Scientists and regulators are particularly sensitive about youth. Smoking or use of any substance is definitely undesirable for this age group. Despite the ban on the sales of tobacco cigarettes that have been implemented throughout the world, youth still initiate smoking. Smoking prevention should be the priority for this age group.

There are also discussions about electronic cigarettes acting as a “gateway to smoking”. Understandably, this has created concerns that need to be addressed. At the same time, it is important that any regulation will ensure that smokers have adequate access to life-saving electronic cigarettes. I have been studying in detail the issue of electronic cigarette use among youth. To understand the matter of electronic cigarette use by youth, it is important to examine patterns of use, frequency of use and the smoking history of adolescents using electronic cigarettes. Also, it is crucial

to monitor the smoking rates among youth over time. The following facts should be considered when discussing electronic cigarette regulation:

- A. **Electronic cigarette use in youth is largely experimental and confined to those with a positive smoking history, while regular use by never-smoking adolescents is rare.** Data from the CDC National Youth Tobacco Survey (NYTS) 2015 showed that current smokers were > 11 times more likely to report current electronic cigarette use compared with never-smoking adolescents [11,12]. Frequent electronic cigarette use was reported by only 0.3% of never smokers. Similar findings were reported from the Monitoring the Future Survey in the US [13]. In 2018, less than 1% of never-smoking youth were frequent electronic cigarette users while smoking youth were 17 times more likely to be current electronic cigarette users compared with never-smoking youth [14]. A recent study concluded that the data from the CDC survey do not support the claims of a new epidemic of nicotine addiction stemming from the use of electronic cigarettes [15]. Among current electronic cigarette users who had never tried tobacco products, responses consistently pointed to minimal dependence from electronic cigarettes. Similar findings were reported in the UK [16].
- B. **The growing popularity in experimental electronic cigarette use has been accompanied by the fastest and strongest reduction in smoking rates among US youth. This rejects any claims about gateway to smoking effects.** The most crucial issue that will determine future health risk for youth is the change in smoking prevalence over time. From 2011 to 2019, the period when electronic cigarettes became popular, smoking rates in US middle school kids was reduced from 4.3% to 2.3% while in US high school kids it was reduced from 15.8% to 5.8% [17]. This has been the fastest reduction and the lowest smoking rate ever recorded in US history, with smoking being virtually eliminated among US youth.
- C. **The unprecedented reduction in smoking rates in the US shows that electronic cigarettes may act as a distraction from smoking.** It is important to remember that some adolescents have a rebellious character and are willing to try different things or engage in risky behaviors. The common liability model dictates that youth prone to try different things are more likely to try electronic cigarettes and tobacco cigarettes. If the only option is tobacco cigarettes, then these adolescents will inevitably end-up using tobacco cigarettes. US state-based data suggest that there are increased smoking rates among adolescents in states with stricter regulation compared to those with fewer regulations on electronic cigarettes [18,19].

In conclusion, currently available evidence is compelling in supporting the potential of electronic cigarettes to act as smoking substitutes, with expected health benefits for smokers. Additionally, frequent electronic cigarette use by youth is largely confined to those who smoke or have smoked tobacco cigarettes, while youth smoking rates are continuously declining at a rapid pace even with the increase in electronic cigarette experimentation. The latter rejects the claims about gateway-to-smoking effects. Regulation should ensure access of smokers to balanced information and to a variety of products. Regulation should be reasonable, realistic, risk proportionate and different from the regulation of tobacco cigarettes. In the UK, the National Institute of Clinical Excellence actively recommends that health care workers should advise smokers about the potential utility of electronic cigarettes as smoking cessation modalities [20] while the UK Parliament Science and Technology Committee recommended an even more liberal regulatory framework for electronic cigarettes in order to further strengthen their effectiveness as a smoking cessation measure

[21]. Vape shops are being established in public hospitals in the UK. All these indicate the acceptability of the evidence on the safety and efficacy of these products, and the valuable prospects of strengthening the tobacco control measures through a harm reduction strategy incorporating electronic cigarettes.

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