



*Università degli Studi di Catania*

DIPARTIMENTO DI MEDICINA CLINICA E SPERIMENTALE

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3 November 2020

Select Committee on Tobacco Harm Reduction

Dear Senators,

My name is Riccardo Polosa and I am full tenured professor of Internal Medicine at the University of Catania (Italy). In 2001, I have established the first smoking cessation center in Sicily and carried out several research studies on smoking behavior and health impact of cessation since then. I have been carrying out research on vapor products since 2010. My research team published the first randomized controlled trial of e-cigarettes in 2013. I submit the following testimony for consideration in response to a request from Committee Secretary Dr Patrick Hodder to assist the Select Committee on Tobacco Harm Reduction to get a better understanding about the impact that cigarette substitution may have on Australian smokers.

I am happy for my submission to be a public submission and be published on the internet.

The compulsion to smoke is very difficult to break and even for those who do quit smoking, relapse is the norm; for unsupported quit attempts, 80% relapse in the first month (Benowitz, 2010), and for smokers who utilize treatment, 75% fail within six months, with the large majority resuming smoking within two weeks (US HHS, 2010). Even for those who quit smoking during hospitalization and intended to stay quit, 25% relapsed *on the first day after discharge* (Mussulman *et al.*, 2019). Consequently, there is a pressing need for alternative and more efficient means to reduce or prevent harm from smoking.

Harm reduction is a treatment strategy to reduce the harms caused by particular behaviours, one of which is drug use. The tactics include amending regulations and bans that increase harm, empowering people with accurate information, and offering alternatives such the adoption of risk reduction actions (for example, clean needles) and the substitution of lower-risk drugs (for example, methadone maintenance). Tobacco harm reduction seeks to prevent or reduce the damage caused by the toxins generated by tobacco combustion for smokers unable or reluctant to stop, rather than aiming at complete abstinence from nicotine use (Zeller and Hatsukami, 2009). Of note, the World Health Organization's *Framework Convention on Tobacco Control* (WHO, 2003) acknowledges harm reduction as an integral part of a comprehensive approach.

Displacing deadly combustible tobacco products with non-combustion products that deliver nicotine with a lower toxic and risk profile is key to tobacco harm reduction. Three classes of products can fulfil this role: snus (oral use tobacco), e-cigarettes (vapor products), and tobacco heated products (heat-not-burn). The conclusive evidence for the harm reduction potential offered by these products (based on the reductions of toxicity in these products compared to smoking cigarettes) has been presented in authoritative governmental reports (US National Academies of Sciences, Engineering and Medicine book, *Public Health*



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*Consequences of E- Cigarettes, 2018; Evidence Review of E-Cigarettes and Heated Tobacco Products. A Report Commissioned by Public Health England, 2018).*

These products, although not completely risk-free, offer an alternative to quit or die. As a practicing physician and head of one of the most active smoking cessation clinic in Italy, I advise smokers who are unable or unwilling to quit (as well as smokers intending to quit who categorically refuse taking antismoking medications) to at least consider trying substitute products. Our research in COPD patients, asthmatics, people with high blood pressure and individuals with schizophrenia using vaping products show clear benefits with objective evidence for harm reversal.

Giving smokers an alternative with efficient nicotine delivery means that they might prefer one of these products over deadly cigarettes. Because the alternatives incur substantially less risk than smoking tobacco cigarettes, tobacco harm reduction will produce better outcomes at individual and at population level. On the contrary, a restrictive approach that severely limit access to harm reduction products within populations of consumers who currently smoke tobacco could be damaging to public health.

I hope Australian leaders will reconsider their national policies and promote a judicious integration of their existing tobacco control programs with tobacco harm reduction strategies.

I would like to comment on several of the terms of reference based on our research

**The established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment**

We conducted the world's first randomised control trial on nicotine vaping for smoking cessation in 2013. [1] In a trial of 300 smokers not intending to quit, using first generation vaping products, we found:

“Switching to e-cigarettes resulted in significant smoking reduction and smoking abstinence with a substantial number of quitters (26.9%) still using these products by week-52.”

“In view of the fact that subjects in this study had no immediate intention of quitting, the reported overall abstinence rate of 8.7% at 52-week was remarkable.”

Subsequent research has used more effective devices and smokers who are motivated to quit. The latest studies are summarized in the 2020 Cochrane Review which concluded that vaping nicotine is an effective quitting aid and is significantly more effective than nicotine replacement products. [2]

**The established evidence on the uptake of e-cigarettes amongst non-smokers and the potential gateway effect onto traditional tobacco products**

In a study on youth vaping in the US, we examined data from the National Youth Tobacco Survey in 2015. [3] We found

“Although there is reasonable concern about the recent increase in ever and past 30-day e-cigarette among U.S. youth, the data reported here show that the majority of e-cigarette use is experimental or infrequent, while regular use is minimal, among never smokers.”



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“Frequent use was rare (only 1.7% of all participants) and the majority of those using e-cigarettes were already smoking tobacco cigarettes.”

We also reviewed the 2016 Surgeon General report which concluded e-cigarette use among youth and young adults is becoming a major public health concern in the United States of America [4].

Our review concluded “The U.S. Surgeon General’s claim that e-cigarette use among U.S. youth and young adults is an emerging public health concern **does not appear to be supported by the best available evidence** on the health risks of nicotine use and population survey data on prevalence of frequent e-cigarette use.” Indeed, all of the evidence presented in the Surgeon General’s discussion of nicotine harm does NOT apply to e-cigarette use, simply because it relies almost exclusively on exposure to nicotine in the cigarette smoke and not to nicotine present in e-cigarette aerosol emissions.

#### **Any other matter**

Our research has also looked at the effect of nicotine vaping on health in smokers who switch. We have found significant improvements in COPD [5], asthma [6, 7] and blood pressure [8] in smokers who switch from smoking.

In 2019, we reviewed the effect of vaping on respiratory health and concluded [9]

“There is growing evidence to support the relative safety of EC emission aerosols for the respiratory tract compared to tobacco smoke [4,14,159]. Public Health England estimated, on the basis of a review of 185 studies, that vaping an e-cigarette is likely to be at least 95% less harmful than smoking a regular cigarette [13]. In 2016, the Royal College of Physicians reaffirmed this figure, estimating the risk of longterm inhalation of e-cigarette aerosol to be unlikely to exceed 5% of the risk associated with long-term cigarette smoking [12]. This review article shows that although some potential effects on respiratory cell types can be shown in vitro, and low levels of chronic irritation of the respiratory tract can be anticipated at certain levels of vaping, these effects are much less than those of smoking. The clinical evidence confirms that ECs are unlikely to raise significant health concerns for the respiratory tract under normal conditions of use.”

Our systematic review of the safety of e-cigarettes concluded [10]

“Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes. Research will help make electronic cigarettes more effective as smoking substitutes and will better define and further reduce residual risks from use to as low as possible, by establishing appropriate quality control and standards.”

“It is obvious that some residual risk associated with EC use may be present, but this is probably trivial compared with the devastating consequences of smoking.”



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“Due to their unique characteristics, ECs represent a historical opportunity to save millions of lives and significantly reduce the burden of smoking-related diseases worldwide.”

Yours Sincerely

Prof. Riccardo Polosa

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