



Response

Asking the wrong questions about e-cigarettes? A response to Stan Shatenstein

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We would like to thank Shatenstein (2014) for his interesting comments in response to our commentary on e-cigarettes (Farsalinos & Stimson, 2014). We noted several misconceptions and contradicting arguments presented in Shatenstein's Viewpoint that need to be clarified.

Smoking substitution is a welcomed effect of e-cigarette use. In fact, this is the only reason why part of the public health community supports and endorses e-cigarette use by smokers. However, it cannot be supported that such an effect automatically characterizes e-cigarettes as having physiologic functions above or more intense from what is expected from common products and hence would warrant classifying them as medicines. In the same way, if people are willing and able to substitute red meat with vegetables (which is beneficial to health and may lead to several physiologic changes in the human body, such as improvement in cholesterol levels or treatment of obesity) it would be awkward to support the view that vegetables should be considered medications. Shatenstein seems to have misunderstood the main concept of tobacco harm reduction. It is a strategy of providing products that are used in order to provide pleasure to the users, and substitute the pleasure perceived from smoking (which is the most harmful form of nicotine intake) with that of using an alternative product (which is less harmful). Such products are not used in the form of medications, although they result in partial or complete substitution of smoking (Ramström, 2003).

As scientists we are unwilling to enter to the "legal word game" of characterizing e-cigarettes as smoking cessation or smoking substitution products. Since many scientists supporting the role of e-cigarettes are also clinicians, being in very close contact with smoking patients, the end-result is the same irrespective of the words used: stopping the use of tobacco cigarettes by substituting them with a less harmful alternative. Unfortunately, legal definitions have created more confusion rather than making things clear.

In our manuscript, we specifically present the argument that the origin of nicotine (i.e. from tobacco) cannot be used to support medicinal regulation for e-cigarettes. Herein, we will repeat the example of biodiesel, which cannot be considered a vegetable

product just because it is derived from plants. The purpose, the way and patterns of use and the final composition of a product are the key factors in classifying it, not the identification of single components in them and their original source. Moreover, it is a legal paradox to define some but not all nicotine products as medications. If nicotine is having physiologic effects at such an extent that it should be classified as a medication, why are tobacco products (cigarettes, cigars, smokeless tobacco-snus) not classified as medications? Nicotine use existed before being classified as a medication; the latter was done in order to facilitate the production of NRTs by pharmaceutical companies.

We disagree that smokers use e-cigarettes in the same way as NRTs or other medications. The main difference is that medicinal smoking cessation products are not made with the purpose of providing pleasure to the user. Thus, smoking substitution with the use of tobacco harm reduction products should not be considered a medicinal intervention. In fact, the medicinal regulation, if applied to these products, would likely contribute to their failure as smoking substitutes, due to requirements for specific and uniform dosing and consistent absorption. That would deprive users from the ability to self-adjust their use based on their personal preference. Products like e-cigarettes provide pleasure to the user; that is why they are preferred by part of the smoking population instead of medications, and this justifies the availability of a variety of devices and flavors (Farsalinos et al., 2013).

Shatenstein calls nicotine "a drug" and believes that e-cigarettes are used as a method to self-titrate drug intake. Nicotine is a naturally occurring substance and, as mentioned previously, exists in many products which are not labelled as medications. The same applies for other products, such as caffeine. It has long been established that cigarette dependence is not just a chemical phenomenon: there is a psycho-behavioral aspect too (Buchhalter, Acosta, Evans, Breland, & Eissenberg, 2005). Nicotine is a substance responsible for an important part of the cigarette dependence phenomenon, but it is compatible with daily social life (Bell, 2013) and contributes minimally to smoking-related disease. The fact that the purity of nicotine used in e-cigarettes is (and should be) following USP or Eur. Ph. standards should be applauded rather than used as a reason to apply medicinal regulation.

The concept of tobacco harm reduction does not dictate that the products should be absolutely harmless. Referencing the newspaper article about exploding batteries is in reality misleading since

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the problem is attributed to the lithium batteries present in many consumer products (e.g. cellphones) and not to e-cigarettes per se (Farsalinos & Polosa, 2014). For the issue of nicotine, we agree that it is not an absolutely safe substance, but it is safe enough to be recommended as long term substitute by major medical authorities (Medicines and Healthcare Products Regulatory Agency, 2010). Moreover, we agree with the statement about the grave historical error in allowing cigarette marketing to flourish; we are now witnessing the result of this, the large burden of smoking on health worldwide. E-cigarettes are not part of the problem but part of the solution. Pursuing the absolutely safe product is useless from a public health perspective if it ends up creating a product which is not acceptable by smokers. We have seen this in the past, in the case of NRTs and their limited efficacy as smoking substitutes (Moore et al., 2009). It is our ethical obligation to provide smokers with a less harmful alternative, rather than punishing them for the inability of medical science to develop very effective smoking cessation medications (Moore et al., 2009; Rigotti et al., 2009). The key issue is to understand the risk-benefit ratio rather than the absolute risk. This is also the main principle behind every consumer product, but also in medicinal regulation; there is no medication without side effects or contraindications, however they are approved for use because the risk-benefit profile is favorable. Moreover, the frequently heard argument about the lack of long-term studies, although true, cannot justify a request for restrictions on e-cigarette use. Even for medications, which may be used for years in some cases (e.g. anti-hypertensives), no regulatory agency is asking for long-term safety data before being approved for use. Post market monitoring is applied in these cases, and we support the same for e-cigarettes.

Finally, we were surprised that Shatenstein characterized as “remarkable” and “unusual” our comments about the positive experience of nicotine perceived by smokers. We are witnessing that some parts of the tobacco control movement have distanced themselves from science and are engaged in promoting arguments which are either unsupported by evidence or which involve misrepresenting or misinterpreting evidence. But this is not science. It is well known through scientific research that “Nicotine induces pleasure and reduces stress and anxiety” (Benowitz, 2010) and that some smokers would prefer an alternative product to maintain perceived pleasure but reduce harm (Bell, 2013; Britton & Edwards, 2008). There should be no censorship on scientific findings. Failing to understand this, and demonizing or marginalizing smokers, will not solve the problem of tobacco-related morbidity and mortality. It is our duty to understand smokers and why they smoke; this is the only way to reach our goal of providing them with the necessary tools to reduce the impact of smoking on

their health. Finally, rather than supporting unfounded arguments (e.g. e-cigarettes being a gateway to smoking or imposing added and excessive risk in dual users), we, as scientists, should stick to evidence-based arguments and findings. Such findings are not and cannot be influenced by any funding because they are continuously verified and reproduced; therefore, they are proven to be consistent and reliable (Farsalinos and Polosa, 2014; Hajek, Etter, Benowitz, Eissenberg, & McRobbie, 2014). Everyone supports the need for some regulation on e-cigarettes (to ensure quality of the products and to define smokers as the targeted population for their marketing), but we strongly support our original position that classifying e-cigarettes as medications is not justified and may be damaging for public health.

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