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Formaldehyde From E-Cigarettes - It's Not as Simple as Some Suggest

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Supporting information

Additional supporting information may be found in the online version of this article at the publisher's web-site:

Supporting Material S1 Bates CD, Farsalinos KE. Complaint under the Code of Conduct of the Committee on Publication Ethics: Letter in the *New England Journal of Medicine* Jensen et al (2015), Hidden Formaldehyde in E-cigarette Aerosol, 20 April 2015.

S2 Letter to *New England Journal of Medicine*, from 40 academics and experts in support of the complaint about the research letter published in the *NEJM* on Hidden Formaldehyde in E-cigarette Aerosol, 20 April 2015.

FORMALDEHYDE FROM E-CIGARETTES—IT'S NOT AS SIMPLE AS SOME SUGGEST

In their communication here [1], and previously in the *New England Journal of Medicine* [2], Bates & Farsalinos (referred below to as B&F) make numerous assertions and assumptions that are not supported by facts. We address these as follows:

B&F: 'The authors had rigged up a battery and atomiser combination that when operated at a higher voltage setting would mean the atomiser ran very hot and constituents in the liquid would create thermal decomposition products, including formaldehyde. The flaw in the experiment is that under these conditions the vapour tastes so acrid and harsh that human users will not inhale it ...'

Response: (a) Use of the term 'rigged up' suggests that we established makeshift or special conditions to make the tests, when in fact we used a commercial e-cigarette device with available power settings; (b) regarding the statement that 'in our experiments the atomiser ran very hot', all e-cigarette coils necessarily reach high temperatures to create the aerosol(s) of propylene glycol and/or glycerol that form the basis of most e-cigarette liquids. That the conditions used were not relevant to real users is *ipso facto* false, given that we used a commercial device at available settings, notwithstanding the speculations of B&F regarding how the vaped aerosols we evaluated would have tasted to anyone; and (c) B&F are entitled to speculate that use of the higher power setting in our work constituted 'overheating',

and led necessarily to vapour characteristics for all humans (and e-cigarette fluids used) of 'acrid', 'harsh', and non-inhalable. However, that view seems highly tenuous, especially because of the very high concentrations of flavor chemicals we have found in many e-cigarette fluids [3]. In fact, the tobacco industry has used flavorants to overcome smoke that is 'acrid' and 'harsh' for many years [4–6].

B&F: 'It would have been reasonable for the authors to conclude that under certain conditions, overheating of the atomiser could result in high levels of formaldehyde that could pose a risk to users...'

Response: B&F are welcome to speculate about 'overheating', etc. However, in our Letter [7] we have presented only facts as we found them. We stated clearly that we did not detect the formaldehyde-containing compound when we ran the tests at the lower power setting, and saw it at high levels only at the higher power setting that was available on the commercial device that we used.

B&F: '...but to engage in the kind of health impact modelling exercise they did and to report the results so prominently without the required caveats, in our view, is likely to mislead readers and judging from many of the headlines, this is indeed what happened'.

Response: Calculations of cancer risk based on established cancer slope factors are the internationally accepted basis for cancer risk estimates and corresponding regulatory actions. As just one example, using the same cancer slope factor as employed in our work, Pilidis *et al.* [8] computed predicted numerical cancer risk values due to formaldehyde in indoor and outdoor air in urban Ioannina, a medium-sized (100 000 inhabitants) city in northwestern Greece. Further, despite what B&F imply, our Letter clearly makes the comparison only for formaldehyde in cigarettes versus formaldehyde in e-cigarettes and, for the latter, as used only at the higher power setting we employed. We also emphasized these points in our earlier reply Letter in the *New England Journal of Medicine* [9].

Regardless of how extensively they may be regulated, and how useful they will be in reducing smoking, it is clear that electronic nicotine delivery systems (ENDSs) are here to stay. Less clear are the extents to which this technology may be safer than habitual use of tobacco products, and whether ENDSs may, by themselves, lead to dependence on nicotine as well as, unfortunately, other 'vapable' addictive drugs.

Declaration of Interests

None.

Keywords Cancer risk, Electronic cigarettes, e-cigarettes, formaldehyde, health effects, risk, vaping, watts.

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E-CIGARETTES NEED TO BE TESTED FOR SAFETY UNDER REALISTIC CONDITIONS

In our view, Pankow *et al.* have not addressed adequately the key criticism of their report: that they used results from laboratory tests of e-cigarettes under conditions that rarely occur in practice to calculate a human cancer risk. Pankow *et al.* did not counter the point that their experiment created the well-recognized, and very unpleasant,

‘dry puff’ phenomenon, when the power input and atomizer combination causes high temperatures that create a very unpleasant taste so that users avoid this combination [1–3]. Farsalinos *et al.* [4] have confirmed that aldehydes are contained in the aerosol at high levels only under these ‘dry-puff’ conditions. The point is that users limit their exposure to dry puff conditions by adjusting the power input, puff depth and frequency and liquid flow to ensure that they avoid this unpleasant experience, whatever the combination of battery and atomizer used. An experiment that overlooks this human control feedback cannot provide reliable data on human exposures.

Pankow *et al.* argue that flavours would mask the acrid taste of the dry puff; but this is speculation, and contradicted by the fact that the phenomenon is reported by e-cigarette users who are using flavoured e-liquid. Moreover, flavours in e-cigarettes are not added to mask any harsh and unpleasant taste but because flavourless e-liquids are bland and boring. The authors’ conclusions, together with a press release from the *New England Journal of Medicine*, predictably created a misleading impression of the harmfulness of e-cigarettes.

For the future, we recommend that tests of the safety of e-cigarettes in laboratory conditions be accompanied by user tests to assess how likely it is that those conditions would arise in practice, and that researchers exercise appropriate caution when generalizing their findings.

Declaration of interests

K.E. reports that some of his studies on electronic cigarettes were performed with unrestricted funds provided to the Onassis Cardiac Surgery Center by FlavourArt and Nobacco. K.E. publishes a blog commenting on research on e-cigarettes and its implications at www.ecigarette-research.org/. C.B. is a long-standing and continuing advocate of ‘harm reduction’ in tobacco and other public health policies and has written extensively on e-cigarettes at www.clivebates.com.

Keywords Atomiser, cancer risk, dry puff, e-cigarettes, e-liquid, formaldehyde

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