Flawed e-cigarette formaldehyde paper should be retracted – formal complaint and supporting letter published

written by Clive Bates | 9 September 2015



Remember this? Our complaint to NEJM and case for retraction is published.

Background: Flawed paper on e-cigarettes and formaldehyde published in New England Journal of Medicine

On 22nd January 2015 the New England Journal of Medicine published a paper: *Jensen et al, Hidden Formaldehyde in E-cigarette Aerosol* . It contains the following sensational claim (emphasis added, cross references omitted for clarity)

> *If we assume that inhaling formaldehyde-releasing agents carries the same risk per unit of formaldehyde as the risk associated with inhaling gaseous formaldehyde,* ***then long-term vaping is associated with an incremental lifetime cancer risk of 4.2×10−3. This risk is 5 times as high (…), or even 15 times as high (…) as the risk associated with long-term smoking****.*

Unsurprisingly with a claim like that, it gained huge worldwide publicity. The trouble is that this conclusion is completely unreliable and is based on measurements made in 'dry puff' conditions which no vaper will tolerate for more than an instant. The calculated cancer risk is therefore a work of fiction. This paper and its flawed methodology attracted a barrage of criticism documented here by me: Spreading fear and confusion with misleading formaldehyde studies and notably in technical posts by Konstantinos Farsalinos: here and here.

The next stage was to organise a proper complaint – this is now published.

Complaint to the New England Journal of Medicine calling for retraction

On 20th April 2015, Dr Farsalinos and I made a formal complaint to the NEJM calling for the paper to be retracted under guidelines published by the Committee on Publication Ethics (COPE). 40 experts in the field wrote a supporting letter to NEJM backing the complaint.

On 9th September 2015, the complaint was made public and published in the journal *Addiction,* along with a letter summarising the case for retraction, a reply from the authors of the NEJM paper, and a response from Bates/Farsalinos to their reply. It is now on the record and at the links below as published in *Addiction,* October 2015 online version.

1. Letter from Bates/Farsalinos to *Addiction* outlining the basis of the case for retraction from NEJM. Research letter on e-cigarette cancer risk was so misleading it should be retracted
2. Reply from some of the original authors of the paper published in NEJM (Pankow et al): Formaldehyde from e-cigarettes—it's not as simple as some suggest. This fails to address or acknowledge the weakness in their method…
3. Further response to Pankow et al, by Bates/Farsalinos reiterating the central flaw in their work. E-cigarettes need to be tested for safety under realistic conditions
4. *Addiction* includes as Supplementary material the Bates/Farsalinos April 2015 detailed complaint to NEJM and April 2015 supporting letter to NEJM from 40 experts – this is the first public visibility of these documents.

Guide to the case for retraction so far

The editors of the New England Journal of Medicine declined to withdraw the paper – we were not surprised by this. But neither do we think they mounted a credible argument of defence of the paper.

I have documented the case for retraction and all the exchanges relevant to this case. It meets the criteria for retraction under the COPE Retractions Guidelines – the findings are completely unreliable and the "integrity of the academic record" is compromised. The worldwide publicity generated was based on a wholly flawed methodology and the paper continues to be cited in formal literature and by activists as if it is is meaningful for human exposure.

1. A short guide to why the *Hidden Formaldehyde* paper should be retracted under COPE guidelines: Hidden formaldehyde in e-cigarette aerosol: summarising the case for retraction
2. A full account of all the exchanges related to this case: E-cigarettes and formaldehyde – anatomy of a flawed study– including the exchanges the editor of the NEJM.

Updates

- 16 November 2015: After receiving a short email from the editor of the NEJM, I replied with a letter detailing six adverse consequences flowing from the publication of this letter: More on New England Journal of Medicine fake formaldehyde scandal
- 20 April 2016: I have posted a critique on PubMed Commons.

My comment for media

Clive Bates said:

> *The paper on e-cigarettes and formaldehyde published in the New England Journal of Medicine created worldwide alarming media headlines suggesting e-cigarettes could create certain cancer risks that would be five to fifteen times higher than for cigarette smoking. But it turns out this was based on completely unrealistic e-cigarette measurements using a flawed methodology that should not have been used to characterise human exposure or cancer risk. The findings*

are unreliable, the publicity unjustified and, under ethical guidelines designed to protect the integrity of the academic record, it follows that the paper should be retracted. We will continue to press the authors and the journal to do the right thing with this paper, which is to pull it.