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February 12, 2020

Barry London, MD, PhD
Editor-in-Chief
Journal of the American Heart Association
JAHA@journalaha.org
VIA EMAIL

Nancy Brown
CEO
American Heart Association
nancy.brown@heart.org
VIA EMAIL

RE: Electronic cigarette use and myocardial infarction among adults in the US Population
Assessment of Tobacco and Health.
Journal of the American Heart Association 2019;8:e012317. DOI:10.1161/JAHA.119.012317.

Dear Dr. London and Ms. Brown,

This letter responds to Dr. London's letter of February 10, 2010, with a status update on the additional analysis concerning the subject paper and to suggest a proposed resolution. We also wanted to express our appreciation of the pressure that the journal has been under from Dr. Rodu and other e-cigarette advocates.

Dr. Bhatta and I continue to stand by the paper as published. We accurately reported our analysis, including the potential limitation related to the timing of heart attacks using the analysis that was originally accepted by the reviewer and editors. We have no objection to doing and reporting the additional analysis that you have requested once we have access to the data. However, we want to be clear: We will not retract this paper and we strongly object to any efforts by JAHA to retract the paper.

1. **Avoid Litigation**: Dr. Bhatta and I want to avoid having to escalate this matter and commence litigation. Given that we do not yet have access to PATH, as discussed more fully below, we were surprised to receive your letter threatening to retract our paper on Wednesday, February 12 at 5 pm EST. Further, the proposed retraction language is both inaccurate and damaging. As Dr. London and I have discussed several times, the reviewer accepted the way that we implemented his or her suggestion and the paper was published. Retraction would imply some malfeasance on our part, which you know is not the case. If JAHA proceeds with the proposed improper retraction notice, we may have no choice but to commence litigation. We would prefer that

cooler heads prevail, and all parties take the time to resolve this matter after Dr. Bhatta and I have access to the data.

2. **No Access to PATH:** We have agreed to conduct the additional analysis you requested. As I have written Dr. London several times, unfortunately the University of Michigan has not yet restored access to PATH for us (or anyone else at UCSF). I also have learned that UM has cut off investigators at other universities. This issue has been elevated to the Vice Chancellor for Research here at UCSF who is trying to get this issue resolved. As we previously discussed the necessity of tying the deadline for getting the analysis done to the time that our access to PATH is restored, and as we do not yet have the necessary access to PATH, we have been unable to complete the additional analysis. Your letter of February 10 states, in part: “we requested the additional analysis be completed 90 days after publication of the correction notice regarding the article listed above.” To reiterate what I have written to Dr. London several times, the additional analysis cannot be completed until our access to PATH is restored, an event which has not yet occurred.
3. **Inaccurate Retraction Statement:** In contrast to the reality of the ongoing situation, your retraction statement is incorrect: “The authors agreed to comply with the editors’ request to conduct the revised analysis but have not provided the revised analysis by the deadline set by the editors.” This statement states that we have refused to do the additional analysis, which you know is not the case. Indeed, on November 17, 2019, I wrote Dr. London: “Dr. Bhatta and I have prepared the code to do the additional analysis you have requested, so we should be able to do the analysis reasonably quickly after access is restored.” For *JAHA* to assert the retraction is based on the failure of Dr. Bhatta and I to comply with an agreement to provide the revised analysis by the deadline set by the editors is inaccurate and damaging.
4. **Failure to Follow Normal Scientific Protocol**

As I emailed Dr. London on July 23, 2019, this whole situation has evolved outside normal scientific discourse:

We have to say that this whole exchange strikes us as outside usual scientific discourse, since I first learned of Rodu and Plurphanswat’s letter from *USA Today*, not you.

If you believe that the issues Rodu and Plurphanswat raise are worth airing to the scientific community, we request that you request them to provide a more complete description of their analysis so that we can properly respond to it in the correspondence section of *JAHA* and allow the scientific community to judge these issues. (Rodu has published many papers in which he re-analyzes data in other papers, claiming that his analysis nullifies published papers. In his criticism of one of our earlier papers we believe that his result depended on an overspecified model. See, for example, <https://pediatrics.aappublications.org/content/141/4/e20173594/tab-e-letters>.)

Rodu and Plurphanswat wrote, ‘We reproduced the entire Bhatta-Glantz analysis. When current vapers who had a heart attack before using e-cigarettes were correctly reclassified as non-exposed, the ORs for daily and some-day vapers were 0.69 (CI = 0.22 – 2.12) and 0.18 (CI = 0.05 – 0.66) respectively. In short, vapers were much less likely to have had a heart attack, not twice as likely.’ Given the very small number of MIs among e-cigarette users in their sample, is likely even smaller than in our Table S6, it is

surprising that their result for some-day e-cigarette users reached statistical significance. In addition, assuming that they accurately reproduced our analysis, one issue with their analysis is that they are only addressing first heart attacks, not re-infarctions, as we discuss in connection with the alternative analysis in Table S6.

In any event, the full details of their analysis need to be provided so we can properly respond.

We also request that you ask Rodu and Plurphanswat provide a full disclosure of their relationships with the tobacco companies. As the *USA Today* article reported, they are extensive.”

5. **No Misconduct**: The decision of JAHA to retract the paper is an extreme action that should be limited to papers that reflect serious misconduct. The International Committee of Medical Journal Editors statement on “Scientific Misconduct, Expressions of Concern, and Retraction” states: “Scientific misconduct in research and non-research publications includes but is not necessarily limited to data fabrication; data falsification including deceptive manipulation of images; purposeful failure to disclose relationships and activities; and plagiarism” (<http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/scientific-misconduct-expressions-of-concern-and-retraction.html>). The ICJME also has extensive protocols defined for dealing with possible retractions, which do not appear to have been followed by JAHA. The Editors of JAHA know there is no evidence that Dr. Bhatta or I engaged in any of these practices. To incorrectly imply otherwise is extremely damaging to us.
6. **Good Faith Efforts During the Peer Review Process**: As I detailed in my letter to Dr. London dated September 30, 2019, we engaged with JAHA and the peer reviewers in good faith and accurately presented and reported their results. In particular, as detailed in that letter of September 30, while there was some misunderstanding of the specific supplemental analysis requested by the reviewer, the analysis that we presented during the peer review process substantially addressed the question raised by the reviewer. As I wrote Dr. London:

In any event, it is important to keep in mind that this discussion is about a supplementary analysis, not the main analysis in the paper. As the paper states, restricting the data as we did substantially dropped the number of MIs and the supplemental analysis was not statistically significant. *Reviewer 2 understood and accepted our supplementary analysis and, after we responded to the original comment, recommended publishing the paper as it is with primary analysis (which is based on the whole dataset) despite the issues discussed in this letter.* [emphasis in original]

To reiterate: Doing the additional alternative analysis will not change the main analysis in the paper.

7. **Ongoing Public Relations Attack**: It is important for AHA and JAHA to recognize there continues to be an ongoing, organized public relations effort to attack the authors and this paper, including specific efforts to pressure the journal, as illustrated by a post on February 9, 2020 on the e-cigarette advocacy group Consumer Advocates for Smokefree Alternatives Association website and mailer to its mailing list (<http://www.casaa.org/news/02-09-20-weekend-heads-up-round-up/>). JAHA appears to be insensitive to the ongoing public relations attack against the authors. Caving in to this orchestrated campaign by e-cigarette interests will do serious harm not

only to our reputations, but also to the reputations of UCSF, AHA, and JAHA.

Like Rodu's original attack in *USA Today*, the public relations effort is not how scientific discourse is supposed to proceed.

8. **Proposed Next Steps:** We still believe that following normal scientific protocol and having Drs. Rodu and Plurphanswat publish their criticism in enough detail to allow use to respond to the technical issues as an Article Comment (<https://www.ahajournals.org/jaha/article-types>) and allow us to respond would be the appropriate next steps. Such a process would allow the scientific community to consider their arguments and our response in judging the paper's conclusions.

If the Editors at JAHA still wish to pursue the serious action of retraction, such a course should only be taken in accordance with established protocols outlined by the ICJME. To the extent AHA or JAHA unilaterally attempt to retract the paper, we intend to pursue all available remedies.

Thank you for your consideration. We look forward to your prompt response.

Sincerely yours,



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cc: Dharma Bhatta, PhD
Philip Gregory
Greta Schnetzler
Brian Smith