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Dear Dr Kavanagh,

We have carefully evaluated the issues raised in the letter you sent to us on December 19, 2016. The authors have provided a response to these concerns, we have reviewed the protocol and other associated documents, we have obtained outside review, and we have reviewed the matter fully among the editors.

You raise three types of concerns: 1) potential misinterpretation of the data (however there were no concerns regarding the actual data); 2) changing metrics regarding the ClinicalTrials.gov registration which were clerical in nature (however fidelity to the protocol was maintained); and 3) delay in results reporting (with results being reported subsequently). None of the concerns raised question the integrity of the data which underlie the report in our pages nor have any been identified. Thus we see no issue raised regarding the integrity of the research that requires action from us.

The issues you note regarding how to interpret the study results and that you disagree with the interpretation are best debated in the scientific community as part of ongoing discussion to improve healthcare policy.

Sincerely yours,

Jeffrey M. Drazen, M.D.
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