Reviewer’s report

Title: Regulatory and Policy Tools to Address Unproven Stem Cell Interventions in Canada: The Need for Action

Version: 0 Date: 18 Apr 2019

Reviewer: Kirstin Matthews

Reviewer's report:

I think this is a new and original commentary on subject that has been covered extensively. It summaries the issues and problems related to unproven stem cell interventions. In addition, it gives actionable items to making change in a specific jurisdiction (Canada) although the lessons an ideas can be applied in other national contexts. Many commentaries have been written about this issue, but less have addressed how to move forward. I have only two minor issue which can be easily addressed.

First, I object to the use of the term "therapies" or "treatments" related to unproven interventions. They may imply that while unproven they are actually effective. Instead, I would request revising to use other terminology such as 'intervention' or 'procedure' which are more neutral.

Second, in the advocacy section they call for engagement to push for new changes in regulation. It would be helpful if they also discussion factors that will make this challenging. Not only will those making money on these procedures resist changes, you will also most likely find individuals who obtain the procedures resistant to changes. Patient advocates with debilitating disease who believe these interventions can and are helping them have powerful voices that those pushing for regulation should be aware of as well as ways to combat. While a full discussion of these advocates is beyond the scope of this commentary, it would be good to mention within the 'advocacy' section opposition they might face.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
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Yes
Are the conclusions drawn adequately supported by the data shown?
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Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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