Reviewer’s report

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

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Reviewer: Insoo Hyun

Reviewer's report:

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This is a well-written and timely article on an important topic, which makes it appropriate for this journal. The authors discuss several regulatory and policy tools that are available in Canada to address the growing problem of the commercial marketing of unproven stem cell therapies to patients. These tools are: Health Canada's jurisdiction over the stem cell market; the Competition Bureau; professional regulation; litigation; and advocacy. These all seem like sensible and potentially effective mechanisms, but, as the authors note, one of the chief difficulties preventing effective change using these mechanisms is lack of political and bureaucratic will. Given this latter point, could the authors provide a bit more discussion/argument around how best to reverse this lack of will (aside from their general calls for advocacy)? Is there an underlying political and ethical critique the authors have in mind and can articulate? Could this paper have an added ethical dimension to it that argues that the lack of political and bureaucratic will is a moral failure of leadership? Perhaps the authors do not share this harsher outlook, but if they do, it would be good to instill this paper with a sharper critical edge and a bit more bite.

Regarding the many regulatory and policy tools the authors identify, I believe there are a couple of areas for additional analysis that the authors should consider. First, with regard to the regulation of minimally manipulated autologous cells, how would Health Canada avoid the objection that it would be over-extending its reach by interfering with the medical practices of Canadian physicians. In the U.S., as in Canada, physicians are given leeway in how they decide to provide medical services to their patients, as long as they are not using complex biologics and unapproved drugs and are not conducting an investigational study. Second, litigation may prove to be a policy tool with limited effectiveness, if Canada is anything like the U.S. In the U.S. several patients have sued stem cell "clinicians" before, but these cases were usually settled out of court and were bound up with non-disclosure agreements, thus preventing the kind of societal impact that the authors envision. Would it be the same in Canada? Aside from these two points, the regulatory and policy tools the authors outline are sensible and are likely to be effective if pursued seriously.
One minor point: The first sentence of the manuscript should read, "A range of stem cell therapies IS now widely offered directly to consumers in the United States and Canada."

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

Yes

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