

BMJ - Decision on  
Manuscript ID  
BMJ.2017.042589

**Body:**

30-Jan-2018

Dear Dr. Gaffney

# BMJ.2017.042589 entitled "Healing an Ailing Pharmaceutical System: A Prescription for Reform"

Thank you for sending us this paper and giving us the chance to consider your work. We feel it is much improved but have some further requests before we can move ahead and accept the piece.

The editors' comments are listed below:

:: Can you specify US and Canada in the title: "Healing an Ailing Pharmaceutical System in the United States and Canada: A Prescription for Reform"

:: Can you include a Standfirst at the beginning of the article.

:: Analysis articles don't have abstracts. Can you include 3-5 bulleted summary points in a Key Messages box in its place.

:: Thank you for shortening the article, we appreciate that this will have been a challenge. Although we're happy to make an exception for this article regarding length and number of references (there are many more than we would usually allow for Analysis articles) we'd like you to remove the display items that summarize findings from references (Table 1 & 2. E-Table 1-4). We appreciate that you wanted to retain the cost and savings estimates in the manuscript. We've discussed this internally again but I'm afraid we can't accommodate it in the journal, please remove it.

:: The article is much clearer in the Discussion regarding the formidable political opposition that these reforms would likely face. However, can you include a few sentences in the introduction that frames the piece as being ambitious and far reaching and better acknowledges the various contextual factors that will make it difficult to implement? This could even include how this group came together and what you set out to do. This could head off the easy criticisms about how realistic these proposals are.

:: There's a big gap (6 paragraphs) between proposing two divisions with NIH/CIHR and explaining the function of the second division. Can you name the two divisions when you first mention them: "The new institutes would have two divisions (E-Figure 1). The first - the Drug Innovation Division... we propose the creation of new Clinical Trials Divisions"

:: We're not able to point to unpublished data, can you point to a different reference or remove these?

"(The comparable 5 Canadian figure for 2016 is 45% [Lexchin J, unpublished data])"

"Ten drugs approved in Canada under its "Notice of Compliance with conditions" pathway have remained on the market for more than 6 years without the completion of required postmarketing studies; of these, 6 have been on the market for more than 10 years (Joel Lexchin, unpublished data)"

:: "The recently enacted 21st Century Cures Act in the US creates even more such pathways... for approval of new indications for drugs... Such evidentiary changes"

There's an odd paragraph break here with the new paragraph still directly related to the preceding sentence.

We hope that you will be willing to revise your manuscript and submit it within 4-6 weeks. When submitting your revised manuscript please provide a point by point response to our comments and those of any reviewers.

Please note that resubmitting your manuscript does not guarantee eventual acceptance, and that your resubmission may be sent again for review.

Once you have revised your manuscript, go to <https://mc.manuscriptcentral.com/bmj> and login to your Author Center. Click on "Manuscripts with Decisions," and then click on "Create a Resubmission" located next to the manuscript number. Then, follow the steps for resubmitting your manuscript.

You may also click the below link to start the resubmission process (or continue the process if you have already started your revision) for your manuscript. If you use the below link you will not be required to login to ScholarOne Manuscripts. before completing the submission.

If accepted, your article will be published online at [bmj.com](http://bmj.com), the canonical form of the journal. Please note that only a proportion of accepted analysis articles will also be published in print.

I hope you will find the comments useful. Please don't hesitate to contact me if you wish to discuss this further.

Yours sincerely

Paul Simpson, PhD  
International Audience Editor