

From: "fgodlee@bmj.com" <fgodlee@bmj.com>
Date: Monday, 6 July 2015 10:36 pm
To: "Jureidini, Jon (Health)" <Jon.Jureidini@sa.gov.au>
Cc: "eloder@bmj.com" <eloder@bmj.com>, Peter Doshi <pdoshi@rx.umaryland.edu>
Subject: Re: Study 329

Dear Dr Jureidini,

Many thanks for your letter. I quite understand your concerns. You are right to say that there are few or no precedents against which to compare this article. We ourselves are feeling our way, both with the RIAT process since this is the first full RIAT research paper we will publish, and with the specific challenges posed by this particular study and you as the paper's authors. I want to stress that we are proceeding in good faith with the clear aim of publishing the article as soon as possible provided we can do so safely.

I understand that the paper is largely now in a state that would be acceptable to publish and am grateful for the work you have put in to respond to the requests for revision. We also understand that most of the issues that the paper raises are already in the public domain, that the lack of effectiveness and misbranding was a subject of the Department of Justice ruling that led to GSK paying out \$3bn a few years ago, and that GSK is fully aware of the paper and its contents.

However, it is our view that publication of the paper still carries risks, and we want to mitigate as far as possible before publication. This will increase the chances of a smooth passage for the paper after publication.

These risks are more editorial than legal, but after detailed discussion over the past two weeks we have narrowed them down to one aspect of the study: the categorisation of the adverse events, and more specifically the self harm and suicidal ideation. It is on this categorisation that we want to have independent checks. Yes, this is more than we have done in relation to other research papers we have published but as I said at the outset, this paper is unprecedented on various counts.

We believe that this checking could be done quite quickly, and we will cover the cost. Peter Doshi is the best person to give the detailed account of what is needed and the time frame over which this could be done. We are already seeking someone suitable to undertake the checks. Importantly they must be independent of you as authors and of The BMJ. Provided you are willing to continue to work with us on this, we will contact GSK as soon as possible to ask them to make their data accessible to the person we identify.

Please be assured that we remain committed to your paper and to the spirit of the RIAT enterprise. We are honoured and proud that you have chosen The BMJ for this important work and hope very much to be in a position soon to conclude things to everyone's satisfaction.

All best wishes, Fiona Godlee

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On 6 July 2015 at 09:22, Jureidini, Jon (Health) <Jon.Jureidini@sa.gov.au> wrote:

Dear Dr Godlee

Please find a letter attached requesting help with our predicament.

Jon Jureidini

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