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James Shannon
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Dear Dr Shannon

Re: Access to study 329 data

I appreciate your prompt response (dated 12 December 2013) to my 10 December letter.

Your reply raises a number of issues. Below, I have addressed two issues that relate to the RIAT process, and a third issue that is beyond its scope but nevertheless warrants comment.

1. We assume from your not commenting on our question about constraints on access and publication that there are no areas that you can foresee impacting on our ability to publish in the manner we propose. However we note with some concern that the contract GSK sent us contains the sentence 'At any time upon the request of GSK, all tangible expressions, in any media, of GSK Confidential Information in Researcher's possession shall be delivered to GSK, or at GSK's option, destroyed.' We seek your comment on the implication of this sentence for data that has been responsibly extracted from your database.

2. In the spirit of conducting a thorough independent review, we will not be complying with your request to forward our interim results of discrepancies between data and the adverse events tables to you until we have completed our work, when we will make the results public. Also, we prefer not to communicate by phone, as this form of communication is not public.

   I also want to put on record that your comments about suicidality and Paxil seem disingenuous. Without any meta-analysis, and even ignoring the adverse events coding problems, GSK had good reason to be concerned about and make public the dangers of Paxil in children based on study 329 alone. Yet you seem to imply that it came as a surprise to GSK when the subsequent analyses were conducted and showed that adolescents treated with Paxil had an increased risk of suicidality.

3. You confirmed that GSK has not taken action to ensure that patients who took part in this trial have been briefed regarding the origin of any injuries they may have sustained and the implications for future treatment. Does this also apply to patients in other GSK trials?

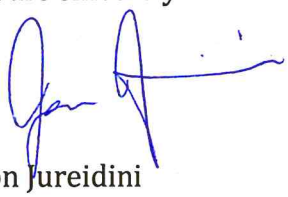
   We think responsibility for follow-up of patients in trials is in fact an important issue that has not received the attention it warrants, and we propose to explore it further. To this end, I would be grateful for answers to the following:

   - What is the regulatory or other basis of the standard procedure that 'the follow up of patients is the responsibility of the investigator and treating clinician'?

   - Given that your 'standard procedure' is to rely on investigators and treating clinicians to discharge this duty of care, what support and information do you provide to them to ensure that they can adequately do so with a drug like Paxil that has long-term dangers and implications for the subjects' use of other medications, particularly when the adverse events were revealed in the analysis of the trial at hand?
     Members of our team who have participated as clinicians in GSK trials can confirm that they received no feedback from GSK about the results of the trials they participated in, nor any feedback about events that happened in trials in which they had enrolled patients.
     We are also aware of patients enrolled in Paxil trials who suffered adverse effects to which Paxil may well have contributed but the possible role of Paxil was not raised by investigators or treating clinicians.

   We hope that you will agree that this is an important issue that has not been properly dealt with to date, and one to which GSK should work with us towards resolving.

Yours sincerely



Jon Jureidini

On behalf of the Study 329 RIAT team

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