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Dear Professor Jureidini

Thank you for your letter of February 11 2014.

I think we both agree that for adolescents treated with paroxetine there is an association with an increased risk of suicide related events, as described in the 2006 paper by Apter et al¹. As I explained in my previous letter, GSK carried out multiple paroxetine paediatric trials that showed an inconsistent and variable pattern of efficacy and safety results. A statistically significant difference in suicide-related adverse events and a signal emerged only when adverse event data were further interrogated and data from individual trials pooled together. And on that basis I do not agree with many of the assertions you make in your letter.

I am pleased that, following the independent panel's review of your research proposal, you and your team now have access to the anonymised patient-level data you requested. Approximately 250 of the CRFs for study 329 that we committed to providing you are also now available and the remainder will follow over the next month. I recognise that with these data now available you will be ready to carry out your analysis. It is good that we have reached this point and I will, of course, be happy to discuss the conclusions of your analysis following its peer-review and publication in a scientific journal.

With regard to the follow-up of patients in clinical trials we continue to believe that, in line with good clinical practice guidelines, investigators and treating physicians should have primary responsibility for ensuring patients receive the appropriate medical care both during and after a trial. We agree they are the physicians who will be most familiar with patients' medical histories and are best placed to help patients in the medical management of any condition. We also agree that the approach to the follow up of patients in clinical trials is an important topic and, as I have mentioned before, we would be very willing to explore how we could involve other relevant parties and discuss this topic further.

¹ Apter A, Lipschitz A, Fong R et al Evaluation of Suicidal Thoughts and Behaviors in Children and Adolescents Taking Paroxetine Journal of Child and Adolescent Psychopharmacology 2006; 16: 77-90

Along with other interested parties, GSK is participating in discussions related to the Institute of Medicine's report that you mention, *Discussion Framework for Clinical Trial Data Sharing: Guiding Principles, Elements, and Activities*. I look forward to reviewing the report's recommendations.

Yours sincerely

A handwritten signature in black ink, appearing to read "James Shannon". The signature is written in a cursive style with a large initial "J" and "S".

James Shannon
Chief Medical Officer