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September 4, 2013

Sir Andrew Witty
CEO, GlaxoSmithKline
980 Great West Road
Brentford, Middlesex TW8 9GS
United Kingdom

Dear Sir Andrew

You may recall that I wrote to you (April 26, 2013) expressing concerns about the published report of SmithKline Beecham and GlaxoSmithKline's Study 329 of paroxetine in children and adolescents. I received a response from Dr Kraus (May 3, 2013) declining to request retraction of the published paper.

Following the publication of the restoring invisible and abandoned trials (RIAT) paper by Doshi et al. in the BMJ[1], your company was notified by the RIAT authors by email on 14 June 2013 that Study 329 was amongst the studies requiring restoration. This gave GSK 30 days to signal its intent to publish a corrected version.

GSK did not signal its intent to do so within 30 days. Consequently on 15 July 2013, I declared my intent to work with a team of scientists to republish Study 329, in accordance with the RIAT guidelines.

Shortly afterwards, GSK set up an online process for researchers to 'submit research proposals and request anonymised data from clinical studies'.[2] Although this process was for studies conducted since 2007, there was an opportunity to 'enquire about the availability of data from our clinical studies that are not listed on the site'.

I made such an enquiry in relation to Study 329 on 4 August. However, I have had no response. The GSK website still designates the status of my query as 'under review', and there is no means to find anything more through that website. I am therefore seeking your help in gaining access to the anonymised case report forms for all participants in Study 329.

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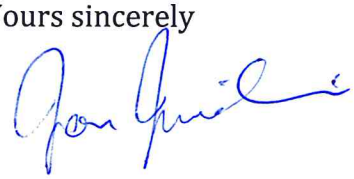
[1] http://www.bmj.com/content/346/bmj.f2865
[2] https://clinicalstudydata.gsk.com/

Your company had already agreed to make data from study 329 public as a consequence of the 2004 consent order of the New York State Attorney General's office.[3] The response that I received from Dr Kraus stated that "GSK does not agree that the article is false, fraudulent or misleading", so your company will want the individual level data made publicly available to confirm that.

I therefore trust that you will arrange for the data to be made available to me in a timely manner, and I look forward to hearing from you. Please let me know if you will be unable to provide me with a definitive response within 10 days.

Yours sincerely



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[3] Consent Order, dated 08/26/2004, for Civil Action No. 04- CV-5304 MGC, People of the State of New York vs. GlaxoSmithKline http://tinyurl.com/84226ly, see page 7:

"In addition, for the same period, GSK shall make available to the public on-line Clinical Study Reports of GSK-Sponsored Clinical Studies of Paxil® in adolescent and pediatric patients, to the extent such Clinical Study Reports are not otherwise included in the CTR."

"Clinical Study Report" (p.2) is defined as:

"Clinical Study Report" of a Clinical Study means a description of the protocol, all the Data, and the clinically relevant conclusions drawn from the Data, including the answers to the questions posed in the protocol."