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September 30, 2013

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

Dear Sir Andrew

As you know, I am coordinating a multidisciplinary team which has declared its intent to restore Paroxetine trial 329.[1]

I have already corresponded with you, most recently on 4 September 2013. You will have seen the responses that were written by Dr John Kraus (3 May 2013) about the proposed retraction of the published report of Study 329, and from Dr James Shannon (6 September 2013) about my request for de-identified case report forms (CRFs) for all subjects in study 329.

As you may know, part of the restoration process is the re-running of the original analyses reported in the Clinical Study Reports (CSRs) and any linked paper(s). Before running any analyses we need to check the datasets both for acute and maintenance (continuation) phases of participant exposure to paroxetine and imipramine with special regard to harms. This check is aimed at ensuring completeness and reliability of the dataset.

On June 25, GSK (through Perry Nisen) expressed support for the RIAT process, telling Peter Doshi, as first author of the RIAT declaration, "However, by making the Clinical Study Reports available we are very happy for others to publish on the records if they wish to and if journals consider the work to be of scientific merit."

Unfortunately it appears that even after publication in 2012 of most of the remaining appendices on your website following involvement with the New York State Attorney General's Office, CRFs are not yet available.

Your website points out 'GSK will consider requests for additional information from the reports that is required for a defined research question and methodology'.[2]

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[1] http://www.bmj.com/content/346/bmj.f2865?tab=responses

[2] http://www.gsk.com/media/resource-centre/paroxetine/paroxetine-paediatric-and-adolescent-patients.html

Our Enquiry (#638) on your website eventually elicited a response (13 September 2013) that informed us that we could apply for access via the Data Access System, but the response raises three concerns:

1. is not clear that the Data Access System provides access to CRFs

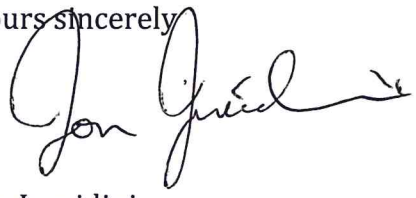
2. the clinical study report and appendices posted on GSK's are not searchable because they are scanned images

3. the application process requires submission of an analysis plan, but such a plan is irrelevant when restoring a publication where our primary focus is the original analysis plan drawn up and implemented by your own statisticians.

In summary, I am writing to you to ask you to authorize release of the original de-identified CRFs for trial 329 as well as searchable copies of the electronic patient level data, in a format such as SAS XPORT, so that we can restore the publication of trial 329 in a fair, complete and publicly transparent way.

I look forward to your answer.

Yours sincerely



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