

April 26, 2013

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

Dear Sir Andrew,

Study 329: A multi-center, double blind, placebo controlled study of paroxetine and imipramine in adolescents with unipolar major depression.

I write to you as the CEO of GlaxoSmithKline in regard to an on-going complaint about a fraudulent journal article under the lead authorship of Martin Keller entitled 'Efficacy of paroxetine in the treatment of adolescent major depression: A randomized, controlled trial' that was sponsored by GSK and appeared in the July 2001 issue of the *Journal of the American Academy of Child & Adolescent Psychiatry*.¹ This frequently cited paper has misled clinicians and academics; at least 75 scientific articles have reproduced its false claims about outcomes, thereby supporting off-label prescribing of paroxetine.

Study 329 clearly failed to demonstrate efficacy or safety for paroxetine in adolescents, and yet the paper claimed "paroxetine is generally well tolerated and effective for major depression in adolescents". I, along with other scientists, have documented the many problems with this paper that contributed to misreporting of efficacy and safety outcomes in study 329.²

In light of a recent \$3 billion settlement in which your corporation pleaded guilty to misbranding of paroxetine (Paxil), we request that you write to Dr. Andrés Martin, the editor of *Journal of the American Academy of Child & Adolescent Psychiatry* to request retraction of the Keller *et al.* article, which was a key piece of evidence in the government's case for off-label promotion by GSK.

Your corporation has so far failed to take responsibility for a published report that has harmed young patients who were prescribed paroxetine on the basis of this misleading article. As the CEO of GSK, you have the opportunity to correct the scientific record. I respectfully urge you to do so.

Yours sincerely,

Jon Jureidini, MB, PhD
Clinical Professor
Discipline of Psychiatry

¹ MB Keller, ND Ryan, M Strober, RG Klein, SP Kutcher, B Birmaher et al. (2001) Efficacy of paroxetine in the treatment of adolescent major depression: a randomized, controlled trial. *J Am Acad Child Adolesc Psychiatry*. 40:762-772

² Jureidini, J. and McHenry, L., Mansfield, P. (2008). Clinical trials and drug promotion: selective reporting of study 329. *International Journal of Risk and Safety in Medicine*, 20(1–2):73–81; McHenry, L. and Jureidini, J. (2008). Industry-sponsored ghostwriting in clinical trial reporting: A case study. *Accountability in Research*, 15(3):152–167; Newman, M., (2010) *BMJ* 341: c6985.