Department of Psychological Medicine Cardiff University Hergest Unit Ysbyty Gwynedd BANGOR Wales LL57 2PW Tel : (01248) 384452 Fax : (01248) 371397

19th May 2006

Sir Graeme Catto General Medical Council Regent's Place 350 Euston Road London NW1 3JN

Dear Dr Catto,

I have had no reply from you in response to my letter of April 21st; not even an indirect acknowledgment of receipt through Mr Cox-Brown. I enclose the previous letter, as I think it is important that you have it and its linked material.

I expect you will not answer this letter either, but perhaps your delay has stemmed from the time taken to digest the implications of the letter we both, as healthcare professionals, have had from GlaxoSmithkline two weeks ago (enclosed). You will note that this points to a greater than 6-fold increase in the risk of suicidality in adults on paroxetine, when GSK quite recently were denying to the world in general that there was any such risk, and denying it in particular to the MHRA in a process to which Dr Nutt was party.

In MHRA's Expert Working Group report on SSRIs published in December 2004, as well as in an article on February 19th in the BMJ (Gunnell et al), there is no hint of this problem. A key thing that "saves" the SSRIs as a group and paroxetine in particular is that both report and article cited 3 suicides on placebo and 1 on paroxetine in placebo controlled trials. This seemed implausible from the outset and begged the question as to whether MHRA or any of their experts had asked to see further details of these placebo suicides.

I expect that neither you or others in the GMC have had the time to access the material GSK has posted on their website in connection with the letter you received from them. If you do though, you may not only understand this letter better but also the issues that have so consumed Drs Nutt and Goodwin. I enclose a key appendix. This gives the narrative summaries for all suicides in controlled trials. These were previously confidential but all experts advising MHRA will have had access to them. You will see from this that one of the placebo suicides happened 33 days after the trial was over. There is some case for including suicides up to 30 days, but none for inclusion after that.

A second suicide was put on Prozac and given ECT at the time of his suicide but is counted as a placebo case. The third is downright mysterious and deserves the interest of an investigative journalist.

These three placebo suicides were "created" against a background of MHRA and GSK accepting that they had inappropriately miscoded run-in suicides and suicidal acts under the heading of placebo in the past and giving the clear impression that nothing like this would ever happen again. A member of the public might wonder whether Dr Nutt, who had been an expert member of the CSM at the time, showed the same interest to investigate these dodgy statistics, as he seems to have shown in having me investigated under this heading.

Given GSK's new willingness to disclose, I would invite you to consider asking them for any documents they hold that might indicate they regard(ed) Dr Nutt as someone who would defend their position while appearing to offer an independent view.

I gather you meet Dr Nutt from time to time. I also expect you would be reluctant to write to him to make the following suggestion. But when next you meet, you might consider – as a friend - suggesting to him that he make an FOI request to GSK. Whether or not he was aware of being used or regarded in this fashion, as the suicide appendix indicates, it might be prudent to be aware of documents that could come into the public domain.

A further option is to avail of a legal nicety corporations make use of and treat GSK as a person. On this basis, I would invite you to consider whether GSK's involvement in behaviour that has led to fraud actions against the company elsewhere should be subject to review by the GMC. The role of any physicians such as David Nutt – and I could mention others - in turning at the very least a blind eye to what was going on I would have thought might also be subject to review by the GMC.

I would appreciate a response to this letter, from someone within GMC, if only to indicate the basis on which you are precluded from responding.

Yours sincerely

David Healy