

January 30, 2004

Dr. Janet Woodcock Director Center for Drug Evaluation and Research U.S. Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Dear Dr. Woodcock:

The Federal Advisory Committee Act (FACA) requires that committees established to advise the federal government not include members who have conflicts of interest and be fairly balanced. The Center for Science in the Public Interest only earlier this week learned of the new members of the Psychopharmacologic Advisory Committee, which will be one of two committees meeting Monday, February 2, 2004, to consider the connection between the use of SSRIs and suicidality in children.

It appears that at least three of the scientists on the panel do not meet the conflicts-of-interest test in the statute and should be removed from the committee. They are:

- \* Dr. Wayne K. Goodman, who has studied sertraline (Zoloft) on a grant from Pfizer.
- \* Dr. Neil D. Ryan, who is a consultant for GlaxoSmithKline, maker of paroxetine (Paxil), has been paid by Glaxo to evaluate the data on Paxil and suicidality and to design further studies on the use of that drug.
- \* Dr. Philip W. Wang, who has appeared as an expert witness on behalf of GlaxoSmithKline in a wrongful death case involving the use of Paxil.

Receipt of industry funding may not be cause for removal from a committee. Such scientists can be offset by those who do not, as it appears to have been done in this case. However, including on the committee scientists with direct ties to both the companies *and* the drugs under investigation appears to be a direct violation of FACA and is tantamount to allowing the defendant in a case to serve on the jury.

We believe that the three scientists in question do not bring such unique expertise to this committee that similar expertise could not be obtained from unbiased sources. They do not deserve waivers. Having an

objective committee would serve both the public's and the FDA's interests by increasing the quality and credibility of whatever advice the committee ultimately provides.

Sincerely,

Merrill Goozner Director, Integrity in Science Project Center for Science in the Public Interest

cc: Ms. Anuja Patel, Executive Secretary, Psychopharmacologic Advisory Committee