

**Following an article in the Baltimore Sun
entitled "FDA gets sweeping powers to better protect consumers"
GSK responded with the following letter to the editor:**

To the Editor:

Your article "**FDA gets sweeping powers to better protect consumers**" (9.21.2007) points to the need for increased transparency of safety data from the pharmaceutical industry, as if companies do not already make that data available. This is simply not the case – particularly for GlaxoSmithKline (GSK).

GSK was one of the first pharmaceutical companies to develop a Clinical Trial Register to make data from its studies publicly available, including Paxil clinical trials. The company has posted results of more trials on its register than any other company, making them widely available to the public and the scientific community for review.

The author mentions Avandia as an example of lack of transparency, however prior to and since Avandia's approval in 1999, GlaxoSmithKline has been transparent in publicizing peer-reviewed publications, presenting data at medical meetings, and posting data on more than 100 clinical studies on Avandia on the clinical trial register. GSK submitted comprehensive analyses of its data on Avandia to regulatory agencies worldwide, including the FDA, and also posted this information to the company's clinical trials registry

Like other companies, GSK also posts summaries of studies underway on clinicaltrials.gov. To further support increased transparency of drug study results in the industry, GSK has been invited by the US National Library of Medicine and WHO to work toward agreement on standards for a national or international database so these tools become an effective vehicle for data transparency.

Sincerely,

Dr. Ronald Krall
Chief Medical Officer
GlaxoSmithKline