Center for Medical Consumers * Center for Science in the Public Interest
Consumers Union * Government Accountability Project
National Research Center for Women & Families * National Women's Health Network
Union of Concerned Scientists * U.S. PIRG * WoodyMatters

May 24, 2007

Dr. Andrew C. von Eschenbach
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20856

Dear Dr. von Eschenbach,

The American public is once again dismayed to discover that the Food and Drug Administration (FDA) has approved a drug whose risks may vastly outweigh its benefits. A study released Monday, May 21 in the *New England Journal of Medicine* indicates that Avandia may significantly increase the risk of heart attacks. Since diabetics are already at high risk of cardiovascular events as a result of their disease, the possibility of a drug-related increased risk of heart attack calls into question the wisdom of the continued use of this drug, as well as the basis on which it was approved.

In light of this study, and faltering public faith in the integrity of the FDA drug approval process, we write to urge you to ensure that the composition of any advisory committee that is being convened to review the safety of Avandia be free of any conflict of interest. At the minimum, no member of this committee should have had any financial ties to GlaxoSmithKline, Avandia's maker, for the past 36 months.

No law currently mandates that the FDA use only non-conflicted scientists on its advisory committees. But history teaches us that when scientists have conflicts of interest, the well being of the public may be compromised. Last December, a company-funded study of Avandia showed no increased heart attack risk when comparing rosiglitazone (Avandia) to metformin, a commonly prescribed generic drug widely used for glycemic control. Every author of that study either worked for or had financial ties to GlaxoSmithKline.

In February 2005, ten of the 32 scientists on the advisory committee that considered the safety of Cox-2 inhibitors, including Vioxx, had ties to the drug companies that made the products. The scientists voted to permit the companies to continue marketing the drugs, even though Vioxx had already been withdrawn from the market and had been implicated in tens of thousands of deaths.

By staffing the Avandia advisory committee with scientists from diverse specialties who are non-conflicted, you will send a message that the FDA cares about avoiding conflicts of interest and evaluating drugs on the basis of unbiased scientific findings.

The Avandia panel is just a first step in restoring public confidence. We urge you to take all steps necessary, including an expanded outreach to Schools of Public Health, to ensure that all

future FDA advisory committees include only non-conflicted voting members, and to drastically curb the use of waivers to permit members with conflicts to participate on these committees.

Very truly yours,

Paul Brown
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