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FDA Knew of Avandia's Dangers Nearly Five Years Ago, Memo Shows

by Public Citizen

The Food and Drug Administration (FDA) knew nearly five years ago about the dangers associated with the diabetes drug Avandia, an internal FDA memo shows. A study released Monday by the New England Journal of Medicine showed a 43 percent increase in heart attacks in people using Avandia.

In a letter sent today to FDA Commissioner Andrew von Eschenbach, Public Citizen described how the 2002 memo showed that FDA scientists recommended that labels for Avandia and Actos, another widely prescribed diabetes drug, be amended to include mention of post-marketing reports of heart failure among patients taking the two drugs. To date, the label hasn't changed.

"The failure of [the FDA](#) to act on the recommendations made almost five years ago by its Division of Drug Risk Evaluation is yet another case in which the conclusions of scientists who are engaged in post-market [drug safety](#) review are not taken seriously enough or addressed soon enough," said Dr. Sidney Wolfe, director of the Health Research Group at [Public Citizen](#). "As a result, millions of people – to the detriment of their health – are prescribed drugs whose risks are dangerously understated, instead of being prescribed safer, equally or more effective alternative drugs."

The July 16, 2002, memo shows that, at the time, the FDA had 47 adverse reaction reports in which the use of Avandia (25 cases) and Actos (22 cases) resulted in hospitalization for heart failure. As of last fall, the number of such cases had increased to 803 (415, Avandia; 388, Actos). The total number of prescriptions filled for Avandia and Actos in 2006 was 22 million (11 million for each).

Wolfe called on the FDA to either put a black-box-warning on the drugs or to ban them altogether. He also noted that the post-market drug safety review division should be independent from the rest of the Center for Drug Evaluation and Research, and that legislation to make it independent was introduced this year by Sens. Chris Dodd (D-Conn.) and Charles Grassley (R-Iowa) but was not included in legislation recently passed by the Senate. The bill has not yet passed the House, which could make this change.

[Click here to read the FDA memo](#) (PDF).

[Click here to read Public Citizen's letter](#) to the FDA's Dr. von Eschenbach

Opinion and Analysis by Adams

The discovery of this memo demonstrates, once again, that **the FDA operates in conspiracy with Big Pharma** to hide the dangers of prescription drugs that pose a real safety threat to Americans. As I have stated many times on this website, the FDA has become the No. 1 threat to the health and safety of the American people. It is now an agency that acts as the marketing department of Big Pharma, covering up the drug industry's lies, plotting to "disappear" damaging findings, and accelerating

the approval of drugs that are killing Americans at a rate not even witnessed during the Vietnam War.

The FDA is a rogue agency that has abandoned real science and abandoned its stated mission of protecting the public from unsafe drugs. I believe we are way past merely needing to reform the FDA; I think it is time to investigate and prosecute its top decision makers for engaging in crimes against humanity. For more details about the true history of the FDA, including armed raids, book burnings, scientific fraud, intimidation and censorship tactics, read my latest book, [Natural Health Solutions and the Conspiracy to Keep You From Knowing About Them](#).

Statistically, the FDA has become a far greater threat to the safety of Americans than terrorism. Consider this: If a terrorist set off a nuclear bomb in a football stadium, killing 50,000 people in an instant, **that would only be half the number of Americans killed each year by FDA-approved drugs**. And yet the FDA shows no signs whatsoever of reforming its criteria for drug safety or divesting itself from Big Pharma influence. In fact, thanks to the U.S. Senate, the FDA will soon be even more financially intertwined with drug companies who pay "user fees" to the FDA to have their drugs approved.

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