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FDA's Decision to Restrict Sale of Diabetes Drug Avandia Still Jeopardizes Public Health

Statement of Dr. Sidney Wolfe, Director, Public Citizen's Health Research Group

By failing to ban the dangerous diabetes drug, Avandia, generic name rosiglitazone, the Food and Drug Administration (FDA) again caved to industry pressure. Although the FDA has made progress highlighting the risks of using Avandia by severely restricting the drug, it did not go far enough. Too many people could still be exposed to this dangerous product. Rather, the FDA should have acted with its European counterpart and outright banned Avandia from the market.

Why did it take the FDA so long to decide that a drug with no evidence of any advantage in health benefits, but abundant evidence of a variety of risks compared to other diabetes drugs, should be severely restricted? Why did it not ban this unsafe product?

More than three years ago at an FDA advisory committee meeting, Public Citizen urged the FDA to ban Avandia. Since then, 9 million prescriptions for the drug have been filled in the United States. This means that, just in the past three years alone, tens of thousands more patients have needlessly suffered hospitalizations for heart failure or deaths than would have had they taken Actos, a comparable, but safer drug.

There is not a single study finding that Avandia is safer than Actos, but there are numerous studies finding that Avandia is more dangerous than Actos. The FDA and GlaxoSmithKline have acted recklessly in allowing Avandia to stay on the market for so long after its unique dangers have been known.

The FDA should reconsider its decision to merely restrict such a hazardous product and directly remove it from the market.

Public Citizen petitioned the FDA in 2008 to ban Avandia.

To learn more about Public Citizen's work on Avandia, please visit:
http://www.citizen.org/Page.aspx?pid=1255.

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