PATIENT SAFETY BLOG

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Eight years on, diet drug Meridia withdrawn from market

A diet drug which safety advocates called to be withdrawn from public use eight years ago has finally bit the dust. Under pressure from the Food and Drug Administration, the drug's manufacturer, Abbott Laboratories, voluntarily pulled the drug from the market due to longstanding concerns that it increased the risk of heart attacks and strokes.

"There was no identifiable population of patients for whom the benefits of Meridia outweighed its risks," said John Jenkins, MD, director of the office of new drugs at the FDA. "Meridia's continued availability is not justified when you compare the very

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modest weight loss that people achieve on this drug to their risk of heart attack or stroke."

The move was described as "commendable but dangerously too late," by Sidney Wolfe, MD, a member of the FDA's Drug Safety and Risk Management Committee and director of the Health Research Group of Public Citizen, a consumer and health advocacy group.

The pressure from the FDA came after results of a clinical trial involving more than 10,000 patients showed that people who took Meridia had a 16% increase in relative risk of heart attacks. The trial also showed that individuals taking Meridia only lost approximately 2.5% more weight than those on placebo and that the weight loss didn't last very long.

Abbott maintained these results weren't relevant because most of the individuals in the trial had cardiovascular disease and should not have taken the drug in the first place. The company continues to maintaion that for the right patients, the drug is safe.

European regulators took the drug off the market in January 2010. An FDA advisory committee was split on whether to remove the drug, but the ultimately decided to recommend doing so because "there was no identifiable population of patients for whom the benefits of Meridia outweighed its risks," Jenkins said, adding that he did not believe Meridia users would have any residual increased risk once they stopped taking the drug.

Source: The New York Times

You can view an abstract of the clinical trial that led to the FDA recommendation here.

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