Public Citizen Sues FDA for Failing to Act on Request to Ban Dangerous Dose of Alzheimer's Drug Aricept

FDA Ignoring Its Own Findings That Higher Dose Poses Grave Risks But Is No More Effective Than Lower Dose

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The Food and Drug Administration (FDA) has dragged its feet for too long on a petition calling on the agency to stop allowing the drug Aricept to be marketed at doses that can cause severe — and even fatal — side effects, Public Citizen said in a lawsuit filed today. The suit asks the court to compel the FDA to act.

The suit follows a petition from Public Citizen in May 2011 urging the FDA to immediately remove from the market a 23 milligram (mg) dose of Aricept and to add to lower-dosage (5 mg and 10 mg) forms of Aricept and the generic counterpart, donepezil, warnings against use at a higher dosage. The agency has yet to act on the petition.

Aricept was approved in 1996 as a treatment for Alzheimer's at a dose of 5 or 10 mg daily. Before the patent expired in November 2010, the drug maker, Eisai, sought approval for a 23 mg version, on which it would have an additional period to market without generic competition.

A study presented to the FDA in 2009 failed to show that the 23 mg version was more effective than lower doses. But the high dose was associated with a much higher incidence of vomiting, which, in patients with Alzheimer's disease, according to the FDA, "can lead to pneumonia, massive gastrointestinal bleeding, esophageal rupture or death."

Based on the study results, the primary medical reviewer at the FDA recommended that agency deny the company's application to market the higher-dose 23 mg version of the drug. That recommendation was rejected by the director of the FDA's Division of Neurology Products, Dr. Russell G. Katz. The approval allowed Eisai to market Aricept 23, exclusively, for three years.

Public Citizen is asking that the court declare unlawful the FDA's failure to act on Public Citizen's petition and order the FDA to issue a decision on the petition.

"A primary function of the FDA is to protect citizens from harm caused by needlessly dangerous drugs, in this case a drug no more effective but significantly more dangerous than the lower doses of Aricept," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. "By ignoring Public Citizen's petition for more than a year, the agency has ignored this responsibility and instead has chosen to support the profit interests of a large pharmaceutical company. During the past year alone approximately 350,000 prescriptions have been filled in the U.S. for Aricept 23, with total sales of $91 million. Allowing Esai to exploit and harm vulnerable patients with Alzheimer's disease is unconscionable."

To read the full text of the lawsuit, visit http://www.citizen.org/documents/PC-v-FDA-Aricept-Complaint.pdf.

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Public Citizen is a national, nonprofit consumer advocacy organization that has worked to protect health, safety and democracy since 1971.