High doses of Alzheimer's drug Aricept should be banned, Public Citizen says

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High doses of the Alzheimer's drug Aricept should be banned because they are no more effective than low doses and have a sharply increased risk of adverse effects, the advocacy group Public Citizen and a Johns Hopkins University geriatrician said Wednesday in a petition to the Food and Drug Administration.

Aricept, known generically as donepezil, is one of the very few drugs available for treating Alzheimer's disease, but it provides only a very modest slowing in the cognitive and functional deficits associated with the disease. Yet the drug is widely used "due primarily to two factors: the understandable desperation of those who care for patients with Alzheimer's disease and a relentless promotional campaign by drug companies," said co-petitioner Dr. Thomas Finucane of Hopkins.

Aricept has been approved by the FDA in dosages of 5 to 10 milligrams for patients with mild to moderate cases of Alzheimer's and in a dose of 10 to 23 milligrams for more severe cases. The petition asks the FDA to ban the 23-mg version of the drug and to warn patients and physicians against taking two 10-mg. pills per day if the higher dosage is removed from the market.

Clinical trials of Aricept submitted to the FDA for approval show no significant benefit from the 23-mg version compared to the 10-mg version, the petition said. But the increased adverse effects from the higher dosage include a slowed pulse rate, nausea, vomiting, diarrhea, urinary incontinence, fatigue, dizziness, agitation, confusion and

anorexia. Vomiting, which occurred more than 3 { times more frequently in those taking the high dosage, is a particularly dangerous side effect for Alzheimer's patients, the petition says, because it can lead to pneumonia, massive gastrointestinal bleeding, esophageal rupture and even death.

"With no evidence of an added advantage in benefit to patients, the clear increase in risk should have been more than adequate grounds for denying approval," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. "It is inexcusable that FDA approved this higher dose. Its prompt removal would belatedly fulfill the agency's mission to allow only drugs whose benefits outweigh their risks to be marketed."

Public Citizen has a long history of campaigning against drugs that it considers dangerous or ineffective.