



the compassion to care, the leadership to conquer

---

FOR IMMEDIATE RELEASE

CONTACT: Toni Williams, 202-638-8666, [toni.williams@alz.org](mailto:toni.williams@alz.org)

## **FDA SEEKS TO INCLUDE THOSE MOST AFFECTED BY ALZHEIMER'S DISEASE IN THE DRUG REVIEW PROCESS**

*- Alzheimer's Association Statement -*

**Washington, DC (November 13, 2007)** – The Food and Drug Administration (FDA) has expanded its Patient Consultant and Patient Representative Programs to include individuals in the early stages of Alzheimer's disease and their caregivers. The FDA made the change in response to a request by the Alzheimer's Association encouraging the agency to give people directly affected by Alzheimer's a more active role in the review and approval of new Alzheimer drugs.

“People who are living with this terrible disease have much to offer to the pharmaceutical industry, researchers and government regulators and their voices must be heard,” said Harry Johns, president and CEO of the Alzheimer's Association. “We are pleased that the FDA understands the value of involving Alzheimer families in regulatory decisions that affect them and appreciate that the agency was so responsive in expanding their patient consultant program.”

Similar to the programs that already exist for those with cancer and Parkinson's disease, the Alzheimer patient consultants and representatives will participate in FDA advisory committee meetings and advise on topics such as clinical trial design and the development of guidelines for clinical research. Involving those with the disease and their primary caregivers will increase the FDA's capacity to make informed regulatory decisions that are sensitive to the needs and preferences of this population. Following rigorous training by FDA staff, all involved will have access to materials for review and the opportunity to offer input on a variety of issues.

The Alzheimer's Association request to the FDA grew out of extensive conversations with families across the nation struggling with the disease, many of whom felt that the drug development process was not always responsive to their needs. The Association held a Research Roundtable meeting in Washington at which persons with Alzheimer's, family caregivers, researchers, FDA regulators and Alzheimer's Association leaders discussed the risk and benefit trade-offs involved in drug development. Following the meeting, the Association published articles on the issue in its scientific journal and subsequently forwarded the recommendation on the patient consultancy program to the FDA. This was followed by meetings with FDA leadership to move the issue forward.

“The FDA has been quite open to working with the Alzheimer’s Association on ways to increase the attention and priority of Alzheimer issues within the agency,” said Stephen McConnell, vice president of Advocacy and Public Policy for the Alzheimer’s Association. “The Alzheimer’s Association’s goal is to ensure treatments that are safe and effective can get through the regulatory review process as quickly and efficiently as possible, while also being responsive to the special perspective of those who will benefit from them. The FDA has been a willing partner with the Association in this effort.”

###