



Accelerate Cure/Treatments for Alzheimer's Disease

EMBARGOED FOR RELEASE
UNTIL 9:00 a.m. E.S.T.
November 14, 2006

CONTACT: Joan Hurwitz
w: 202-293-2856
c: 703-244-6783
jhurwitz@agingresearch.org

ACT-AD COALITION CALLS FDA'S NEW FOCUS ON NEUROLOGICAL DISEASES A POSITIVE FIRST STEP

Coalition urges agency to make Alzheimer's disease a priority

Washington, DC -- The ACT-AD Coalition (Accelerate Cure/Treatments for Alzheimer's Disease) called today's announcement by the Food and Drug Administration (FDA) that it has taken steps to increase its focus on Alzheimer's disease (AD), a positive first step toward making the disease a priority.

"ACT-AD is committed to making Alzheimer's disease a national health priority," said Daniel Perry, chairman of ACT-AD. "Improved communications within FDA around Alzheimer's disease is a positive first step toward achieving our goal of rapid review for the growing number of products in the pipeline that address this devastating disease."

The FDA announced that it has created an Intra-agency Neurology Working Group that will include experts involved in the regulation of drugs, biologics and medical devices. According to FDA, the group will meet regularly to expand awareness of leading-edge developments, enable sharing of expertise and provide for greater consistency of review standards and processes. The group is chaired by Dr. Celia Witten of the Center for Biologics Evaluation and Research and Dr. Robert Temple of the Center for Drug Evaluation and Research.

The FDA also announced that it will provide opportunities for patient advocates and family caregivers to participate in the review of new treatments for neurological diseases. Specifically, FDA will expand its existing Patient Consultant program to include AD advocates and caregivers to advise FDA during the development of new products. FDA will also invite AD advocates to participate in FDA advisory committee meetings that address marketing approval decisions and in response to issues that arise with products in the marketplace.

MORE...

ACT-AD COALITION/p. 2

Representatives of ACT-AD met with Acting FDA Commissioner Andrew von Eschenbach and other FDA leaders in July to explore ways of updating drug procedures and policy regarding AD. ACT-AD also asked FDA to find ways to engage patients and families in the development process. In calling for an increased focus, ACT-AD underscored both the growing impact of AD as the nation's population ages, as well as the need for FDA to keep pace with the discovery of emerging therapies that could potentially halt or reverse Alzheimer's disease. Currently available drugs only provide temporary relief of the symptoms rather than alter the course of the disease.

“As the country races toward an Alzheimer's explosion that will affect 5.6 million people by 2010 and could bankrupt the U.S. health care system, the FDA's new focus is significant, and could make meaningful treatments that change the course of the disease available before another generation of patients and their caregivers are lost,” said Perry. “We look forward to working with the FDA to continue to explore ways to extend the rapid approval mechanisms it has so effectively used for other life-threatening diseases, such as cancer and HIV-AIDS, to promising drugs for Alzheimer's.”

What is Alzheimer's Disease?

Discovered by Alois Alzheimer in 1906, AD affects 4.5 million Americans and causes millions more to leave the workforce to care for loved ones who eventually need around-the-clock attention. It is a universally fatal progressive neurodegenerative disorder that results in cognitive deterioration that affects many areas of daily function. As the disease progresses, people suffer severe cognitive deterioration, confusion, disorientation, and personality and behavior changes. The greatest risk factor for Alzheimer's is age. One in 10 people over age 65 and nearly half of those over 85 have this fatal disease.

AD costs the U.S. economy more than \$100 billion/year and U.S. business costs are \$61 billion annually of which almost half (\$36.5 billion) results from lost productivity of employee caregivers. By 2050, it is estimated that Medicare will be spending more than \$1 trillion to care for those with Alzheimer's and other dementias.

What is ACT-AD?

Formed in February 2006, the ACT-AD coalition is currently comprised of 47 national not-for-profit groups representing patients, caregivers, consumers, older Americans and health advocates. The Coalition is supported in part through an educational grant by Elan Corp. and Wyeth.

For more information about the ACT-AD Coalition, its collaboration with the FDA, and other Coalition efforts to fight AD, visit www.ACT-AD.org.

###

