



Avalere Health Compares FDA Review of Several Categories of Drugs Including Alzheimer's Disease

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Washington, DC – There are noticeable differences in the way the FDA reviews potential Alzheimer's disease (Alzheimer's), HIV/AIDS, and cancer therapies, says a new analysis released today by Avalere Health. The study was sponsored by a coalition of not-for profit organizations called ACT-AD (Accelerate Cure/Treatments for Alzheimer's Disease).

In its analysis, Avalere found that while the FDA met its congressionally mandated review timelines, 88 percent of HIV/AIDS drugs received "priority reviews" versus 40 percent of Alzheimer's drugs. It also found that products for HIV/AIDS and selected cancers obtained "first cycle" approvals far more frequently than Alzheimer's products (96 percent, 94 percent, and 60 percent, respectively). Both priority reviews and first cycle approvals have an impact on how quickly products enter the marketplace.

"This analysis presents an initial identification of potential differences in the FDA review process and thus speed to market for Alzheimer's products as compared to other therapies," said Lauren Barnes, a director at Avalere Health and lead author of the analysis. "More research is warranted to fully understand the reasons that underpin these differences."

Congress passed the Prescription Drug User Fee Act (PDUFA) in 1992 as a way to expedite review of medical therapies. Post enactment of PDUFA, there is a large body of published data on how many therapies have been reviewed for FDA approval. However, few studies have attempted to compare review times of different therapeutic classes that represent both current and looming public health threats.

Avalere researchers extracted product information from a set of publicly available and proprietary databases. They analyzed specific date references as to when a drug passed a specific FDA review milestone (such as investigational new drug (IND) submission date, new drug application (NDA) submission date, approval date) to determine the length of time each product spent between review milestones. The analysis focused solely on FDA review times per product and did not consider clinical differences between and among products.

"This analysis shows that the federal government can make a positive difference in accelerating introduction of new medicines for the most daunting diseases Americans face," said Daniel Perry, chair of the ACT-AD Coalition. "Our member organizations look forward to working with the FDA to help ensure that the looming Alzheimer's epidemic is treated with the same sense of urgency as other pressing public health threats."

An estimated five million people in the U.S. currently have Alzheimer's; that number will swell by the millions by the year 2020 if current trends persist. Current treatments offer some

symptomatic relief, but none affect underlying disease progression. As a result, Alzheimer's is life-threatening. Age is the number one risk factor for developing the disease.

Avalere has published other work that discusses the unique challenges that Alzheimer's poses to the federal government, including the U.S. long-term care system, Medicaid expenditures, and the country's workforce.

The paper, "Comparative Analysis of FDA Review Times for Alzheimer's, HIV/AIDS, and Cancer Therapies" was prepared for the ACT-AD Coalition by Lauren Barnes, Allison Colbert, and Dan Mendelson, all of Avalere Health. Wyeth Pharmaceuticals provided grant funding for the research.

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Avalere Health is a leading advisory company focused on business strategy and public policy. It serves a diverse client base, which includes Fortune 500 healthcare technology companies, federal government agencies, and major medical foundations. The company is organized into seven substantive areas - Medicare, Medicaid, Reimbursement, Long-Term and Post-Acute Care, Health Information Exchange, Evidence-Based Medicine, and Education. Anchored by a comprehensive research engine and staffed by experts in business, medical product commercialization, and health policy, Avalere provides strategic guidance, objective analytic research, and quality educational programs focused on the full range of healthcare issues facing our nation.

ACT-AD is a growing coalition of 50 national organizations representing patients, providers, caregivers, consumers, older Americans, researchers and employers seeking to accelerate development of potential cures and treatments for Alzheimer's. The Coalition is directed by an Advisory Council made up of representatives from Alliance for Aging Research (AAR), Alzheimer's Foundation of America (AFA), American Society on Aging (ASA), National Alliance for Caregiving (NAC), National Association of Area Agencies on Aging (n4a), National Consumers League (NCL), Research!America, and the Society for Women's Health Research.