May 2, 2025

The Honorable Andy Harris
Chair
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
House Appropriations Committee
Washington, DC 20515

The Honorable Sanford Bishop
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
House Appropriations Committee
Washington, DC 20515

Re: FDA Report Language Request to Improve Access to Psychiatric Medicines for Older Americans by Ensuring Accurate Information about Safety

Dear Chair Harris and Ranking Member Bishop:

The undersigned members of Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness) and other partners are writing to strongly urge you to include language in the report accompanying the fiscal year (FY) 2026 House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration (FDA), and Related Agencies to advance access to necessary care for Medicare beneficiaries living with Alzheimer's and other neurocognitive impairment. Project PAUSE is an ad hoc coalition of national organizations advocating about improvements in clinical, regulatory, and legislative policies in long-term care.

Background

Since 2008, all atypical antipsychotic medications have carried a boxed warning related to older adults with neurocognitive impairment. In the 15 years since, the FDA has not reevaluated this warning, despite additional scientific evidence, updated clinical guidance, and new medicines entering the market with more favorable safety profiles. Regardless of a drug's specific safety profile, all atypical antipsychotics receive the same boxed warning with no drug-specific assessment and no consideration of the type or severity of neurocognitive impairment, severity of behavioral and psychological symptoms, or the presence of comorbidities.

The class-wide application of a non-specific boxed warning creates confusion for patients, caregivers, and health care providers in treatment decision-making. The boxed warning also negatively impacts access to antipsychotics for this patient population by increasing the likelihood of physician reluctance to prescribe. The result for patients is undertreatment or treatment with older, less effective medications, which have their own risks and side effects. For some patients, because their symptoms are not appropriately managed, they may experience traumatic discharges from the nursing homes caring for them because of behaviors that endanger themselves and others.

FY 2026 Requested Report Language

Recognizing that outdated labeling of critical neuropsychiatric medicines holds the potential to impact care and treatment for older Americans, Congress included in the FY 2024 Appropriations Bill report language (Report 118-124) directing the FDA to hold a public workshop to reassess the application of a boxed warning for all atypical antipsychotic medications, with a specific focus on risks associated with the use of these medicines in older adults with dementia-related psychosis. As directed, FDA held the public workshop on December 10, 2024 as a first step in the reevaluation of the boxed warning.[1] The agency has indicated that it will use insights from the workshop to identify additional data and analyses needed to assess the boxed warning's necessity.

Given the significant and ongoing need for accurate information about the safe and effective use of treatments for neuropsychiatric symptoms among older individuals with dementia-related psychosis, Project PAUSE is respectfully requesting that Congress direct FDA to swiftly determine and execute next steps and provide an update on its assessment of any needed changes to the class-wide boxed warning for antipsychotic medications.

For FY2026, we urge the subcommittee to support language, accompanying the House Ag-FDA appropriations bill, that directs FDA to prioritize and expedite its review and report back to Congress with its assessment of any needed changes to the class-wide application of the boxed warning label. We believe these actions are necessary to ensure accurate information for individuals living with neurocognitive impairment, their families, and their providers about the risks and benefits of these treatments and help facilitate access to necessary care for older adults with dementia-related psychosis. A draft of suggested report language is below for the subcommittee's consideration.

Recommended Report Language Request for FY2026 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill

> *Boxed Warnings in Drug Product Labeling. - The Committee continues to be concerned that the class-wide application of warning labels for antipsychotic medications, established in 2008, has not been updated to reflect additional scientific evidence, changes to clinical guidance, and the entry of new medicines with different mechanisms of action onto the market and that this outdated labeling may be impeding patient access to appropriate care and treatment. The Committee appreciates FDA's responsiveness in holding a December 2024 public workshop on Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders as directed in the FY2024 Committee report 118-124. The Committee urges FDA to prioritize and expedite its*

[1] https://healthpolicy.duke.edu/events/mortality-and-antipsychotic-use-dementia-related-behavioral-disorders

> *review of appropriate use and severity of risks for antipsychotic medications in older adults with mental health conditions associated with dementia. The Committee requests FDA provide its assessment of any needed changes regarding the class-wide application of warning labels for antipsychotic medications to the Committee no later than 90 days after enactment of this Act.*

Clinically necessary care must be within reach for older adults living with Alzheimer's and other neurocognitive impairment. We remain greatly concerned that outdated warning labels required by FDA are gravely thwarting timely access to life-enhancing and, ultimately, lifesaving medications and therapies for older adults with psychosis. Further, we believe the aforementioned actions will help modernize the agency's approach to such important treatments, which in turn, will protect help improve outcomes for individuals with these conditions while also encouraging innovation.

Thank you for your consideration of this request and for your leadership in advancing high-quality care for patients.

Sincerely,

Alliance for Aging Research
American Society of Consultant Pharmacists
American Association for Geriatric Psychiatry
American Association of Psychiatric Pharmacists
Caregiver Action Network
Depression and Bipolar Support Alliance (DBSA)
HealthyWomen
Huntington's Disease Society of America
LeadingAge
National Community Pharmacists Association
Rural Minds
The Balm In Gilead, Inc.
Voices of Alzheimer's