Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders

Virtual Public Meeting
December 10, 2024
12:00-4:00 pm ET

Agenda

Background and Workshop Objective

In 2005, the U.S. Food and Drug Administration (FDA) added a Boxed Warning to all atypical antipsychotic medications based on the analysis of randomized controlled studies showing increased mortality in older adults with dementia-related psychosis. The Boxed Warning was later extended in 2008 to conventional antipsychotics. However, with additional scientific evidence becoming available and clinical practice guidance changes occurring since that time, as well as with the introduction of new treatments to the market, there is an opportunity to re-evaluate the need and value of the Boxed Warning included in the approved labeling of antipsychotic medications for impacted populations.

The Duke-Margolis Institute for Health Policy, under a cooperative agreement with the FDA, is convening a virtual public workshop to review data regarding risks associated with the use of medications in the antipsychotic class in older adults with behavioral and psychiatric symptoms associated with dementia. Attendees will hear insights from experts on a re-analysis of the data that supported the regulatory action related to the Boxed Warning as well as findings from a recently conducted literature review. Workshop attendees will also hear reflections from participants on the available evidence and further considerations related to the assessment of risks associated with the use of antipsychotics within this patient population.

12:00 pm **Welcome and Overview**
Nancy Allen LaPointe, Duke-Margolis Institute for Health Policy

12:05 pm **FDA Opening Remarks**
Tiffany Farchione, U.S. Food and Drug Administration

12:15 pm **Session 1: Introduction to Antipsychotic Use in Dementia-related Behavioral Disorders**
Objective: During this session, presenters from the FDA will orient workshop attendees to relevant background information, including a clinical overview of behavioral and psychiatric symptoms of dementia as well as relevant regulatory history of the Boxed Warning for antipsychotics. Following presentations, clarifying questions from the audience will be addressed by speakers as time allows.

Moderator: Nancy Allen LaPointe, Duke-Margolis Institute for Health Policy

Presentations: Julia Biernot, U.S. Food and Drug Administration
Shamir Kalaria, U.S. Food and Drug Administration

12:50 pm **Session 2: Review of Data Analysis and Literature Review Findings**

Objective: This session will include a presentation reporting out the findings of a meta-analysis of randomized controlled trial data as well as a summary of relevant scientific literature. Following presentations, clarifying questions from the audience will be addressed by speakers as time allows.

Moderator: Christina Silcox, Duke-Margolis Institute for Health Policy

Presentations: Jessica Jung, U.S. Food and Drug Administration
Fengyu Zhao, U.S. Food and Drug Administration

1:45 pm **Break**

2:00 pm **Session 3: Stakeholder Perspectives on Considerations Regarding the Use of Boxed Warnings for Antipsychotics**

Objective: During this session, participants will provide additional perspectives and considerations related to increased risk in mortality and the use of antipsychotics in dementia-related behavioral disorders, particularly in older adults. This session will include one speaker presentation followed by moderated discussion among panelists, which will incorporate audience questions submitted live in addition to prepared questions from the moderator.

Moderator: Christina Silcox, Duke-Margolis Institute for Health Policy

Presentation: Daniel Weintraub, University of Pennsylvania School of Medicine

Panel: Jacobo Mintzer, Medical University of South Carolina
Russ Paulsen, USAgainstAlzheimer's
Sue Peschin, Alliance for Aging Research
James Taylor, Caregiver/Care Partner
Daniel Weintraub, University of Pennsylvania School of Medicine

2:55 pm **Session 4: Opportunities for Further Characterizing Value and Need for Boxed Warnings for Antipsychotics**

Objective: During this session, participants will consider what outstanding clinical and scientific questions may need to be addressed through future efforts related to the increased risk in mortality with the use of antipsychotics in individuals affected by behavioral and psychological symptoms of dementia, including risk modifiers. A brief presentation will be followed by panelist discussion, which will include how interested parties can contribute to alignment on additional actions needed to ensure safe and effective treatments are available to impacted patients in this population.

Moderator: Nancy Allen LaPointe, Duke-Margolis Institute for Health Policy

Presentation: Shamir Kalaria, U.S. Food and Drug Administration

Panel: Rebecca Edelmayer, Alzheimer's Association
Valentina Mantua, U.S. Food and Drug Administration
Kristina McLinden, National Institute on Aging
Paul Rosenberg, Johns Hopkins University School of Medicine
Mat Soukup, U.S. Food and Drug Administration
Chad Worz, American Society of Consultant Pharmacists

3:55 pm **Closing Remarks and Adjournment**
Teresa Buracchio, U.S. Food and Drug Administration

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