



CMA WEEKLY ALERT EXTRA

FOOD AND DRUG ADMINISTRATION CAUTIONS AGAINST USING ANTIPSYCHOTIC DRUGS TO TREAT BEHAVIORAL DISORDERS IN ELDERLY PATIENTS WITH DEMENTIA

Having determined from 17 placebo-controlled studies “that the treatment of behavioral disorders in elderly patients with dementia with atypical (second generation) antipsychotic medications is associated with increased mortality,” the Food and Drug Administration has issued a Public Health Advisory and will require drug manufacturers to label the drugs with a Black Box warning against such off-label use. FDA, “Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances” (Public Health Advisory, Apr. 11, 2005).

Although the drugs are approved by the FDA for treatment of schizophrenia and mania, their off-label use with elderly patients with dementia has led to deaths from heart-related events, such as heart failure, or infections, chiefly pneumonia.

All three drug classes of atypical antipsychotics are associated with increased mortality. Drugs included in the FDA’s Advisory are Zyprexa, Abilify, Risperdal, Seroquel, Clozaril, Geodon, and Symbyax.

The FDA may also require a similar warning label for older antipsychotic medications, which limited data suggest may also be associated with similar increases in mortality for elderly patients.

The Advisory is available at <http://www.fda.gov/cder/drug/advisory/antipsychotics.htm>; the FDA Talk Paper at <http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01350.html>.

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