

From the editor



Do 'black boxes' make demented patients safer?

Is the FDA being overly zealous with its “black box” warnings? The latest advisory—associating atypical antipsychotics with increased mortality among patients with dementia—joins another black box linking these drugs to potentially fatal diabetes. And, as of October, black boxes warn of “clinical worsening” and “suicidality” associated with using SSRI antidepressants in children and adolescents.

An FDA analysis of 5,111 demented patients in 16 trials found about a 1.6-fold increase in mortality among those receiving atypical antipsychotics. According to the Alzheimer’s Association, the risk of death is “real but small;” 1.5% to 2% of the patients receiving antipsychotics died, compared with 1% of those receiving placebo.

Atypical antipsychotics are useful—at times life-saving—for many agitated elderly patients, and this new labeling should not be used as the basis to withhold these drugs from patients who might benefit from them.

Of course, black boxes are not unique to psychotropics. The COX-2 inhibitor arthritis drugs and others recently have joined more than 200 drugs with these warning labels. What leads the FDA to dichotomize drugs into “black-boxed” or “not black-boxed?” And why do black boxes seem to be proliferating?

I think the reason is that the FDA has been criticized for not doing more to prevent adverse drug events and is feeling the pressure. If someone has an adverse event after taking a black-boxed drug, the FDA can now say something like, “I told you so.” This is, as far as I can tell, the same reason for the Department of Homeland Security’s color-coded terrorism threat levels. One could argue that the much-maligned five-level terror rating system (from green to red) is more rational than the FDA’s two-level system, black or not black.

Congress has been debating whether the terrorism threat system is useful or is unnecessarily alarming the public and making us less safe. We should be asking the same questions about the FDA’s black box system.

A handwritten signature in black ink, appearing to read "James Hillard". The signature is stylized and somewhat cursive.

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