

The black box warning for sertraline (30) reads, in part:

WARNING. Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

d. Summary

The black box warnings include statements that a physician with specific experience be involved in administering the drug. The warnings identify specific populations especially susceptible to toxicity, such as children or patients with cardiac disease. The warnings refer to animal studies, for example animal toxicity studies showing that the drug results in death to embryo. Moreover, the warnings mandate that the patient be closely monitored or observed. These, as well as other types of warnings, are a recurring theme in package inserts.

II. POTENTIAL AMBIGUITY OF WRITING IN PACKAGE INSERTS

The issue of ambiguity of writing on package inserts has found its way into the popular culture, as demonstrated by the dialogue in an episode of *Leave It To Beaver* (31) involving an 8th grade boy (Wally) and his mother (June):

Wally: Mom, it says here, "TAKE ONE PILL TWICE A DAY."

June: That's right!

Wally: Well gee, how do you take the same pill twice?

Of particular interest to medical writers is guidance from the FDA on potential sources of ambiguity, for example ambiguity relating to timing. The FDA informs us that, "[i]f

³⁰ Package insert. Pfizer, Zoloft® (October 2008).

³¹ Connelly J, Mosher R. New Doctor, in *Leave It To Beaver*. Gomalco Productions. 1958.