

# What Every Psychologist Should Know About the Food and Drug Administration's Black Box Warning Label for Antidepressants

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In 2004, the Food and Drug Administration released a black box warning label for all antidepressants, indicating an increased risk for suicidality in children and adolescents. The label was subsequently updated in 2007 to include those up to 24 years of age. Data have since emerged to indicate changes in clinical practice patterns of nonspecialists (i.e., nonpsychiatrists) prescribing medications. Among the changes reported in practice patterns are an increased likelihood of referral and a decreased willingness to prescribe antidepressants. Findings also indicate marked reductions in ambulatory visits for depression among children and adolescents, lower rates of diagnosis of depression in this age group, a spillover effect to adults, inaccurate understanding of the actual risk communicated on the warning label (on the part of primary care practitioners), and increased suicide rates among children and adolescents. Recent findings have important implications for practicing psychologists, and specific recommendations are offered.

*Keywords:* black box warnings, selective serotonin reuptake inhibitors, depression, suicidality, primary care

In 2004, the Food and Drug Administration (FDA) placed a black box warning label on all antidepressant drugs (including selective serotonin reuptake inhibitors [SSRIs]) used with children and adolescents (FDA Center for Drug Evaluation and Research [CDER], 2004). In 2007, the label was updated and expanded to include young adults up to 24 years of age (FDA CDER, 2007). The current label targets the risk for “suicidal thinking and behavior (suicidality)” (FDA CDER, 2007, p. 1) in children, adolescents, and young adults. The expanded label also includes information about the benefits of antidepressants with older adults (ages 65 and older) along with a reminder that “suicide is a known risk of

depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide” (FDA CDER, 2007, p. 1). Since implementation of the warning label, concerns have surfaced about whether the nature of the risk communicated on the label is accurately understood by the general public and by practitioners, along with the possibility that the label has had unintended consequences in clinical practice patterns and treatment decisions. In short, misunderstanding the severity of the risk (e.g., believing there is a risk for death) communicated on the label could influence prescribers' decisions about whether to provide care as well as patients' decisions about pursuing or receiving treatment. It is important for practicing clinicians, medical and otherwise, to accurately understand and communicate the nature of risk described on the label, thus allowing parents and patients to make well-informed decisions about treatment options, including both medication and psychotherapy.

The complete warning label is available at the following Web link: <http://www.fda.gov/cder/drug/antidepressants/default.htm>. In addition to the label, information is available to health care professionals, patients, and family members in the medication guide, a supplemental document intended to clarify relevant facts and clinical recommendations. Both documents are available at the Web link provided.

The 2004 and 2007 labeling changes were the result of an analysis of available FDA antidepressant trials data and subsequent recommendations from the FDA's Psychopharmacologic Drugs Advisory Committee. The pediatric trials included a total of 4,400 patients, and the adult trials included over 77,000 patients with major depressive disorder and other psychiatric disorders. The primary purpose of the label is to warn consumers (and remind health care practitioners) of the heightened risk of suicidal thinking and behaviors in children, adolescents, and young adults taking antidepressant medications; it does not mention a risk for death by suicide. The label warns of clinical worsening, particularly during

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the “initial few months of a course of drug therapy” (FDA CDER, 2007, p. 2), with a specific recommendation for careful monitoring and observation during the initial phase of treatment.

Drug–placebo differences in the number of cases of suicidality per 1,000 patients across the aggregated FDA trials varied considerably across age groups: 14 additional cases for those under 18 years old and 5 additional cases for those 18–24 years old, with decreased risk noted among those 25–64 years old (1 fewer case) and those older than age 65 (6 fewer cases; FDA CDER, 2007). Despite evidence of a decrease in risk for those 25–64 years of age, the observed difference was not significant. The difference for those over age 65 was significant. Although the observed drug–placebo differences for those under age 18 were statistically significant, the relative magnitude was arguably small, with the clinical meaningfulness open for debate. As is evident, the general trend is for increased risk of suicidal thinking and behaviors (but not death) for those younger than 18 years of age and for reduced risk for those over age 65.

Several important facts are frequently overlooked and often misunderstood about the warning label (both the initial and revised versions): First, there were no suicides across 4,400 patients in the pediatric trials (i.e., children and adolescents). Although there were suicides in the adult trials, the “number was not sufficient to reach any conclusion about drug effect on suicide” (FDA CDER, 2007, p. 2). In other words, the adult suicide rates were comparable across both the placebo and clinical arms. Subsequent reanalysis of the FDA adult data for SSRIs, other antidepressants, and placebo confirmed comparable suicide rates (total  $N = 77$ ) across clinical and placebo arms, evidencing no increase in suicide risk with antidepressant use (Gunnell, Saperia, & Ashby, 2005; Khan, Khan, Kolts, & Brown, 2003).

Second, although statistically significant, the rates of suicidality (increased suicidal thinking and behaviors) were low in the aggregated pediatric trial data. In terms of actual numbers ( $N = 4,400$ ), there was a suicidality rate of 4% ( $N = 176$ ) in the clinical arm and a rate of 2% ( $N = 88$ ) in the placebo arm. The net outcome of this comparison is that a 2% suicidality rate (difference between the clinical and placebo arms) dictated a warning label for all antidepressant medications. That means that 88 patients drove a warning label in a sample of 4,400. It is important to consider that for those 88 patients, we have no way of knowing the severity of the suicidality (i.e., nonspecific suicidal ideation versus nearly lethal suicide attempts) because suicidality was broadly defined. The observed suicidality rate was actually comparable to that found in other studies targeting antidepressant use in children and adolescents (Mosholder & Willy, 2006). The same can be said for adults, with studies evidencing no marked increase in the suicidality rate beyond that seen with placebo (Gunnell, Saperia, & Ashby, 2005; Khan et al., 2003). The clinical significance of this low suicidality rate, particularly in contrast to the overall treatment efficacy of antidepressants (and other psychosocial treatments), is certainly debatable and an issue that has received little attention in the literature.

Third, although there was variability, the follow-up periods for both the pediatric and adult trials were very short (i.e., several months). Accordingly, the normal course of risk over time is unknown. It is simply not known if initial risk of suicidality resolves, persists, or escalates over time for those under age 18.

This is a critical question for those providing and receiving treatment.

Fourth, neither the warning label nor the medication guide provides any age-related data regarding suicide risk, offering no context for the findings. This context is actually critical to understanding the nature of risk, an important point when weighing a decision about treatment. A quick review of suicide rates in the United States helps put the FDA data into context. Those under age 24 are actually at the lowest risk for suicide when compared to older adults. According to the latest data available, the suicide rate (per 100,000) is 0.7 for children 5–14 years old, 10.0 for those 15–24 years old, 12.4 for those 25–34 years old, 14.9 for those 35–44 years old, 16.5 for those 45–54 years old, 13.9 for those 55–64 years old, 12.6 for those 65–74 years old, and 16.9 for those older than 75 (Kung, Hoyert, Xu, & Murphy, 2008). The general trend for increasing risk with age is confirmed by the observation that the elderly represented 12.4% of the general population in 2005 but accounted for 16.6% of the suicides, in contrast to the young who made up 14.2% of the general population and accounted for 12.9% of the deaths by suicide. The FDA data do not indicate an increased risk for death by suicide for children, adolescents, and young adults taking antidepressants, a finding consistent with what researchers have known about suicide risk for this group for many years. It is also important to consider data regarding trends in suicidality. As Kessler, Berglund, Borges, Nock, and Wang (2008) have pointed out, data from the National Comorbidity Surveys (1990–1992 and 2001–2003), targeting 18- to 54-year-olds, indicate no significant changes in suicide ideation or attempt rates during this time.

Given that as many as 75% of depressed patients pursuing treatment receive medications and that an estimated 48% receive both medications and psychotherapy, it is important for practicing psychologists to have an accurate understanding of and familiarity with the FDA black box warning label (Olfson et al., 2002). The bulk of prescribed medications are SSRIs (over 58% of all prescribed antidepressants), and the majority of care is provided by nonpsychiatrists (Olfson et al., 2002). Although most psychologists do not provide medical advice (except for those appropriately trained and credentialed), they are involved with a great many individuals taking medications and play active roles in helping maintain treatment compliance, whether psychotherapy treatment provision is a part of that process or not. For example, increasing numbers of psychologists are working in primary care settings and medical centers (Zilberg & Carmody, 2005). The primary goals of this brief article are to familiarize practicing psychologists with the current research available regarding the FDA black box warning label for antidepressants and to provide a context for understanding, interpreting, and distilling implications for clinical practice. The warning label and some observed consequences have clear implications for day-to-day clinical practice for psychologists, including facilitating an accurate understanding of the nature of risk communicated to parents, patients, and family members, making subsequent treatment decisions, and facilitating compliance with care.

### Is There Evidence of Possible Unintended Consequences?

Since the FDA black box warning label emerged, questions and concerns have been raised about its potential impact on clinical

practice (including a decreased willingness to prescribe antidepressants among nonpsychiatric specialists and the increased likelihood of referral to specialists), patient and provider understanding of the actual risk, patient willingness to pursue treatment, and eventual treatment compliance. Pfeffer (2007) summarized many of the concerns for children and adolescents: “the FDA advisories may have had the unintended effect of discouraging the prescription of antidepressants for pediatric patients and pediatric utilization of antidepressants without compensatory increases in other specific treatments” (p. 843).

There is ample evidence available that the volume of antidepressant prescriptions for children and adolescents has dropped significantly since the warning label was issued (Lineberry, Bostwick, Beebe, & Decker, 2007). Lineberry et al. (2007) reported a 20% decline in antidepressant prescriptions filled for children and adolescents following the implementation of the warning label. Although not causal in nature, Lineberry et al. also reported that approximately 70% of nonpsychiatrist physicians endorsed changes in clinical practice patterns, including an increased likelihood they would refer to a psychiatrist as well as a decreased willingness to prescribe and monitor antidepressants themselves. It is remarkable that only 30% of generalists reported no changes in their clinical practice since the implementation of the warning label. Lineberry et al. concluded that “large numbers of both generalists and non-psychiatric physicians who formerly would have written antidepressant prescriptions themselves are choosing instead to refer patients to psychiatrists or other mental health specialists” (p. 520). This finding is consistent with previous research demonstrating that FDA warning labels are linked to decreased prescribing patterns (Lasser et al., 2002). Increased referral to mental health specialists raises concerns about an overall decrease in rates of care because anywhere from 30% to 75% of patients have been found to no-show for their initial mental health appointment (Westra, Boardman, & Moran-tynski, 2000). The net outcome of generalists making referrals to psychiatrists rather than providing the care themselves may well be that fewer people get much needed treatment. Evidence has emerged to support this hypothesis.

Libby et al. (2007) found a significant decrease in the number of children and adolescents receiving diagnoses of depression, with the lowest rates in over a decade. They noted that from 1999 to 2004, rates of diagnosis of pediatric depression almost doubled (from 3 to 5 per 1,000). Following the FDA warning label, rates returned to 1999 levels, essentially being cut by 70%, with pediatricians and primary care physicians accounting for the largest reductions in new diagnoses. They noted that SSRI prescriptions being filled fell below trend expectations by 58%. They also provided data that there was no evidence of increased use of other treatment options, such as psychotherapy, despite evidence of their effectiveness in treating suicidality (Rudd, Joiner, & Rajab, 2004). Consistent with the concerns raised by Lineberry et al. (2007), the data appear to indicate that fewer depressed children and adolescents are receiving a diagnosis of depression and subsequent treatment (either medication or psychotherapy). One possible interpretation offered by Libby et al. is that fewer parents are willing to seek care for their children given the risks raised by the warning label. Similarly, Gibbons et al. (2007) found a 22% drop in SSRI prescription rates for children and adolescents both in the United States and in the Netherlands. They also noted that in the Nether-

lands, the youth suicide rate increased by 49% following the warning label, with an inverse relationship observed between the suicide rate and SSRI prescriptions. There were similar findings in the United States, with an 18% increase in the suicide rate for children, adolescents, and young adults (i.e., those under age 20) from 2003 to 2004. The most recent U.S. data available in 2005 indicate that rates have remained notably higher than expected (Bridge, Greenhouse, Weldon, Campo, & Kelleher, 2008), with an apparent persistence of the problem over a 2-year span.

Some of the most compelling evidence of potential unintended consequences from the warning label comes from Katz et al. (2008). Katz et al. found a more than threefold increase in the child and adolescent suicide rate in Canada since the warning label was issued (an increase from 4 in 100,000 before the label to 15 in 100,000 after the warning label). The increase occurred simultaneously with a marked decline in both rates of antidepressant prescriptions and the frequency of ambulatory visits for depression, despite the observation that prior to the warning label, prescriptions of antidepressants were on the rise (similar to U.S. trends). Katz et al. calculated relative risks and 95% confidence intervals for the change in the slope of the trend line over time. Following the warning label, the prescription rate decreased significantly for children and adolescents (relative risk = 0.86 and 95% confidence interval = 0.81–0.91) as well as for young adults (relative risk = 0.90 and 95% confidence interval = 0.86–0.93). These findings raise concerns not just about possible changes in clinical practice patterns, but also about patients’ and parents’ willingness to pursue treatment.

There is also evidence of a spillover effect with adults. Valuck et al. (2007) found that diagnoses of depression in adults experienced similar and significant reductions since the emergence of the warning label. Using a sample of adults with newly diagnosed depression from an integrated claims database, they found the average percentage of adults with new depressive episodes was 88.6% prior to the warning label and 77.5% afterward, with an annual rate of decline of 7.7% (in contrast to 1.69% prior to the warning label). They concluded the most likely explanation was a spillover effect from the warning label, even though the label targeted those 24 years of age and younger. Evidence of a potential spillover to the adult population is particularly problematic given FDA and other findings of lower risk for adults over 24 years of age taking antidepressants, along with evidence of a significant decline in risk for the elderly.

As mentioned earlier, one of the primary purposes of the warning label was to increase the frequency of provider contact and the intensity of monitoring following an antidepressant prescription for children and adolescents. The medication guide recommends that patients be “monitored closely and observed closely for clinical worsening . . . during the initial few months of a course of drug therapy” (FDA CDER, 2007, p. 2). Initial evidence suggests this has not occurred. Morrato et al. (2008) found that fewer than 5% of all patients met the FDA contact recommendations prior to the warning label and that the rate was unchanged after the introduction of the black box warning label.

Cordero, Rudd, Bryan, and Corso (2008) approached the problem from a slightly different perspective, exploring whether non-specialist prescribing practitioners accurately understood the risk information provided on the warning label. They found an error rate of 91%, with the overwhelming majority of practitioners

reporting that there was a risk for death for children and adolescents taking antidepressants. With evidence of lower diagnosis and prescription rates, the concern is that the warning label may well be frightening patients, parents, and practitioners alike, with even nonspecialist prescribing health care providers believing there is a risk for death by suicide. Also of concern, over 90% of participants reported sharing verbal information with patients to clarify the nature of risk described on the warning label (i.e., the nature of the risk incurred). Although practitioners reported no subsequent changes in parents' willingness to allow their child to take antidepressant medications, objective outcome and tracking data were not collected.

### Considering Treatment Effectiveness When Determining Suicide Risk

As mentioned earlier, the magnitude of the difference in rates of suicidality across the clinical and placebo arms of the aggregated FDA trials for children and adolescents was statistically significant, but the clinical meaning is certainly open to debate. As reviewed earlier, the observed rates of suicidality are not out of the ordinary for treatment trials, with rates comparable to those for placebo (Gunnell, Saperia, & Ashby, 2005; Khan, Khan, Kolts, & Brown, 2003). Although there were suicides in the adult trials, the difference across placebo and clinical conditions was insufficient to claim a drug effect (meaning they were comparable). As part of the debate, it is important for all mental health clinicians to be aware that recent evidence in the literature actually demonstrates a reduction in suicide risk with SSRI use, with markedly low rates of SSRI antidepressants reported in the toxicology results of suicide cases (Ryan, 2005). Erlangsen, Candudas-Romo, and Conwell (2008) found that only 1 in 5 older adults was taking antidepressants at the time of suicide. Additionally, they discovered that the male suicide rate declined by 9.7 suicides per 100,000 for men taking antidepressants and by 3.3 suicides per 100,000 for women, essentially a 10% decline in both groups. The net result is that antidepressants were found to reduce risk in a significant fashion with the elderly, consistent with the often unrecognized element in the FDA warning label and medication guide.

Convergent data are now available indicating marked clinical improvement and lower risk for suicide following treatment with SSRI medications (Khan et al., 2003; Martinez et al., 2005; Simon, Savarino, Operskalski, & Wang, 2006). Khan et al. (2003) found suicide rates of depressed patients taking antidepressants to be comparable to those of patients taking a placebo in a sample of over 48,000. Similarly, Valuck, Libby, Sills, Giese, and Allen (2004) demonstrated markedly lower risk for suicidality among adolescents continuing SSRI treatment for 6 months or longer in comparison to those being treated for less than 2 months in a sample of over 24,000. More specifically, they found no increased risk for a suicide attempt after treatment with SSRI (in contrast to other antidepressants) following an index major depressive episode, and they found a reduction in risk when treatment endured for at least 6 months. To date, the convergence of evidence suggests that treatment efficacy needs to be factored in when considering risk.

The implications of these findings cut across a number of clinical domains, including the need to increase physicians' and patients' awareness of the availability (and effectiveness) of alter-

native treatments for depression and related problems, such as treatment with psychotherapy (cf. David-Ferdon & Kaslow, 2008).

### Implications for Psychologists in Clinical Practice

Recent findings targeting the FDA black box warning label for antidepressants have important implications for psychologists in clinical practice. Regardless of setting, it is likely that psychologists will have contact with a client or patient taking antidepressant medications as a primary or secondary treatment (Olfson et al., 2002). It is important that psychologists have an accurate understanding of the warning label and share this information with their patients, patients' parents, and other professionals, particularly physicians in primary care settings. Among the salient points are the following:

First, the FDA black box warning label does not indicate an increased risk for death by suicide, only for suicidality (defined as suicidal thinking and behaviors). This is true for children, adolescents, and young adults. There were no suicides in the child and adolescent aggregated trials, and although there were suicides in the adult trials, there was no conclusive data that the medications elevated the risk for death by suicide beyond that seen with a placebo. The rates were comparable for adults across the clinical and placebo arms. There are a number of studies offering convergent evidence as well.

Second, the warning label defines suicidality as heightened risk of suicidal thinking and behaviors and recommends the need for closer monitoring during the initial phase of treatment. No evidence is available to suggest that the label has had its intended impact, with comparable follow-up rates before and after the label. An effort needs to be made to improve follow-up monitoring during the initial phase of treatment with antidepressants. Psychologists can play a role in facilitating and even conducting follow-up monitoring, particularly in primary care settings.

Third, the warning label includes mention of reduced risk for suicidality among the elderly, an often unrecognized and important element. Despite including these data, there is evidence of a spillover effect with adults. The hope is that an accurate understanding of the label will result in informed treatment decisions and higher rates of care.

Fourth, many nonspecialists prescribing antidepressants do not have an accurate understanding of the risk stated on the warning label, with most believing and communicating a risk for death (i.e., an error rate of 91%). An accurate communication of risk allows parents and patients to make informed treatment decisions.

Fifth, many nonspecialist providers give supplemental verbal information to clarify the nature of risk communicated on the warning label. Initial data suggest this information is frequently inaccurate. Correcting errors is likely important in helping patients and parents make informed decisions about treatment.

Sixth, emerging evidence shows that the warning label is changing clinical practice patterns, leading to fewer diagnoses of depression, a reduced willingness to prescribe, and a reluctance to pursue treatment. In addition to correcting misunderstandings about the label, psychologists can also make sure patients and parents are aware of all treatment alternatives, including psychosocial ones, that have been proven effective. Psychotherapy is a proven alternative for the treatment of depression in children and adolescents (David-Ferdon & Kaslow, 2008).

Seventh, although not causal in nature, the most recent data indicate a threefold increase in suicide rates among children and adolescents, coupled with a decline in ambulatory care for depression. Psychologists need to recognize the potential unintended consequences of the warning label.

Psychologists can serve as a scientific resource, providing accurate and timely information in clinical practice. They can also take on a number of additional roles, including consultant, facilitator, and direct treatment provider.

As consultants across both the inpatient and outpatient spectrum, psychologists need to provide accurate and thorough information to both patients and other professionals. Psychologists can serve a critical consultation role in primary care, facilitating an accurate and thorough understanding of the current literature on the FDA warning label for primary care providers. As consultants in primary care settings, psychologists have unique access that not only can improve the accuracy of understanding about the original intent of the FDA warning label and subsequent research findings, but can also help quell unnecessary fearfulness about the potential risks, balancing issues of risk against comparable data on treatment efficacy. The hope is that the net result would be an improved understanding of the actual risk, coupled with improved availability of treatment options, including both medications and psychotherapy.

As facilitators, psychologists can play a critical role in helping patients and their parents make informed treatment decisions. In some cases, this may mean clarifying for the primary care physician the actual nature of risk for antidepressant use. It may well be that an accurate understanding of the risk communicated on the warning label would increase the likelihood that the primary care physician or prescriber would feel comfortable writing and managing a prescription without referral to a specialist. Once a decision is made, psychologists can help facilitate follow-up and monitoring during the early phases of treatment, the real goal of the warning label.

As treatment providers, psychologists can offer individual psychotherapy (or related psychosocial treatment) as the primary or secondary treatment. Given the data indicating less compensatory treatment for depressed children and adolescents, psychologists can play an important role in communicating with physicians about the availability and efficacy of psychotherapy.

The data that have emerged suggest not only that the FDA warning label has not resulted in improved follow-up monitoring for those prescribed antidepressants, but also that the label has likely had unintended consequences. Given their broad range of skills and competencies, psychologists are in a unique position to help clarify the original intent of the warning label and facilitate informed decisions on the part of parents, patients, and fellow professionals. The data available about the impact of the FDA warning label for antidepressants are compelling and suggest some potential unintended consequences. We would not suggest removing the label, recognizing that the risks of medications need to be clearly and accurately communicated and understood. Available data, however, raise serious questions about whether either is happening, and the consequences of this are potentially lethal. Good treatment decisions about whether to pursue medications, psychotherapy, or both require an accurate understanding of risk-to-benefit ratios. Only then can informed decisions be made about care.

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### Call for Nominations

The Publications and Communications (P&C) Board of the American Psychological Association has opened nominations for the editorships of **Experimental and Clinical Psychopharmacology**, **Journal of Abnormal Psychology**, **Journal of Comparative Psychology**, **Journal of Counseling Psychology**, **Journal of Experimental Psychology: Human Perception and Performance**, **Journal of Personality and Social Psychology: Attitudes and Social Cognition**, **PsycCRITIQUES**, and **Rehabilitation Psychology** for the years 2012–2017. Nancy K. Mello, PhD, David Watson, PhD, Gordon M. Burghardt, PhD, Brent S. Mallinckrodt, PhD, Glyn W. Humphreys, PhD, Charles M. Judd, PhD, Danny Wedding, PhD, and Timothy R. Elliott, PhD, respectively, are the incumbent editors.

Candidates should be members of APA and should be available to start receiving manuscripts in early 2011 to prepare for issues published in 2012. Please note that the P&C Board encourages participation by members of underrepresented groups in the publication process and would particularly welcome such nominees. Self-nominations are also encouraged.

Search chairs have been appointed as follows:

- **Experimental and Clinical Psychopharmacology**, William Howell, PhD
- **Journal of Abnormal Psychology**, Norman Abeles, PhD
- **Journal of Comparative Psychology**, John Disterhoft, PhD
- **Journal of Counseling Psychology**, Neil Schmitt, PhD
- **Journal of Experimental Psychology: Human Perception and Performance**, Leah Light, PhD
- **Journal of Personality and Social Psychology: Attitudes and Social Cognition**, Jennifer Crocker, PhD
- **PsycCRITIQUES**, Valerie Reyna, PhD
- **Rehabilitation Psychology**, Bob Frank, PhD

Candidates should be nominated by accessing APA's EditorQuest site on the Web. Using your Web browser, go to <http://editorquest.apa.org>. On the Home menu on the left, find "Guests." Next, click on the link "Submit a Nomination," enter your nominee's information, and click "Submit."

Prepared statements of one page or less in support of a nominee can also be submitted by e-mail to Emmet Tesfaye, P&C Board Search Liaison, at [emnet@apa.org](mailto:emnet@apa.org).

Deadline for accepting nominations is January 10, 2010, when reviews will begin.