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Rapid response

[Re: Does long term use of psychiatric drugs cause more harm than good?](#)

As this important question is debated, it is essential to note that the reporting of results from longer-term, government-funded studies of psychiatric drugs has often been done in a manner that has protected psychiatry's guild interests, rather than in a manner consistent with the dictates of good science. This necessarily biases any public discussion and consideration of the "evidence" on this question.

Here are two examples of this corruption, (which we detail in our recently published book, *Psychiatry Under the Influence*.)

a) In the TADS study of depressed adolescents, an NIMH-funded trial that helped resurrect the prescribing of fluoxetine to pediatric patients, the researchers reported that "there were no differences between groups in rates of suicidal events" at the end of 36 weeks. In fact, if the data presented in a table in a 2009 report is carefully parsed, it can be seen that 17 of the 18 youth who attempted suicide during the 36 months were on fluoxetine at the time of their attempt. This finding was obscured in this way: if youth were randomized to placebo or cognitive behavioral therapy alone, and then switched to fluoxetine after the initial 12-week treatment period, with their suicide attempts occurring after that switch, their suicide attempt was still attributed to the placebo group, or the CBT-alone group.

b) In the NIMH-funded STAR*D study, which was touted as the "largest and longest study ever done to evaluate depression treatment," the researchers announced that "the overall cumulative remission rate was 67%," and, it appeared, based on the relapse rates reported in a 2006 article, that 50% to 66% of the remitted patients had remained well during the one-year follow-up. This was a pretty decent result. But then an independent researcher, Ed Pigott, used a Freedom of Information request to access the protocol and other study data, and he determined that only 38% of the 4,041 patients who entered the study remitted according to protocol criteria, and even more important, that only 108 of the 4,041 were still in the trial and well at the end of one-year, a documented stay well-rate of 3%. All of the other patients had either never remitted, relapsed, or dropped out of the study.

Based on the results presented by the investigators, these two NIMH studies have been said to provide evidence that support the longer-term use of psychiatric drugs. Unfortunately, the deconstruction of the two studies, which reveals quite different results, doesn't regularly inform the debate about the merits of psychiatric drugs. There are many such examples of this corruption that can be detailed, and it is easy to see why this impairs any societal—or scientific—discussion about the longer-term merits of psychiatric drugs.

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Kennard, B. "Assessment of safety and long-term outcomes of initial treatment with placebo in TADS." *Am J Psychiatry* 2009; 166 (3):337-44.

Vitiello, B. "Suicidal events in the treatment for adolescents with depression study (TADS)." *J Clin Psychiatry* 2009; 70 (5): 741-7. See figure 1 for data showing drug exposure before suicidal event; see table 1 for assignment of suicidal events by randomization.

Rush, AJ. "Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: A STAR*D report." *Am J Psychiatry* 2006; 163 (11):1905-17.

Pigott, H. "Efficacy and effectiveness of antidepressants." *Psychother Psychosom* 2010; 79 (5):267-79. Also, Pigott, H. "Star*D: A tale and trail of bias." *Ethical Human Psychology and Psychiatry* 2011; 13 (1):6-28.

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