

MEDICAL MEMO

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Antidepressant Safety in Children

In mid October 2004 the US Food and Drug Administration (FDA) announced new warnings and precautions to strengthen safeguards for children and adolescents treated with antidepressant medications. A "black box" warning is to be added to the package inserts and a Medguide (small information pamphlet) is to be handed out when the prescription is picked up at the pharmacy. The caution and added information is to ensure parents are aware of the possibility of increased suicidal thinking and behavior that may occur in a small percentage of children and adolescents especially during the early phase of treatment. Monitoring and communication between parent, patient, and doctor are encouraged. The main medications affected are the SRI (Serotonin Reuptake Inhibitor) antidepressants which include Prozac (generic is fluoxetine), Zoloft, Paxil (paroxetine), Luvox (fluvoxamine), Celexa, and Lexapro. The FDA caution does affect all antidepressants though that seems even more questionable. Please see my website (leeheyemd.com) [medicine charts](#) for information about and the names of the various antidepressants.

What led to this action? The FDA and a team at Columbia University recently reported that in a review of 24 studies using antidepressants (mostly SRI's) in over 4400 youth (children and teen) patients the rate of suicidal thoughts or behavior amongst youth taking placebo (fake pills) was 2 % and that the rate amongst youth taking antidepressants was 4 %. There were no completed suicides in any of these 4400 patients. Thus, the actual risk was that 2 of every 100 youth who took antidepressants had suicidal thoughts or behavior possibly related to the medicine and that 98 out of every 100 did not.

How do we make sense of this information? The no deaths in 4400 studied youths is very important to remember. In the last 10 years since these medicines have become available for youth there has been a 25% decrease in the suicide rate among youth leading to literally thousands of saved lives and many more improved lives. Many doctors

view the FDA action and media attention as over-reaction based on politics rather than science. This is why these medicines will remain excellent options. So why might 2% of youth taking these medicines have an increase in suicide thoughts or actions? One reason is that suicide risk is higher for some people early in recovery when they have improved enough that they have the energy to act on such impulses but have not yet improved enough for the impulses to go away. A related possibility is that if the patient has energizing, disinhibiting, or agitating behavioral side effects their usual behavior or typical personality may temporarily be altered enough that they may do things they wouldn't normally do. (See my [Medical Memo](#) newsletter Summer 1999 issue entitled "[What Are Behavioral Side Effects?](#)") Although I have not seen this energizing side effect result in suicidal or violent behavior I think this is the kernel of truth behind the data and affects whether and which medicine I choose since some medicines are less likely to have this energizing effect. Another possible explanation for an increase in self harm ideas or behavior is that the diagnosis is in error and therefore the medicine choice is not optimal. These possibilities are a main reason why appointments are more frequent in the early stages of recovery. Medicine is most appropriate for moderate to severe or complicated cases and when other treatments have failed. At times medicine alone is enough but most often combining psychotherapy, environmental changes, and/or behavioral therapies with medicine is best.

Summary: When prescribed and monitored appropriately for Depression, Obsessive Compulsive Disorder, and various Anxiety and Panic Disorders these medicines can be extremely helpful in restoring function and helping youth (and adults) live normal lives.



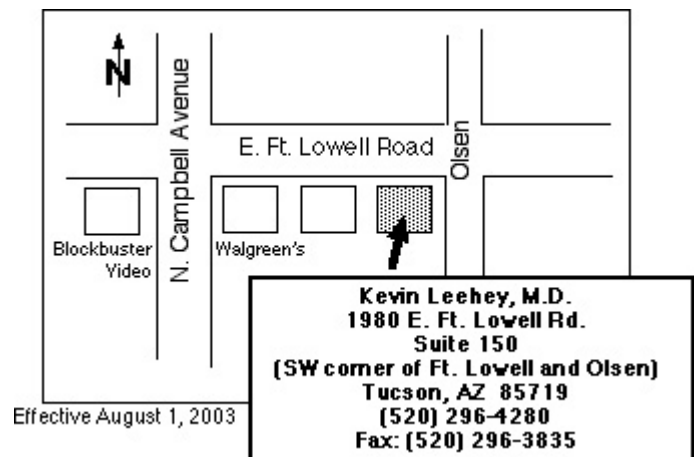
Cymbalta, A New Medication Option

In the fall of 2004 the new SNRI (serotonin and norepinephrine reuptake inhibitor) Cymbalta (duloxetine) was approved by the FDA and became available for use in adults for Depression and diabetic neuropathy pain. It is also expected to prove helpful for anxiety, panic, OCD, and possibly for other physical pain disorders in all age groups. Cymbalta combines the serotonin increasing action of SRI's (Prozac, Zoloft, Celexa, etc) with the norepinephrine increasing action of Wellbutrin (bupropion) and Strattera (atomoxetine). This dual action makes Cymbalta a broader spectrum potentially more effective medicine. Some such medicines with multiple actions help pain and physical symptoms of depression more than single action options. Cymbalta is most similar to Effexor (venlafaxine) which is also a dual acting SNRI. However, Cymbalta's dual effect begins right away while Effexor has only the serotonin benefit until the dose is raised high enough for the norepinephrine effect to kick in. Dual action also means more potential side effects than single action meds. These include possible negative side effects on nausea, energy, sleep, sexual effects, sweating, blood pressure, or weight.

Taking it with or soon after food and starting at a low dose lessen the chance of nausea. Headaches may be less common with Cymbalta than with placebo (ie, it may help prevent headaches). Interactions with other medicines are relatively few. Alcohol is best avoided. Like all medicines it is to be avoided if possible in pregnancy and probably in breast feeding. Capsules are available in 20, 30, and 60 mg doses. Dose ranges from 20 to 120 mg a day taken once or split up twice a day with the most common expected dose around 60 mg a day. As with other antidepressant and most anti-anxiety medicines it is best tapered on and off – not stopped suddenly. Like other such medicines, although its effect may begin in the first few days, generally it takes 1 to 3 weeks to kick in and a good month to see what a given dose will do. Cymbalta, which some jokingly say sounds like the name of a character from Lion King, is a favorably anticipated new option whose overall value will become clearer with time. Please see my website (leehey.md.com) [medicine charts](#) for more information.

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