

# HEALTH REPORT

VOLUME 11

ISSUE 31

## FDA SAYS ANTIDEPRESSANT LABELS SHOULD WARN ABOUT SUICIDAL THINKING, BEHAVIOR IN YOUNG ADULTS

The Food and Drug Administration (FDA) has asked makers of all antidepressant medications to update existing labels to include warnings about increased risks of suicidal thinking and behavior, known as suicidality, in young adults ages 18 to 24 during initial treatment (generally the first one to two months).

The proposed labeling update follows similar labeling changes made in 2005 that warned of a suicidality risk in children and adolescents who use antidepressants. At that time, the FDA requested manufacturers add a black box warning to the labeling of all antidepressants to describe this risk and to emphasize the need for appropriate monitoring and close observation, particularly for younger patients taking these medications.

Also in 2005, the FDA began a comprehensive review of 295 individual antidepressant trials that included over 77,000 adult patients with major depressive disorder (MDD) and other psychiatric disorders, to examine the risk of suicidality in adults who are prescribed antidepressants. In December 2006, the FDA's Psychopharmacologic Drugs Advisory Committee agreed that labeling changes were needed to inform health care professionals about the increased risk of suicidality in younger adults using antidepressants.

### School shooters on antidepressants

The proposed label changes come on the heels of the Virginia Tech student massacre, but are apparently not related. News reports have been focusing on the possibility that the gunman was or had been on antidepressant medication. The reports cited more than a dozen other school shootings where students either were medicated or were coming off medication. The withdrawal period has been reported as possibly even more dangerous.

The antidepressant drugs requiring new labels are:

Anafranil (clomipramine)	Limbitrol	Seroquel (quetiapine)
Asendin (amoxapine)	Ludiomil (maprotiline)	Sinequan (doxepin)
Aventyl (nortriptyline)	Marplan (isocarboxazid)	Surmontil (trimipramine)
Celexa (citalopram hydrobromide)	Nardil (phenelzine sulfate)	Symbyax (olanzapine/fluoxetine)
Cymbalta (duloxetine)	nefazodone HCl	Tofranil (imipramine)
Desyrel (trazodone HCl)	Norpramin (desipramine HCl)	Tofranil-PM (imipramine pamoate)
Elavil (amitriptyline)	Pamelor (nortriptyline)	Triavil (perphenazine/amitriptyline)
Effexor (venlafaxine HCl)	Parnate (tranlycypromine sulfate)	Vivactil (protriptyline)
Emsam (selegiline)	Paxil (paroxetine HCl)	Wellbutrin (bupropion HCl)
Etrafon (perphenazine/amitriptyline)	Pexeva (paroxetine mesylate)	Zoloft (sertraline HCl)
fluvoxamine maleate	Prozac (fluoxetine HCl)	Zyban (bupropion HCl)
Lexapro (escitalopram hydrobromide)	Remeron (mirtazapine)	
	Sarafem (fluoxetine HCl)	