

## SPINE SAFETY NOTICE:

### **Information for Healthcare Professionals:**

Antidepressant Medications –

Updated Product Labeling To Include New Warnings About Suicidal Thinking and Behavior In Young Adults

According to MedWatch, FDA notified healthcare professionals that the Agency proposed that makers of all antidepressant medications update the existing black box warning on the prescribing information for their products to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment. The proposed labeling changes also state that scientific data did not show this increased risk in adults older than 24 years of age and that adults 65 years of age and older taking antidepressants have a decreased risk of suicidality.

Modifications have been made to the WARNINGS and PRECAUTIONS sections of the drugs listed below, black box warnings have been added, and the medication guides have been updated. The revised labeling now addresses the increased 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 any 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.

The complete MedWatch 2007 Safety Labeling Changes, including links to the updated prescribing information, medication guide, FDA Press Release and Antidepressant Information Page regarding this issue, are available as follows:

### **Link to changes submitted in July 2007:**

<http://www.fda.gov/medwatch/SAFETY/2007/jul07.htm>

Norpramin® (desipramine hydrochloride tablets, USP)  
Nortriptyline Hydrochloride® Oral Solution, USP  
Pamelor® (nortriptyline HCl) Capsules and Oral Solution, USP  
Remeron® (mirtazapine) Tablets  
RemeronSolTab® (mirtazapine) Orally Disintegrating Tablets  
Seroquel® (quetiapine fumarate) Tablets

Tofranil-PM® (imipramine pamoate capsules)

**Link to changes submitted in August 2007:**

<http://www.fda.gov/medwatch/SAFETY/2007/aug07.htm>

Celexa® (citalopram hydrobromide) Tablets and Oral Solution  
Cymbalta® (duloxetine hydrochloride) Delayed-Release Capsules  
Effexor® (venlafaxine hydrochloride) Tablets  
Effexor XR® (venlafaxine hydrochloride) Extended-Release Capsules  
Lexapro® (escitalopram oxalate) Tablets and Oral Solution  
Limbital® (chlordiazepoxide) (amitriptyline HCl) DS (double strength) Tablets  
Marplan® (isocarboxazid) Tablets  
Nardil® (phenelzine sulfate tablets, USP)  
Parnate® (tranylcypromine sulfate) Tablets  
Paxil® (paroxetine hydrochloride) Tablets and Oral Suspension  
Paxil CR® (paroxetine hydrochloride) Controlled-Release Tablets  
Pexeva® (paroxetine mesylate) Tablets  
Prozac® (fluoxetine capsules, USP, fluoxetine oral solution, USP, fluoxetine delayed-release capsules, USP)  
Sertraline® Hydrochloride Tablets and Oral Concentrate  
Sinequan® (doxepin HCl) Capsules and Oral Concentrate  
Surmontil® (trimipramine maleate)  
Symbyax® (olanzapine and fluoxetine HCl capsules)  
Wellbutrin® (bupropion hydrochloride) Tablets  
Wellbutrin SR® (bupropion hydrochloride) Sustained-Release Tablets  
Wellbutrin XL® (bupropion hydrochloride extended-release tablets)  
Zyban® (bupropion hydrochloride) Sustained-Release Tablets

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at [http://www.spine.org/spine\\_safety\\_notices.cfm](http://www.spine.org/spine_safety_notices.cfm). This information is provided as a service for information and education only.