

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:  
Fentanyl Transdermal Patches –  
Recall Due to Gel Leak That May Lead to Respiratory Depression and  
Overdose**

According to MedWatch, Actavis Inc. announced a nationwide recall of certain lots of Fentanyl transdermal system CII Patches sold in the United States and labeled with an Abrika or Actavis label. The product may have a fold-over defect which can cause the patch to leak and expose patients or caregivers directly to the fentanyl gel. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. The lots covered by this recall include doses of 25, 50, 75, and 100 mcg/hr and are listed in the firm's press release.

See the complete MedWatch 2008 safety summary, including a link to the firm's press release, at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Fentanyl>

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 Web site at

<http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.