

Medication Safety: FDA Announces Pilot “Drug Watch” Informational Program.

On May 10, 2005 the US Food and Drug Administration (FDA) announced it is developing a pilot medication-safety-awareness program entitled “Drug Watch.”

According to the FDA, it is developing this pilot program as a reaction to public and Congressional criticism of the way the FDA has handled emerging safety considerations with the drug Vioxx and certain antidepressants used with pediatric patients.

Drug Watch will be an Internet web page on which the FDA will post significant emerging safety information that the FDA has received about certain drugs or classes of drugs while the FDA is still actively evaluating the information.

Posting of safety-related information on the Drug Watch web page in and of itself will not constitute a formal statement from the FDA that the drug is in fact dangerous or that it is deemed by the FDA to be inappropriate for use.

The FDA points out that after drugs are deemed generally recognized as safe and become widely prescribed for use in large populations of patients, reports of previously unknown side

effects can present themselves of which health-care professionals need to be made aware.

The FDA’s goal will be to share emerging safety information before the FDA has fully determined its significance or taken formal regulatory action. The FDA says it wants patients and healthcare professionals to have the most current information the FDA has concerning the potential risks and benefits of marketed drug products.

The Drug Watch Internet web page is not currently up and running. The FDA has posted a web page containing a full explanation of what it intends to do when it does initiate the Drug Watch web page at http://www.fda.gov/cder/guidance/6657dft.htm#_Toc102985740.

The FDA’s May 10, 2005 announcement in the Federal Register is available on our website at <http://www.nursinglaw.com/drugwatch.pdf>.

The FDA will accept public comments until August 8, 2005 before it goes ahead with implementation of this new program.

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Pages 24606 – 24607

Job-Related Mental Stresses: Court Disallows Injured Nurse’s Worker’s Compensation Claim.

A licensed practical nurse worked in a facility for developmentally disabled adults.

A change in policy at the facility resulted in more higher-functioning patients being re-assigned to a physically less restrictive environment, meaning that the nurse’s unit’s population makeup shifted toward more difficult, demanding patients more prone to aggressive acting out.

The nurse twice was kicked by her patients. She sustained relatively minor injuries. Her worker’s compensation claims for her medical expenses were honored and paid.

The nurse also began to suffer depression and other mental problems which required outpatient and inpatient care which her physicians related to her job stress.

Being subjected to aggressive behavior by mentally-challenged patients is not an extraordinary and unusual condition of employment as a nurse in a developmental facility, as it occurs frequently and is the subject of specific training for facility employees.

It is not unexpected that the nurse would have fear of loud and aggressive behavior by patients.

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The nurse eventually accepted voluntary termination under a workforce reduction program, then filed for worker’s comp long-term disability based on her work-related depression.

The Court of Appeals of South Carolina upheld the worker’s compensation commissioner’s ruling that this nurse’s job stress was not an occupational illness and did not qualify her for worker’s comp disability benefits.

There was nothing unique or extraordinary about her experiences working on the unit. All of the stresses she experienced, including fear of injury and actual injury, were an ordinary part of the job she had chosen, the court said. ***Doe v. Dept. of Disabilities & Special Needs***, __ S.E. 2d __, 2005 WL 894791 (S.C. App., April 18, 2005).