Improper Monitoring Of Medications: Nurse Ruled Negligent In Patient's Death From Seizure.

Judgment was recently entered by the Ohio Court of Claims against the state department of mental health in a wrongful death claim which centered on the errors and omissions of a registered nurse employed by the department.

The court was particularly concerned over the fact that the evidence supported allegations asserted in the lawsuit by the family that the nurse, in "direct defiance" of the attending physician's orders, delayed a change in the patient's anti-psychotic medication from Mellaril to Navane, although it was not clear from the court's review of the autopsy findings why the court thought that this caused or contributed to the patient's death.

The patient died from a myocardial infarction during an episode of seizure activity. At autopsy there was *no* Tegretol, the anti-seizure medication prescribed for the patient, found in his blood.

The court record recited a long list of factors, such as reports by the non-professional staff at the residence of the patient's seizure activity and generalized ill health, and non-compliance which should have been apparent from the patient's self-reporting med logs and from his unused medications, to alert the nurse to redouble her efforts to effect medication compliance, for which the court faulted the nurse for the patient's death. **Hitch vs. Ohio Department of Mental Health, 662 N.E. 2d 106 (Ohio Ct. Cl., 1995).**

The patient had voluntarily committed himself for psychiatric care, and then went to live in an aftercare residence. A visiting nurse was responsible for seeing that he took his prescribed neuroleptic and anti-seizure medications.

Although she could not force him to take his meds, she was responsible for visiting him at least once a week, for checking his self-reporting medication logs and for monitoring his medication cassette for compliance.

The nurse deliberately delayed a physician-ordered change in his anti-psychotic medication.

Repeated staff reports of petit mal seizure activity did not lead the nurse to bring about compliance with his anti-seizure medication regimen, as was her legal duty.

OHIO COURT OF CLAIMS, 1995.

Medical Device User Facility And Manufacturer Reports Of Adverse Events: FDA Delays Date New Rules To Take Effect.

As reported in this newsletter in February, 1996 (Legal Eagle Eye Newsletter for the Nursing Profession 4(5) p. 3) the FDA has promulgated extensive new regulations which now *require* healthcare facilities which fall within the definition of users of medical devices to report adverse events associated with use of such devices to the FDA, when death or serious injury results to a patient.

Due to numerous complaints which have been filed with the FDA, principally by manufacturers, **the FDA has extended the effective date of the new regulations from April 11, 1996 to July 31, 1996,** to permit those affected by the new regulations additional time to come up to speed on the new legal requirements which have been imposed upon them.

The FDA *does not* appear to have the intention to amend the new regulations in any manner to respond to the complaints which have been filed, but appears to intend to publish explanatory comments in the future to facilitate compliance.

FEDERAL REGISTER, April 11, 1996, Pages 16043 - 16045.