

## Cell / Tissue Donor Eligibility: New Guidance From FDA.

On May 25, 2004 the US Food and Drug Administration announced the availability of a draft document entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues and Cellular and Tissue-Based Products."

Use of the recommendations contained in the draft document is not mandatory at this time.

The draft document is being published for public comment, a requirement any Federal agency must follow before issuing mandatory new regulations in final form.

We have placed the seventy-eight page non-copyrighted document on our website at <http://www.nursinglaw.com/tissuedonors.pdf>.

FEDERAL REGISTER May 25, 2004  
Page 29835

## Seizure Disorder: Hospital Provided Nurse Reasonable Accommodation.

A registered nurse had a history of seizure disorder which her physician had stated was under control with medication.

The hospital agreed, as long as it did not impose any undue hardship on the hospital, to honor a medical restriction that she work no more than five days in a row followed by two days off.

The nurse objected to having to work on a weekend during a nursing shortage, citing her seizure disorder.

After objecting to weekend work the nurse was put on leave pending a letter from her doctor stating her seizures were still under control. The letter was not forthcoming after six months. The US Circuit Court of Appeals for the Tenth Circuit found no disability discrimination in the hospital terminating her. **Johnson v. Shawnee County**, 2004 WL 1260305 (10th Cir., June 9, 2004).

## Perioperative Nursing: Sponge Inside Patient, Nurses Faulted, But Consequences Disputed.

The Court of Appeals of Michigan, in a recent unpublished opinion, expressed the following as a statement of the legal standard of care for perioperative nurses with respect to sponge and instrument counts:

*The applicable standard of practice or care of the surgical nursing staff assisting in the operating room is to make a proper and correct count of the surgical sponges and/or instruments prior to the closure of an incision; and to notify the surgeon(s) of an improper count prior to closure to ensure that no surgical sponges and/or instruments are retained inside a patient's body prior to closure.*

The court went on to say it is fairly straightforward that perioperative nurses and their employer can be held legally responsible for the medical costs

***A registered nurse with a background in surgical nursing can give an expert opinion as to the legal standard of care for surgical nurses.***

***However, a nurse does not have the education or professional training to offer a medical opinion linking the patient's death from cancer to delay in cancer treatment caused by a second surgery to remove the sponge.***

COURT OF APPEALS OF MICHIGAN  
UNPUBLISHED OPINION  
June 3, 2004

and the patient's pain and suffering related to a second surgery to remove a retained sponge or instrument and to correct the internal adhesions.

However, the court still threw out the patient's family's case. The patient's expert witness, an RN, offered her expert opinion that the second surgery to remove the retained surgical sponge delayed the patient's treatment for cancer and that the delay resulted in her death.

The court did not rule whether that was actually true. The court took the tack that a nurse would not have the medical expertise to offer such an opinion and without a viable expert opinion the case was without merit. **Renswick v. Providence Hosp.**, 2004 WL 1222924 (Mich. App., June 3, 2004).