Legal Briefs

GENE A. BLUMENREICH, JD
AANA General Counsel
Fine & Ambrogne
Boston, Massachusetts

Nurse anesthetists and prescriptive authority

Part of the confusion over whether the practice of nurse anesthesia is the practice of medicine is whether nurse anesthetists "prescribe" anesthetic agents. In most institutions, no one fills out a prescription blank for the anesthetics. Does this mean the CRNA is prescribing? The law governing the health care field is interpreted in such a way as to give great latitude to health care professionals to work out their own procedures. Since most surgery cannot be performed without anesthesia, scheduling a patient for surgery is generally equivalent to the prescription of anesthesia. This can only be done by a physician.

Physician involvement is also reflected in the anesthesia standards of the Joint Commission on Accreditation of Health Care Organizations that a licensed independent practitioner (one assumes a physician) is *responsible* for the determination of the patient's physical status and capacity to undergo anesthesia even though the licensed independent practitioner need not perform these functions directly.

The significance of the physician decision was illustrated in *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (U.S. Ct. of Apps. 5th Cir, 1974). An infant contracted polio after having received Sabin oral polio vaccine at a public health clinic. The vaccine was administered by a registered nurse and there were no doctors present. The issue was whether Wyeth Laboratories had an obligation to warn parents that the drug could be harmful. Wyeth claimed that its obligations were satisfied by its inclusion of package inserts designed to warn physicians.

There was testimony that while the public health nurse who administered the vaccine was aware of the warnings, she did not pass these warnings on to the parents of the infant. In general, the law requires that a product is not unreasonably dangerous if it is accompanied by proper directions and warnings.

The court held that, since the prescribing physician takes into account "the propensities of the drug and the susceptibility of the patient" manufacturers of prescription drugs are *not* obligated to give warnings to the general public. Where, however, there is no prescribing physician, the justification for excepting prescription drugs from the requirement of giving warnings to consumers evaporates. The manufacturer of a polio vaccine should know that these vaccines are often administered in public health clinics without a physician present. Therefore, the drug manufacturer was required to warn or see that the patient was warned.

How the law applies to nurse anesthetists

In the field of anesthesiology, more than 50% of the anesthetics are administered by CRNAs. Does this mean that under the principles of *Reyes v. Wyeth Laboratories* the drug manufacturers owe a duty to the general public to warn or see that the patient was warned? It would seem that a determination by a physician that surgery is appropriate, necessarily includes a determination that the benefits of the surgery outweigh the risks inherent in anesthesia. This is *precisely* the physician involvement the court found missing in *Reyes v. Wyeth Laboratories.*

Court decisions make clear that the fact that drugs administered by CRNAs does not mean that CRNAs are "prescribing" them within the meaning of the statutes. These decisions recognize that CRNAs select the agents and may know more about the agents than the "prescribing physician."

Frank v. South

In one of the earliest cases to deal with the functions of nurse anesthetists, *Frank v. South*, 175 Ky. 416, (Kentucky, 1917), Margaret Hatfield was accused of practicing medicine. The court noted (page 423) that *"the mere giving of medicines which are prescribed by a physician in charge who has made a diagnosis and determined the disease and determined the remedy and directs the manner and the time and the character of the medicines to be administered, has never been considered engaging in the practice of medicine."*

The court went on to note (page 427):

"It is however, contended that the trained nurse, who administers an anesthetic, must, at some time, exercise her own judgment and thus bring her within the definition of 'to practice medicine' in this, that the surgeon is engaged with his duties in performing the operation and it may become necessary to apply another anesthetic, instead of the one being used. . . . If a physician makes a diagnosis and discovers the ailment of the patient, who is attended by a nurse, and prescribes certain medicines to be given, when the medicine already given shall affect the patient in a certain way, to determine when the medicine should be given requires the exercise of some degree of judgment by a nurse; . . . in all these contingencies, the nurse would have to exercise some degree of judgment but to hold that such would constitute her a practitioner of medicine and prohibit her from the rendition of such services, it would have the effect . . . to deprive the people of all services in sickness other than those which are gratuitous, except when rendered by a licensed physician."

Kemalyan v. Henderson

The courts understand that the physician prescribes "anesthesia" and often leaves it up to the nurse anesthetist to determine the specifics. In the case of *Kemalyan v. Henderson*, 277 P.2d 372 (Wash., 1954), the surgeon testified that the nurse anesthetist knew considerably more about administering an anesthetic than he did and that "he left completely to her discretion the administration of the ether to the plaintiff." He also testified that all surgeons in Spokane customarily relied wholly on the nurse anesthetist or a physician anesthetist supplied by the hospitals to administer anesthetics during surgical operations. Three other surgeons called by Dr. Henderson testified to the same effect.

Carlson v. Javurek

In the case of *Carlson v. Javurek*, 526 F.2d 202 (1975), the surgeon testified that he had made a medical decision not to use Penthrane® as an anesthetic in the surgery and communicated that decision to the nurse anesthetist. "At another point in this testimony, he stated that while the nurse anesthetist normally chose the anesthetic to be used, it was the 'custom' in the hospital for the nurse anesthetist to follow any direct orders from the surgeon." The nurse anesthetist admitted that she would have followed the physician's direct order, but she denied having any conversation with the surgeon prior to the surgery.

The court held that if the surgeon had arrived at a medical decision relating to the administration of an anesthetic to his patient, he must communicate this decision to the nurse who will administer the medication and that the nurse would be obligated to follow the surgeon's order or, at a minimum, advise the surgeon of her disagreement. If the surgeon had made this determination and failed to communicate it to the nurse anesthetist, the surgeon was liable.

The case was sent back to the trial court for determination of the facts because of the dispute in testimony. However, it is interesting that the case acknowledges the appropriateness of the nurse anesthetist selecting the medications and applying them in the absence of a specific medical decision to the contrary.

As indicated by the case and as this column has stated before (see "The duty to independently assess proper nursing functions" by Betsy Wolfe, June 1986, Vol. 54, No. 3, pp. 222-224, *AANA Journal)*, even a medical decision to the contrary does not excuse the CRNA from evaluating the patient. The CRNA would, however, first be obligated to discuss a disagreement over the anesthetic to be used with the physician.

Swayze v. McNeil Laboratories

In the case of *Swayze v. McNeil Laboratories, Inc.*, the U.S. Court of Appeals for the Fifth Circuit was asked to apply the principles of *Reyes v. Wyeth Laboratories* to anesthetics. The plaintiff argued that a drug company was obligated to warn the public about the dangers of an anesthetic because the anesthetics were often administered by nurse anesthetists.

The court disagreed, pointing out that the presence of the surgeon distinguished the case of anesthesia. The court acknowledged that anesthetics were customarily administered by CRNAs who were permitted to determine dosages but this did not require a drug company to warn the general public.

Swayze, it must be pointed out, is a case between an injured patient and a drug company. No CRNA was

a party to the case and no one addressing CRNA interests was involved. The court makes many false assumptions about the capabilities of CRNAs (just as the very same court had done five years earlier in *Jefferson Parish Hospital v. Hyde* prompting the AANA to file its brief *Amicus Curiae* in the United States Supreme Court).

Other pertinent cases

A number of cases have stated that one of the reasons drug companies must provide information in package inserts and other materials is to warn nurse anesthetists. In the case of *Holley v. Burroughs Wellcome Company*, 348 S.E.2d 772 (North Carolina, 1986) and 330 S.E.2d 228 (Ct. of Apps. North Carolina, 1985), the patient suffered irreversible brain damage resulting from malignant hyperthermia. Because the anesthesiologist testified during his deposition that he did not rely on any information supplied by the drug companies concerning the use of their anesthetics, the trial court ordered judgment for the drug companies.

The trial court's position was that even if the materials prepared by the drug company did not contain satisfactory disclosure of the risk of malignant hyperthermia, if the anesthesiologist did not rely on them, there was no way the drug companies would have been held liable for failure to disclose the risk of malignant hyperthermia.

The case was appealed to the North Carolina Court of Appeals and ultimately to the North Carolina Supreme Court. One of the reasons that the trial court was overruled was that whether or not the anesthesiologist relied on the insert, it was important that the information be made available to nurse anesthetists and the anesthesiologist's testimony that he did not rely on the packaging insert did not excuse the drug company from warning the nurse anesthetist who administered it.

Conclusion

There must be medical participation in the determination to provide anesthesia to patients. These cases show that where there has been a medical decision to anesthetize, as there is when surgery is scheduled, the requirement is satisfied and the courts do not require or expect the physician to participate in the administration.