Restrictions on CRNAs imposed by physician-controlled insurance companies

Recently, we have become aware of several cases of physician-controlled insurance companies attempting to restrict the practice of nurse anesthesia by adopting restrictive endorsements or raising premiums for physicians working with nurse anesthetists. These endorsements are based on a misleading and inaccurate picture of the liability of a surgeon when working with a CRNA. In addition, these endorsements often raise serious anti-trust issues.

Endorsements concerning liability

Some physician-controlled insurance companies have recently adopted endorsements requiring surgeons to follow certain procedures when working with CRNAs. The president of one insurance company wrote that “the courts have dictated that [surgeons] will be held to the standard of care which can only be furnished by a trained anesthesiologist.” The president’s letter further contended that the courts have dictated that if the insured physician uses an anesthesiologist, then the anesthesiologist is responsible for any injuries related to the anesthesia and that if the insured physician uses a CRNA, then the surgeon is “frequently held responsible for the bad result caused by an anesthesia failure.”

These statements of legal liability are simply wrong. The courts do not look at the status of the anesthesia administrator but at the degree of control the surgeon exercises over the anesthesia administrator—whether or not that administrator is a CRNA or an MD. Liability depends on the facts of each case and the extent to which the surgeon has control over the anesthesia administrator. Therefore, there are cases where surgeons have been held liable for the negligence of a CRNA and cases where they have not; just as there are cases where surgeons have been held liable for the negligence of an anesthesiologist and cases where they have not.

Often, Nurse Practice Acts require that CRNAs act under the supervision or direction of a physician. Numerous cases hold that mere supervision or direction is insufficient evidence to hold a surgeon liable. In Baird v. Sickler, 69 Ohio St.2d 652 (1982), the Ohio Supreme Court, after an extensive review of the decided cases, found no case where a surgeon was held liable for the negligence of a CRNA based solely on the surgeon’s statutory obligation of supervision. It is clear from case law that in order for a surgeon to be liable for the acts of the anesthesia administrator, the surgeon must be in control of the administrator's actions and not merely be supervising or directing the administrator.

Most lawyers, and surprisingly many people in the health care industry, are unaware that the administration of anesthesia by nurse anesthetists is such a widespread, long-standing and acceptable practice in the health profession. Nurse anesthetists have been administering anesthetics for approximately 100 years and courts have long supported the administration of anesthesia by nurses. Nurse anesthetists are found in every practice setting from major metropolitan hospitals to rural and urban public hospitals. More than 50% of anesthesia services in today’s hospitals are provided by nurse anesthetists who practice in collaboration with, or under the direction of, physicians, dentists or other health professionals. In rural areas, nurse anesthetists provide more than 70% of the anesthesia care. Every state in the country recognizes the role of nurse anesthetists and authorizes them to provide anesthesia services. Until the 1970’s, there were many more nurse anesthetists than anesthesiologists and even with the recent “glut” of physicians, the numbers of nurse anesthetists and anesthesiologists are approximately the same. The United States Court of Appeals for the Ninth Circuit recently confirmed what nurse anesthetists have long known: nurse anesthetists directly compete with anesthesiologists. Bhan v. NME Hospitals, Inc. et al., 772 F.2d 1467 (9th Cir. 1985).

Quality of anesthesia outcome is the same

There is a difference between the type of educa-
tion that nurse anesthetists and anesthesiologists receive. Anesthesiologists receive a medical education before their anesthesia education and practice. The basic curriculum of an accredited nurse anesthesia educational program requires 24 months of study (sometimes in the very same program attended by those studying to become anesthesiologists) and is offered at baccalaureate and master’s degree levels or as a certificate-granting program. Licensed professional nurses entering these programs must have a minimum of one year of nursing experience in an acute care setting, although the typical applicant has at least two years of nursing experience in an intensive care unit. Clearly, anesthesiologists are in school longer than CRNAs. Does this, however, make any difference in practice?

The studies of the quality of the outcome of anesthesia between anesthesiologists and CRNAs conclude that there is no difference regarding the quality of care rendered by an anesthesiologist and the quality of care rendered by a CRNA. While this conclusion may be surprising to the less knowledgeable, an understanding of the nature of anesthesia would lead one to expect this. The vast majority of anesthesia-related accidents have nothing to do with the level of education of the provider. The most common anesthesia accidents are hypoxia and premature intubation and extubation. All of these accidents result from lack of attention, not lack of education. In fact, the recently announced Harvard Medical School standards in anesthesia are directed toward monitoring, which reiterates the basic point: most anesthesia incidents relate to lack of attention, not lack of education. Anesthesia seems to be an area where, beyond a certain level, outcome is only minimally affected by medical knowledge but is greatly affected by factors such as attention, concentration, organization and the ability to function as part of a team; factors towards which all professions strive but which no profession may claim a monopoly.

**Increased premiums**

Some physician-controlled insurance companies are charging higher premiums for physicians who employ or supervise CRNAs. Non-physician controlled insurance companies, however, do not impose higher premiums or restrictive endorsements on physicians working with CRNAs. St. Paul Fire & Marine Insurance Company, the insurance company of the AANA-sponsored liability plan, has advised us that there is no evidence that physicians working with CRNAs have a higher rate of claims made against insurance companies than physicians working with anesthesiologists. Furthermore, there is no evidence that physicians working with CRNAs incur greater expenses per claim than physicians working with anesthesiologists. No insurance company charges surgeons who work with CRNAs more than surgeons who work with anesthesiologists except physician-controlled insurance companies.

**Endorsements raise serious anti-trust issues**

Because these restrictions are not based on quality of care or insurance underwriting considerations, why are they adopted? It is difficult to come to any conclusion other than they may be an effort to restrict the practice of CRNAs and to increase the use of anesthesiologists solely for the financial benefit of anesthesiologists. The United States Supreme Court looked at a very similar issue in the case of *American Society of Mechanical Engineers v. Hydrolevel Corporation*, 102 S.Ct. 1935 (1982).

The dispute in *Hydrolevel* involved a professional society that established standards for the engineering industry and two competing engineering companies, Hydrolevel Corporation and McDonnell & Miller, Inc. Hydrolevel’s products had a time delay feature that McDonnell’s products did not have. The vice president of McDonnell was also vice chairman of the subcommittee of the professional society that interpreted the engineering standards published by the professional society. The vice president of McDonnell met with the chairman of the subcommittee about Hydrolevel’s timing device and the chairman prepared a response that concluded that the time delay feature may not be safe. As a result of this response, McDonnell’s sales representatives advised potential customers that Hydrolevel’s devices failed to satisfy the professional society’s standards and successfully discouraged customers from buying Hydrolevel’s products.

Hydrolevel then brought a lawsuit against the professional society on the theory that the professional society, through the conduct of its officials, violated the federal anti-trust laws. The United States Supreme Court agreed with Hydrolevel and decided that an organization can be held liable for the actions of one of its agents whenever the agent is acting within the scope of his or her “apparent authority.”

Many physician-controlled insurance companies have anesthesiologists on their Boards of Directors. A Board of Directors that includes anesthesiologists and excludes CRNAs would seem to have a clear bias in favor of anesthesiologists and against CRNAs. Just as the engineer in the *Hydrolevel* case used a professional society to unfairly compete in the boiler area, the anesthesiologists may be unfairly using the insurance company to compete with nurse anesthetists. And the *Hydrolevel* case is a clear warning that this activity is a violation of the federal anti-trust laws.
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Before prescribing, please consult complete prescribing information, of which the following is a brief summary.

**CAUTION:** Federal Law Prohibits Dispensing Without Prescription

**DESCRIPTION:** SUFEKTA is a sterile, preservative-free, aqueous solution containing sufentanil citrate equivalent to 50 μg per ml of sufentanil base for intravenous injection. The solution has a pH range of 3.5-6.0

**INDICATIONS AND USAGE:** SUFEKTA (sufentanil citrate) is indicated as an analgesic adjunct in the maintenance of balanced general anesthesia. As a primary anesthetic agent for the induction and maintenance of anesthesia with 100% oxygen in patients undergoing major surgical procedures, such as cardiovascular surgery or neurosurgical procedures in the sitting position, to provide favorable myocardial and cerebral oxygen balance or when extended postoperative ventilation is anticipated. See dosage chart for more complete information on the use of SUFEKTA.

**CONTRAINDICATIONS:** SUFEKTA is contraindicated in patients with known hypersensitivity to the drug.

**WARNINGS:** SUFEKTA should be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids. An opioid antagonist, resuscitative and intubation equipment and oxygen should be readily available.

SUFEKTA may cause skeletal muscle rigidity, particularly of the trunkal muscles. The incidence and severity of muscle rigidity is dose related. Administration of SUFEKTA may produce muscular rigidity with a more rapid onset than that seen with fentanyl. SUFEKTA may produce muscular rigidity that involves the skeletal muscles of the neck and extremities. The incidence can be reduced by 1) administration of up to 1/4 of the full paralyzing dose of a non-depolarizing neuromuscular blocking agent just prior to administration of SUFEKTA or dosages of up to 8 μg/kg; 2) administration of a full paralyzing dose of a neuromuscular blocking agent following loss of consciousness when SUFEKTA is used in anesthetic dosages (above 8 μg/kg) titrated by slow intravenous infusion; or 3) simultaneous administration of SUFEKTA and a full paralyzing dose of a neuromuscular blocking agent when SUFEKTA is used in rapidly administered anesthetic dosages (above 8 μg/kg). The neuromuscular blocking agent should be compatible with the patient's cardiovascular status. Adequate facilities should be available for postoperative monitoring and ventilation of patients administered SUFEKTA. It is essential that these facilities be fully equipped to handle all degrees of respiratory depression.

**PRECAUTIONS:** General: The initial dose of SUFEKTA should be appropriately reduced in elderly and debilitated patients. The effect of the initial dose should be considered in determining supplemental doses. Vital signs should be monitored routinely. Nitrous oxide may produce cardiovascular depression when given with high doses of SUFEKTA (see CLINICAL PHARMACOLOGY). The hemodynamic effects of a particular muscle relaxant and the degree of skeletal muscle relaxation required should be considered in the selection of a neuromuscular blocking agent. High doses of pancuronium may produce increases in heart rate during SUFEKTA-oxygen anesthesia. Bradycardia has been reported infrequently with SUFEKTA-oxygen anesthesia and has been responsive to atropine. Respiratory depression caused by opioid analgesics can be reversed by opioid antagonists such as naloxone. Because the duration of respiratory depression produced by SUFEKTA may last longer than the duration of the opioid antagonist action, appropriate surveillance should be maintained. As with all potent opioids, profound analgesia is accompanied by respiratory depression and diminished sensitivity to CO₂ stimulation which may persist into or recur in the postoperative period. Appropriate postoperative monitoring should be employed to ensure that adequate spontaneous breathing is established and maintained prior to discharging the patient from the recovery area. Interaction with Other Central Nervous System Depressants: Both the magnitude and duration of central nervous system and cardiovascular effects may be enhanced when SUFEKTA is administered to patients receiving barbiturates, tranquilizers, other opioids, general anesthetics or other CNS depressants. In such cases of combined treatment, the dose of one or both agents should be reduced.

**Depressants:** Both the magnitude and duration of central nervous system and cardiovascular effects may be enhanced when SUFEKTA is administered to patients receiving barbiturates, tranquilizers, other opioids, general anesthetics or other CNS depressants. In such cases of combined treatment, the dose of one or both agents should be reduced.

**Head Injuries:** SUFEKTA may obscure the clinical course of patients with head injuries. Impaired Respiration: SUFEKTA may obscure the clinical course of patients with head injuries. Impaired Respiration: SUFEKTA should be used with caution in patients with pulmonary disease, decreased respiratory reserve or potentially compromised respiratory function. In such patients, opioids may additionally decrease respiratory drive and increase airway resistance. During anesthesia, this can be managed by assisted or controlled respiration. Improved Hepatic or Renal Function: In patients with liver or kidney dysfunction, SUFEKTA should be administered with caution due to the importance of these organs in the metabolism and excretion of SUFEKTA.

**Carcinogenesis, Mutagenesis and Impairment of Fertility:** No long-term animal studies of SUFEKTA have been performed to evaluate carcinogenic potential. The micronucleus test in female rats revealed that single intravenous
doses of sufentanil as high as 80 pg/kg (approximately 2.5 times the upper human dose) produced no structural or mutagenic activity. See ANIMAL TOXICOLOGY for reproduction studies in rats and rabbits.

Pregnancy Category C: Sufentanil has been shown to have an embryotoxic effect in rats and rabbits when given in doses 2.5 times the upper human dose for a period of 10 days to over 30 days. These effects were most probably due to maternal toxicity (decreased food consumption with increased mortality) following prolonged administration of the drug. No evidence of teratogenic effects has been observed after administration of sufentanil in rats or rabbits. There are no adequate and well-controlled studies in pregnant women. Sufentanil should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery: There are insufficient data to support the use of sufentanil in labor and delivery. Therefore, such use is not recommended.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sufentanil is administered to a nursing woman.

Pediatric Use: The safety and efficacy of sufentanil in children under two years of age undergoing cardiovascular surgery has been documented in a limited number of cases.

Animal Toxicology: The intravenous LD₅₀ of sufentanil is 16.8 to 18.0 mg/kg in mice, 11.8 to 13.0 mg/kg in guinea pigs and 10.1 to 12.5 mg/kg in dogs. Reproduction studies performed in rats and rabbits given doses of up to 2.5 times the upper human dose for a period of 10 to over 30 days revealed high maternal mortality rates due to decreased food consumption and anoxia, which preclude any meaningful interpretation of the results.

ADVERSE REACTIONS: The most common adverse reactions of opioids are respiratory depression and skeletal muscle rigidity. See CLINICAL PHARMACOLOGY, WARNINGS, and PRECAUTIONS for the management of respiratory depression and skeletal muscle rigidity. The most frequent adverse reactions in clinical trials involving 320 patients administered sufentanil were: hypotension (3%), hypertension (3%), chest wall rigidity (3%) and bradycardia (3%). Other adverse reactions with a reported incidence of less than 1% were: Cardiovascular: tachycardia, arrhythmia, gastrointestinal: nausea, vomiting, Respiratory: apnea, postoperative respiratory depression, brachycephaly, dermatological: itching, erythema. Central Nervous System: chills, Miscellaneous: ephraephrew muscle movement.

DRUG ABUSE AND DEPENDENCE: Sufentanil (sufentanil citrate) is a schedule II controlled drug substance that can produce drug dependence of the morphine type and therefore has the potential for being abused.

OVERDOSAGE: Overdose would be manifested by an extension of the pharmacological actions of sufentanil (see CLINICAL PHARMACOLOGY) as with other potent opioid analgesics. However, no experiences of overdose with sufentanil have been established during clinical trials. The intravenous LD₅₀ of sufentanil in male rats is 7.34 to 12.5 mg/kg (see ANIMAL TOXICOLOGY for LD₅₀ in other species). Intravenous administration of an opioid antagonist such as naloxone should be employed as a specific antidote to manage respiratory depression. The duration of respiratory depression following an overdose with sufentanil may be longer than the duration of action of the opioid antagonist. Administration of an opioid antagonist should not preclude more immediate countermeasures. In the event of over-dosage, oxygen should be administered and ventilation assisted or controlled as indicated for hypoxia or apnea. A patent airway must be maintained, and a nasopharyngeal airway or endotracheal tube may be indicated. Intravenous fluids and vasoressors for the treatment of hypotension and other supportive measures may be employed.

DOSAGE AND ADMINISTRATION: The dosage of sufentanil should be individualized in each case according to body weight, physical status, underlying pathological condition, use of other drugs, and type of surgical procedure and anesthesia. In obese patients (more than 20% above ideal body weight), the dosage of sufentanil should be determined on the basis of lean body weight. Dosage should be reduced in elderly and debilitated patients (see PRECAUTIONS).

A world leader in anesthesia research.

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U.S. Patent No. 3,998,834
7,988,264 M
January 1986, March 1986
JP 608
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