

Package Brochures

To the Editor.—As you know, during a recent civil suit against an anesthesiologist, a package brochure of the drug manufacturer was introduced in evidence at the trial. In spite of somewhat contrary testimony given by renowned anesthesiologists, testifying as expert medical witnesses, this brochure bore great weight in influencing the trial judge and jury in a verdict against the defendant anesthesiologist.

If the package literature supplied by drug manufacturers is to be used as evidence in liability suits against anesthesiologists, manufacturers must prepare this literature carefully, and anesthesiologists must even more carefully scrutinize each item of package literature of any drug they intend to use.

After a review of only a few brochures from packages of drugs, it is evident that these brochures make claims as to the efficacy of a drug, its value and its lack of ill effects; then present a number of qualified precautions, limitations, and other recommendations for the prevention or treatment of adverse reactions. These statements are so inclusive and encompassing that it suggests the intent is to protect the manufacturer from any possible legal action as a result of the use of the drug. While an expert anesthesiologist may not agree with all of the recommendations made by the manufacturer, to a judge and jury, he seems to have a poor defense when he has not followed the minute details and broad recommendations of the manufacturer.

Last week several samples of a local anesthetic were presented to me by a manufacturer's representative. Examination of the literature supplied in each package of the drug revealed a number of interesting points. One of the first statements made in the brochure was "No contraindications to the use of this drug are known." Following this statement are a number of cautions, precautions, and recommendations. The manufacturer recommends the drug for caudal and peridural anesthesia, but does not recommend it "for injection into the subarachnoid space for spinal anesthesia." The brochure further states, "Intravascular or intrathecal injection may cause

serious complications." Should a drug that might produce serious complications when injected intrathecally be injected into the epidural space? It is also of note that the manufacturer supplies two different 1 per cent solutions of the drug; one in saline with a preservative added, the other in Ringer's solution without preservative. These two solutions are recommended respectively "for infiltration; and nerve block anesthesia only," and "for caudal and peridural anesthesia only." This does not seem logical. I do not believe that any anesthesiologist would want to use a drug in a vehicle for one method of regional anesthesia that was not suitable for regional anesthesia of another type, particularly when the areas are in such close proximity as are the subarachnoid and epidural spaces.

While some of these statements are undoubtedly based upon lack of clinical trial of the drug in the production of spinal anesthesia, I still cannot rationally use a drug for peridural anesthesia that is not equally acceptable for spinal anesthesia.

I realize that a number of the statements in package brochures are made because of the policies of the Federal Food and Drug Administration, since the package brochures are considered a portion of the label. However, it does not seem fair for drug manufacturers to make excessive claims for a drug and at the same time impose severe limitations on anesthesiologists in their use in order to cover every possible legal loophole. (*Note:* The opinions expressed in this letter are entirely those of the writer and are not necessarily those of the Department of the Navy or Department of Defense and are not to be construed as a statement of official policy.)

Sincerely yours,

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Artificial Respiration

To the Editor.—After having attended the International Convention on Life Saving Techniques on March 11–20 in Sydney, Australia, upon the invitation of the University of Sydney Post-Graduate Committee, it occurred to me