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

that a brief report about this convention may be of interest. Australia seemed the logical location for such a convention because of the importance of and interest in water safety and resuscitation in that country. The convention was organized by the University of Sydney Post-Graduate Committee in Medicine, jointly with the Australian Life Saving Associations. During the first four days there were interesting programs of three groups, which met separately: (1) the medical committee, (2) the lay rescue groups, (3) experts who gave papers on "Dangerous Marine Creatures." On the fifth day, the three groups met jointly.

The Medical Committee's main task was to review the pros and cons about exhaled air resuscitation (rescue organizations in the British Commonwealth until that time taught the manual methods as first choice methods of artificial respiration). Also new work on drowning was presented: D. Halmagyi and H. Colebach of the University of Sydney presented data on lung pathology following the introduction of small amounts of water into the lungs; the work on drowning of J. Redding's group at the Department of Anesthesiology, Baltimore City Hospitals included a demonstration of the need for plasma infusion in addition to artificial respiration with oxygen, for resuscitation after near-drowning in sea water. The Medical Committee, which consisted of Anesthesiologists, Internists, and Physiologists from five different countries, and of medical officers of the British Commonwealth, agreed to the following conclusions and recommendations:

1. "The most efficient type of artificial ventilation of the lungs is intermittent positive pressure breathing. Manual artificial respiration is less effective."
2. "Expired air artificial respiration is recommended as the best universally applicable field type of artificial respiration."
3. "The best methods of expired air artificial respiration provide an adequate airway, are free from air leaks and provide adequate inflation pressures."
4. "The most important single factor in providing airway patency is maximal backward tilting of the head. In some persons in addition to the backward tilt of the head, forward displacement of the mandible and/or separation of the lips may be necessary."
5. "The recommended methods of expired air respiration are mouth-to-mouth and mouth-to-nose according to circumstances."
6. "Accessory apparatus and appliances, such as masks and artificial airways, are of some value in certain circumstances as adjuncts to expired air respiration (but no recommendations are made regarding their use)."
7. "The Silvester-Brosch and the Holger-Nielsen are the recommended methods of manual artificial respiration. The Silvester-Brosch provides better lung ventilation but the Holger-Nielsen may be the preferable method in some circumstances."
8. "100% Oxygen given through a suitable machine provides better resuscitation than expired air respiration or manual respiration. This should only be given by fully trained professional rescue personnel."
9. "Closed chest manual systole may be a significant advance in the rescue of persons about to die of circulatory arrest from ventricular fibrillation or standstill."

Point (9) refers to recent work of W. Kouwenhoven and associates at the Johns Hopkins Hospital, who showed that effective artificial circulation is possible by compressing the heart between sternum and spine.

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Fluothane Anesthesia

To the Editor.—I am intrigued by a recent article in your journal comparing blood pressure and heart rate changes during Fluothane, cyclopropane, ether, and nitrous oxide-thiopental-narcotic anesthesia ("Changes in Blood Pressure and Pulse Rate During Fluothane Anesthesia: A Comparative Clinical Study," by Jack Moyers and Charles B. Pittinger, ANESTHESIOLOGY 20: 605, 1959). The paper was timely and well written, but I believe the conclusions were wrong. Drs. Moyers and Pittinger picked out "at random" 200 charts representing patients anesthetized with one of four different anesthetic agents. They con-