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In Reply:—We appreciate Abouleish's comments. The purpose of our letter was to alert clinicians to a potential risk and to suggest preliminary guidelines for the safe administration of a second dose of local anesthetic following a "failed" single-injection spinal technique.

Our letter suggested that maldistribution of local anesthetic within the subarachnoid space is a common cause for a "failed" single-injection spinal anesthetic (*i.e.*, failure occurs because hyperbaric local anesthetic accumulates in a restricted sacral distribution). Abouleish agrees that maldistribution may occur with continuous spinal anesthesia but asserts that the mechanism for failure of a single-injection spinal is "altogether different." He stresses that an important cause for failure of a single-injection spinal is the low site of lumbar puncture. The mechanism he considers responsible for this failure ("the longer distance . . . to reach the higher thoracic segments . . . with an appreciable amount of drug loss to the caudal area due to the position of the injection site at the down-slope of the lumbar curvature") is, in fact, maldistribution.

Our letter further suggested that, if failure has occurred because of maldistribution, there is the potential (albeit less than with an indwelling catheter) for repeated injections to distribute in the same restricted pattern; this restricted distribution could result in neurotoxic concentrations of local anesthetic. Accordingly, we recommended that if an injection is repeated, the technique should be modified to avoid reinforcing the same distribution. The alternative Abouleish provides (repeat injection at a higher interspace) is, in fact, a specific example of the type of modification of technique that we have suggested.

We have not suggested that maldistribution of local anesthetic is the sole cause for failure of a single-injection spinal anesthetic: technical errors such as positioning of the needle with the bevel partly within the epidural space or movement of the needle out of the subarachnoid space do, in fact, occur. However, we believe that Abouleish's suggestion always to administer the *same* dose of local anesthetic for the repeated injection is, at times, unsafe. We have suggested, instead, that clinicians assess the likelihood of technical error, and dose accordingly. Consequently, aspiration of cerebrospinal fluid should be attempted immediately following injection of local anesthetic. If cerebrospinal fluid cannot be aspirated after injection and if careful sensory examination (conducted after sufficient time for development of sensory anesthesia) reveals no evidence of blockade, we believe it is reasonable to repeat the injection with the same dose of local anesthetic. However, if aspiration is positive, it should be assumed that the full dose of local anesthetic has been delivered intrathecally; the combined dosage from the two injections should not exceed the maximum a clinician would consider reasonable to administer in a single injection. We find it inconsistent that Abouleish accepts local anesthetic maldistribution as a cause of neurologic injury with a continuous spinal technique but does not believe that the same mechanism of injury could occur when local anesthetic is administered as a repeated single injection; modification of technique alone does not ensure that maldistribution will not recur. We also find inconsistent his failure to perceive risk from repeated injections of local anesthetic in light of his recommendation to avoid epinephrine in the second dose because "excessive doses of epinephrine can lead to neurologic complications."

Finally, Abouleish is correct in asserting that the risk of neurotoxicity with a repeated single-injection spinal remains to be established. However, it should be appreciated that the information within the closed claim database was used not to generate, but to confirm, our suspicion of this potential risk. The data, although very limited, do appear to confirm this suspicion.

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(Accepted for publication November 25, 1991.)

Anesthesiology
76:477–478, 1992

Truth in Advertising: FDA Approval and the Physician's Responsibility

To the Editor:—An anesthesiologist recently took issue with a drug advertisement in the Journal.[1] He noted that although the Food and Drug Administration (FDA) had "approved" the drug for one limited and nonsurgical indication, the manufacturer clearly was recommending it to anesthesiologists who must use it in a different way. This led him to question the propriety of allowing such an advertisement to appear in the Journal.

In reply, the Editor properly noted that once a drug is available for some clinical use, it is also available for extension into other areas. At the risk of unduly complicating a good and succinct answer, I would like to expand on that reply. The explanation may be of interest.

The legitimate availability of a drug to physicians depends on FDA approval. It is not the drug that is approved, though, but rather the drug's *labeling*. For a drug to reach the marketplace, the FDA must evaluate the drug's safety and effectiveness. It must then approve the truthfulness of its labeling according to specific criteria. Once this is done, and the drug is lawfully available for *some* indication, each physician has sole discretion over how and why the drug is used in a particular patient.[2] This is how a drug's use may be extended into areas beyond those originally considered by the FDA.

When the FDA was called into existence by the Food, Drug, and Cosmetic Act of 1938, Congress was explicit in stating that the FDA should not regulate the practice of medicine between physician and patient. Courts have subsequently held that a physician's use of legally obtained medications is the practice of medicine and that a physician may lawfully vary a drug's conditions of use from those approved in the package insert. As a general principle, the FDA may not interfere with medical practice by limiting a physician's ability to prescribe according to his or her best judgment.

A problem arises when one tries to judge the advertisement in the