

Anesthesiology
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In Reply:—The letter from Dr. Severinghaus states that benzocaine absorbed from the skin, mucous, or pulmonary membranes commonly causes methemoglobinemia. We have studied the Federal Register as well as the many references contained therein and find the Federal Register, Volume 44, Number 234 dated Tuesday, December 4, 1979 states, "The panel concludes that the occurrence of methemoglobinemia following the use of benzocaine is rare; the panel concludes it can be classified as an uncommon idiosyncratic response that is in no way injurious or life-threatening. The panel further states that benzocaine is one of the most widely used and safest topical anesthetics found in over-the-counter (OTC) preparations."

In a 1985 letter to us, Dr. John Adriani wrote, "The lethal dose of benzocaine has never been determined because there has never been a reported case of a fatality in a human being from the ingestion of the drug."

The panel further concluded that the available epidemiologic data on allergy, irritancy, and other reactions are inconclusive and in no way support the contention that benzocaine is a potent sensitizer.

There have been over 1 billion applications of Hurrricane® and only

one known report of methemoglobinemia. In addition, there are at least 24 other benzocaine-containing products used in dentistry daily throughout the United States. In addition, obstetricians, surgeons, otolaryngologists, gastroenterologists, and others use benzocaine daily. Many hospitals and clinics use benzocaine prior to or during various scoping procedures. Further, many people who spend time in the sun use benzocaine products to treat sunburn quite effectively and safely.

Based on the wide, safe, and effective use of Hurrricane® and the many other benzocaine-containing products, all should be applauded, commended, and recommended for a superlative record of safety and effectiveness.

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In Reply:—The relationship between methemoglobinemia and benzocaine is well-known, documented, and researched, as evidence by the extensive list of references. The authors have, however, neglected to include the extensive evidence that the government and scientific experts have placed only minimum importance on the incidence of methemoglobinemia *vis-a-vis* the enormous quantity of the drug used daily both in over-the-counter and prescription products.

Speaking only for Cetylite Industries and its product, Cetacaine Spray, the following facts should provide a proper perspective. For the year 1989 only, based on the total number of bottles multiplied by the number of doses contained in each bottle, approximately 26,000,000 doses were administered. Even if the two-s dose is used as the consumption rate, 13,000,000 professionally dispensed patient applications represent quite a significant figure.

Cetylite Industries has been producing and marketing Cetacaine for 35 y. Even the four cases of methemoglobinemia reported to the Food and Drug Administration (FDA) were multiplied by 100, there still would not be sufficient statistically valid evidence to condemn benzocaine by suggesting its removal from products that contain it. Even the authors' reference to "50 reports" does not support their findings, which admit to only one questionable reported case of mortality from benzocaine-associated methemoglobinemia.

A specific package warning to address the rare incidence of methemoglobinemia would contradict the findings of the blue-ribbon panel that investigated the subject and the conclusions of the FDA.

Among the expert panel findings were the following: 1) "the panel concludes that benzocaine when properly formulated is a safe and effective analgesic, anesthetic, and anti-pruritic on the intact or damaged skin" (44 Fed. Reg. 69799); and 2) "the Panel concludes that the occurrence of methemoglobinemia following the use of benzocaine is rare. Normal infants and children are no more prone to its development than adults. Why this simple, non-oxidizing chemical compound should cause this response on rare occasions is not known, but the Panel concludes it can be classified as an idiosyncratic response that is in no way injurious or life threatening. (44 Fed. Reg. 69797, December 4, 1979).

To include in the package insert every possible adverse reaction, however rare, creates a cumbersome document. The result is a further reduction of the all too few interested professionals and consumers that even take the time to read the literature. I believe that a package insert of such large proportions that it reduces its readership serves primarily to protect the manufacturer from liability rather than protect the consumer, physician or his patient from possible harm.

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A Double-lumen Endobronchial Tube for Tracheostomies

To the Editor:—Double-lumen endobronchial tubes (DLTs) are routinely used during thoracic operations. Prior to the introduction of DLTs constructed of polyvinyl chloride (PVC), all DLTs were made of red rubber. Rubber DLTs were seldom used for patients with tra-

cheostomies since tubes small enough to fit through a stoma have too small an internal lumen for safe one-lung ventilation.¹⁻³ Conventional DLTs made of PVC can be used with tracheostomies, but because of the shortened length of the upper airway, special attention is required