precedent for standards of performance for ventilatory apparatus. In France, there are now stringent regulations controlling standards and a testing scheme for ventilators which is bindng on the manufacturer.

The next problem which Epstein's study brings up is the placement of responsibility in correcting potential hazards inherent in a piece of equipment. It is the responsibility of an automobile manufacturer to notify owners and recall the cars for repair when a hazardous design problem is identified. The Food and Drug Administration requires drug manufacturers to warn physicians of all possible adverse effects in the package inserts. Furthermore, the drug makers must keep physicians abreast of new information about harmful side-effects of their products by direct mail. If medical devices were controlled like drugs and automobiles, the manufacturer of one of the ventilators tested by Epstein would have to notify physicians and institutions who had purchased its machine that it is not adequate as a pediatric assistor because of its excessively long response time. At present, however, and in spite of federal legislation introduced as early as 1967, there are no laws governing such medical devices. While some manufacturers of ventilators have been extremely conscientious about notifying the users of their equipment about hazards and modifying the equipment, others have tended to take the attitude of "let the buyer beware."[3] This attitude will force the enactment of laws regulating medical devices. Such laws will no doubt evoke many problems similar to those we now face as a consequence of federal drug control.

The adage that unsafe drivers cause more accidents than unsafe automobiles also has application here. The best ventilator available can be a lethal instrument in the hands of unskilled personnel. Ventilators must be properly maintained and properly cleaned. Patients undergoing continuous artificial ventilation must be under constant, expert supervision. Standards for ventilators will improve patient care, but we should not lose sight of the fact that the most important factors in the care of the patient who needs continuous artificial ventilation are a knowledgeable physician and the continuous presence of well-trained respiratory therapists and nurses.

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Anesthesia

BOWEL-GAS EXPLOSION An explosion of gas in the large bowel ignited by electrocautery led to the death of a patient undergoing elective colonic interposition for esophageal stricture. Various factors leading to the accumulation of explosive gases in the bowel include: fermentation; a milk-rich diet with production of hydrogen; a legume-rich diet with production of methane. Nitrous oxide anesthesia may have contributed to the considerable distention of the bowel noted prior to the explosion. (*Hussey, J. L., and Poise, A. J.: Bowel-gas Explosion: An Unusual Surgical Complication, Amer. J. Surg. 120: 103 (July) 1970.*) ABSTRACTER'S COMMENT: Although the nitrous oxide anesthesia (actually nitrous oxide, halothane and oxygen) may have been partially responsible for the distention of the bowel, the increased concentration of oxygen available in the bowel lumen because of the 60/40 ratio of nitrous oxide/oxygen anesthetic mixture being administered may have increased the risk of explosion.