

**JOINT TESTIMONY OF THE AMERICAN SOCIETY OF
ANESTHEIOLOGISTS and THE NEW YORK STATE SOCIETY OF
ANESTHEIOLOGISTS, INC.**

BEFORE THE SENATE STANDING COMMITTEE ON INSURANCE

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PART I
PATIENT SAFETY INITIATIVES

Chairman Breslin, Senators Duane and Schneiderman and members of the Senate Insurance, Health and Codes Committees, thank you for holding this important hearing. I am Dr. Robert Lagasse, past president of the New York State Society of Anesthesiologists.

The American Society of Anesthesiologists (ASA) is a national, nonprofit association of approximately 43,000 physicians and other scientists from around the world engaged or especially interested in the medical specialty of anesthesiology.

The New York State Society of Anesthesiologists, Inc. (NYSSA) is a component member of ASA consisting of approximately 2,900 New York State physicians engaged in the medical specialty of anesthesiology. As a component member of the ASA, our members strive to adhere to the ASA standards, guidelines, and statements.

Since its founding in 1905, ASA has worked to improve the anesthesia experience for patients and is considered one of the pioneers in the field of patient safety. Patient safety has improved largely due to advances in anesthesiology and it is generally agreed that anesthesia is safer than it has been in the past. In fact, ASA's comprehensive patient safety efforts over the past three decades were denominated a "gold standard" for medical specialties in the December 1998 Institute of Medicine report on patient safety, *To Err is Human*.¹ ASA and NYSSA appreciate the opportunity to further educate members of the New York State Senate on our efforts to advance patient safety.

In order to fully appreciate the advances in anesthesia safety, one should begin by recognizing the risks involved in anesthesia just forty years ago. From the 1950's through 1970's, reports estimated that anesthesia care caused a mortality rate of 1-2/ 10,000 anesthetics. Further, anesthesiologists constituted 3 percent of physicians and generated 3 percent of the malpractice claims, but those claims accounted for a disproportionately high 12 percent of medical liability insurance payout.

Coupled with national media attention on the risks of anesthesia, ASA undertook a massive effort in the late 1970's to improve the anesthetic mortality rate by determining the cause of adverse anesthesia-related outcomes and focusing on ways to avoid such causes.

In the early 1980's important advances in technology became available. Electronic monitoring that extended the human senses (inspired oxygen measurement, capnography, and pulse oximetry) allowed genuine real-time continuous monitoring of oxygen delivery and patient ventilation and oxygenation. Importantly, in 1989, the Department of Health adopted 10 NYCRR Section 405.13 of the Health Code establishing a statewide uniform standard for the delivery of anesthesia in hospitals and provides, in part [see in particular 405.13(b)(2)(iii) emphasis added]:

(b) *Operation and service delivery.* Policies governing anesthesia services shall be designed to ensure the achievement and maintenance of generally accepted standards of medical practice and patient care.

(1) All anesthesia machines shall be numbered and reports of all equipment inspections and routine maintenance shall be included in the anesthesia service records. Policies and procedures shall be developed and implemented regarding notification of equipment disorders/malfunctions to the director, to the manufacturer and, in accordance with section 405.8 of this Part, to the department.

(2) Written policies regarding anesthesia procedures shall be developed and implemented which shall clearly delineate pre-anesthesia and post-anesthesia responsibilities. These policies shall include, but not be limited to, the following elements:

(i) Pre-anesthesia physical evaluations shall be performed by an individual qualified to administer anesthesia and recorded within 48 hours, prior to surgery.

(ii) Routine checks shall be conducted by the anesthetist prior to every administration of anesthesia to ensure the readiness, availability, cleanliness, sterility when required, and working condition of all equipment used in the administration of anesthetic agents.

(iii) All anesthesia care shall be provided in accordance with accepted standards of practice and shall ensure the safety of the patient during the administration, conduct of and emergence from anesthesia. The following continuous monitoring is required during the administration of general and regional anesthetics. Such continuous monitoring is not required during the administration of anesthetics administered for analgesia or during the administration of local anesthetics unless medically indicated.

(a) An anesthetist shall be continuously present in the operating room throughout the administration and the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care. If there is a documented hazard to the anesthetist which prevents the anesthetist from being continuously present in the operating room, provision must be made for monitoring the patient.

(b) All patients must be attended by the anesthetist during the emergence from anesthesia until they are under the care of qualified post-anesthesia care staff or longer as necessary to meet the patient's needs.

(c) During all anesthetics, the heart sounds and breathing sounds of all patients shall be monitored through the use of a precordial or esophageal stethoscope. Such equipment or superior equipment shall be obtained and utilized by the hospital.

(d) During the administration and conduct of all anesthesia the patient's oxygenation shall be continuously monitored to ensure adequate oxygen concentration in the inspired gas and the blood through the use of a pulse oximeter or superior equipment. During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm.

(e) All patients' ventilation shall be continuously monitored during the conduct of anesthesia. During regional anesthesia, monitored anesthesia care and general anesthesia with a mask, the adequacy of ventilation shall be evaluated through the continual observation of the patient's qualitative clinical signs. For every patient receiving general anesthesia with an endotracheal tube, the quantitative carbon dioxide content of expired gases shall be monitored through the use of endtidal carbon dioxide analysis or superior technology. In all cases where ventilation is controlled by a mechanical ventilator, there shall be in continuous use an alarm that is capable of detecting disconnection of any components of the breathing system.

(f) The patient's circulatory functions shall be continuously monitored during all anesthetics. This monitoring shall include the continuous display of the patient's electrocardiogram, from the beginning of anesthesia until preparation to leave the anesthetizing location, and the evaluation of the patient's blood pressure and heart rate at least every five minutes.

(g) During every administration of anesthesia, there shall be immediately available a means to continuously measure the patient's temperature.

(iv) Intraoperative anesthesia records shall document all pertinent events that occur during the induction, maintenance, and emergence from anesthesia. These pertinent events shall include, but not be limited to, the following: intraoperative abnormalities or complications, blood pressure, pulse, dosage and duration of all anesthetic agents, dosage and duration of other drugs and intravenous fluids, and the administration of blood and blood components. The record shall also document the general condition of the patient.

(v) With respect to inpatients a post-anesthetic follow-up evaluation and report by the individual who administered the anesthesia or by an individual qualified to administer anesthesia shall be written not less than three or more than 48 hours after surgery and shall note the presence or absence of anesthesia related abnormalities or complications, and shall evaluate the patient for proper anesthesia recovery and shall document the general condition of the patient.

(vi) With respect to outpatients, a post-anesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff shall be documented for each patient prior to hospital discharge.

(3) Safety precautions shall be clearly identified in written policies and procedures specific to the department and include, but not be limited to:

- (i) safety regulations posted;
- (ii) routine inspection and maintenance of equipment;
- (iii) use and maintenance of shockproof equipment;
- (iv) proper grounding; and
- (v) infection control.

During the 1980's, other engineering advances made anesthesia delivery systems safer, such as gas ratio protection that prevented accidental shut off of oxygen flow. The Food and Drug Administration anesthesia machine checkout protocol was developed and widely adopted. Improvements in anesthesia medications afforded more specific and controllable pharmacological actions and fewer dangerous side effects.

In 1984, ASA President E. C. Pierce, Jr., MD, created a new ASA standing committee on Safety and Risk Management, emphasizing the need to address the causes of patient injury. That same year, Dr. Pierce and Harvard colleagues convened the International Symposium on the Prevention of Anesthesia Mortality and Morbidity, which constituted the first organized examination of what was soon to be known as "anesthesia patient safety."

However, two of ASA's most significant contributions to patient safety occurred the following year- the creation of the Anesthesia Patient Safety Foundation (APSF) and the Closed Claims Project. By creating APSF, ASA became the first medical organization to create a foundation to focus on patient safety. APSF is a nonprofit corporation representing the anesthesia provider community, equipment manufacturers, insurers and other stakeholders. The sole purpose of APSF is to raise the levels of consciousness and knowledge of anesthesia safety issues through fostered research and publication of extensive patient safety materials in a variety of media. ASA's contributions were recognized in the Agency for Health Research and Quality's study, "Making Health Care Safer: A Critical Analysis of Patient Safety":

“The American Society of Anesthesiologists (ASA), for example, formed the Anesthesia Patient Safety Foundation in 1984 and has since promulgated a number of reforms that have substantially changed the routine practice of anesthesia.... While no evidence directly links the initiatives to improved patient safety, there is little doubt that these reforms resulted in substantial advances. In fact, the standards of care promoted by the ASA have been widely adopted and now represent the recognized minimum level of appropriate care.”ⁱⁱ

ASA’s Closed Claims Project began under the auspices of ASA’s Committee on Professional Liability. At the time the project was initiated, it became increasingly difficult for anesthesiologists to obtain professional liability insurance. The goal was to identify causes of loss, improve patient safety, and thereby relieve the insurance problem for anesthesiologists. Since the project’s creation, ASA has worked in cooperation with the nation’s professional liability insurers to analyze closed claims related to adverse anesthesia incidents in an effort to determine the causes of those incidents. Today, professional liability carriers insuring approximately one-half of all practicing anesthesiologists provide anonymous, closed-claims files for study, and specially trained volunteer members of our Society examine and develop analytical data for each file. The data is compiled over extended periods of time, and the results are then published in scientific journals for use by all concerned. The data developed by this method are extremely reliable and have contributed directly to the success achieved by the specialty in reducing the anesthesia mortality rate.

ASA’s Closed Claims Project continues to receive national attention. In 2005, The Joint Commission (TJC) issued a white paper titled, “Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury.” In the report, TJC commends ASA’s leadership role in advancing patient safety:

“One of health care’s principal patient safety success stories is anesthesiology. The American Society of Anesthesiologists uses case analysis to identify liability risk areas, monitor trends in patient injury, and design strategies for prevention. Today, the ASA Closed Claims Project – created in 1985 – contains 6,448 closed insurance claims.ⁱⁱⁱ Analyses of these claims have, for example, revealed patterns in patient injury in the use of regional anesthesia, in the placement of central venous catheters, and in chronic pain management. Results of these analyses are published in the professional literature to aid practitioner learning and promote changes in practices that improve safety and reduce liability exposure.”^{iv}

The research work of APSF dovetails with the even broader research effort supported by the Foundation for Anesthesia Education and Research (FAER), which was formed by ASA in 1986 and today continues to be supported by ASA, many of its component societies and a number of pharmaceutical companies and anesthesia equipment manufacturers. FAER’s mission is to raise the standards of the specialty by fostering education, research and scientific progress in anesthesiology. More than 300 research grants have been awarded by FAER since its inception. In 2009, donor contributions funded research projects that will investigate a wide range of anesthesia-related topics, from exploring how morphine tolerance develops at different ages to using optogenetics to study the neural correlates of consciousness. ASA contributes more than \$1 million annually to this undertaking.

ASA also has been engaged since the 1980s in an intense program to develop anesthesia-related practice parameters. Minimum clinical practice standards, which must be adhered to by all providers, have been published in the areas of preanesthesia care, intraoperative monitoring and postanesthesia care. Evidence-based practice guidelines have been developed on such subjects as management of the difficult airway, obstetrical anesthesia, preoperative fasting, pulmonary artery catheterization and sedation and analgesia.

ASA has produced a series of 30 patient safety videotapes for use in anesthesiology residency programs and institutional continuing education programs. In October 1999, ASA's House of Delegates adopted comprehensive guidelines for office-based anesthesia, and since then, ASA has convened both an informational conference and an advocacy workshop oriented toward the development of state regulations for office-based procedures. ASA participated in a task force jointly sponsored by the American Medical Association and the American College of Surgeons, the result of which has been to establish and advocate agreed safety-oriented guidelines for office-based surgery. These guidelines serve as a model for many state office-based regulations.

ASA also is one of six national health care organizations that joined together to promote the adoption of the Joint Commission on Accreditation of Healthcare Organizations' Universal Protocol for preventing wrong-site surgery errors in U.S. hospitals. Since 2004, all Joint Commission-accredited hospitals, ambulatory care and office-based surgery facilities are required to take a "time out" before a surgery begins. The "time out" is a final step before a surgical procedure to verify that the correct procedure will be performed on the correct patient. The "time out" is one of several requirements of the Universal Protocol that applies to millions of surgeries performed annually.

ASA's contributions continue to receive national recognition. In 2005, an article in *The Wall Street Journal*, "*Once Seen as Risky, One Group of Doctors Changes Its Ways. Anesthesiologists Now Offer Model of How to Improve Safety, Lower Premiums,*" remarked that:

"A 1999 report by the Institute of Medicine noted that 'few professional societies or groups have demonstrated a visible commitment to reducing errors in health care and improving patient safety with one exception: anesthesiologists...'"

"If there were any specialty where you said, 'Show me who has done anything right,' I would point to the anesthesiologists... They have really made some inroads and impact."

"All this has helped save lives. Over the past two decades, patient deaths due to anesthesia have declined to one per 200,000 to 300,000 cases from one for every 5,000 cases..."^v

With all of these improvements, ASA remains committed to further improving anesthesia safety. Most recently, the ASA House of Delegates created the Anesthesia Quality Institute (AQI) in 2008. The AQI was created to expand its focus on patient health and safety by fostering advances in quality of care measurement that lead to improvements in the delivery of anesthesia medical care. The mission of the AQI is to "develop and maintain an ongoing registry of case data that helps anesthesiologists assess and improve patient care. Organize the registry so that

anesthesiology practice groups desire to submit their case information, and so that individual anesthesiologists, practice groups, researchers, and professional societies find the data useful for improving the quality of care.”^{vi}

The eventual goal is to provide a resource for anesthesiologists to obtain patient safety and quality management data and to meet regulatory requirements designed to improve patient care. AQI data will be useful for activities ranging from faculty education to outcomes measurement to emerging federal efforts to ensure performance improvement.

Although each of these initiatives has contributed significantly to reducing adverse events, ASA submits that it is truly the synergy created by the interaction of these efforts — together with the introduction of improved anesthesia equipment and the increasing number of superbly trained anesthesiologists entering the medical marketplace — that represents the touchstone of the specialty’s unique success in this area.

PART II **RELATIONSHIP BETWEEN MALPRACTICE LITIGATION AND HUMAN ERRORS**

Please see attached copy of an article entitled “Relationship between Malpractice Litigation and Human Errors” by Steve D. Edbril, M.D., and Robert S. Lagasse, M.D., from Anesthesiology 1999; 91:848-55.

ⁱ Institute of Medicine (IOM). (1999). *To err is human: Building a safer health system* (p. 124-125, 142). Washington, DC: National Academy Press.

ⁱⁱ Agency for Health Research and Quality. (2001). *Making Health Care Safer: A Critical Analysis of Patient Safety* (p. 610). Rockville, Maryland.

ⁱⁱⁱ As of 2009, the project consists of an in-depth investigation of 8954 closed insurance claims. For additional information, see <http://depts.washington.edu/asaccp/ASA/index.shtml>.

^{iv} The Joint Commission on Accreditation of Healthcare Organizations. (2005). *Healthcare at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury*. Retrieved at http://www.jointcommission.org/NR/rdonlyres/167DD821-A395-48FD-87F9-6AB12BCACB0F/0/Medical_Liability.pdf

^v Joseph T. Hallinan, *Once Seen as Risky, One Group of Doctors Changes Its Ways. Anesthesiologists Now Offer Model of How to Improve Safety, Lower Premiums*. The Wall Street Journal. June 21, 2005. Page A1.

^{vi} <http://www.aqihq.org/Introduction.aspx>