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COMPETITION AND SAFETY IN THE DELIVERY OF ANESTHESIA SERVICES

HEARING

BEFORE THE

SUBCOMMITTEE ON ANTITRUST, BUSINESS RIGHTS, AND COMPETITION

OF THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

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COMPETITION AND SAFETY IN THE DELIVERY OF ANESTHESIA SERVICES

WEDNESDAY, JUNE 7, 2000

U.S. SENATE,
SUBCOMMITTEE ON ANTITRUST, BUSINESS RIGHTS,
AND COMPETITION,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The committee met, pursuant to notice, at 2:03 p.m., in room SD–226, Dirksen Senate Office Building, Hon. Mike DeWine (chairman of the subcommittee) presiding.

Also present: Senator Specter.

OPENING STATEMENT OF HON. MIKE DeWINE, A U.S. SENATOR FROM THE STATE OF OHIO

Senator DEWINE. Good afternoon. Welcome to the Judiciary Committee, Subcommittee on Antitrust, Business Rights, and Competition, for today's hearing on competition and safety in the delivery of anesthesia services.

As many of you know, for several years, a controversy has been brewing about the standards and the rules that guide the delivery of anesthesia services to Medicare patients. The physician community, for the most part, has argued that safe administration of anesthesia requires advanced and specialized medical education and that anesthesia services should either be provided by or supervised by an anesthesiologist or other medical doctor. This position has been opposed by many Certified Registered Nurse Anesthetists, known as CRNA's, who argue that the CRNA's are perfectly capable of providing safe and effective services and, in fact, already provide such services, especially in rural areas.

In a nutshell, the doctors argue that this is a safety issue. The CRNA's believe that doctors are using the safety argument to limit competition in the provision of anesthesia services and exclude them from the market.

This type of dispute commonly arises when rules and standards are being formulated or changed. From an antitrust point of view, it is difficult to resolve these disputes, but basically it comes down to whether the standards are, in fact, reasonable. Reasonable standards assure quality, increase consumer confidence, and allow an industry to grow freely.

On the other hand, unreasonable standards or standards that are not related to product quality can harm consumers by excluding products or services that consumers might otherwise choose. The analysis of any particular set of standards and whether they

are appropriate is, of course, dependent on the specific structure of the industry and must be done on a case-by-case basis.

Now, in this particular instance, the standards at issue have been in place since 1966, when HCFA imposed a minimum standard of care for delivery of anesthesia to Medicare patients, specifically, that anesthesia delivery must be supervised by a physician. In 1992, HCFA issued a proposed rule which, among other things, restated that anesthesia administered by a CRNA must be done under the supervision of the operating practitioner or an anesthesiologist. In fact, HCFA specifically found, "we do not believe it would be practical to adopt as a national minimum standard for care a practice that is allowed in only some States. . . . In view of the lack of definitive clinical studies on this issue and in consideration of the risk associated with anesthesia procedures, we believe it would not be appropriate to allow anesthesia administration by non-physician anesthetists unless under supervision by either an anesthesiologist or the operating practitioner."

In December 1997, however, HCFA issued a proposed rule that would eliminate the physician supervision requirement for CRNA's. HCFA acknowledged that there has been no new studies comparing outcomes between patients who have received doctor-supervised anesthesia versus those who received anesthesia without the supervision of a doctor. Instead, the rationale offered for the proposed rule was essentially that HCFA is interested in decreasing regulatory requirements and increasing State flexibility. HCFA argues that anesthesia regulations are an appropriate area to do so, given that the anesthesia-related death rate is extremely low.

Again, this proposal has generated a great deal of controversy. The CRNA's are supporting the rule change as a long overdue correction to the market which will allow them to compete fairly and freely against the anesthesiologists. The anesthesiologists consider the proposal to be a medical mistake which will imperil the safety of patients.

Now, personally, although I am generally in favor of deregulation wherever possible, I am concerned about this proposed rule and I have already publicly stated this. It is always difficult to determine whether standards are being used for anticompetitive purposes or if they are useful and reasonable regulations for a particular industry. It is particularly difficult and important in the medical field, where the lives of the patients are at stake.

Accordingly, before making changes to medical regulations, I think it is incumbent upon the Federal government to be as certain as possible that changes will not harm patient care. In this instance, HCFA has, in my opinion, failed to take the required steps. HCFA is considering changing the Federal requirement for physician supervision of anesthesia delivery without having conducted a comparative outcome study to determine whether removing the physician supervision requirement will have a negative impact on the health and safety of Medicare patients.

In order to ensure against any premature change to the current Federal standard, I have introduced a bill, along with Senator Harry Reid, to require that the Secretary of Health and Human Services conduct a comparative outcomes study on the impact of

physician supervision on the mortality and adverse outcome rates of Medicare patients related to the provision of anesthesia services.

Now, despite my concerns about the proposed rule, I understand that many CRNA's believe that the rule change is long overdue and that the CRNA's themselves have been critical of those in the physician community who have been fighting the proposed rule. I think that today's hearing is a good opportunity to hear from both sides of this very controversial and also very important issue.

Accordingly, we will be receiving testimony from four witnesses today, two who support the proposed rule, one who opposes it, and one witness who will describe the most recent outcomes study in this area. That study is a potentially important part of this debate and we look forward to exploring it today. More generally, this hearing will be a good opportunity to discuss with our witnesses whether this proposed rule is best looked at from the perspective of safety, competition, or both.

Let me turn at this point to my colleague from Pennsylvania for an opening statement, Senator Specter.

Senator Specter.

STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SPECTER. Thank you, Mr. Chairman. The issue as I see it is whether there ought to be Federal control or State control, just that direct and that simple. My background comes from living in a city of two million, somewhat reduced now, and living in a town of 5,000, Russell, KS, and I know that the availability of anesthesiologists is very different in downtown Philadelphia as opposed to downtown Russell. When this issue has come before the Subcommittee on Labor, Health, Human Services, and Education, that has been the perspective that I have brought to it.

There is no doubt that there is a very high-powered, high-cost lobbying battle going on between the respective parties here and it is not a very pretty situation, in my opinion. I am not going to get involved in it beyond that point.

I have a little hard time understanding, candidly, the antitrust jurisdiction on this matter. If we are considering legislation for additional studies, that is a matter for the subcommittee which I chair or the Labor and Health Committee which Senator Jeffords chairs. Again, I do not want to get into a turf battle here, but I am searching for antitrust implications on this issue. I have been on this Antitrust Subcommittee for a long time and have had some experience in litigation in antitrust matters and I am a little lost as to a jurisdictional basis here.

I have had an open door to talk to anybody who wanted to come see me about this matter, and I was urged to talk to Dr. Silber, which I did. I met with Dr. Silber at the 30th Street Station in Philadelphia. It saves a constituent a day of travel and $200 in train fair if the Senator is going to meet him at the train station as opposed to meeting him in a corridor in a Senate office building. I talked to Dr. Silber about his approach, and I understand the gravamen and thrust of Dr. Silber's approach is that direction is better than supervision. I see an affirmative nod, may the record show. And directions when the anesthesiologist is there all the

time as opposed to supervision, when there may be four people that he is looking after who may be attended by someone else.

The standard which HCFA currently has does not deal with the issue of direction versus supervision. The standard that HCFA has really talks only about supervision. Dr. Silber would like to have direction. I can understand why. When I am subject to operative procedures, I would like to have direction, myself.

I would like to see the highest standards applied everywhere, but it is a question as to who is to make the decision. There are just very, very different considerations that operate out of Topeka, KS, the State capital of Kansas, and Harrisburg, PA, the State capital of my State now.

When the issue has arisen as to what the Secretary of HHS ought to do, this is what the Labor-HHS report says. "The committee urges the Secretary to base retaining or changing the current requirement of physician supervision of anesthesia services in Medicare on scientifically valid outcomes data," so that what the subcommittee which I chair has talked about is scientific data. That is what we are looking at.

This is not the first issue to come to Capitol Hill in which there are proposals for studies and re-studies and re-re-studies. The process will take its course. But I think when you strip it all down, it is a question of whether there are differences among the States and whether our Federal system is going to be respected, and it is not just a matter of States' rights as a generalization and as a platitude, it is a matter of whether there are real differences between rural areas and big city areas and how you can provide the best kind of care for patients in circumstances which differ very, very widely. Thank you, Mr. Chairman.

Senator DEWINE. I appreciate my colleague from Pennsylvania's comments, and I understand his concern about jurisdiction. I would say this, though, that the full title of this subcommittee, as my colleague well knows from his many years of service here, is Antitrust, Business Rights, and Competition. We have in the last few years looked at a number of different issues, everything from college football to aviation to telecommunications, et cetera, and any one of those hearings could have probably been handled in another subcommittee, which probably had concurrent jurisdiction. I do not know that there is anything this subcommittee ever deals with where, without too much of a stretch of the imagination, we could have concurrent jurisdiction with another committee.

I think it is interesting that in this case, the CRNA community has made this an issue of competition and I think that is what it does boil down to. It is a balancing test. We look at many things here, but clearly, the issue of competition has been raised and, therefore, it is a legitimate issue for this subcommittee. I think anytime further that we are examining and reexamining rules and standards that regulate a profession, those rules and regulations need to be examined to discover whether they are reasonable regulation of the industry or inappropriate rules that unfairly exclude competitors. And so again we get back to the area of competition.

At this point, I would like to include in the record a statement from Senator Strom Thurmond.

[The prepared statement of Senator Thurmond follows:]

PREPARED STATEMENT OF HON. STROM THURMOND, A U.S. SENATOR FROM THE STATE OF SOUTH CAROLINA

Mr. Chairman, I am pleased that the Subcommittee is holding this hearing on competition and safety issues surrounding the delivery of anesthesia services.

Under current policy, the Health Care Finance Administration ("HCFA") requires Medicare patients receiving anesthesia to have a medical doctor present while the anesthesia is being delivered. Now, despite the lack of any new information that would support a change from the established practice, HCFA is preparing to abolish the requirement that physicians supervise the administration of anesthesia.

The many medical doctors who choose to specialize in anesthesiology play an important role in patient care. While I am sensitive to the need for increased competition as a means to lower the spiraling costs of health care, we must be very cautious in reducing the safeguards on patient care. I am further concerned that if Medicare no longer deems the services of anesthesiologists to be necessary, the door would be open for Medicare to start denying payments for anesthesiologists even in cases where the services of an anesthesiologist are manifestly warranted.

One recently completed study at the University of Pennsylvania, which will be published this summer in a peer-reviewed scientific journal, raises concern. It suggests that where an anesthesiologist is not involved in the medication of a patient, there are 2.5 excess deaths per thousand Medicare general surgical and orthopedic cases without complications. The study also states that when there are post-operative complications, the lack of involvement by an anesthesiologist may contribute to as many as 6.9 excess deaths per thousand patients.

I believe further study is needed regarding this matter before any major policy changes are made. S. 818, the Safe Seniors Assurance Study Act of 1999, would require the Secretary of Health and Human Services to study the wisdom of a proposal to change the minimum level of care Medicare patients should expect in receiving anesthesia. I believe this legislation is a reasonable approach at the present time.

Senator DEWINE. Let me introduce our panel, beginning on my left. Dr. Michael Fallacaro is a Certified Registered Nurse Anesthetist, a Doctor of Nursing Science, and the Chair of the Department of Nurses at Virginia Commonwealth University.

Dr. Ellison Pierce is the Executive Director and Past President of the Anesthesia Patient Safety Foundation. He was Chair of the New England Deaconess Hospital Department from 1972 to 1996 and also has served as Past President of the American Society of Anesthesiologists.

Dr. Jeffrey Silber is Director of the Center for Outcomes Research at the Children's Hospital of Philadelphia, Associate Professor of Pediatrics and Anesthesia at the University of Pennsylvania School of Medicine.

Jan Stewart is a Certified Registered Nurse Anesthetist and Advanced Registered Nurse Practitioner and is the 1999–2000 President of the American Association of Nurse Anesthetists.

We welcome all of you. We look forward to the testimony this afternoon. Doctor, we will start with you. Thank you for joining us. We are going to set the time limit here at 5 minutes. We will not be too strict about that. We would like for you to keep your comments within the 5 minutes if you could and then that will give us more time for questions. If you go over a few minutes, a couple minutes, that is okay. Your written statements, which we have received and we appreciate very much, will now become a part of the record.

Doctor, thank you.

PANEL CONSISTING OF MICHAEL D. FALLACARO, PROFESSOR AND CHAIR, DEPARTMENT OF NURSE ANESTHESIA, VIRGINIA COMMONWEALTH UNIVERSITY, RICHMOND, VA; ELLISON C. PIERCE, JR., M.D., EXECUTIVE DIRECTOR, ANESTHESIA PATIENT SAFETY FOUNDATION, BOSTON, MA; JEFFREY H. SILBER, M.D., DIRECTOR, CENTER FOR OUTCOMES RESEARCH, THE CHILDREN'S HOSPITAL OF PHILADELPHIA, PHILADELPHIA, PA; AND JAN STEWART, PRESIDENT, AMERICAN ASSOCIATION OF NURSE ANESTHETISTS, SEATTLE, WA

STATEMENT OF MICHAEL D. FALLACARO

Mr. FALLACARO. Thank you very much. Chairman DeWine, Honorable Senators of the committee, their staffs, presenters, and guests, I am Michael Fallacaro, CRNA, Doctor of Nursing Science, Professor and Chair of the Department of Nurse Anesthesia at Virginia Commonwealth University. I appreciate the opportunity to address this committee relative to nurse anesthesia education, its past, its present, and its future. Nurse anesthetists take great pride in our history, our education, our practice, and our contributions to the field of anesthesiology.

It has been well over 100 years, dating back to the late 1870's, that surgeons began to invite nurses to come to their hospitals. These surgeons believed that the establishment of a nursing specialty in the field of anesthesia would resolve the problems of high mortality rates they associated with the occasional anesthetist, a physician, a nurse, a medical student, or anyone who happened to be free when surgery was attempted. Nurses responded to that call, and by 1914, four nurse anesthesia educational programs were in existence.

Prior to World War I, the U.S. Army and Navy sent nurses to notable surgical and anesthesia centers for preparation as anesthetists to meet projected military needs. Nurse anesthetists gained a remarkable reputation for their service in World War I. In fact, they have been called to service in far greater numbers than any other anesthesia provider in every war or conflict this Nation has endured in the 20th century.

In 1931, our national association, the American Association of Nurse Anesthetists, was founded with the primary objective to assure the educational quality of nurses who would provide much of the anesthesia services in this country.

As science and technology advanced, affecting the field of anesthesiology, the educational standards and admission requirements for these programs accommodated such changes. From the 1970's onward, nurse anesthesia education has progressively moved from hospital-based certificate programs to university hospital cooperative programs at the baccalaureate level until 1998, when all accredited nurse anesthesia programs had to be at the graduate level, 24 to 36 months in length, offering at least a Master of Science degree.

The typical applicant to the nurse anesthesia program I chair at Virginia Commonwealth University is 32 years of age. They must be a registered nurse, possessing an undergraduate degree in science with a superior grade point average and high scores on the National Graduate Record examinations. Additionally, our appli-

cants average at least 3 years of critical care hands-on nursing experience. We choose only the best applicants, having far more applications than we can accommodate.

Once enrolled, the graduate students enter a rigorous 72-credit hour, seven-semester program of study. Course work includes advanced physiology, medicinal chemistry, advanced pharmacology, pathophysiology, a research core, extensive principles of anesthesia, and a demanding clinical practicum. The Council on Accreditation of Nurse Anesthesia Educational Programs accredits our programs and our graduates must write the national certification exam administered by the Council on Certification of Nurse Anesthetists. Both of these councils are autonomous bodies, nationally recognized by appropriate government and civilian groups.

In total, most certified registered nurse anesthetists will have spent near 10 years overall in preparation for practice. Despite the lengthy education of both CRNA's and physician anesthesiologists, length of education is never the guarantee for competence or quality. We must look to learner outcomes and their capabilities and performance in positions for which they are prepared. CRNA's score very high in that regard.

Graduates of our programs are prepared to practice as full-service anesthesia providers, working with and without anesthesiologists. Today, you will find a single nurse anesthetist serving as the sole provider of anesthesia on isolated military missions, such as Kosovo and Macedonia, and routinely on naval aircraft carriers and isolated bases, such as Reykjavik, Iceland, with no anesthesiologist present. Further, such competence is imperative because CRNA's are the sole providers in close to one-third of America's hospitals, as well as the majority of rural hospitals.

Anesthesia is now safer than it has ever been. Better education for both CRNA's and anesthesiology residents may be one of the causes. However, the most important factor, as many credible providers will confirm, are the advances in science and technology that have brought us better drugs, equipment, monitoring capability, better surgeons and less-invasive surgical techniques.

Regardless of why, the fact is, St. Paul Insurance Company, which is the Nation's largest provider of liability insurance for health care professionals, has reported that from 1988 to 1998, nurse anesthetists' liability premiums decreased across the country by a full 52 percent, demonstrating the high quality of care provided by CRNA's is recognized and fully appreciated by the insurance industry, as well.

Despite the opinion of the American Society of Anesthesiologists and the American Medical Association, anesthesia is not the exclusive practice of medicine or any one discipline. Anesthesia is a body of knowledge unto itself and is taught as such, an art grounded in science. It is far more accurate to state that it is within the scope of practice of a physician, a nurse, a dentist, a podiatrist, or whoever to deliver anesthesia so long as they have been properly educated and certified to do so.

I would like to close by saying, God forbid you or any of your loved ones should ever need surgery or anesthesia. However, if a need arises, I would like to assure you that research has proven anesthesia care safe and I now stand at the ready, along with over

28,000 of this Nation's enlightened CRNA's, to answer your call, and thank you.

Senator DEWINE. Doctor, thank you very much.

[The prepared statement of Mr. Fallacaro follows:]

PREPARED STATEMENT OF MICHAEL D. FALLACARO, DNS, CRNA

My name is Michael D. Fallacaro. I am a certified registered nurse anesthetist (CRNA), Doctor of Nursing Science, Professor and Chair of the Department of Nurse Anesthesia at Virginia Commonwealth University. I appreciate the opportunity to offer my testimony to this committee regarding nurse anesthesia education and preparation, and how that translates into high quality health care for patients across the country. Nurse anesthetists take great pride in our history, our education, our practice, our contributions to the field of anesthesia, and our national association, the American Association of Nurse Anesthetists (AANA).

HISTORY OF THE EDUCATION AND PROFESSION OF NURSE ANESTHESIA

It was well over one-hundred years, dating back to the late 1870's, when surgeons began to invite nurses to come to their hospitals, learn how and provide anesthesia services for the purpose of enhancing the safety of anesthesia for their patients. These surgeons believed that the establishment of a nursing specialty in the field of anesthesia would resolve the problems of high mortality rates they associated with the occasional anesthetist—a physician, nurse, medical student, or anyone who happened to be free. Nurses responded to that call, and surgeons, both in their laboratories and the operating rooms taught the first nurses to become anesthetists.

Initially, the need for anesthetists was so great, that some of the more notable teams of surgeons and nurse anesthetists trained other nurses, physicians, and dentists in short courses of a few weeks or months. By 1909, the need for formalized nurse anesthesia educational programs was evident. By 1914, four such programs, each approximately six months in length, were in existence. These programs included both academic and clinical courses and were built on the applicable science known at the time. Their nurse applicants were graduates of professional nursing education programs. They usually had a few years of nursing experience, and held a nursing license or registration from the state. Both physicians and nurse anesthetists served as instructors in the academic and clinical portions of these programs.

Prior to World War I, the U.S. Army and Navy sent nurses to these notable centers to be prepared as anesthetists based on projected military needs. Many nurse anesthetists signed up with the Red Cross, becoming Army or Navy nurses and accompanying these units to Europe. Nurse anesthetists gained a remarkable reputation for their service in WWI. They also trained other nurses and physicians as anesthetists in British and French hospitals during that war. World War I served as a major impetus to increase the number of educational programs for nurse anesthetists in the U.S., and programs were developed in numerous major hospitals and medical centers.

At this time, there were a few physician anesthetists who devoted their full practice to anesthesia. However, AMA did not recognize the anesthesiology medical specialty until 1940, about a half century after the nurse anesthesia specialty was formalized. At that time there were only 285 anesthesiologists devoting their full practice to the field. Of these only about 33% were certified in the specialty. Further, there were only 7 anesthesiology residencies of at least a year in length at the beginning of World War II. According to a noted hospital historian, there were 17 qualified nurse anesthetists for every one anesthesiologist in 1942.

During the war, the military also undertook to prepare both physician and nurse anesthetists to meet their needs. While the war-time physician training program in the Army was four-five months in length, according to Dr. Robert B. Dodd, an anesthesiologist who had taken such training, the Army Nurse Corps configured their nurse anesthesia education program to meet the AANA's curricular standards when and where possible. These were six months in length. The Army prepared about 2,000 nurse anesthetists during World War II, including four Army nurse anesthetists who spent three years as POWs after the attack on the Philippines. There were no anesthesiologists stationed in the Philippines at that time. Put simply, CRNA's have been an integral part of the nation's armed forces and tend to be the predominant anesthesia provider in combat situations.

EDUCATIONAL STANDARDS HAVE BEEN CONSISTENTLY HIGH

One of the primary aims for AANA upon its founding in 1931 was to assure the educational quality of nurses who would provide much of the anesthesia services in this country. Setting standards for the educational programs and developing a program approval system were the first critical undertakings of the AANA. During World War II, the AANA moved forward with its plans to develop an accreditation process for nurse anesthesia educational programs, and a national certification examination for nurse anesthetists. The first certification examination was given in 1945. A more formalized nurse anesthesia education accreditation program was developed and implemented in 1955. As science and technology advanced affecting the field of anesthesiology, the educational standards for these programs changed to accommodate such changes, as did admission requirements.

In addition to expanding the academic component, the clinical program was also expanded, growing to one year in length in the 1950s, expanded to 18 months in the 1960s, and in 1970, it was mandated that the programs be at least 24 months in length. Like anesthesiology residencies, most of the nurse anesthesia programs during this period were hospital based. Many nurse anesthesia educational programs co-existed with anesthesiology residency programs, using the same textbooks, and attending many of the same classes. This co-existence of nurse anesthesia education and anesthesiology residency training came about despite the American Society of Anesthesiologists adopting an ethical code stating that anesthesiologists that participated in the education and practice of nurse anesthetists were in violation of the ASA code of ethics.

The first graduate program to prepare nurse anesthetists within a University setting was initiated in 1969, awarding graduates of that program masters degrees and eligibility for certification. From the 1970s up to today, nurse anesthesia education has progressively moved from hospital-based certificate programs to University-Hospital cooperative programs at the baccalaureate level, until 1998, when all accredited nurse anesthesia programs had to be at the graduate level, offering at least a Master's degree.

A growing number of our programs have their own, or have access to anesthesia and critical care simulators where students can gain experience through simulation prior to entering the operating room and learning on actual patients. As educational technology changes the profession continues to make adjustments based on their value for application to our particular field, just as we modify the basic and advanced curriculum based on changes in the science and technology.

Today's graduate nurse anesthesia programs range from 24 to 36 months in length, depending upon the university. The typical applicant to the nurse anesthesia program is approximately 32 years of age, they must be a registered nurse possessing an undergraduate degree in science with a superior grade point average and must have scored well in the national graduate record examination. Additionally, applicants must possess at least one year of critical care hands-on professional nursing experience. Gaining admission to a nurse anesthesia program is difficult; many apply but acceptances are reserved for only the best and brightest. Once enrolled, graduate students enter a rigorous full-time program of study. Coursework includes Advanced Physiology, Medicinal Chemistry, Advanced Pharmacology, Pathophysiology, a research core, extensive Principles of Anesthesia content and a demanding Clinical Practicum. The anesthesia portion of the education for nurse anesthetists is very similar to the anesthesia education received by physician anesthesiologists.

But here is one difference between nurse anesthetists and anesthesiologists. Upon successful completion of study, nurse anesthetists graduates must pass a national certification examination administered by the Council on Certification of Nurse Anesthetists, an autonomous body recognized by the U.S. Department of Education. They must be recertified every two years thereafter in order to continue practicing the profession of anesthesia. It is my understanding that board certification is not required for anesthesiologists.

In total, most CRNAs will have spent nearly 10 years in preparation when one considers undergraduate work, critical nursing experience and up to 3 years of graduate nurse anesthesia study. Even in light of the substantial time commitment in CRNA education preparation, we must all be careful not to necessarily equate competency or quality of any provider with the duration in years of their preparation alone. Instead we should judge educational preparation in terms of the quality of the time spent in study and outcomes of such preparation, which for nurse anesthetists have been measured and continue to be exemplary.

Our educational programs are conducted utilizing university faculty, nurse anesthetists, basic and applied scientists, pharmacologists, physicians (including anes-

thesiologists), and others. Clinical instruction of students is performed by both CRNAs and anesthesiologists. AANA has had four autonomous credentialing Councils since the mid-1970's—Accreditation, Certification, Recertification, and one for Public Interest that also serves as the appellate body for the other Councils. These are multidisciplinary Councils, including members of the CRNA communities of interests. They include CRNAs, hospital administrators, anesthesiologists, surgeons, students, and public members. They are fully compliant with national standards promulgated by federal and civilian oversight/recognition organizations, both federal and civilian. Their credentials are accepted by State Boards of Nursing in recognizing CRNAs as advanced practice nurses. The National Council of State Boards of Nursing has evaluated our examination and certification process and deemed it psychometrically credible.

NURSE ANESTHETISTS PROVIDE HIGH QUALITY, SAFE ANESTHESIA

Graduates of our programs are prepared to practice as full service anesthesia providers, working with and without anesthesiologists. This is imperative because CRNAs are the sole anesthesia providers in close to ⅓ of America's hospitals—as well as in a majority of rural hospitals. We must prepare them well, to meet the needs of the American people wherever they live.

The U.S. military has long recognized the superior education and the quality of care that nurse anesthetists provide. Nurse anesthetists have gained a remarkable reputation for their service in every war and conflict the United States has participated since World War I. In fact they have been called to service in far greater numbers than any other anesthesia provider in every war or conflict this nation has ever endured. Today you will find a single nurse anesthetist serving as the sole provider of anesthesia on isolated missions such as Kosovo and Macedonia, with no anesthesiologists present. Nurse anesthetists routinely work alone on aircraft carriers and on isolated bases such as Reykjavik, Iceland. The reputation of CRNAs in the military is undisputed.

Anesthesia is now safer then it has ever been. In the past 20 years we have seen dramatic improvements in both CRNA and anesthesiologist educational preparation. We have experienced an explosion in advanced patient monitoring technology giving us vital moment-to-moment physiologic information. Our pharmaceutical industry has equipped providers with far safer therapeutics. Additionally, nursing care, preventative health care, and patient education have all contributed to safer outcomes. The fact is, that anesthesia has gotten increasingly safer over the years. In fact, St. Paul Insurance Company, which is the nation's largest provider of liability insurance for healthcare professionals (both CRNAs and anesthesiologists included) has reported that from 1988 to 1998, nurse anesthetists liability premiums decreased across the country by a full 52 percent, which demonstrates the high quality of care and safety record provided by CRNAs recognized and fully appreciated by the insurance industry as well.

Despite the opinion of the American Society of Anesthesiologists and American Medical Association, anesthesia, is not the exclusive practice of medicine or any one discipline. Anesthesia is a body of knowledge unto itself and is taught as such "an art, grounded in science." It is far more accurate to state that it is within the scope of practice of physicians, nurses, dentists, podiatrists, etc. . . . to deliver anesthesia care so long as they have been properly educated and certified.

CONCLUSION

Our aim, as it has always been is to prepare highly qualified nurse anesthetists capable of meeting America's needs for anesthesia service. However, we would like to assure you that research has proven anesthesia care is safe regardless of whether a CRNA or anesthesiologist administers it. CRNAs have an excellent safety record, and they provide high quality anesthesia care in all types of settings. I hope that you will keep these indisputable facts in mind as you face this controversial issue. I look forward to responding to any questions you may have.

Senator DEWINE. Dr. Pierce.

STATEMENT OF ELLISON C. PIERCE, JR., M.D.

Dr. PIERCE. Mr. Chairman and members of the subcommittee, I am Ellison C. Pierce, Jr., M.D., Executive Director and Past President of the Anesthesia Patient Safety Foundation, APSF. I am also a Past President of the American Society of Anesthesiologists and

still am Associate Professor of Anesthesia at the Harvard Medical School.

APSF is a nonprofit corporation representing the anesthesia provider community, equipment manufacturers, insurers, and other parties concerned with the issue of anesthesia safety. The purpose of APSF is to raise the levels of consciousness and knowledge about anesthesia safety issues, both through fostered research and publication of patient safety materials in a variety of media. The current annual budget of our foundation is approximately $500,000, all of which is dedicated to the dissemination of information designed to improve anesthesia safety and to sponsor research on patient safety issues.

I understand that the subcommittee today is considering the appropriate relationship between competition and safety in the delivery of health care services. Although I think I understand the importance of competition in our economy, I would like principally to discuss the role of private and public regulation in improving patient safety in the anesthesia field. The issue of competition is discussed in ASA's written statement to this hearing, a copy of which I have reviewed.

In December of last year, the Institute of Medicine, in its now very well known report on the incidence of medical errors, repeatedly cited the specialty of anesthesiology as having assumed that patient safety leadership role over the past two decades. This has been the result of an integrated attack by anesthesiologists and others on the root causes of anesthesia-related mortality and morbidity, an effort in which my Anesthesia Patient Safety Foundation has played a very significant part.

In my view, the current anesthesia patient safety campaign was precipitated by a 1982 nationally televised program on anesthesia mishaps entitled, "The Deep Sleep," noting that some 6,000 Americans were dying or suffering brain damage in anesthesia-related incidents each year. Following this broadcast, intense interest developed in the anesthesia community toward making our specialty safer.

At the national level, the American Society of Anesthesiologists in the mid-1980's initiated an integrated effort to attack the problem. It initially formed a Committee on Patient Safety and Risk Management, a step which eventually led to the formation of our foundation as a free-standing organization representing all those interested in the issue.

At about the same time, it developed a program through its closed-claims study to determine the cause of adverse anesthesia incidents. Today, professional liability insurers representing about half the practicing anesthesiologists provide anonymous closed-claims files for study by specially trained volunteer members. Analytical data are compiled over extended periods of time and results are published in scientific journals.

Perhaps the most important purpose of this hearing is the fact that research fostered by APSF and the closed-claims study have led to the development by ASA of a series of practice parameters or standards. In terms of patient safety, the best known of these standards are basic standards for pre-anesthesia care, standards for basic anesthesia monitoring, and standards for post-anesthesia

care. These standards specify the minimal requirements for sound anesthesia practice and require, among other things, that the patient's oxygenation, ventilation, circulation, and temperature should be continually evaluated. In effect, they make use of the pulse oximeter and the capnograph mandatory.

Although the standards are not technically binding on anyone, including ASA members, their existence as national definitions of proper care compel adherence, either because professional liability insurers now require them or because any anesthesia provider not following them would be at severe risk of legal action following an adverse event.

Development of these standards by ASA is certainly anti-competitive in the sense that they constrain anesthesia providers as a practical matter from delivering anesthesia care in some less-demanding and perhaps less-costly manner not using the standards as they wish. In my judgment, these standards are essential to the process by which the specialty of anesthesia has markedly improved its record.

Safety-oriented documents by the ASA House of Delegates also call for medical direction of non-physician members of the anesthesia care team. The medical supervision requirement essentially parallels that of the Medicare standard that I understand now is under significant debate in the Congress.

This association has opposed the proposed elimination of this requirement. In a letter dated February 17, 1998, the foundation executive committee wrote, "A basic tenet of medicine is, first do no harm. Administration of anesthetics is a high-risk activity. Prior to making any change in the existing supervision requirement, the burden of proof must be based on definitive evidence that the change in practice is safe. No such evidence exists. If the proposed rule is enacted in the absence of evidence that the change in practice is safe, HCFA will have set a dangerous precedent by having shifted the burden of proof, in my view, in the wrong direction."

[The letter referred to can be found on page 60 of the Appendix.]

Dr. PIERCE. It is not my purpose here to further draw anesthesia into this debate as to the wisdom of the HCFA proposed change. Even though I personally support your bill, Mr. Chairman, that would require HCFA to undertake a definitive outcome study prior to considering the wisdom of the proposed rule.

I would say, incidentally, that our newsletter and research efforts have been directed over these 15 years equally to nurse anesthetists and anesthesiologists because we have felt very strongly that safety in anesthesia is the responsibility of all providers.

My only point is that regulation, whether public or private, in the name of medical safety should not be constrained by application of the principles of competition and, in my judgment, the true legitimacy in safety terms of the current HCFA restraint can only be established by scientific data not yet in hand. Thank you.

Senator DEWINE. Doctor, thank you very much.

[The prepared statement of Dr. Pierce follows:]

PREPARED STATEMENT OF ELLISON C. PIERCE, JR., M.D.

Mr. Chairman and Members of the Subcommittee, I am Ellison C. Pierce, Jr., M.D., Executive Director, and Past President of the Anesthesia Patient Safety Foundation (APSF). Since 1960, I have been a member of the faculty of the Harvard

Medical School, and from 1972 to 1996, I was chair of the New England Deaconness Hospital Department of Anesthesia. I am also a Past President of the American Society of Anesthesiologists.

Founded in 1986, APSF is a nonprofit corporation representing the anesthesia provider community, equipment manufacturers, insurers and other parties concerned with the issue of anesthesia safety. The purpose of APSF is to raise the levels of consciousness and knowledge about anesthesia safety issues, both through fostered research and publication of patient safety materials in a variety of media. The current annual budget of APSF is approximately $500,000, all of which is dedicated to the dissemination of information designed to improve anesthesia safety and to sponsor research on patient safety issues. APSF is the model, incidentally, upon which the National Patient Safety Foundation—sponsored by the AMA, was organized.

I understand that the Subcommittee today is considering the appropriate relationship between competition and safety in the delivery of health care services. Although I think I understand the importance of competition in our economy, I would like to discuss the role of private and public regulation in improving patient safety in the anesthesia field. The issue of competition is discussed in ASA's written statement to this hearing, a copy of which I have reviewed.

In December of last year, the Institute of Medicine, in its now well-known report on the incidence of medical errors, repeatedly cited the specialty of anesthesiology as having assumed a patient safety leadership role over the past two decades. Although various statistics have been cited to demonstrate the radical improvement in anesthesia safety during this period, the soundness of this conclusion is perhaps best demonstrated by the fact that average anesthesia professional liability insurance premiums have dropped over this period to approximately one-third their levels twenty years ago. This has been the result of an integrated attack by anesthesiologists and others on the root causes of anesthesia-related mortality and morbidity—an effort in which my organization has played a significant part.

In my view, the current anesthesia patient safety campaign was precipitated by a 1982 nationally-televised program on anesthesia mishaps, entitled "The Deep Sleep", noting that 6000 Americans were dying or suffering brain damage in anesthesia-related incidents. Following this broadcast, intense interest developed in the anesthesia community toward making our specialty safer.

Several events occurred in rapid succession after the broadcast. An international symposium of anesthesia morbidity and mortality was held in Boston, and at about the same time, the Department of Anesthesia at Harvard Medical School promulgated the first standards requiring the intra-operative monitoring of patients, including the requirement that an anesthesia practitioner must be present in the operating room at all times during the administration of anesthesia. Contemporaneously, manufacturers of anesthesia equipment made a significant contribution with the introduction of the pulse oximeter to measure blood oxygen levels and the capnograph to measure carbon dioxide in the breath.

At the national level, ASA in the mid-1980's initiated an integrated effort to attack the problem. It initially formed a committee on patient safety and risk management, a step which eventually led to the information of APSF as a free-standing organization representing all those interested in the issue. At about the same time, it developed a program—through its closed claims study, to determine the causes of adverse anesthesia incidents. Today, professional liability insurers representing about half of all practicing anesthesiologists provide anonymous closed claims files for study by specially-trained volunteer ASA members. Analytical data are compiled over extended periods of time, and the results are published in scientific journals for use by all concerned.

Perhaps most important for purposes of this hearing is the fact that research fostered by APSF and the closed claims study have led to the development by ASA of a series of practice parameters, or standards, for the practice of anesthesiology. In terms of patient safety, the best known of these are the Basic Standards for Preanesthesia Care, the Standards for Basic Anesthesia Monitoring, and the Standards for Postanesthesia Care.

These standards specify the minimum requirements for sound anesthesia practice, and require among other things that the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated. In effect, they make the use of the pulse oximeter and capnograph (or similar equipment) mandatory: although the Standards are not technically binding on anyone, including ASA members, their existence as national definitions of proper care compel adherence—either because professional liability insurers now require them or because any anesthesia provider not following them would be at severe risk of legal action following an adverse event.

Development of these standards by ASA is certainly anticompetitive, in the sense that they constrain anesthesia providers as a practical matter from delivering anesthesia care in some less demanding, and perhaps less costly, manner as they wish. But in my judgment, these standards are essential to the process by which the specialty of anesthesiology has markedly improved its safety record.

Safety-oriented documents approved by ASA's House of Delegates also call for medical direction of non-physician members of the anesthesia care team. This medical supervision requirement essentially parallels the current Medicare standard that I understand is now under significant debate in the Congress. APSF has opposed the proposed elimination of this requirement: in a letter dated February 17, 1998 (attached), the APSF Executive Committee commented:

"A basic tenet of medicine is "first do no harm". Administration of anesthetics is a high risk activity. Prior to making any change in the existing supervision requirement, the burden of proof must be based on definitive evidence that the change in practice is safe. No such evidence exists! If the proposed rule is enacted in the absence of evidence that the change in practice is safe, [the Health Care Financing Administration] will have set a dangerous precedent by having shifted the burden of proof in the wrong direction."

It is not my purpose here further to draw APSF into the debate as to the wisdom of the HCFA proposed change, even though I personally support your bill, Mr. Chairman, that would require HCFA to undertake a definitive outcomes study prior to considering the wisdom of the proposed rule change. My only point is that regulation—whether public or private—in the name of medical safety should not be constrained by application of the principles of competition, and in my judgment, the true legitimacy in safety terms of the current HCFA restraint can only be established by scientific data not yet at hand.

I close by saying that I am proud of the record of APSF and my specialty in improving anesthesia safety over the past two decades, and I hope the Subcommittee will share with me and my organization the sense that we are only beginning. New anesthetics, new equipment, new teaching methods such as use of anesthesia simulators are continually coming into play, and though we still have much to learn through research about safety techniques and appropriate standards in anesthesia, the challenge for all of medicine is equally great. I urge the Congress to support this process. Thank you.

Senator DEWINE. Dr. Silber.

STATEMENT OF JEFFREY H. SILBER, M.D.

Dr. SILBER. Mr. Chairman, members of the subcommittee, thank you for giving me the opportunity to make this presentation before you today. I am Jeffrey Silber, Director of the Center for Outcomes Research at the Children's Hospital of Philadelphia. I have been conducting medical outcomes studies using the data from the Health Care Financing Administration since 1987 and have developed numerous tools for the proper adjustment of outcomes data so that meaningful comparisons across providers can be made. I have published widely in this field.

In 1992, we published a paper in the journal Medical Care using Medicare data which showed that hospitals with higher percentages of board-certified anesthesiologists had lower rates of death in those patients with complications, otherwise known as lower failure-to-rescue rates. In 1995, we published a second study in the Journal of the American Statistical Association. That study found similar results using different data.

These studies interested the American Board of Anesthesiology, and as a result, in July 1995, our group, through the Children's Hospital of Philadelphia and the University of Pennsylvania, was awarded an $88,000 grant from the American Board of Anesthesia to explore the influence of board certification in more detail. From that ongoing study, though not directly requested by the ABA and using methodology developed as part of other Agency for Health

Care Research and Quality supported studies, our group has recently completed a study of medical direction provided by the anesthesiologist on patient outcomes. This afternoon, I would like to share some interesting findings from that research, briefly discuss the methodology, then talk about the significance of this work as it relates to current policy questions.

Our study showed that the lack of an anesthesiologist was associated with an increase of 2.5 excess deaths per 1,000 patients and an even higher number, 6.9 deaths per 1,000 patients, when there were complications.

We also found three provider-level factors remained significantly associated with lower mortality rates after full adjustment: First, higher registered nurse-to-bed ratio; second, larger hospital size; and third, the personal performance or medical direction by an anesthesiologist. All three factors were significant and independently related to lower mortality.

These study results are cause for concern and raise important questions regarding the quality of care delivered to Medicare patients undergoing general surgical and orthopedic procedures who did not have an anesthesiologist personally perform or medically direct their anesthesia care. Here is how we developed the study and the methodology used.

Our study compared the outcomes of surgical patients whose anesthesia care was personally performed or medically directed by an anesthesiologist, the directed cases, with the outcomes of patients whose anesthesia care was not personally performed or medically directed by an anesthesiologist, the undirected cases. Under HCFA billing rules, personal performance and medical direction require direct and extensive involvement of the physician in the anesthesia procedure.

Medicare claims records were analyzed for all elderly patients in Pennsylvania who underwent general surgical or orthopedic procedures between 1991 and 1994. The study involved 194,430 directed and 23,010 undirected cases across 245 hospitals. Outcomes studied included the death rate within 30 days of the hospital admission, in-hospital complication rate, and the failure-to-rescue rate, defined as the rate of death after complications. Cases were defined as being either directed or undirected depending on the type of involvement of the anesthesiologist as determined solely by HCFA billing records. Outcome rates were adjusted to account for the severity of each patient's medical condition and for other provider characteristics using logistic regression models. The final model included 64 patient and 42 procedure covariants plus an additional 11 hospital characteristics often associated with quality of care. Numerous alternative models were developed using different data elements and subsets of the full data set. These are reported at great length in our soon to be published paper in the journal Anesthesiology.

The results from these other adjustments confirmed our main findings. After extensive adjustments for patient and hospital characteristics, we found that lack of direction by an anesthesiologist was associated with an increase of 2.5 excess deaths per 1,000 patients, one excess death in 400 cases. This corresponded to an adjusted death rate of 3.49 percent in the directed group and 3.74

percent in the undirected group. We further found that lack of an anesthesiologist was associated with 6.9 excess deaths per 1,000 patients with complications, one excess death in 145 cases with complications.

After appropriate adjustments, we saw no difference in the rate of complications between directed and undirected groups. However, as we had published in numerous articles prior to this study, complication rates found in Medicare data should not be used for assessing quality due to imprecision in the coding of these complications. Our previous work has shown that adjusted complication rates are almost never correlated with adjusted mortality rates and that adjusted complication rates are best thought of as a severity of illness indicator.

The methodology used for this study was standard for claims-based outcomes research analyses. The techniques of adjustment used in this study are well known, commonly used methods that appear in the medical and statistics literature. Nevertheless, confirmatory studies should be conducted. Such studies ideally should involve case control methodology to most efficiently extract patient charts in the directed and undirected groups. If such studies were to be done as the next logical step in my research agenda, my belief is that we would observe similar results. However, such studies would provide us with greater confidence concerning this important topic.

From my perspective, there are three policy issues raised by these results. First, crucial quality of care results need to be addressed regarding anesthesiologist direction of anesthesia care. Second, our results need to be confirmed by other studies, some involving direct chart review. And third, we need to ask why there are these differences in adjusted mortality and failure to rescue across hospital and provider type and we need to develop better systems that reduce such differences. Reducing the differences would clearly improve the quality of medical care for all Americans.

Thank you, Mr. Chairman and members of the committee. I am ready to answer your questions.

Senator DEWINE. Doctor, thank you very much.

[The prepared statement of Dr. Silber follows:]

PREPARED STATEMENT OF JEFFREY H. SILBER, M.D., PH.D.

Mr. Chairman, Members of the Subcommittee, thank you for giving me the opportunity to make this presentation before you today:

I am Jeffrey H. Silber, M.D., Ph.D., Director of the Center for Outcomes Research at The Children's Hospital of Philadelphia, and Associate Professor of Pediatrics and Anesthesia at The University of Pennsylvania School of Medicine and Associate Professor of Health Care Systems at The Wharton School. I am also an attending physician in pediatric oncology at The Children's Hospital of Philadelphia.

I have been conducting medical outcomes studies using data from the Health Care Financing Administration since 1987, and have developed numerous tools for the proper adjustment of outcomes data so that meaningful comparisons across providers can be made. I have published widely in this field.

In 1992 we published a paper in the journal Medical Care, using Medicare data, which showed that hospitals with higher percentages of board certified anesthesiologists had lower rates of death in those patients with complications (otherwise known as lower "failure-to-rescue" rates). In 1995, we published a second study in the Journal of the American Statistical Association. That study found similar results using different data. These studies interested the American Board of Anesthesiology (ABA), and as a result, in July of 1995 our group, through The Children's Hospital of Philadelphia and The University of Pennsylvania, was awarded an

$88,000 grant from the ABA to explore the influence of board certification in more detail. From that ongoing study, though not directly requested by the ABA, and using methodology developed as part of other Agency for Healthcare Research and Quality supported studies, our group has recently completed a study of medical direction provided by the anesthesiologist on patient outcomes.

This afternoon I would like to share some very interesting findings from that research, briefly discuss the methodology, then talk about the significance of this work as it relates to current policy questions.

Before I do, let me say a few words about the history of outcomes research. Outcomes research techniques have been used since 1968 when Lincoln Moses and Frederick Mosteller, two renowned statisticians, published a now famous report from the National Halothane Study, an observational study assessing the safety of the then new anesthetic agent Halothane. In that report, it was noted that some hospitals had very different deaths rates than other hospitals. Moses and Mosteller performed numerous statistical adjustments, many of which we still use today, and concluded that differences in adjusted mortality rates may reflect differences in quality of care.

Over the past 32 years, literally hundreds of studies have been performed using large data sets across hospitals looking at many different medical questions concerning quality of care. The study I will discuss today is one of many such studies that use large data bases with various forms of medical data to measure differences across providers or hospitals.

Outcomes research uses large numbers of observations in order to detect small effects not readily apparent at any single hospital or within any single provider group. While the data in these large outcomes studies is usually not as refined as in smaller chart review studies, the large sample size often allows us to gain insight into differences in quality of care and outcomes that would not be apparent using other methodology.

Our study showed that the lack of an anesthesiologist was associated with an increase of 2.5 excess deaths per thousand patients, and an even higher number, 6.9 deaths per thousand patients, when there were complications.

We also found that three provider level factors remained significantly associated with lower mortality rates after full model adjustment: (1) higher registered nurse-to-bed ratio; (2) larger hospital size and (3) the personal performance or medical direction by an anesthesiologist. All three factors were significant and independently related to lower mortality.

These study results are cause for concern, and raise important questions regarding the quality of care delivered to Medicare patients undergoing general surgical and orthopedic procedures who did not have an anesthesiologist personally perform or medically direct their anesthesia care.

Here is how we developed the study and the methodology used.

Today, anesthesia services for surgical procedures may or may not be personally performed or medically directed by anesthesiologists. Our study compared the outcomes of surgical patients whose anesthesia care was personally performed or medically directed by an anesthesiologist ("directed cases") with the outcomes of patients whose anesthesia care was not personally performed or medically directed by an anesthesiologist ("undirected cases"). Under HCFA billing rules, personal performance and medical direction require direct and extensive involvement of the physician in the anesthesia procedure.

Medicare claims records were analyzed for all elderly patients in Pennsylvania who underwent general surgical or orthopedic procedures between 1991–1994. The study involved 194,430 directed and 23,010 undirected cases across 245 hospitals. Outcomes studied included death rate within 30 days of hospital admission, in-hospital complication rate and the failure-to-rescue rate (defined as the rate of death after complications).

Cases were defined as being either "directed" or "undirected", depending on the type of involvement of the anesthesiologist as determined solely by HCFA billing records. Outcome rates were adjusted to account for the severity of each patient's medical condition and for other provider characteristics using logistic regression models. The final model included 64 patient and 42 procedure convariates plus an additional 11 hospital characteristics often associated with quality of care. Numerous alternative models were developed, using different data elements and subsets of the full data set. These are reported at great length in our soon-to-be-published paper in the journal Anesthesiology. The results from these other adjustments confirmed our main findings.

After extensive adjustments for patient and hospital characteristics, we found that lack of direction by an anesthesiologist was associated with an increase of 2.5 excess deaths per 1000 patients (1 excess death in 400 cases). This corresponded to

an adjusted death rate of 3.49 percent in the directed group and 3.74 percent in the undirected group. We further found that lack of an anesthesiologist was associated with 6.9 excess deaths per 1000 patients with complications (1 excess death in 145 cases with complications).

After appropriate adjustments, we saw no difference in the rates of complications between the directed and undirected groups. However, as we have published in numerous articles prior to this study, complication rates found in Medicare data should not be used for assessing quality, due to imprecision in the coding of these complications. Our previous work has shown that adjusted complication rates are almost never correlated with adjusted mortality rates, and that adjusted complication rates are best thought of as a severity of illness indicator.

The methodology used for this study was standard for claims based outcomes research analyses. The techniques of adjustment used in this study are well known, commonly used methods that appear in the medical and statistics literature. Nevertheless, confirmatory studies should be conducted. Such studies ideally should involve case-control methodology to most efficiently abstract patient charts in the directed and undirected groups. If such studies were to be done as the next logical step in my research agenda, my belief is that we would observe similar results. However, such studies would provide us with greater confidence concerning this important topic.

From my perspective, there are three important policy issues raised by these results. (1) Crucial quality of care results need to be addressed regarding anesthesiologist direction of anesthesia care. (2) Our results need to be confirmed by other studies, some involving direct chart review. (3) We need to ask why there are these differences in adjusted mortality and failure to rescue across hospital and provider type, and we need to develop better systems that reduce such differences. Reducing the differences will clearly improve the quality of medical care for all Americans.

Thank you Mr. Chairman and members of the committee. I am ready to answer your questions.

Senator DEWINE. Ms. Stewart, thank you very much for joining us. You may proceed.

STATEMENT OF JAN STEWART

Ms. STEWART. Thank you. Good afternoon, Chairman DeWine, members of the subcommittee. I am Jan Stewart and I currently serve as the President of the American Association of Nurse Anesthetists, the AANA. Our 28,000 members provide invaluable access to anesthesia services in literally every type of setting. CRNA's are the predominant anesthesia provider in the armed services, particularly in combat situations, where they have often been deployed without any anesthesiologist. Nurse anesthetists are also the only anesthesia providers in some 70 percent of rural hospitals, and we are the first specialists in the delivery of anesthesia.

The concerns voiced by the anesthesiologists are all about incomes, not outcomes. The safety record of CRNA's does not come into question except at the behest of the anesthesiologist, and thus that questioning seems to be self-serving. Their statements would have you believe that CRNA's must be closely supervised to provide safe care. However, CRNA's are all too familiar with the sundown rule. When the sun goes down, CRNA skills goes up in inverse proportion to the level of daylight, and mystically, the anesthesiologist does not need to be present.

Although CRNA's and anesthesiologists disagree on some fundamental issues, their relationship when the two providers work together in the operating room is overwhelmingly one of cooperation and collegiality. However, the recent attacks that the American Society of Anesthesiologists, the ASA, has made upon the profession of nurse anesthesia are beyond the pale and are damaging to the public's confidence in anesthesia in general.

The messages have often left the public and some members of Congress with the erroneous notion that there will be no physician in the OR if HCFA's proposed regulation is implemented. The ASA has publicly stated in press releases and materials to Capitol Hill that CRNA's will kill people if their proposed regulation goes forward. Now, I do not know about you, but when someone says that I will be killing patients, I tend to get a bit defensive.

These distortions and desperate tactics are not only designed to scare senior citizens but to force Congress into blocking a regulation that has been on the table for years. HCFA has carefully and thoroughly considered the change which will simply allow the States to determine the need for supervision of nurse anesthetists.

Contrary to what the ASA might have you believe, CRNA's will continue to work in a highly interdependent collaborative relationship with surgeons and other physicians in the operating room as we always have. CRNA's are not going to be offering anesthesia to passers by on street corners around America. Clearly, there would not be much need for CRNA services without surgeons. The actual administration of anesthesia for the vast majority of situations will not change. The change in the supervision requirement eliminates the onus on surgeons of the unfounded concern about vicarious liability, and case law clearly shows that surgeons are no more liable when working with an CRNA than with an anesthesiologist.

The change in the regulation also increases the flexibility of health care facilities in their staffing arrangements. The concern that this change in the regulation would displace anesthesiologists is completely unfounded. If health care organizations wanted to do away with their anesthesiologist, it could have been done years ago. Even with the current regulation in place, there is no requirement for anesthesiologists at all. In reality, health care facilities design their anesthesia delivery system according to their own philosophical needs and that clearly will not change. Anesthesiologists will retain their ability to compete in the anesthesia market.

The facts are these. As my colleague has alluded to, the St. Paul, which is the largest insurer of nurse anesthesia for liability premiums, has dramatically decreased the premiums in the last several years. It is hard to see that that would have been the case if anesthesia were unsafe if it were delivered by nurse anesthetists.

HCFA is simply following their current practice, which is to focus on outcomes. HCFA has deferred to State law with respect to other advanced practice nurses as recently as in November 1999.

This issue is about incomes of the anesthesiologists and their desires to suppress legitimate competition, not about patient outcomes. After hearing about the proposed regulation change, former ASA President Bill Owens advised members to consider the socioeconomic impact associated with the proposed regulation.

The study by Dr. Silber, which is held up by the ASA as the holy grail of anesthesia outcome studies, is clearly flawed. The ASA has promised imminent publication for over 2 years. Thus far, only an abstract of the article has been published. One of the co-authors, Dr. David Longnecker, said the study does not explore the role of nurse anesthetists in anesthesia practice, nor does it compare anesthesiologists versus nurse anesthetists. The abstract also admits it remains to be determined whether the findings were the result of

a caregiver or a hospital effect. The death rates cited in the abstract are 100 times greater than the death rates reported in recent years.

The ASA has a lot to answer for. When will these unethical scare tactics stop? When will the ASA stop these self-serving machinations to undermine patient confidence in the health care system? When will they stop the irresponsible and erroneous statements that CRNA's will kill people because of a change in Federal regulation that has absolutely nothing to do with safety or quality?

To paraphrase a famous statement made years ago, I would say to the ASA, at long last, have you no sense of decency, at long last? Thank you.

[The prepared statement of Ms. Stewart follows:]

PREPARED STATEMENT OF JAN STEWART, CRNA, ARNP

The American Association of Nurse Anesthetists (AANA) is the professional association that represents over 28,000 Certified Registered Nurse Anesthetists (CRNAs), which is approximately 94 percent of the practicing nurse anesthetists in the United States. I appreciate the opportunity to testify today regarding nurse anesthetists and our history of promoting competition in the anesthesia marketplace, especially as it pertains to the Health Care Financing Administration's (HCFA) proposed rule to defer to the states on the issue of physician supervision of nurse anesthetists.

As you may know, nurse anesthetists have a long history of promoting and protecting competition between health care providers in order to provide the highest level of care and access to patients. Nurse anesthetists and anesthesiologists are frequently in direct competition with each other. We believe that this competition is helpful to consumers and to the marketplace, as long as the playing field is level. AANA has on numerous occasions supported this position with Congress and federal agencies.

1. The Proposed HCFA Rule Promotes Competition.—If finalized, the 1997 proposed HCFA rule that would defer to the states on the issue of physician supervision of nurse anesthetists would promote greater competition between nurse anesthetists and anesthesiologists. AANA strongly supports the proposed rule because it would ensure greater access to anesthesia care for patients, eliminate physician concerns regarding liability, and enable hospitals and ambulatory surgical centers greater flexibility while maintaining a high level of care.

2. The Current Antitrust Laws are Crucial to Protect Competition and Consumer Choice.—We believe that strong antitrust laws and robust enforcement are crucial to protect competition and consumer choice in the health care system. We have testified before the House Judiciary Committee recently on proposed changes to these laws and expressed our position: changes to these laws would allow anesthesiologists to form cartels that could discriminate against or exclude nurse anesthetists from the marketplace; changes could eliminate competition between anesthesiologists and nurse anesthetists by their use of spurious claims regarding patient health and safety; and changes could unnecessarily drive up the cost of health care coverage for all Americans without any concomitant increase in the quality or availability of health care.

3. The Physician Community Has Attempted to Restrict Practice Opportunities for CRNAs.—Organized medicine has a long record of attempting to restrict opportunities of CRNAs or otherwise control non-physician providers such as nurse anesthetists.

BACKGROUND INFORMATION ABOUT CRNA'S

In the administration of anesthesia, CRNAs perform virtually the same functions as physician anesthetists (anesthesiologists) and work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers, health maintenance organizations' facilities, and the offices of dentists, podistrists, ophthalmologists, and plastic surgeons. Today, CRNAs administer approximately 65% of the anesthetics given to patients each year in the United States. CRNAs are the sole anesthesia provider in at least 65 percent of rural hospitals which translates into anesthesia services for millions of rural Americans.

CRNAs have been a part of every type of surgical team since the advent of anesthesia in the 1800s. Until the 1920s, anesthesia was almost exclusively administered by nurses. In addition, nurse anesthetists have been the principal anesthesia provider in combat areas in every way the United States has been engaged in since World War I. CRNAs provide anesthesia services in the medical facilities of the Department of Defense, the Public Health Service, the Indian Health Service, the Department of Veterans Affairs, and countless other public and private entities.

The most substantial difference between CRNAs and anesthesiologists is that prior to anesthesia education, anesthesiologists receive medical education while CRNAs receive a nursing education. However, the anesthesia part of the education is very similar for both providers, and both professionals are educated to perform the same clinical anesthesia services. CRNAs and anesthesiologists are both educated to use the same anesthesia processes and techniques in the provision of anesthesia and related services. The practice of anesthesia is a recognized specialty within both the nursing and medical professions. Both CRNAs and anesthesiologists administer anesthesia for all types of surgical procedures, from the simplest to the most complex, either as single providers or in a "care team setting."

There are currently 87 accredited nurse anesthesia education programs in the United States lasting between 24–36 months, depending upon the university. As of 1998, all programs offer a master's degree level for advance practice nurses, and these programs are accredited by the Council of Accreditation of Nurse Anesthesia Educational Programs which is recognized by the U.S. Department of Education.

THE PROPOSED HCFA RULE PROMOTES COMPETITION AND ACCESS TO ANESTHESIA

As you know, HCFA issued a proposed rule in December, 1997 that would defer to state law on the issue of physician supervision of nurse anesthetists. Since that time, AANA has supported the rule change for the following reasons:

1. It would place the regulation of healthcare professionals where it belongs—at the state level. The proposed rule defers to state law on the issue of physician supervision of nurse anesthetists, advocating states' rights over federal government regulation in healthcare matters. We are mystified that the anesthesiologists would oppose CRNAs being regulated by the states. At the same time, if the anesthesiologists oppose the removal of a Part A requirement, would they support similar federal restrictions being imposed on anesthesiologists?

2. It promotes flexibility. The deferral to state law gives hospitals and ambulatory surgical centers greater flexibility in the use of anesthesia providers and improving operating room efficiency without affecting quality of care. The proposed rule is supported by the American Hospital Association and the Federation of American Health Systems.

3. It may help to remedy ongoing cases where anesthesiologists deny care. The proposed rule would ensure patient access to safe, high-quality anesthesia care, particularly in rural and inner-city hospitals. This is particularly critical given what has transpired in rural and underserved areas. In Los Angeles, an anesthesiologist refused to provide an epidural to a Medicaid patient in labor unless she could provide a cash payment. The indigent patient could not pay cash and was forced to undergo a delivery without anesthesia. In 1998, a story in the Los Angeles Times reported the case of Mrs. Ozzie Chavez who was told she would have to pay $400 cash in order to get an epidural during her labor. Though she was on MediCal, she offered to pay with a credit card or check but was denied and had to endure a painful delivery because the anesthesiologist demanded cash. According to the news story, this anesthesiologist had denied epidurals to a number of Medicaid patients as well. Interestingly, in the April 2000 issue of the American Society of Anesthesiologists Newsletter, Christine A. Doyle, M.D. writes that "the 'Northridge labor epidural incident' here in California was brilliantly converted by the California Society of Anesthesiologists (CSA) from an apparent disaster into a vehicle for achieving the first increase in Medi-Cal (Medicaid) reimbursement for obstetrical anesthesia in over 10 years." So much for compassion; instead the theme for anesthesiologists seems to be "show me the money." In Utah, it was reported in the Salt Lake Tribune (July 2, 1998) that Kelly DeFeo, a CRNA, volunteered to provide help for children at a school-based clinic in Ogden but was denied the ability to do so since McKay-Dee Hospital—the hospital which apparently cooperated with the clinic refused to allow her privileges. She was barred from volunteering because the hospital policy required anesthesiologist supervision. At least at that time, no anesthesiologist volunteered to provide the services nor was the policy changed so that the CRNA could provide the anesthesia.A few years ago in Montana and Wyoming, anesthesiologists refused to allow nurse anesthetists to provide epidurals even though it is within the scope of practice of CRNAs to do so. This denied numerous women epidurals them-

selves because there were apparently not enough anesthesiologists who were willing to provide the service. The result was that many women were being denied access to epidurals. (Great Falls Tribune, "Epidurals still not available," by Carol Bradley, September 3, 1995; Casper Star Tribune, "Nursing ethics group says epidural access at WMC depends on knowing 'right person'", by Tom Morton, 1993; Denver Post, "Montana women seek deliverance", by Carol Bradley, July, 1995). As these cases demonstrate, it is critically important to ensure access to anesthesia, particularly when anesthesiologists are either unavailable or unwilling to provide certain services in rural or underserved urban areas.

4. The rule addresses liability concerns. It eliminates the misperception some surgeons have that they are liable for the actions of CRNAs due to the federal supervision requirement. We have had many reports from CRNAs around the country about anesthesiologists who have dissuaded surgeons from working with CRNAs or hospitals from employing CRNAs inferring that somehow they are automatically liable for the actions of the CRNA by virtue of the supervision requirement. This assessment, of course, is not legally correct as the surgeon or other physician may rely upon either the CRNA or the anesthesiologist for the anesthesia portion of the case, unless the surgeon or other physician decides to become involved in the delivery of anesthesia. This perception of liability has been artfully used by some anesthesiologists to evict nurse anesthetists from their positions.

5. Finally, the rule recognizes CRNAs and affords them the opportunity to practice within their scope. It recognizes CRNAs for what they are: healthcare professionals who generally have a graduate-level education, who administer 65 percent of all anesthesia in the United States and are the sole anesthesia providers in two-thirds of all rural hospitals. Further, it recognizes that anesthesia care is safer today than it has ever been due to advancements in technology, pharmacology, and provider education.

For all of these reasons, the HCFA rule would enhance competition by providing flexibility in the marketplace, while ensuring continued access to high quality health care. To delay its implementation would only delay the improvements in the marketplace that we believe this rule will bring.

HCFA has made a careful, clinical decision and is under no obligation to further study this issue

It is a fallacy that HCFA has not studied this issue. HCFA has been considering this issue since 1994 when it circulated a draft regulation, three years before it issued the proposed rule in 1997. HCFA has given thoughtful consideration to this issue over the past six years. In addition, HCFA has recognized the merits of federal deregulation of health care providers by deferring to the states on the supervision of other types of clinicians. Reinforcing the nurse anesthetist rule, HCFA has now removed supervision requirements for nurse practitioners and clinical nurse specialists in their Revisions to the Year 2000 Physician fee schedule. (Federal Register 11/2/99; 59415).

HCFA is moving forward deliberately and in an appropriate fashion. Contrary to what the ASA may be telling Congress, HCFA has had no mandated directive from Congress to further study this issue. Report language from the Balanced Budget Refinement Act states in part:

"If the Secretary believes that she has sufficient mortality and quality information regarding the provision of anesthesia services by nurse anesthetists and anesthesiologists, then she could make the appropriate regulatory changes to ensure access to quality care for Medicare beneficiaries."

On March 9, 2000, HCFA informed the American Association of Nurse Anesthetists (AANA) and the American Society of Anesthesiologists (ASA) that it intends to move forward with its proposal to remove the federal requirement that nurse anesthetists must be supervised by physicians. It is expected that HCFA will publish this rule sometime this summer. Clearly the Secretary determined that the voluminous available data was sufficient for her to make her decision.

Regardless of all the available evidence, ASA first began pressing Congress in 1998 for another national anesthesia outcomes study. It is interesting that they were comfortable with the amount of data available in 1994, when the draft proposed rule was first circulated, as they expressed no concerns at that time. It has only been since 1998, once the publication of a final rule appeared to be a possibility, that their concerns about lacking data emerged. AANA has consistently opposed a mandated national study for the following reasons:

1. No previous study has shown a significant difference in the quality of anesthesia care provided by nurse anesthetists and anesthesiologists. Various studies have been done over the years and AANA has compiled a synopsis summarizing the studies—all of which indicate that there is no difference in outcomes. We do not

need yet another study to show us what we already know—that CRNAs provide high quality care that promotes access to health services.

2. In 1990, the Centers for Disease Control examined anesthesia outcomes and concluded that morbidity and mortality rates in anesthesia were too low to warrant a multi-million dollar national study.

3. In 1994, a legislatively mandated study by the Minnesota Department of Health determined there are no studies that conclusively show a difference in patient outcomes by type of anesthesia provider.

4. The ASA's appeal to Congress to legislatively mandate yet another study, which could cost more than $15 million, is simply a tactic to delay HCFA from implementing its proposal to remove supervision. The anesthesiologists have had ample time to perform a study but it was not until HCFA proposed this rule that they suggested any study was necessary. In fact, the anesthesiologists have always heretofore touted the safety of anesthesia, but only now suggest the dangers of anesthesia in order to reinforce their political message.

5. There is no way to objectively study nurse anesthesia outcomes while the supervision requirement is still in place. And we believe this is well known by the ASA. Quite simply, if any study were to be performed under the current regulatory scenario, and it were shown that CRNAs were safe anesthesia providers, the anesthesiologists would simply argue that it was due to supervision, thereby creating an obvious "Catch 22."

The anesthesiologists have frequently changed their tune about this regulation. As for the HCFA rule, Congress should listen to what the ASA had said earlier in this battle: "ASA believes issues relating to treatment of Medicare patients, including anesthesia care, are best dealt with in the context of thoughtful dialogue among the affected parties, and ultimately through the reliance on rule-making process by HCFA, the agency charged by law with the responsibility." (Letter to Congress, May 23, 1995).

They clearly believed that HCFA should be responsible, not Congress, for making this regulatory decision. They reiterated this position a second time in their own Newsletter: ". . . [the issue] belongs there (with HCFA) and not in Congress." (ASA Newsletter, November 1995, Vol. 59, No. 11, p. 5)

Nevertheless, when HCFA appropriately used the regulatory rule-making process as ASA suggested, and decided to propose a deferral to state law on the issue of physician supervision of nurse anesthetists, ASA quickly changed its mind and ran straight to Congress to get it reversed.

Even the ASA's own website and their lobbying materials argued in favor of state regulation. Their materials stated in part: "ASA believes that the qualifications of members of a particular class of health professionals may vary significantly from state to state and that state legislatures and licensing bodies are in the best position to determine the appropriate scope of practice in their jurisdictions." We couldn't agree more.

CRNA'S PROVEN TO PROVIDE HIGH QUALITY CARE

At this point, it is not necessary nor helpful to the healthcare marketplace for Congress to intervene by requiring yet another study about the quality of care that CRNAs provide. There is no question about the safety or quality of care that is provided by CRNAs.

A published article on malpractice data from the National Practitioners Data Bank (NPDB) reveals that from 1990 through 1997, anesthesia-related malpractice claims against physicians outnumber claims against nurses by nearly 7 to 1. Think about that—700 percent more physician anesthesia malpractice codes than nurses. While AANA did not elevate this issue into a question of patient safety, the ASA's relentless attacks on our safety force us to advise Congress that the anesthesiologists have problems of their own.

CRNAs safely provide over 65 percent of the nation's anesthesia. According to the recently released Institute of Medicine report titled "To Err is Human," anesthesia delivery provides a model for advancement in the safe delivery of health care: "Anesthesiology has successfully reduced anesthesia mortality rates from two deaths per 10,000 anesthetics administered to one death per 200,000/300,000 anesthetics administered."

In fact, the Institute of Medicine cites the improvements in anesthesiology numerous times throughout the report. What is interesting is the factors cited include: improved monitoring techniques, the development and widespread adoption of practice guidelines, and other systematic approaches (p. 27); or, technological changes, information-based strategies, application of human factors to improve performance, such as the use of simulators for training, formation of the Anesthesia Patient Safety

Foundation, and having a leader who could serve as a champion for the cause. Nowhere in the IOM report is the astounding increase in anesthesia safety attributed to anesthesiologist supervision of nurse anesthetists. If CRNAs were such a danger to patients, surely the IOM would have cited such a danger in this preeminent report on patient safety. Yet, the IOM only touts how the profession of anesthesia has dramatically improved patient safety. We believe the IOM report speaks volumes about the profession of nurse anesthesia and the quality of care we provide.

We have evidence that senior citizens feel the same way. A nationwide survey of Medicare patients conducted in October, 1999 by Wirthlin Worldwide reveals that 88 percent of Medicare patients would be comfortable if their surgeon chose a nurse anesthetist to provide their anesthesia. Nearly two-thirds of the respondents indicated it would be acceptable for the nurse anesthetist to not be supervised by their surgeon, but work collaboratively with the surgeon who is always present throughout the operation. When supervision is eliminated, CRNAs will continue to work with a physician, usually the surgeon, in a collaborative relationship, and will remain with their patients from the beginning to the end of their procedures. Compared to nurse anesthetists, many anesthesiologists rarely provide hands-on patient care, and even fewer remain with their patient throughout the surgical procedure (when anesthesia is given through the care team in which both nurse anesthetist and anesthesiologist participates).

In fact, we would like to bring to your attention questions about the adequacy of the preparation of anesthesiologists, as raised within their own profession. The anesthesiologists have systematically sought to discredit CRNAs as not having enough education. However, you should take note of the comments recently printed in their own Newsletter. Dr. Michael Ryan, M.D. in his article, "Anesthesiology's Workforce: The Good, the Bad, and the Ugly—A Resident's Perspective" (American Society of Anesthesiologists Newsletter, April, 2000, Vol. 64, Number 4, pp. 17–18) said, in part: "Owing to the isolated nature of our practice, anesthesiologist training in some regard has been one of those specialties that is 'self taught.'" and, "Anesthesiology residents feel short-changed in that hard work is rewarded with less actual training. They have less time to read prior to taking the boards, and they have greater difficulty dealing with the rare but deadly operating room emergency because they are tired and poorly trained."

Yet another article in the same Newsletter, written by Fran Thayer, MD, entitled "Survey of Residency Programs' Didactics" states: "All respondent programs seemed to be suffering a similar problem: a lack of teaching in the operating room."

So while the anesthesiologists will likely disparage our training as insufficient, there are clearly those in their own profession pointing out the flaws of their own educational experiences. In truth, nurse anesthetists are busy providing high quality anesthesia to Medicare and other patients while the physician is still in medical school.

The anesthesiologists' opposition to HCFA's proposal is about income and control, not patient safety. This was clearly demonstrated when their former president said in their own publication: "ASA members should recognize the socioeconomic impact of HCFA's proposal as well. Although the proposed change would not affect the Medicare reimbursement rules for medical direction of nurse anesthetists, it takes little imagination to see that a move away from required supervision of nurse anesthetists potentially erodes the number of cases in which medical direction will apply . . ." (Dr. William Owens, ASA President's update, December 31, 1997).

CRNAs already provide high quality care at a fraction of the cost of anesthesiologists. According to a study conducted by the Medical Group Management Association and published in the October, 1995 issue of Anesthesiology News, the median annual income for nurse anesthetists in calendar year was $72,001 but, the median annual income for an anesthesiologist in 1994 was $244,600. If the finalization of the rule "erodes the number of cases" in which anesthesiologists participate, it is clear that consumers benefit by competition from a lower cost provider that can maintain high quality care.

It is as clear now as it was then, that the real reason for their opposition, apart from losing control over anesthesia, is their likely loss of income. That is the real source of their vitriolic opposition.

THE SILBER STUDY

With all due respect to Dr. Silber, we would like to address the subject of his "soon-to-be-published" study completed at the University of Pennsylvania.

Since September 1998, anesthesiologists have been extolling the virtues of a scientific abstract titled "Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?" The abstract reports the findings of a recent study comparing the out-

comes of surgical patients whose anesthesia was directed by anesthesiologists with patients whose anesthesia was directed by other physicians, such as surgeons. It is peculiar that this study, which the ASA has touted for approximately two years as "about to be published," has not yet been published to our knowledge. From the limited information available about this study, it is also clear that it does not focus on the issue at hand, and we question its applicability to this debate.

On its surface, the abstract appears to present damaging evidence that patient outcomes are better when nurse anesthetists are directed by anesthesiologists. However, a closer examination clearly reveals: the study does not address the question posed by the abstract's title, and the results are inconclusive.

Background

The study was conducted using data obtained from Health Care Financing Administration (HCFA) claims records. The study group consisted of 65,595 Medicare patients distributed across 219 hospitals in Pennsylvania who underwent general surgical or orthopedic procedures between 1991–94. Jeffrey H. Silber, MD, PhD, headed a research team that included three anesthesiologists.

The abstract has been published (Anesthesiology, 1998; 89:A1184); however, no peer-reviewed article about the study results has been published to date.

Study does not answer the question posed by the abstract's title

According to David E. Longnecker, MD, one of the anesthesiologist researchers involved in the study:

"The study . . . does not explore the role of (nurse anesthetists) in anesthesia practice, nor does it compare anesthesiologists versus nurse anesthetists. Rather, it explores whether anesthesiologists provide value to the delivery of anesthesia care." (Source: memorandum from Dr. Longnecker to Certified Registered Nurse Anesthetists in University of Pennsylvania Health System's Department of Anesthesia, October 5, 1998).

When, then, was such a misleading title chosen? The answer can only be for political reasons. Consider these facts:

The abstract was published in the midst of the controversy between anesthesiologists and nurse anesthetists over HCFA's proposal to remove the physician supervision requirement for nurse anesthetists in Medicare cases, and

The study was funded in part by a grant from the American Board of Anesthesiology, which is affiliated with the American Society of Anesthesiologists (ASA). The ASA vehemently opposes HCFA's proposal.

Problems with the data

Careful examination of the "findings" reported in the abstract reveal numerous problems.

Glaring Admission: The researchers conclude the abstract by admitting that it "remains to be determined" whether their findings were the result of a "caregiver or hospital effect" (or, in layman terms, whether their findings were due to the actions of the nurse anesthetists/physicians or to the hospital environments). This admission by the researchers seriously limits the application of the data. The significance of a hospital's environmental characteristics on patient outcomes cannot be underestimated given these facts:

Anesthesiologists are heavily concentrated in urban and suburban areas where they typically practice in well-funded, high-tech, appropriately staffed hospitals and surgical centers.

Nurse anesthetists, on the other hand, often play major roles in rural and inner-city hospitals, facilities where anesthesiologists don't generally work.

What this means is: nurse anesthetists often treat sicker patients in facilities that don't have the same caliber resources to which anesthesiologists are accustomed.

Time Frame: Nurse anesthetists do not diagnose or treat non-anesthesia postoperative complications—they administer anesthesia. According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), anesthesia mishaps usually occur within 48 hours of surgery. The study, however, evaluated death, complication, and failure to rescue rates within 30 days of admission, encompassing not only the time period of the actual surgical procedures, but also a substantial period of postoperative care as well. Therefore, it is impossible to know from the data how many or what percentage of deaths, complications, and failures to rescue occurred within that 48-hour and were directly attributable to anesthesia care.

Death Rates: The data show that the death rate when nurse anesthetists were supervised by anesthesiologists was substantially lower than the death rate when nurse anesthetists were supervised by other physicians. However, the death rates cited in the abstract were more than 100 times the anesthesia-related death rates commonly reported in recent years, regardless of whether the nurse anesthetists

were supervised by anesthesiologists or other physicians! This would lead one to conclude that the high death rates were almost certainly due to nonanesthesia factors, which would be more in keeping with the 30-day time frame of the study.

Further, it has been noted by Dr. Michael Pine, a board-certified cardiologist widely recognized for his expertise in analyzing clinical data to evaluate health care outcomes, that after adjusting the death rates for case mix and severity, the patients whose nurse anesthetists were supervised by nonanesthesiologist physicians were about 15% more severely ill than the patients whose nurse anesthetists were supervised by anesthesiologists. The abstract provides no information to explain why the anesthesiologist-supervised cases involved less severely ill patients.

Complication Rates: After adjusting for case mix and severity, the study found no statistically significant difference in complication rates when nurse anesthetists were supervised by anesthesiologists or other physicians. Dr. Pine noted that poor anesthesia care is far more likely to result in significant increases in complication rates than in significant increases in death rates. Therefore, Dr. Pine concluded that this finding strongly suggests that medical direction by anesthesiologists did not improve anesthesia outcomes.

Failure to Rescue: For the most part, failure to rescue occurs when a physician is unable to save a patient who develop nonanesthesia complications following surgery. Therefore, it is not a relevant measure of the quality of anesthesia care provided by nurse anesthetists.

Patients Involved in More than One Procedure: For reasons not explained in the abstract, patients involved in more than one procedure were assigned to the nonanesthesiologist physician group if for any of the procedures the nurse anesthetist was supervised by a physician other than an anesthesiologist. It is impossible to measure the impact of this decision by the reachers on the death, complication, and failure to rescue rates presented in the abstract.

To emphasize the importance of this, consider the following hypothetical scenario: A patient is admitted for hip replacement surgery. A nurse anesthetist, supervised by the surgeon, provides the anesthesia. The surgery is completed successfully. Three days later the patient suffers a heart attack while still in the hospital and is rushed into surgery. This time the nurse anesthetist is supervised by an anesthesiologist. An hour after surgery, and for reasons unrelated to the anesthesia care, the patient dies in recovery. According to the researchers, a case such as this would have been assigned to the nonanesthesiologist group!

Conclusion of Silber analysis

The following conclusions can be drawn from a careful examination of the abstract "Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?"

The study described has nothing to do with the quality of care provided by nurse anesthetists.

The study does not answer—or attempt to answer—the question posed by the abstract's title.

The timing of the abstract's publication and selection of its title were politically motivated.

At best, the study's findings are inclusive.

It is unfortunate that anesthesiologists have misrepresented the study results to mean that nurse anesthetists need to be supervised by physicians, and specifically, anesthesiologists.

We strongly support the proposed rule and believe that the anesthesiologists have misled Congress and engaged in highly questionable tactics to scare senior citizens. They have designed websites that accuse U.S. Senators of supporting policies endangering the lives of senior citizens by supporting the HCFA rule and misrepresented studies on this issue in order to try and prevail on this issue. We strongly believe that any attempts to characterize this proposed rule as somehow anticompetitive strains credibility, particularly given the numerous antitrust lawsuits which have been brought against various anesthesiologists over the years.

THE CURRENT ANTITRUST LAWS PROTECT COMPETITION AND CONSUMER CHOICE

Based on historical and recent experience, the AANA believes that strong antitrust laws and enforcement serve to protect competition between anesthesiologists and CRNAs. CRNAs provide the same services as anesthesiologists with the same high degree to care. In the market for health services, a market which is widely considered complex and imperfect by economists, this sort of direct competition between rival professional groups should be vigorously defended. While many CRNAs practice in an anesthesia team which includes anesthesiologists and other ancillary support staff, CRNAs also practice as independent providers and receive direct reimbursement from multiple payors, as allowed by federal law. Independent CRNAs

may function as independent contrators—negotiating the best price for the service with different health entities. Therefore, many CRNAs compete directly with their physician colleagues—anesthesiologists. Because of the prevalence of insurance in the health care field, recipients of anesthesia services are seldom the direct payors while physicians benefit from tremendous influence with insurance companies and others who actually pay for health care services. For this reason, the threat of swift and vigorous enforcement of the federal antitrust laws and the deterrent effect that those laws have on anticompetitive conduct are the most important protections that CRNAs have against anticompetitive conduct by physicians who may seek to exclude them from the market because they are lower cost competitors. In light of the power and influence of the medical community on staffing decisions, weakening the antitrust laws by new and sweeping immunity for negotiations between health care professionals and health care plans could undermine the ability of CRNAs to compete with anesthesiologists, or any other similarly positioned health professional.

Further, the current antitrust laws serve to protect the ability of other types of establish health professionals to offer competitive health services. These groups include the nurse-midwives who provide obstetrical care to women in need; optometrists who provide post-op cataract eye care; occupational therapists who diagnose and provide rehabilitation care; and speech-language pathologists. It is no exaggeration to say that the antitrust laws have been a major force enabling nonphysician health professions to compete with physicians when they provide comparable services. Such competition has been an enormous boon to consumers and third party payors who benefit from having a wider choice of highly qualified providers.

A brief history of CRNAs as anesthesia competitors

By the end of the nineteenth century, two developments—the discovery and utilization of anesthesia and the discovery and development of asepsis—resulted in an enormous expansion of the numbers and types of surgeries performed. Consequently, hospital construction flourished as the need grew for operating rooms to accommodate aseptic surgery. Simultaneously, demand grew for anesthesia specialists to focus their attention on the anesthesia care of patients while a physician performed surgery.

Nurses, whose hallmark is monitoring vital signs and administering medications, were a natural choice to provide anesthesia. Physicians turned increasingly to sisters in Catholic hospitals, as well as to other registered nurses from a growing number of nurse training programs, to administer anesthesia with wide acceptance. World War I accelerated the demand for qualified CRNAs. Advances made in medications and equipment and nurse anesthesia education during the war contributed to the nurse anesthetists' dominant position in the anesthesia services field.

Even before World War I, however, the growth and acceptance of the nurse anesthesia profession and its training programs provoked anticompetitive reactions from anesthesiologists. As early as 1911, in a harbinger of future anti-nurse anesthetist activity, counsel for the New York State Medical Society declared that the administration of an anesthetic by a nurse violated the law of the State of New York. The following year, the Ohio State Medical Board passed a resolution stating that only registered physicians could administer anesthesia.

Early efforts to crush the nurse anesthesia profession gained momentum as anesthesiologists organized in their opposition to nurse anesthetists. In 1915, anesthesiologists founded the Interstate Association of Anesthetists ("IAA") which successfully petitioned the Ohio State Medical Board to withdraw recognition of Cleveland's Lakeside Hospital as an acceptable training school for nurses on the grounds that Lakeside's use of nurse anesthetists violated the Ohio Medical Board Act. Nurses and prominent surgeons alike protested the board's decision, and succeeded in having it reversed.

Similarly, in 1917, the Kentucky State Medical Association, with prompting from organized anesthesiologists, passed a resolution prohibiting members from employing nurse anesthetists. In a test lawsuit brought by a nurse anesthetist, the Kentucky Court of Appeals ultimately rejected the proposition that the administration of anesthesia by a nurse constituted the unauthorized practice of medicine.

In 1921, another anesthesiologist group, the American Association of Anesthetists, commenced a boycott by adopting a resolution prohibiting its members from teaching nurse anesthetists. Anesthesiologists also moved into the political arena, supporting legislation which would prohibit qualified nurse anesthetists from administering anesthesia.

Unlike anesthesiologists, the American College of Surgeons, comprised of physicians who utilized nurse anesthetists, opposed legislative prohibitions of nurse-administered anesthesia. In a 1923 resolution, they opposed all legislative enactments which would prohibit qualified nurses from administering anesthesia.

Surgeon support of nurse anesthetists, however, did not stop the anesthesiologists' efforts to keep nurse anesthetists from practicing their profession. In 1933, anesthesiologist associated with the Los Angeles County Medical Association brought a lawsuit against a nurse anesthetist claiming that nurse anesthetists' administration of anesthesia constituted the illegal practice of medicine. As had other courts, the California court found that the administration of anesthesia by nurse anesthetists was not the practice of medicine.

In 1937, the American Society of Anesthesiologists ("ASA") was formed. (The American Association of Nurse Anesthetists had been founded in 1931). Immediately after its inception, the ASA presented a master plan for the eventual elimination of nurse anesthesia to the American College of Surgeons. The plan specified that nurses should not be permitted to continue to provide anesthesia. It also provided, *inter alia,* that a provision should be included in the Minimum Standards of Hospitals (the forerunners of the Joint Commission on Accreditation of Hospitals' standards) directing that the department of anesthesia in each hospital shall be under the direction and responsibility of a well-trained physician anesthetist. The plan cautioned, however, "that no legislation should be forced until physician anesthetists can take over the work in a competent way."

World War II increased the number of anesthesiologist. See the discussion in *United States of America* v. *The American Society of Anesthesiologists,* 435 F. Supp. 147, 150 (SDNY, 1979) at page 150). After the war, the anesthesiologists, as they sought to establish themselves in a civilian economy, renewed their activities against CRNAs. Between 1946 and 1948, the ASA conducted a campaign to discredit CRNAs in the eyes of the public. The campaign was successful in reducing the numbers of nurses attending nurse anesthesia training programs. The campaign was halted when the American Medical Association, the American College of Surgeons, and the Southern Surgical Society expressed their opposition to the ASA's negative publicity, and expressed their support of, and continued intention to utilize, CRNAs.

Attempts to eliminate CRNAs have often been more subtle. For example, in 1947 the ASA adopted an "ethical principle" prohibiting members in good standing from participating in nurse anesthesia programs and from employing or utilizing CRNAs. Measures to enforce the ethical guidelines included the threat to revoke the American Board of Anesthesiology certificates of physicians training nurse anesthetists.

History of antitrust actions brought by CRNAs

CRNAs have brought actions against anesthesiologists for restricting competition. In *Oltz* v. *St. Peter's Community Hospital,* 861 F.2d 1440 (5th Cir. 1988), Oltz, a nurse anesthetist, sued four anesthesiologists and the hospital that gave them an exclusive contract to provide anesthesia services, under the antitrust laws. Oltz charged the anesthesiologist and the hospital with a group boycott, which can be a per se violation of the antitrust laws. The anesthesiologists settled before going to trial.

In affirming the district court's finding that the hospital joined the anesthesiologists' conspiracy to terminate Oltz's billing contract, the Ninth Circuit noted that the anesthesiologists had "pressured the hospital at St. Peter's to eliminate Oltz as a direct competitor." The court found that the anesthesiologists had threatened to boycott St. Peter's unless Oltz's independent billing status was terminated and that the anesthesiologists annual earnings at the hospital increased by forty to fifty percent after Oltz was terminated.

In *Bhan* v. *NME Hospitals, Inc.,* 929 F.2d 1404 (USCA Ninth Cir., 1991) a nurse anesthetist and an anesthesiologist were anesthesia providers in a small hospital in Manteca, California. Surgeons at the hospital decided to attach another anesthesiologist. When the third provider arrived the nurse anesthetist alleged that the anesthesiologist who was to be replaced tried to save his job by suggesting to the hospital administration an all-physician anesthesia policy and the elimination of the CRNA. The CRNA brought suit under the antitrust laws arguing that a physician only anesthesia policy was a coercive boycott. The Ninth Circuit ruled that nurse anesthetists and anesthesiologists directly compete for purposes of the antitrust laws but the trial court held that the Hospital's conduct had to be evaluated under the rule of reason and the case was dismissed.

But the Bhan court added: "On the other hand, a plaintiff may able to establish in a certain situation that the physicians are conspiring to drive the nurses out of business because their services are just as good but cheaper. The hospital may be shown to be acceding to the doctors' wishes because of its wish to retain certain of the doctors' services. In that case, *the practice of excluding nonphysician providers as a class would appear to be anti-competitive.* 929" F.2d at 1412 (emphasis supplied).

In *Anesthesia Advantage, Inc.* v. *Metz,* 708 F. Supp. 1171, 1175 (10th Cir. 1990), four nurse anesthetists in the Denver, Colorado area and their professional corporation, The Anesthesia Advantage, Inc. ("TAA"), brought suit against several anesthesiologists and Humana Hospital. The nurse anesthetists alleged per se violations of the antitrust laws, including price fixing, market allocation and a group boycott. The charges were based on (1) a hospital-instituted "call schedule" for anesthesiologists and the anesthesiology staff's recommendation to adopt guidelines for supervising nurse anesthetists; (2) a conspiracy to induce another hospital to reject a fee-for-service proposal by TAA to provide out-patient ambulatory surgery anesthesia on pre-arranged days; and (3) an attempt to persuade a third hospital to reject a proposal that the hospital use TAA for an obstetric epidural anesthesia program.

The nurse anesthetists alleged that they were "illegally squeezed out of business by anesthesiologists because the presence of CRNAs forced down the market price for anesthesiologist services."

The Tenth Circuit Court of Appeals reversed the trial court's dismissal of the case, and some of the defendants eventually settled the case, by among other things, agreeing that they would not interfere in the future with CRNAs' right to practice anesthesia.

In *Minnesota Association of Nurse Anesthetists* v. *Unity Hospital, et al.,* 208 F. 3rd 655 (8th Cir. 2000), the Minnesota Association of Nurse Anesthetists ("MANA") alleged that three hospitals and their staffs of M.D. anesthesiologists ("MDAs") conspired to terminate nurse anesthetists from the employ of the hospitals for whom they had worked and to put the nurse anesthetists to the Hobson's choice of either working for their competitors—the MDA groups at the hospitals—or ceasing to work at the hospitals. They did so by arranging with the hospitals to implement exclusive or sole-source contracts between each hospital and its anesthesia group. Curiously, however, three hospitals did this at the same time.

MANA alleged that the exclusive contracts, even if they might have been lawful at each hospital individually, were adopted pursuant to a conspiratorial plan among all three hospitals and their MDA groups to prohibit nurse anesthetists, who in the late 1980's had been granted direct billing rights under Congressional legislation, from competing independently of the MDAs at these hospitals. Indeed, the MDAs, according to the evidence, had professed the desire to rid the area of the new, direct, cost driven competition for anesthesia dollars—and the clear threat to their incomes it posed. In the words of their leadership, they vowed to the CRNAs (according to the evidence) that they were not going to "lose one thin dime," "a single dollar," or "power and control." One of the MDAs even enunciated a plan to achieve this goal: "We have a way to take care of the CRNAs in Minnesota . . . without worrying about antitrust. We will get the hospitals to fire the CRNAs and force them to work for us . . ."

But antitrust cases are not proved by motive alone. MANA had to prove the existence of an unlawful conspiracy and an adverse impact on competition. Proving conspiracy has always been difficult, even more so in the last twenty years, as courts pulled in the reins in antitrust cases in several different ways. MANA believed that the evidence it had discovered during the litigation, however, contained various indications that the hospitals and the MDA groups were not making individual decisions but had conspired among themselves to impose these arrangements at all three defendant hospitals. There was evidence that the MDAs had taken advantage of their close relationships to act in concert; proceeded in accordance with a "blueprint" for action supplied under the guide of legal advice by the attorney for the Minnesota Society of Anesthesiologists; exchanged confidential information about the negotiations of the sole source contracts at each hospital; shared information among hospital officials about how they implemented the sole source arrangements; and undertaken suspiciously similar steps in the way the hospitals and MDA groups went about executing these arrangements—even to the point of doing so through the same consultants and negotiating the termination of the nurse anesthetists' employment on very similar terms.

But the Eighth Circuit Court of Appeals rejected the notion that a conspiracy had been proved, partly because it did not find convincing several of the events MANA had alleged to be indicative of a conspiracy. The court found the inter-hospital exchange of information to be a "pro-competitive" exchange designed to enable the hospitals to accomplish efficiencies in sole source contracting. The opinion accepted without much scrutiny the defendants' explanations for their conduct, giving short shrift to competing inferences of conspiracy to be drawn from the contemporaneous behavior of the hospitals and MDAs.

The court did not say that excluding nurse anesthetists from the market is legal. All the case stands for is that, on the litigated facts, the hospitals made (in the court's view) the individual, non-conspiratorial choice to have anesthesiologist-di-

rected anesthesia departments, and did so without violating the antitrust laws. But the antitrust cases are clear that conspiracies by physicians to exclude or restrict the practice or reimbursement of categories of providers are unlawful, whether the effort is directed at nurse anesthetists (*Oltz*), podiatrists (*Hahn* v. *Oregon Physicians' Service,* 868 E. 2d 1022 (9th Cir. 1988)), psychologists (*Virginia Academy of Clinical Psychologists* v. *Blue Shield of Virginia,* 624 F.2d 476 (4th Cir. 1980), cert., denied, 450 U.S. 916 (1981)), osteopaths (*Weiss* v. *York Hospital,* 745 F.2d (2nd Cir. 1984)), or chiropractors (*Wilk* v. *American Medical Association,* 895 F.2d 352 (7th Cir.), cert. denied, 498 U.S. 982 (1990).

PHYSICIAN COMMUNITY ATTEMPTS TO RESTRICT PRACTICE OPPORTUNITIES FOR CRNA'S

To a large degree, this is a turf battle. That is the definition of competition. But this is an important battle in which today's consumer has a major stake. If CRNAs are pushed out of the market, it is not just nurse anesthetists pushed out of the market. It is yet another consumer choice which falls by the wayside and there is a good possibility that anesthesia prices could needlessly rise. It is clear from our history that the anesthesiologists, and some elements of the physician community as a whole, view CRNAs as an economic threat.

The American Medical Association (AMA) has attempted to orchestrate a concerted campaign to restrict practice opportunities for CRNAs. In December 1998, its House of Delegates adopted a resolution calling for the AMA's support of legislative and regulatory proposals defining anesthesia as the practice of medicine—AMA Resolution 216. Specifically, the AMA Resolution 216 states:

1. "That anesthesiology is the practice of medicine."

2. "That the American Medical Association seek legislation to establish the principle in federal and state law and regulation that anesthesia care requires the personal performance or supervision by an appropriately licensed and credentialed doctor of medicine, osteopathy, or dentistry."

What the AMA meant to accomplish by stating that "anesthesiology is the practice of medicine," is to limit the administration of anesthesia exclusively to anesthesiologists and to ensure that CRNAs—when they are permitted to practice at all—are supervised by anesthesiologists at all times and in all settings. Such an interpretation would seriously restrict the ability of CRNAs to practice independently in settings, such as office-based or free-standings surgical centers, where the only physician available is likely to be the operating surgeon. It would also restrict their ability to provide anesthesia services in rural areas where no anesthesiologist may be available.

Currently, the AMA has no way to put its unfair and discriminatory resolution into effect, except to call upon lawmakers to adopt such restrictions. However, AANA advised the House Judiciary Committee when testifying about its opposition to H.R. 1304, that if such legislation was passed, nothing would prevent AMA members from insisting that health plans adopt the most restrictive interpretation of proposal for the administration of anesthesia to their patients. This would be in order to exclude CRNAs from their plan or severely limit their participation. Such a restriction would penalize CRNAs and increase health care costs by eliminating healthy competition between anesthesiologists and nurse anesthetists, and would reduce the options now available to patients, payers and physicians to choose, if they desire, to obtain anesthesia services from independent CRNAs. This resolution has caused some organizations to contact AANA to inquire whether this requires them to employ only anesthesiologists.

Another interesting perspective comes from one of their own members. Consider the comments of former ASA President John B. Neeld, Jr., M.D. In his article "Market Factors Demand the Evolution of the Care Team", in the Georgia Society of Anesthesiology Newsletter (date uncertain) he clearly sets out his ideas about the role of anesthesiologists and nurse anesthetists in the health care system. He said in part:

"In addition to the reduction in demand for services and the reduction in reimbursement for those services, the supply side of Anesthesia personnel has also changed. There is now an excess number of Physician and Anesthetists competing for the same positions. An excess supply has brought the compensation levels that new anesthesiologists are willing to accept close in the salary levels enjoyed by anesthetists that the differential is negligible, particularly when one places a reasonable value on the greater skills, education, and professionalism that the physicians bring to a practice. *Replacement of anesthetists by anesthesiologists is by no means a death knell for these personnel; most practices will always have a need for a certain number of non-physician practitioners to provide economically viable coverage for underutilized anesthetizing locations.* Doing the right thing is frequently unpopular;

doing the wrong thing in this case will deprive patients of the opportunity for improved care and deprive our specialty of the opportunity for continued improvements in our knowledge base and technology that are dependent upon the maintenance of our Educational and Research Institutions and upon the continued attraction of the best and brightest medical students into Anesthesiology. Each of us must step forward and do the proper thing for our patient population, our specialty, and for Anesthesiologists and Anesthetists. *Anesthetists who add value to practices and are loyal to the true concept of a Care-Team should be retained and rewarded; those who do not should be replaced by our Young Physician Colleagues*." (Emphasis added)

We think Dr. Neeld clearly states the apparent agenda of the American Society of Anesthesiologists (ASA): CRNAs who cooperate with anesthesiologists have their place, but those who don't should be replaced by anesthesiologists. We don't know what other conclusion you could reasonably draw from Dr. Neeld's comments. Bottom line for nurse anesthetists: play ball, or be replaced.

Attempts at the State level to restrict the scope of practice for CRNAs

In addition to the AMA Resolution, there has been an increase in activity at the state level to circumscribe the practice opportunities of CRNAs. Many of these restrictions are being hard fought in state legislatures, medical licensure boards and the like. These proposed restrictions include:

Requiring CRNAs to be physician supervised in states that do not currently require such supervision.

Requiring that *anesthesiologists* supervise CRNAs in states that already require physician supervision, by requiring anesthesiologist supervision of CRNAs when anesthesiologists are "available," or by discouraging surgeons from working with CRNAs by requiring that physicians who supervise CRNAs be required to meet criteria possessed only by anesthesiologists (such as advanced anesthesia education and training "appropriate credentials.")

Requiring CRNAs practice to be jointly regulated by the board of medicine and the board of nursing, rather than the board of nursing alone, and

Reducing CRNAs' scope of practice (e.g. limiting the types of anesthesia that a CRNA can perform).

Other analysis of the issue

This activity by the medical community at large is not isolated, and has been recognized by people other than CRNAs. In his book, "Not What the Doctor Ordered, How to End the Medical Monopoly in Pursuit of Managed Care", (McGraw Hill, 1998) Jeffery C. Bauer, Ph.D., explains at length and in specifics, how organized medicine has, over the years, sought to constrain nonphysician providers from gaining a foothold in the healthcare delivery system. His chapter on nurse anesthetists and anesthesiologists provides an interesting perspective from a health care futurist and medical economist. He states in part:

"In the context of this chapter's main theme, I have saved the best example for last. (To be clear and fair, it is the example, not the professional group, that is best.) Nurse practitioners, nurse midwives, and nurse anesthetists are all excellent in their different areas of practice). The CRNA story illustrates perfectly the benefits of competition from qualified nonphysician practitioners and the harmful effects of doctors' anticompetitive efforts to control the market. In particular, it shows why persistent enforcement of antitrust law, something very different from health reform, is needed to protect consumers' welfare from doctors' monopoly when acceptable substitutes are available. . . .

"My reason for featuring the market for anesthesia services is actually quite strong from the economic perspective. Physicians may have been unsuccessful in their ongoing attempts to eliminate nurse anesthetists as an alternative, but they have been remarkably successful in depriving American consumers of the potential economic benefits of potential competition. In other words, doctors have controlled the market to their own economic benefit, which means consumers have been paying uncompetitive prices for anesthesia services. How else could one explain the fact that anesthesiologists have consistently earned more than twice as much as nurse anesthetists while providing the same service?

"The principal measure of economic harm has been the fee that anesthesiologist receive for 'supervising' nurse anesthetists. Unable to prevent state legislatures from licensing CRNAs, anesthesiologists have used their influence with health insurance plans (often as owners or directors) to make sure that payment flowed through the doctor's account. For years, many private health plans have had various schemes that allowed anesthesiologists to charge their full fee for services provided by CRNAs operating under their supervision. (The term is 'medical direction' in the arcane language of Medicare reimbursement. This technicality allows an anesthe-

siologist to be partially reimbursed for 'medically directing' up to four CRNAs as a time. It is nice work if you can get it . . . and having monopoly power helps.

"You can easily guess the rest of the story: the doctor they pays the nurse anesthetist a lower amount for performing the service, and he pockets the often substantial difference. This difference between an anesthesiologist's fee and the cost of the CRNA who actually provided the service might be justifiable if supervision were necessary, but it isn't. This practice is a textbook example of economic exploitation. It is a sign of unwarranted economic power which makes consumers pay more than what is necessary or fair. It reminds me of featherbedding, the discredited labor practice of using more workers than are necessary. Thanks to modern technology and excellent training, CRNAs do not need medical 'supervisors' any more than railroads needs superfluous brakemen and conductors riding in a caboose.

"Finally doctors have used their economic power to deny or restrict hospital privileges for nurse anesthetists. Even in states where CRNAs have full rights to independent practice and direct reimbursement, anesthesiologists have regularly prevented their nonphysician counterparts from having equal access to operating rooms, the site where most anesthesia is administered. This practice constitutes a significant barrier to entry, one of the key indicators of monopoly power in economic theory and antitrust law.

"This brief look at the market for anesthesia services shows that medical monopolists have many ways to suppress competition, even when qualified nonphysician practitioners receive licenses for independent practice. CRNAs have achieved much of the recognition sought by other advanced practice nurses, but consumers are still denied a free, fully informed choice in the marketplace because doctors continue to defend 'captain of the ship' authority with the outdated argument that they are unique (i.e., better). The many successes of CRNAs in a still imperfect market remind us that the medical monopoly must be fought on many fronts.

"To armchair economists, the story might seem to have a happy ending. Anesthesiologists' incomes have fallen dramatically in the past few years, which might be interpreted as a sign that competition has finally prevailed in this market. More than one force could be at work here, however, so do not jump to simple conclusions. Managed care has certainly exerted some downward pressure on money paid to hospital-based physicians. An oversupply of anesthesiologists is also believed to be a major explanatory factor. Anesthesiologists' professional associations are already working on plans to reduce the number of training positions and to restrict the entry of foreign medical graduates into residency programs.

"These efforts must not become red herring that divert our attention from the market's long-term problems, unjustifiable restrictions on consumer choice and related barriers to entry. Believe me, anesthesiologists have not lost interest in this issue just because they have realized they are too numerous. They are pushing like never before to control CRNAs. Monopolists do not go down easily when their incomes are threatened. Intensive, anesthesiologist-led efforts to place restrictions on nurse anesthetists have been initiated within the past two years in several areas of the country, including the bellwether states (in terms of health policy) like Ohio, Minnesota, New York, New Jersey, Pennsylvania, and Oregon.

"'A proposal made by the Oregon delegation to the 1997 mid-year meeting of the AMA House of Delegates serves as fitting proof that doctors are still fighting all advanced practice nurses to retain their monopoly power:

"Whereas, Increasing pressure by special interest groups has persuaded state legislators to introduce legislation unjustifiably expanding scopes of practice of alternative and allied health workers; and Whereas, Many healthcare workers seek to legislate their ability to practice medicine, rather than obtain a high level of expertise and competence through medical school education and training; and Whereas, Medical decisions for patients are best made by medical doctors; and Whereas, There is considerable confusion on the part of the public and some legislators regarding the qualifications and training of healthcare workers versus medical doctors; and Whereas Education of the public and legislature needs to occur to replace confusion and ignorance with facts; therefore be it RESOLVED, That is the it is the policy of the American Medical Association to protect the public by supporting medical doctors against efforts advanced by alternative providers seeking increased medical control of patients by legislatively expanding their scopes of practice without physician directions and state boards of medical examiners oversight.'"

Dr. Bauer concludes that the resolution was reaffirmed by the Delegates as a statement of existing AMA policy.

This academic analysis of the situation between nurse anesthetists and anesthesiologists is enlightening, as it shows from a neutral source what this battle is all about—competition.

ANESTHESIOLOGISTS HAVE PROBLEMS OF THEIR OWN

Clearly a case can be made that to the extent there are adverse events in anesthesia, both providers share in that unfortunate fact. However, a recent spate of activities should be brought to light, given the relentless attacks that anesthesiologists have made on CRNAs.

In April of this year, an Army anesthesiologist was charged with involuntary manslaughter of a high school student at Walter Reed Army Medical Center. The allegations are that the anesthesiologist improperly administered an antibiotic too rapidly causing the death of a young girl during what should have been routine surgery. There were further allegations that the anesthesiologist attempted to cover up, "lying to doctors who were trying to save" her. (Washington Post, "Doctor's Lies Not Fatal, Lawyer Says", by Steve Vogel, April 26, 2000).

Senator DEWINE. Let me thank all of you. I want to start, if I could, maybe by talking a little bit about and focusing on Dr. Silber's study. I have a couple of questions for him, we can have a little discussion about the study itself and then we will get into some other areas, as well.

First, Doctor, you testified and you mentioned that you had, what, an $88,000 grant from the American Board of Anesthesiology to examine the influence of board certification on outcomes, is that correct?

Dr. SILBER. That is correct.

Senator DEWINE. Was there any other source of funding for your study? You may have already mentioned it and I apologize.

Dr. SILBER. While the study has been going on, we have received grants from the Agency for Health Care Research and Quality that relate to developing methodology and that methodology was applied to our study. So indirectly, we have been funded through that agency, and also, we have self-funded this work because the $88,000 grant which we received in 1995 only represents about one-quarter of the cost of this study. It is a major study that has taken us a long time to do.

Senator DEWINE. When will that actually be published?

Dr. SILBER. In about 3 weeks.

Senator DEWINE. In about 3 weeks. Where will it be published?

Dr. SILBER. In the journal, Anesthesiology.

Senator DEWINE. So we can look forward to seeing the entire study at that point?

Dr. SILBER. Yes.

Senator DEWINE. I want to make sure that—I am sorry.

Dr. SILBER. I was going to make one other point, if I may. I am sorry.

Senator DEWINE. Sure.

Dr. SILBER. That we had done a line of work looking at the influence of board certification on outcome prior to the issuing of that grant, which is why the American Board of Anesthesiology was interested in our work. We had published a few papers prior to that time. So this was not a new work that we just took on because of the grant. We were following our line of research during that period.

Senator DEWINE. I want to make sure that I fully understand exactly, and you have gone over this but I am just going to ask you to go over it again. In layman's terms, explain exactly what you studied so we understand what you studied and maybe what you did not study.

Dr. SILBER. We looked at the Medicare claims data for patients who underwent general surgical or orthopedic procedures in Pennsylvania for 1991 through 1994. So we had the billing data. We——

Senator DEWINE. Excuse me, if I can.

Dr. SILBER. Yes?

Senator DEWINE. Why did you use the billing data?

Dr. SILBER. Well, that is the only data available from Medicare and it is a very rich source of data. It has a wealth of information on the illnesses of the patients and their previous hospitalizations, and from the Medicare data we know exactly when the patients died. So it is a great data set that lets us know what was done to the patient in the hospitalization, how sick were they when they went into the hospitalization and when they died.

Senator DEWINE. To follow up on that, what is the relevance of using the 30-day period? For a layman, I might think, well, if something happens 15 days later or 25 days later, what does that have to do with the whole issue that we are talking about today?

Dr. SILBER. I approached this subject through the field of health services research, and the gold standard in most studies that use claims data is 30-day mortality, or 30 days after hospitalization. That is because many different factors that can occur during an operation or during the initial treatment of a patient that may influence their ultimate survival later on in the hospitalization. So by looking at 30-day mortality, you have a long enough period to see what effects might occur from things that went on during the hospitalization. It is not too long so that other risks would enter in. So it is generally considered the gold standard for looking at outcomes.

Now, the trouble with using anesthesia-related deaths, which was alluded to by Jan Stewart, is that it is a very restrictive definition. To talk about one death in 250,000 probably is really not the true estimate of how many patients might die from an operative procedure or from an anesthesia procedure because people can die days or weeks after the surgical event with problems that were related to the surgical event. So the classic time period is 30-day mortality, and that is why we use that.

Senator DEWINE. And so there is no attempt to distinguish why that person died?

Dr. SILBER. What we do in these analyses is adjust for how sick the patient was when they went in for the hospitalization, and then we ask what was different about their care, they were directed or they were undirected, and then we ask, were they alive or dead at 30 days. That accounts, by adjusting for how sick the patient was initially and what the procedure was, then what we are left with is the residual difference in the death rates is the difference related to the initial factor, meaning direction or undirection.

Senator DEWINE. OK. Go ahead. Thank you very much. Now go ahead and tell us, again, what you were comparing here.

Dr. SILBER. We looked at patients who were directed and undirected in Pennsylvania——

Senator DEWINE. Do you want to give me your definition of those terms or the standard definition?

Dr. SILBER. The definition that we used was as follows. A patient was directed if we found evidence that an anesthesiologist billed for

their services for anesthesia. So in the directed group, we were referring to cases that had anesthesiologists directing their care. There were some instances where we had non-anesthesiologists directing care. We only looked and only counted patients who were directed by an anesthesiologist as being in the directed group.

The non-directed group means you were not directed by an anesthesiologist, which meant that you might have been either supervised by a physician who was not an anesthesiologist or supervised by an anesthesiologist.

Direction——

Senator DEWINE. So as a practical matter, I want to make sure I understand the universe and how it really works if I am being operated on, and anyone can jump in if they disagree with what the doctor is saying, but he happens to be the person I am talking to at this moment, so jump in.

But explain to me what the universe is. In the United States today, what are the potential combinations on this issue? If I were to be operated on tomorrow, what might I encounter?

Dr. SILBER. Your anesthesia care can be performed personally by an anesthesiologist. It can be performed by a team of an anesthesiologist and a nurse anesthetist. Or it could be performed by a nurse anesthetist who was not directed by an anesthesiologist but was supervised by a physician. That would be the universe of possibilities in the Medicare population.

Senator DEWINE. OK. The first one is the anesthesiologist personally does it.

Dr. SILBER. Personally performing the case.

Senator DEWINE. OK. The second option is what?

Dr. SILBER. If the anesthesiologist works with the nurse anesthetist and is directing the case. And our definition of directed included personally performed or directing. That was in our directed group. You had an anesthesiologist physically present for your case, whereas——

Senator DEWINE. Does that mean at all times? What does that mean?

Dr. SILBER. There are regulations according to the Health Care Financing Administration that relate to the times that you have to be in the operating room. There are critical times that you must be there in order to bill for those services.

Senator DEWINE. In order for the term of art——

Dr. SILBER. Directed.

Senator DEWINE [continuing]. Directed.

Dr. SILBER. That is correct.

Senator DEWINE. And your third possibility——

Dr. SILBER. I am calling that group the undirected case, or the undirected group, and that undirected group would include cases where nurse anesthetists were supervised but they were not directed.

Senator DEWINE. And do you want to tell me what supervised means?

Dr. SILBER. Supervised is a term that really is used when you do not direct, so that basically signing off on a chart would constitute supervision, but there would be some interaction between the physician and the nurse anesthetist. I would maybe ask——

Senator DEWINE. Somebody jump in. What does it mean? Who is there? Who is in my room while I am being operated on?

Dr. PIERCE. Well, it does vary enormously across the country from rural to city areas and even from city to city, but the last category, the so-called non-directed but supervised, would include rural areas usually in which the nurse anesthetist operates or gives anesthesia with only the surgeon present, and that is called supervision because that is what the Medicare law requires. I do not remember the——

Senator DEWINE. So the supervision, does that mean the supervision is actually then provided by that operating surgeon?

Dr. PIERCE. By that surgeon.

Senator DEWINE. By that surgeon who is operating on the patient.

Dr. PIERCE. If there is not an anesthesiologist involved, the supervision, according to Medicare rules at the moment, is provided by the surgeon.

Senator DEWINE. Is everybody OK with all this?

Ms. STEWART. That is true. I would point out——

Senator DEWINE. Ms. Stewart, jump in here.

Ms. STEWART. I would point out, Mr. Chairman, that those rules for medical direction are for payment purposes. They are not quality standards. They are for—there are seven conditions of participation under Part B for an anesthesiologist in order to be paid for medical direction, and that is what medical direction refers to are those payment modality conditions.

Senator DEWINE. But they do—I understand it is a payment issue, but it also does tell us something about what actually happens. There is a relationship between that and the real world——

Ms. STEWART. That is a theoretical relationship.

Senator DEWINE. Theoretical, OK.

Dr. PIERCE. Well, I must say that I have not prepared for this with help from the American Society of Anesthesiologists because, indeed, my only interest for 25 years has been patient safety. I would point out that, however, during this 25 years, I practiced in the anesthesia care team mode with a large group of physicians and nurse anesthetists and most of our anesthesia consisted of an anesthesiologist and a nurse present, usually on a directed basis of one to two nurses being directed by the anesthesiologist.

In those 25 years, we never did a case, morning, noon, night, Saturday, Christmas, or any other time at all unless the anesthesiologist was present for the induction of anesthesia, and I do not understand some statements made by the AANA indicating that this is not true. Not once in my life did a nurse in my group give anesthesia without the anesthesiologist. So I start back where I was. It is a very complicated question. It varies all over the map and I think you can find almost any situation you want to look for.

Dr. SILBER. But to simplify things, in our study, we make it simple.

Senator DEWINE. To get back to your study, which is where——

Dr. SILBER. To get back to the study——

Senator DEWINE [continuing]. And I took you off of it, so I apologize, but I wanted to make sure we got our terms and everything set here. Go ahead.

Dr. SILBER. But what we did was we looked at cases that had an anesthesiologist present in the OR because the billing suggested they were present in OR and those cases where the anesthesiologist was not present. So the directed meant the anesthesiologist was there and the undirected cases meant we did not have evidence that the anesthesiologist was actually there. So that, in the simplest form, we are looking at an anesthesiologist involved with the case directly and one that is not. I hope that that is——

Senator DEWINE. I want to come back to you, but go ahead. Ms. Stewart, go ahead.

Ms. STEWART. I would like to say that all this, you know, the dialogue around medical direction has been going on a long time, too——

Senator DEWINE. I understand.

Ms. STEWART [continuing]. But what we are talking about in this hearing is the elimination of supervision by physicians, whether that be anesthesiologists or operating practitioners of any ilk. It really does not have to do with the quality of what is delivered in any given care team setting or what happens with those conditions of participation. It is the elimination of supervision under Part A for facility payment and not for providers.

Senator DEWINE. Good. I want to get to that in a minute because what I want to do is, to make it very clear what the study did do, and then I am going to ask for all of your comments about what the significance of the study is. If you could finish, Doctor, I will try not to interrupt you again.

Dr. SILBER. We created this data set that looked at who were directed and who were not directed. We looked at their 30-day mortality status and we adjusted for many different medical conditions that one should adjust for when trying to compare across two groups. We would not want it to be that one group had sicker patients and therefore looked worse because they had sicker patients.

After adjusting in numerous ways using Medicare data and also adding to Medicare data special data from Pennsylvania—Pennsylvania is a special State because it has physiologic data that it collects on every discharge—we included physiological data in the analysis and found the results to be the same. We found that difference in outcome, and that was that there were 2.5 excess deaths per 1,000 cases in the group that was not directed, and we also found 6.9 excess deaths per 1,000 cases with complications.

Senator DEWINE. All right. Now, Doctor——

Dr. PIERCE. Let me just say one more word about the differences.

Senator DEWINE. Excuse me. What I want to do, and I am going to give each one of you a chance, I want to know what you think the significance of the study is, and then if anyone wants to talk about what you think the significance of this study is in regard to the ultimate issue here that we are talking about. Maybe we will start with the person who did the study. Doctor, what does this mean? What does this tell us? If you were to write for Time magazine, or Newsweek or the New York Times tomorrow or the Cleveland Plain Dealer, what would you write about the study? What does it mean?

Dr. SILBER. To me, the study means that if I am operated on, I would want my care directed by an anesthesiologist, that I would

have a higher rate of survival if I have an anesthesiologist directing my care. That is the first point in why it is significant. This is not a hospital effect. We adjusted greatly for differences across hospitals. This is an effect from, as best we can tell, from the provider, from the anesthesiologist direction versus lack of direction.

Now, to me, that is important because I would be concerned about any regulation that might change the chance that the average patient gets direction by an anesthesiologist. The Senate will have to decide whether these regulations will increase or decrease the chance that a patient gets direction from an anesthesiologist. But what my study says is that patients survive—there is higher survival in patients who have direction by an anesthesiologist.

Senator DEWINE. Let me do this. You say there is a higher rate of survival if an anesthesiologist directs the care.

Dr. SILBER. Right.

Senator DEWINE. You say the second question then, in your opinion, is whether or not these proposed regulations will decrease or increase, change in any way that fact, the number that we have today, is that correct?

Dr. SILBER. Yes.

Senator DEWINE. Now, let me ask the rest of the panel, number one, if you agree with what Dr. Silber's two statements are. Number one, is that what it shows, in your opinion, and number two, is that ultimately the issue, and if it is ultimately the issue, as he says, number two, what do you think the change in regulations would do? What will the change in regulations do?

Mr. FALLACARO. I believe, Senator, with all respect to Dr. Silber, that his statement is a leap of faith at this point.

Senator DEWINE. OK. Why?

Mr. FALLACARO. Right now, as an academician, I do not even consider an abstract. I sit on editorial boards that will not even look at an abstract until that paper has seen the light of day and is opened up to the scientific community for rebuttal. I have not had the privilege of looking at Dr. Silber's data, but I can tell you a couple of concerns that I have about it.

He stated in his testimony that he was funded and his funding was for, as I understand it, the effect of board certification on outcomes, not to look at the differences between nurse anesthetists and anesthesiologists. So I would like the record clear on that, unless I am mistaken.

The second thing is, because the article is not published and in my mind has no scientific credibility until that time, I do not believe that it is on point, and let me explain. The high death rates that Dr. Silber cites in his study are 200 times—200 times that of the Institute of Medicine's report that Dr. Pierce just talked about as being significant from anesthesiology's contributions. They cannot both be right on this issue.

I think so far as the three outcomes that were looked at, I am very concerned about a statement in the abstract that says this. It says, admissions involving more than one procedure were assigned to the non-anesthesiologist group if for any procedure the nurse anesthetist was supervised by a non-anesthesiologist, and let me explain what that means to me. That means if somebody comes into the hospital and has four procedures in a row and any one of those,

any one of those was done by a nurse anesthetist with a surgeon, then it gets assigned to the nurse group. That is what it says. Admissions involving more than one procedure were assigned to the non-anesthesiologist group if for any procedure the nurse anesthetist was supervised by a non-anesthesiologist.

Example, if somebody comes in for open heart surgery and they need a cysto, a look into their bladder, and I happen to be the nurse anesthetist doing that with a surgeon and that is on the first admission, the second admission he comes in and has open heart with an anesthesiologist, the third admission has a carotid with an anesthesiologist and he dies 30 days out, it appears that that is assigned to my group. It appears that it is a huge selection bias, one again, that—again, I only see the abstract in front of me.

The other thing that makes me very concerned is that I know that complications occur much more frequently, much more frequently than mortality. Yet in Dr. Silber's study, he states that after he does the statistical tests, that complications were not significantly different, and I had to do some work and look into some of his older articles to see what those complications were, and he lists things such as psychosis, internal organ damage, wound infection, gangrene, all things that could lead to mortality but things I think all anesthesia providers would agree that have little impact upon our work that we do.

The thing that is most temporal, most temporal to anesthesia is complications, and the fact that there is no significant difference validates what we have been saying, that there is no significant difference, in my mind, at least.

Finally, the title suggests a comparison. This study clearly is not a comparison, and where Dr. Silber states that the number of anesthesiologists were associated with, I would say it is coincidental that they were there, that there is clearly no cause or effect that shows that anesthesiologists were definitely involved in intervention on any of those deaths. These are just some of the concerns I have with the study.

And then one final thing, Senator. Unlike Dr. Pierce, I have worked in all settings, one of which was I was a sole anesthetist in a rural community working under the direction of the surgeon alone, the surgeon alone, just me and the surgeon doing anesthesia and I was the only provider in that care and that is a model that is prevalent in the vast majority of rural hospitals in this country. The issue that I have heard over and over again is we want to remove supervision. I thought the issue was we wanted to defer supervision to State law so that States that have different demographics can look at need of their populus and serve that need appropriately.

Senator DEWINE. Dr. Silber, do you want to, while it is fresh in your mind, I will give you the chance if you want to to respond to anything about the study.

Dr. SILBER. Let me respond. I have to say, it is a bit unfortunate that the paper is not out yet. It will be out in 3 weeks, and almost—in fact, all of the comments that you have raised are addressed in that paper.

The first matter, on the high death rates, that the death rates in our study showed 2.5 per 1,000 whereas it is often stated that

the mortality rates in anesthesia are only one in 250,000. I want to state that it is comparing apples to oranges. The anesthesia death rate statistics are talking about deaths during the operation or within the first 24 hours of the operation. They are very restrictive. So of course the rates will be low. Any time you restrict the death to right during the operation, you will have less of them. Health services researchers know that those are biased numbers and that is why we used the unbiased figure of 30-day mortality.

So our study is not inconsistent with the studies tracking anesthesia mortality over time, but we are talking about all the different effects that can happen during the operation that later can lead to death, not death within 24 hours, and I think that can explain that.

In terms of the question about more than one procedure, we did a number of analyses in the paper coming out looking at whether multiple procedures makes a difference. Our results were unchanged when we put in a variable for multiple procedure or not. We also, and you have to read the paper and I apologize for just having an abstract, but it will be out in 3 weeks, if you had any direction by an anesthesiologist during any day during the hospitalization, that day would be considered a directed day. So many of the situations that have just been brought up would not apply.

The concept that complications were the same and, therefore, there is really no difference between providers, I just do not think is correct. The definition of complications that we used was not a definition that talked about direct anesthesia complications because you cannot do that with Medicare data. What you can do with Medicare data is get a rough idea about what complications occurred and we used that as a severity adjustment. Please do not look at the equal rates of complications in this study as a statement for equivalence in quality. Look at the mortality rates. The data is very good on mortality and it shows a considerable difference.

Finally, the comment about who funded the study. Again, we started this line of work well before we knew anything about regulatory changes that might occur with anesthesiologists and nurse anesthetists. We have had a history of doing research in this area and it was natural that we were funded from a group that was interested in this same topic. I think the study will stand for itself and I look forward to the time when everyone can read it, which will be in about 3 weeks, and then I do not think these questions will be brought up.

Senator DEWINE. Your study, of course, did not measure outcomes for unsupervised CRNA's, correct?

Dr. SILBER. If a CRNA was unsupervised, they might have fallen into the undirected group. Remember, we do not have data on unsupervised versus supervised. Our data was directed versus not directed. So it is possible in the not directed group, that group that had higher death rates, that could possibly include unsupervised cases.

Senator DEWINE. Dr. Pierce, let us go to you. Tell us what this study means.

Dr. PIERCE. Yes. I have not read the study. I did read the abstract and I think I am not qualified to comment on that subject until after I read the study.

I wanted to emphasize a little bit more, though, about my own practice in a very large hospital attached to the Harvard Medical School, that indeed at night and weekends during emergency surgery, all of the anesthesia was provided by the anesthesiologist. Only during the daytime did we work in the nurse care team with the nurse anesthetist. What I am trying to do is emphasize the variability, enormous variability in methods of practice across this country. Again, this is not an area in which I keep up with particularly.

I would say somewhere between—I can be corrected—30, 40 percent of all anesthesia is administered by an anesthesiologist by him or herself; some 8 or 10 percent is, largely in rural hospitals, but still some 8 or 10 percent is administered by a nurse anesthetist alone; and the in between 30 to 40 percent and the 10 percent are various combinations of nurse anesthesia care teams, anesthesiologists working with residents and what have you. So it is extraordinarily variable.

Senator DEWINE. Any other comment about that study, what it means? I understand you want to read it, but——

Dr. PIERCE. Well, epidemiology, outcome studies, are the most difficult thing that is on the face of the earth, and everybody years before and especially since the IOM study is insisting on outcome evaluations for everything. But they are extraordinarily difficult to do. They are extraordinarily expensive to fund. And even though I have worked in standards for 25 years, I am not sure these outcome studies are going to be very numerous, so I just want to wait and read the paper when it comes out.

Senator DEWINE. That is fine. That is fair enough. Ms. Stewart, do you want to comment?

Ms. STEWART. Sure. I would just like to reiterate that the proposal under consideration for this hearing is the elimination of supervision under Part A, and lest anyone think that that has anything to do with the anesthesia care team, I would just like to restate that this provision lies in Part A of Medicare for facilities to be paid. Most likely, if this provision comes into play, it is when a nurse anesthetist is being, "supervised" by a surgeon and there are not any anesthesiologists around.

This proposal is not going to remove the anesthesiologist from the place where they are already working. That is not the design, that is not the intent, and that is not going to be the outcome of what will happen. That is really not—it is off-point to discuss medical direction because that is not what this is about. Anesthesiologists and nurse anesthetists are going to continue to work together in the operating room like they do now. This is not going to change that.

As I said earlier, if those facilities who have both providers in their operating rooms delivering care wanted to change that, they could have done that at any time. There is no requirement anywhere to have anesthesiologists to deliver anesthesia except by the facility standards, and that is not going to change. Facilities are going to be free to keep their standards as they are. States are

going to be free to impose supervision or not as they see fit. This is not an issue about complete lack of oversight or collaboration with nurse anesthetists. That is not what this is about in the least.

And when we talk about safety standards, the nurse anesthetists, just to let you know, have been active in safety and quality for the entire duration of our lifetime as an organization. It was why we were put together. We were the first group to publicly accept the prestigious Harvard safety standards. We wrote OB guideline standards and we were the first group to write standards for office-based anesthesia. We have been in the forefront of leading education and safety ever since the inception of our organization. It is a very on-point concern for us.

Dr. PIERCE. I do not think we know what the result will be after this rule is removed, if it is removed. I am unable to predict relationships in hospitals between nurse anesthetists and anesthesiologists 2 to 3 years down the road. I think that is impossible to do. What I do know is that you do not regulate aviation State by State, and if you turn this over to State by State regulation of this issue, and I have already stated why I believe it should be not changed until the studies are available, you are going to end up with 50 more similar contests to what we are going through now with both organizations making claims and statements. Certainly what the ASA has said is no worse, in my view, than what the AANA said. It is just not a fortunate situation.

Mr. FALLACARO. Senator, if I may, again, being in academia, if somebody had asked me ahead of time, why are you opposed to a study, I am not opposed to studying things and phenomena when they deserve to be studied, when they are phenomena that raise their heads, when there are problems and issues at hand. And up until just a few minutes ago, I had always thought, along with many of my colleagues, that the Joint Commission on Hospital Organizations standards of complications of anesthesia were those things that were within 48 hours of the procedure or things that were linked to us.

What Dr. Silber asks us to buy is that things out to 30 days, deaths out to 30 days that we may be associated with, I do not think our malpractice insurance carriers want to hear this. I do not think we want to see that our death rates are now 200 times what is predicted. Again, I just think that this is out of the blue from all traditional studies I have seen in the area, and as Dr. Pierce has said, to do kinds of outcome studies are very expensive, very, very difficult to control because of the different practice settings.

And again, with respect to Dr. Silber, no amount of statistical control can account for flaws in design. And again, if we are looking at a nurse anesthetist versus anesthesiologist, then why were anesthesia complications not the ones that we would want to consider the most in looking at these things?

So again, I look forward, as well, to reading the paper, because again, I also feel there may be trouble in Pennsylvania that I want to look at, as well, if there are that many deaths.

Dr. PIERCE. I would say that the JCAHO Joint Commission attempts over the last 10 years to look at anesthesia mishaps and morbidity have not been successful. They have had a reporting system now for 2 or 3 or 4 years and they do not get any reports be-

cause the hospitals are afraid of legal factors. That is another major issue with the IOM report. How that is going to turn out, no one knows. But my summary is that we simply do not know the incidence of anesthesia morbidity and mortality. We can only take an educated guess.

Senator DEWINE. Dr. Silber, do you want to comment? Then I am going to move on to some other questions.

Dr. SILBER. We did a study. We have data and we are going to present that data. It is going to be published in 3 weeks. I hope everyone reads it and then they will make their own conclusions. But there are not many other studies out there. I think there needs to be more studies done on this issue. Mine is not the final study. It should not be considered the final study on this issue. There should be more studies. There should be studies that look at the actual chart and review the charts in patients who had directed and undirected care, look at the deaths and the survivors in those different groups. More research is needed. Mine is not the definitive study.

But I just have to say that the use of 30-day mortality is absolutely the gold standard in health services research. The use of anesthesia-related deaths, which my colleague on my right has stated, is a statistic that is good for following anesthesia practice over time, but it does not get at the true amount of deaths that are caused by variations in anesthesia practice. We did it the right way and we did it the way that my colleagues in health services research would say would be the right way and I stand by that.

Senator DEWINE. Ms. Stewart, let me move, if I could, back to the rural area again. You state in your testimony that the proposed HCFA rule will increase access to anesthesia care in those rural areas. My understanding is that under current rules, the only requirement is that CRNA's be supervised by a physician and that in rural areas, then, that physician is certainly often the operating doctor or the attending physician.

Even if the HCFA rule goes into effect and supervision is not required, it seems clear that a surgeon or attending physician will still need to be present to perform the procedure, so the patient will be faced with the exact same requirements, a doctor and a CRNA. Is that correct? And if that is correct, then how does removing the supervision requirement increase access to these services?

Ms. STEWART. Thank you for asking, Mr. Chairman. The problem that we have seen with the supervision requirements in those underserved areas is that the surgeon erroneously believes in some instances that they assume the liability of the actions of the nurse anesthetist—we refer to that as vicarious liability—because they have been named the supervising physician.

Now, in the vast majority of situations, the operating practitioner does not know as much about the anesthesia as the nurse anesthetist, and if they perceive that they are then liable for the actions of the nurse anesthetist, there is worry that since they do not really know how to direct anesthesia, or would they want to, they worry that they are then going to be liable for something that the nurse anesthetist may do. Now, we have been able to show in case law that surgeons are no more liable working with nurse anesthetists than anesthesiologists, but the problem that we find is that

there is some disincentive in those underserved areas for those places to bring CRNA's in because the surgeons object to working with them because of the perception of liability on their part, if you followed that long track.

Senator DEWINE. No, please explain it again.

Ms. STEWART. OK. When a nurse anesthetist and a surgeon work together, the surgeon may have concerns that if the nurse anesthetist does something that causes an adverse outcome, the surgeon could be held liable for that because he is the supervisor.

Senator DEWINE. OK.

Ms. STEWART. OK, and we refer to that as vicarious liability.

Dr. PIERCE. This concept——

Senator DEWINE. Let her finish.

Ms. STEWART. What we find is that in some areas, surgeons have wanted to bring in either—they either will not do their cases because there is no anesthesiologist or they want to hire an anesthesiologist in for themselves. There are all sorts of permutations about that. What we found is a disincentive for nurse anesthetists to be utilized in those underserved areas.

Senator DEWINE. So what then actually happens? There is this disincentive to get this CRNA in there, so as a practical matter—I am the patient—what does that mean to me? What happens? Do I get operated on or not?

Ms. STEWART. You may or you may not.

Senator DEWINE. OK.

Ms. STEWART. You may have to drive to a major regional medical center to have your surgery done, which may be quite removed from your home.

Senator DEWINE. All right. So the options are, what your testimony is, I may have to go someplace else, a big city, to get operated on——

Ms. STEWART. Or a larger city.

Senator DEWINE [continuing]. Or a larger city, or if the operation takes place, then who is there? The surgeon is there and an anesthesiologist is brought in?

Ms. STEWART. It could be a nurse and anesthesiologist or an anesthesiologist that is there to oversee the care. There are all sorts of different ways that could happen. There is no one answer to that. But it does cause some impediment to the delivery of anesthesia care in some of those underserved areas.

Senator DEWINE. OK. We will take that and I will come back to you in a minute. Comments on that? Dr. Pierce, you had started to talk, so I am going to let you go first.

Dr. PIERCE. I think the vicarious liability concept has changed dramatically in the last 20 or 25 years in my understanding in that surgeons are no longer found liable for the acts of the nurse anesthetist. So I do not think it will affect the number of nurse anesthetists in rural areas at all.

Senator DEWINE. Well, I think what you are both saying, though, is it is not a question of law, it is a question of perception.

Ms. STEWART. With all due respect, Dr. Pierce, we do still see it happening in the rural areas. Unfortunately, the surgeon colleagues of yours and mine have not quite gotten the message that the rules have changed.

Senator DEWINE. Dr. Silber, you were next.

Dr. SILBER. I think the three main results from my study have relevance to this question. We found, first of all, that direction reduced the death rate. We also found that the higher the nurse-to-bed ratio, the lower the death rate. And we found that the larger the hospital, the lower the death rate. All three had independent effects. If you think about——

Senator DEWINE. Give that to me again. The larger the hospital——

Dr. SILBER. The larger the hospital, the more nurses per bed and direction by an anesthesiologist were the three factors that influenced mortality.

Senator DEWINE. So you are telling us those are the three things that, as a consumer, if I could, I would check?

Dr. SILBER. That is right. So now if you think about a regulation that might make it easier for one to get their procedure out in the periphery at that hospital that cannot afford an anesthesiologist, that probably, if they cannot afford an anesthesiologist, probably is not going to have as high a nurse-to-bed ratio and is not going to be as large, my study would be—the results from my study would make one somewhat concerned. So I think we have to look at the whole picture when we think about these regulations.

Senator DEWINE. Mr. Fallacaro.

Mr. FALLACARO. I think ease of access is something that we can talk about, but I think taking care of a major rural population of this country is of utmost importance, those who cannot travel to large medical centers. Again, I work in a small community hospital where there was no anesthesiologist and this was in New York State and the medical liability, Mutual Insurance Company, at that time said that because of the supervision—quote, because the nurse anesthetist needed to be supervised, that that may indeed add added liability to the surgeon. The surgeons were nervous and frightened.

Anesthesiologists are willing to supervise nurse anesthetists and take added liability because they are compensated for it. Surgeons are not. If they were, they might be a different story. But they are not, so therefore the surgeon says, "Mike, you are doing great anesthesia, but boy, oh boy," you know, and the surgeon knows nothing about anesthesia. Again, you are doing great anesthesia, there is nothing wrong, but we may want to get an anesthesiologist down here or in here, and then they had tremendous trouble trying to find somebody to come down because, again, even Dr. Orkin, an anesthesiologist researcher, has cited over and over that to get anesthesiologists to move to these areas is very difficult. It is an access issue.

Senator DEWINE. Dr. Pierce, let me go back to you, if I could. As I mentioned at the beginning of the hearing today, the antitrust analysis that must be done when examining if standards are anticompetitive is a very fact-based analysis. Specifically, one must examine all the facts and circumstances to determine if the standards set are reasonable to assure quality and consumer confidence.

In your testimony, you discuss the voluntary standards for preanesthesia care, basic anesthesia monitoring, post-anesthesia care, and then you conclude that they are all reasonable under that test.

Let me ask you, though, what about the current HCFA rule that requires physician supervision of CRNA's? Is that reasonable or, in your opinion, does it unfairly exclude CRNA's from the market? I will give, the rest of you a chance to respond. Dr. Pierce?

Dr. PIERCE. Well, I am the only anesthesiologist speaking today, and again, I have spent my last 20 years in the safety side of anesthesia, but I guess I should take the opportunity to point out the difference in education between an anesthesiologist and nurse anesthetist. It is really not 10 years versus 12 to 14 years. It is a very different background of education. Anesthesiologists go to medical school, or college for 4 years, medical school for 4 years, internship, which in many ways is the same as being an ICU nurse, and then 3 to 4 years as a resident. So we are talking about 4, 8, 9, 10, 11, 12, 13, 14.

And my view is that anesthesia is the practice of medicine. We are medical doctors. We make decisions about the illness the patient has. Most of the patients now come into surgery at age 75 or 80, are severely ill in other systems, renal, lungs, heart, and I just think the physician approach to these patients is safer. That is simply all I can tell you about that question.

Senator DEWINE. Who else wants to comment?

Mr. FALLACARO. I have been practicing anesthesia for 20 years. I am not practicing medicine. If I were practicing medicine, you should charge me as doing so, as a legally practicing—I am not. This scope of practice issue, I served several years on the New York State Board for Nursing. This scope of practice issue, should I charge Dr. Pierce with practicing nursing if he comes in and takes a blood pressure? Again, anesthesia is a body of knowledge unto itself and for 100 years, it has been within the scope of practice of nurses to be able to administer anesthesia, as has been many professionals.

And I agree with Dr. Pierce that we do need—OK, hear this now—we do need a medical expert in the operating room. We do not practice anesthesia independently. And again, I am prepared as a nurse, the physician is prepared as a physician, and if I need consultation on a medical condition, I can choose to get that consultation from an anesthesiologist, from a surgeon, from a cardiologist or whatever. We are not practicing without medicine in an intercollaborative manner.

Senator DEWINE. Dr. Silber, any comment on that, or Ms. Stewart?

Dr. SILBER. I just think that we should go back to looking at data and we need to study this problem with more study—we need to look at this problem with more studies and look at it carefully and that my study raises concerns.

Senator DEWINE. Ms. Stewart.

Ms. STEWART. I am sorry, I got derailed by that last comment. I agree with several comments here today, but what we cannot ignore is that anesthesia is incredibly safe today and it has only gotten safer in the last couple decades. I think that is because of a lot of things that have been mentioned here. Our educators are educating us better. Our clinicians are learning more. The drugs are better. Our safety monitoring is better. It is ludicrous to think that this one line in the Federal Register that has to do with pay-

ing the facility is going to jeopardize the safety of what has been being delivered to our patients. The quality and safety is not going to change because of facility payment.

Dr. PIERCE. I would comment that anesthesia is much safer apparently than it was 25 years ago, but it is far from guaranteed to be totally safe. I hear of anesthesia mishaps several times a month across the country. So we have a long way to go to make it absolutely safe. I did not understand the comment by HCFA that anesthesia is so safe, it does not matter anymore. That is simply not true. There are plenty of anesthesia complications.

Mr. FALLACARO. Senator, the one question that I have in my mind is, again, I am glad that Dr. Silber's study is going to be published soon and the issue here would seem to be whether or not you believe or your committee believes that States have the competence and the ability to read his study and make a decision based upon that study. I believe States do. They have done this in other areas, and I speak from experience as working on a State board.

Senator DEWINE. Let me ask all of you a question, and maybe we will start with Dr. Pierce on this one. One concern raised about the proposed rule is that the CRNA's may be allowed to administer anesthesia without supervision by a physician, but even if the proposed rule is enacted, surgeons will still be in the operating room with the CRNA's as they administer the anesthesia. So, how will that be different from the situation that exists today? What will happen out there? Get out your crystal ball. What is the difference? What will we see in 2 or 3 years because of this change, anything?

Dr. PIERCE. That is what I said a few minutes ago. I do not know that any of us has an idea what is going to happen. It may change considerably. There may be far fewer anesthesiologists at major teaching hospitals. I simply do not know. There is speculation about what direction this will go, but it is anybody's guess, Senator.

Senator DEWINE. You are not in the speculation business today, I guess, Doctor. I think some of the other witnesses maybe have a better crystal ball.

Mr. FALLACARO. I think there is a difference in philosophy, and with all due respect to my colleagues on the panel, they believe that nurse anesthetists should be supervised by a physician, but I am going to go out on a limb a little bit, because what I have heard here is less that they believe nurse anesthetists should be supervised by a physician and more that they believe that that physician must be an anesthesiologist, and I will say that there is a bias and a self-interest in there to state that. I, having worked in these environments, I do not believe that is necessary. I believe certainly a surgeon is necessary. I believe medical consultation is necessary.

Dr. PIERCE. Well, I do not think I am really biased, but maybe. However, I go back to the educational qualifications, full medical school, ability to diagnose and treat all diseases, and that is what is necessary in the sick patient. In the healthy young patient, not much difference. I mean, they are not sick. They do not have multiple system diseases. But my mother, your mother, anybody in their 80's have multiple diseases and I think you need the most well-trained and educated diagnosis and treatment of medical illnesses that you can have during your anesthesia.

Senator DEWINE. Dr. Silber.

Dr. SILBER. You know, I study outcomes research so that I can try to improve medical care through identifying factors that can be changed to reduce mortality and I have identified a factor and that is that if you have direction from an anesthesiologist, you have less chance of dying. It seems to me that this regulation is not going to help the situation, it is not going to in any way foster more anesthesiologists practicing in hospitals. It is going to, if anything, decrease them, and so, therefore, that would be my concern, that this legislation is not going to help and it could possibly hurt.

Senator DEWINE. Ms. Stewart.

Ms. STEWART. I would like to comment on a couple of issues, if I might.

Senator DEWINE. Well, if you could, I would like you to try to address my question. I mean, say anything you want to. We have gone on here an hour and a half and we want to make sure everybody has their say today. But what is your prediction in regard to the question that I asked?

Ms. STEWART. As I said in my testimony, I think that the practice of anesthesia will remain as it is for the vast majority of situations. I think that——

Senator DEWINE. And the changes will be what?

Ms. STEWART. The changes would be in those underserved areas where surgeons have concerns about their liability for the anesthesia.

Senator DEWINE. Now go ahead.

Ms. STEWART. OK. I have been doing what we call locum tenens anesthesia for the last couple years and I am licensed, have been working in five different States in all regions of this country delivering anesthesia in literally every situation, working in surgeon's offices where the only physician is the surgeon himself and I am the only anesthesia provider. I work in community hospitals. I worked in Indian health hospitals. I worked in giant tertiary care centers where I work in a very close collaborative relationship with anesthesiologists. I have to say that if you can name some permutation of how anesthesia is delivered, I have probably seen it.

It is not like this rule is going to somehow remove anesthesiologists from those underserved areas. They are not there now and the patients are receiving very good care out there. It is not like removing supervision for facility payment is going to take away an anesthesiologist where there was not one to begin with, and it is not going to take away the anesthesiologists where they are now. As I said a few times, they are there in those situations because of the choice of the facility and some ethic that underlies that choice and how it is made. I think all areas that deliver safe quality anesthesia care are going to continue to do that. That is not the thrust behind this.

And the other thing that I would say is I have heard a couple allusions to the fact that when I go to sleep, I want an anesthesiologist. Well, maybe we should ask some of the other anesthesiologists who have asked me personally to give their anesthesia to them or their family or their children. The most critical person I have ever worked with in an anesthesia department asked me personally to deliver her anesthesia.

Dr. PIERCE. I did not quite——

Senator DEWINE. I am sorry.

Dr. PIERCE. I did not understand that last statement.

Senator DEWINE. Do you want to repeat it, Ms. Stewart?

Ms. STEWART. If nurse anesthetists——

Senator DEWINE. I think maybe the last part is what he did not understand, your examples.

Ms. STEWART. I am getting there.

Senator DEWINE. OK.

Ms. STEWART. If nurse anesthetists do not deliver safe care, then why would an anesthesiologist who really understands what needs to be done in anesthesia and what it takes to deliver it, why would they ask me personally to deliver their anesthesia if I was not safe?

Dr. PIERCE. I am not sure that is relative. I have had anesthesia 5 times in the last 3 years and 3 or 4 of the 5 times, I had a nurse anesthetist with medical direction by an anesthesiologist and that was my choice. I think that is straightforward.

Ms. STEWART. The instances I am referring to were without medical direction.

Senator DEWINE. Let me say, I think this has been a very good hearing, a very helpful hearing. I will be more than happy to let any of you make one additional comment, if you would like to.

Mr. FALLACARO. Sure. Again, I want to tell you that I work very closely with anesthesiologists and I have a lot of respect for them as physicians and as my colleagues. This, Senator, is a copy of the Richmond Times Dispatch. There is a full-page ad in there that says, "Medicare wants to take this doctor away during your surgery." Now, which doctor are they referring to? They are not referring to the surgeon, otherwise nobody can operate. So what they are implying is that Medicare wants to take away the anesthesiologist. Number one, Medicare has never required that an anesthesiologist be there.

Number two, it says, "Your life may be in danger. Medicare says that it will no longer require a doctor to supervise during surgery." That is not what Medicare is saying. Medicare is saying it will defer to State law on that issue.

I think this is intolerable. It is a scare tactic to scare our senior citizens into calling Senators, like Senator Robb's name here, to force them to make an action. I think this action is intolerable.

Senator DEWINE. Dr. Pierce.

Dr. PIERCE. I urge the committee, subcommittee, to look at the advertising and comments on both sides. I do not want to get into a contest.

Senator DEWINE. Dr. Silber, one last shot.

Dr. SILBER. Again, what our study has shown is there is a benefit to direction and it seems to me that that should lead us to worry about what would happen if there was less supervision. If we see that more training and direction by an anesthesiologist is beneficial, then taking away that influence in the supervision category might be problematic and I would urge more research on this subject.

Senator DEWINE. Ms. Stewart, you get the last word.

Ms. STEWART. Wow. Thank you. Although I have appreciated Dr. Silber's comments and the depth of his research, it is really not to

the point of the discussion of supervision. Supervision for the purposes of our discussion here and for the vast majority of its application has to do with surgeons being the supervising physician for nurse anesthetists who are working without anesthesiologists. That does not take away the merits that Dr. Silber is offering in his research, but it is really not on point to today's discussion. It feels a little like a smokescreen to the discussion because there were not anesthesiologists in these areas that we are discussing, and they are not being taken away. They were never there.

Senator DEWINE. I want to thank all of you, and actually, Ms. Stewart, I get the last word because this is the Senate.

Ms. STEWART. That seems appropriate. It is your house.

Senator DEWINE. I will make a few comments. Let me thank all of you for being here. I think it has been a very good hearing. As we can tell from this hearing, as we knew before we came into it, this is a very contentious issue. I do think, though, that today's hearing has been helpful and has allowed us a good opportunity to explore a number of very important issues. Most importantly, it has allowed us a chance to consider the impact of the proposed HCFA rule on the market for anesthesia delivery and on the health of our seniors. We have heard a wide range of opinions on a number of competition in health care issues and it is clear that there is a great deal of dispute on some of the basic facts of the anesthesia delivery controversy.

I do think that this hearing has made clear that the Silber study does shine some light on the topic, but as pointed out by several witnesses, including Dr. Silber himself, the study clearly has some limitations. The information generated by the study and its limitations have further convinced me that we need a national comparative outcomes study conducted by the Department of Health and Human Services to more fully examine this issue.

As I have said before, this issue is too important to ignore, and that is why we held this hearing. We must not take any chances with the safety and the health of Medicare patients. Before we take any steps as a country to alter the delivery of anesthesia, we must be sure that we protect the health and the safety of our seniors.

Again, I would like to thank our witnesses very much for your testimony. It has been very helpful to us. The committee will stand adjourned.

[Whereupon, at 3:40 p.m., the subcommittee was adjourned.]

APPENDIX

ADDITIONAL SUBMISSIONS FOR THE RECORD

PREPARED STATEMENT OF HON. HARRY REID, A U.S. SENATOR FROM THE STATE OF NEVADA

Good afternoon Mr. Chairman, members of the Committee and distinguished guests. I appreciate the opportunity to share my views with the Committee about the practice of anesthesiology and related safety issues.

On December 19, 1997, the Health Care Financing Committee (HCFA) issued a proposed rule to eliminate its long-standing rule requiring physicans supervision of nurse anesthetists in Medicare and Medicaid cases. In March of this year, HCFA announced its intention to finalize this rule. The proposal has now been finalized by the agency and sent to the Office of Management and Budget for review.

Senator DeWine and I have introduced legislation (S. 818) that states that before HCFA changes its policy, the Secretary of Health and Human Services should conduct a study that looks at the outcome rates of Medicare patients who are cared for by different anesthesia providers. The bill would require the Secretary only to take the results of this study into consideration when issuing a final regulation.

While some contend there is no difference in outcomes between nurse anesthetists and physician anesthesiologists, we must be certain this conclusion is reached based on sound and reliable data, before making changes to our current procedures. Senior citizens have overwhelmingly stated their preference for physician involvement in any necessary anesthesia. If we are to eliminate this requirement, we owe them our careful attention to objective data showing whether or not a change in policy would be safe.

In 1992, HCFA considered the same change and rejected it. After reviewing the then available studies of anesthesia outcomes, HCFA concluded, "In consideration of the risks associated with anesthesia procedures, we believe it would not be appropriate to allow anesthesia administration by a non physician anesthetist unless under supervision by an anesthesiologist or the operating practitioner." HCFA also noted that, "the conditions of participation are intended to be minimum requirements that promote health and safety. We do not believe it would be practical to adopt as a national minimum standard for care a practice that is allowed only in some states."

HCFA now proposes to reverse itself on both of these grounds, without offering any evidence that developments since 1992 make the change appropriate, consistent with HCFA's obligation to protect the health and safety of Medicare and Medicaid patients. Factors contributing to HCFA's 1992 conclusions have not changed at all since 1992, and if anything, there exists even more compelling evidence today to support the wisdom of HCFA's 1992 action.

The one new anesthesia outcomes study since 1992, performed by Jeffery H. Silber, M.D. at the University of Pennsylvania and to be published next month, demonstrates the importance of anesthesiologist involvement. The study found that when an anesthesiologist is not directly involved, there are more deaths than when an anesthesiologist is directly involved in the case. In light of the findings of the Silber study, it is critical that this issue is further studied so that we can ensure that Medicare and Medicaid patients will not be exposed to unnecessary life-threatening and other adverse outcomes.

Members of Congress are ill-prepared to judge the merits of this issue without a scientifically based study of the outcomes of patients who receive anesthesia services from the two different types of providers. To act without such advice would be premature and irresponsible.

Although the rate of adverse anesthesia outcomes has dropped steadily over the past quarter-century, the provision of anesthesia remains inherently dangerous and sometimes unpredictable. We must ensure that the quality of anesthesia care being provided to our oldest and most vulnerable population is the very best available.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS

The American Society of Anesthesiologists (ASA), a national medical specialty organization of some 35,000 physicians and other scientists engaged or especially interested in the practice of anesthesiology, is pleased to offer written testimony on the issue of competition and safety currently before the Subcommittee.

Competition generally compels markets participants to respond to the needs of consumers. Often, however, regulation must protect the public from the dangers of unchecked market forces. Thus, courts allow government to regulate competition in the interest of public safety. Similarly, trade associations may implement standards that restrict unlimited access but promote the quality of service. Whether self-imposed or governmental, such regulations implement beneficial standards to protect the public, while arguably limiting competition.

The benefits of regulation are evident in the standards promulgated by professional associations such as ASA. Quality standards impose a minimum threshold to preserve the integrity of the market for professional activities. Instead of dismissing such standards as anticompetitive, the Supreme Court has recognized that such restraints may actually improve the market for professional services. Indeed, the Court has adopted a less stringent antitrust analysis when a challenged activity seeks to promote a public interest. Professional self-regulation is always subject to review under the "Rule of Reason," under which the benefits of the regulation are weighed against any incidental restrains on competition. This rule recognizes that other interests must often be balanced against any preference for unrestrained competition in the market for professional services.

Protecting public safety is, of course, a paramount concern in the medical services market. Quality treatment requires shielding patients from unrestricted competition that may threaten a patient's well-being. the antitrust laws recognize the obvious importance of such regulation. For example, hospital peer review groups can restrict competition by denying hospital privileges to some doctors due to patient care issues. Despite the fact that such decisions may be viewed as anticompetitive in the short run, the courts recognize that peer review is necessary to protect patients. Although competition remains in the public's interest, regulations promoting safety and quality care are often necessary to strike the proper balance.

The Conditions of Participation applied by the Health Care Financing Administration (HCFA) to hospitals and ambulatory surgical centers are examples of governmental quality restraints that may impede unfettered competition, because they apply standards to which those facilities must adhere in order to participate in the Medicare program. As discussed in Dr. Pierce's testimony before the Subcommittee today, ASA's House of Delegates has approved numerous standards related to anesthesia care which, although not technically binding on and ASA member, as a practical matter restrain member's conduct because of the threat that non-adherence would increased the prospects of legal action in the event of an adverse incident.

One such ASA safety standard is that calling for physician supervision on nonphysician practitioners, a standard that is also reflected in HCFA's current Conditions of Participation for hospitals and ambulatory surgical centers. As is well known, ASA vigorously opposes HCFA's 1997 proposed elimination of this requirement, in place since the inception of the Medicare program, that a nurse anesthetist work under the supervision of an immediately-available anesthesiologist or of the operating surgeon.

HCFA's December 19, 1997 proposed rule addressed numerous changes to the Conditions of Participation (COPs) for hospitals. In March of this year, HCFA announced its intention to finalize this single element of its proposal, and to eliminate its requirement for physician supervision both with reference to hospitals and ambulatory surgical centers. That proposal has now been finalized by the agency and sent to the Office of Management and Budget for review.

To begin to understand the ramifications of HCFA's proposal, it is necessary to appreciate the nature of and risks inherent in the provision of anesthesia care. We therefore include a prefatory section, describing the nature of anesthesia care and the respective training of anesthesiologists and nurse anesthetists. It is clear, based on training alone, that the services provided by anesthesiologists and nurse anesthetists are different services.

I. THE NATURE OF ANESTHESIA CARE—THE PRACTICE OF MEDICINE

The modern practice of anesthesiology is universally recognized as the practice of medicine, involving a wide variety of diagnostic and clinical decision-making functions, including the following:

Preventing a patient from feeling pain or emotional stress during surgical, obstetrical and certain medical procedures.

Evaluating and managing life functions (e.g., breathing, heart rhythm and rate) under the stress of anesthetic and surgical interventions.

Clinical management of the unconscious patient.

Pain management (acute and chronic).

Managing patients who need resuscitation because of heart function or breathing difficulties.

Applying specific methods of respiratory care.

Clinical management of various fluid, electrolyte and metabolic disturbances.

There are three phases to the provision of anesthesia care in connection with most surgical and obstetrical procedures: the preoperative, intraoperative and postoperative periods. Each phase, involves the exercise of medical judgment and decision-making. The planning and management of an anesthetic must integrate the patient's preexisting medical condition, the nature and extent of surgical stress, and a method for providing, as much as possible, a smooth stress- and pain-free postoperative course. In many settings, nurse anesthetists participate in the provision of intraoperative anesthesia care, but always under the supervision of an anesthesiologist or other physician.

Nowhere is management of the continuum of anesthesia medical care more crucial or potentially complex than for the Medicare beneficiary. More than half of the estimated 40 million surgical procedures done each year, or about 20 million in-hospital surgical procedures, are performed on Medicare patients. In this age group, preoperative evaluation often reveals disorders of multiple organ systems, e.g., cardiac, respiratory, renal, musculoskeletal, neurologic. Such conditions have important ramifications in caring for patients undergoing coronary artery bypass, aortic or peripheral vascular surgery, or joint replacement—procedures most often performed in the Medicare age group. These operations are characterized by the potential for significant blood loss, often at an astonishing rate, as well as swift and unpredictable changes in blood pressure, heart rate, heart rhythm and overall heart function.

If the blood pressure suddenly falls, is the cause exacerbation of prior heart disease, a sudden change in heart rhythm, surgical manipulation, inadequate fluid replacement, or some other cause? Initial diagnosis involves rapid assimilation of data from multiple sources—pre-existing history, observation of monitoring devices and the surgical field, etc.—requiring expedited medical decision-making and, as important, periodic reassessment of the situation. Treatment for one diagnosis may be contradicted for another (e.g., blood transfusion for blood loss, fluid restriction for myocardial failure). If currently available data are inadequate for decision-making, what more sophisticated devices are required, such as a pulmonary artery catheter or transesophageal echocardiography?

Obviously, not all operations and anesthetics are characterized by complications; that possibility, however, is present in each and every case—even those involving otherwise healthy patients. Especially is this so in light of the fact that modern anesthesia drugs and techniques have rendered ever older and sicker patients acceptable anesthesia risks, where life-extending surgical procedures are indicated.

Today, anesthesiologists are involved in 90 percent of the anesthetics delivered in the United States. Thirty-five percent of anesthetics are administered personally by the anesthesiologist, and 55 percent are administered by a nurse anesthetist, anesthesiologists assistant (AA),[1] resident, or student nurse anesthetist under the medical direction of an anesthesiologist. The ten percent of anesthetics not involving an anesthesiologist are administered by a nurse anesthetist who is supervised by the operating practitioner. See Abenstein, "Influence of Anesthesia Practice Models on Patient Outcomes" (scheduled for publication in September 1998). Supervision by the surgeon rather than by an anesthesiologist is frequently found in small, rural hospitals that generally care for less critically-ill patients. Anesthetics given in rural hospitals account for less than 5 percent of the total.

[1] The services of anesthesiologists assistants (AAs) are payable under the Medicare Fee Schedule, as are those of nurse anesthetists and residents, except that AAs must always work under the supervision of an anesthesiologist. 42 C.F.R. § 410.69. HCFA has not proposed the elimination of anesthesiologist supervision of AAs.

The education and training of an anesthesiologist are vastly different from those of a nurse anesthetist, and they qualify the anesthesiologist to provide a radically different, more comprehensive service than that offered by a nurse anesthetist.

To become an anesthesiologist, an individual must complete 12 years of education—four years of pre-medical undergraduate education; four years of medical school in which the individual gains knowledge of the fundamental science of the human condition (biochemistry, biophysics, anatomy, pharmacology, physiology and pathology) and receives extensive clinical instruction and experience in diagnosis and therapy; and four years of residency training, three years of which are devoted to clinical training including one year of concentrated study and experience in connection with the most complicated cases. Anesthesiologists receive extensive training in pharmacokinetics, which is the quantitative study of the action of drugs in the body over a period of time, including the processes of absorption, distribution, localization in tissues, biotransformation and excretion, and the factors that affect these processes.

According to published figures from the Journal of the American Association of Nurse Anesthetists, approximately two-thirds of practicing nurse anesthetists have a bachelor's degree—one-third do not. Nursing degrees generally require significantly less science than corresponding pre-medical or other science-based undergraduate degrees. Furthermore, many of the science courses taken by nursing students are survey courses and are not a recognized part of any other science-based curriculum.

Nurse anesthetist training involves a two-year program of technique-oriented instruction and clinical experience, with only modest scientific underpinning. The first year consists of didactic training in subjects such as anatomy, physiology and pharmacology; the second year is primarily clinical experience. While nurse anesthetists study some of the same subject areas as anesthesiologists, the courses again are generally more superficial than the ones completed by medical students. Most importantly, CRNAs are trained to make a nursing assessment of a patient, not a medical assessment.

Nurse anesthetists, who return to school to become anesthesiologists, have the best understanding of the differences in the educational programs and the capabilities of nurse anesthetists and anesthesiologists. In a March 2, 1998 letter sent to HCFA by 64 anesthesiologists who initially trained as nurse anesthetists, the following statement appears:

"Nurse anesthetists who argue in favor of independent practice can have no concept of what they are lacking. We do, because we have been trained both as a nurse anesthetist and then as an anesthesiologist. The difference is simply profound. In an undertaking where the patient's physiologic functions are deliberately slowed or stopped, and where the margin between the routine and the disastrous is literally measured in seconds and in cubic centimeters of drugs, the capacity rapidly and correctly to invoke medical judgment is indispensable."

Nurse anesthetists are not trained to make medical judgments, but are competent under medical direction by an anesthesiologist or under supervision of an operating practitioner who has assumed responsibility for the performance of anesthesia care to:

1. Provide nursing assessment of the patient's health status as it relates to the relative risks involved with anesthetic management of the patient during performance of the operative procedure.
2. Based on the health status of the patient, determine, in consultation with the anesthesiologist or responsible operating practitioner, and administer the appropriate anesthesia plan (i.e., selection and administration of anesthetic agents, airway management, monitoring and recording of vital signs, support of life functions, use of mechanical support devices, and management of fluid, electrolyte and blood component balance);
3. Recognize and, in consultation with the anesthesiologist or operating practitioner, take appropriate corrective action to counteract problems that may develop during implementation of the anesthesia plan;
4. Provide necessary normal postanesthesia nursing care in consultation with the anesthesiologist or operating practitioner; and
5. Provide such other services as may be determined by the medically directing anesthesiologist or supervising operating practitioner.

II. ANESTHESIA CARE SHOULD CONTINUE TO BE PROVIDED BY OR UNDER THE SUPERVISION OF A PHYSICIAN

In its preamble to the proposed rule, HCFA notes the statutory provision that a hospital, seeking to participate in the Medicare and Medicaid programs, must meet

requirements that the Secretary of Health and Human Services finds necessary in the interest of the health and safety of hospital patients. These requirements are set forth in the Conditions of Participation (COPs) for Hospitals (42 C.F.R. Part 482)—the purposes of which "are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals".

HCFA in its preamble then goes on to state that it proposes to move from a process-oriented approach to approval of hospitals, to a result-oriented approach that evaluates performance components as part of the hospital's "overall quality assessment and performance improvement responsibilities". HCFA thus proposes to include "process-oriented requirements only where we believe they remain highly predictive of ensuring dired outcomes. . . ." More particularly, HCFA describes a "fundamental principle" that guided the development of the proposed revised COPs as "Facilitating flexibility in how a hospital meets our performance expectations, and eliminate process requirements *unless there is consensus or evidence that they are predictive of desired outcomes for patients*" (emphasis added).

With respect to anesthesia services, HCFA proposes to "eliminate current rules on which practitioners can administer anesthesia, and what level of supervision must be provided to them", requiring merely that "anesthesia be administered only by a licensed practitioner permitted by the State to administer anesthetics".

HCFA notes that one effect of its proposed staffing and equipment requirement "would be to allow more flexibility to certified registered nurse anesthetists (CRNAs) without oversight by another practitioner. Currently, the anesthesia condition (482.52(a)(4)) requires that a CRNA administer anesthesia only under the supervision of operating practitioner or of an anethesiologist who is immediately available if needed. . . . We emphasize that CRNAs are allowed to practice in this way [without supervision] only where doing so is consistent with State law."

HCFA then goes on to say that in order to achieve uniformity, it proposes to eliminate the requirement that nurse anesthetists be supervised from requirements for ambulatory surgical centers (42 C.F.R. §416.42) and critical access hospitals (42 C.F.R. §485.639). It notes that as to all three types of institutions, however, State law may establish a more stringent condition.

HCFA finally states as to anesthesia care its belief that "it is critical to the health and safety of surgical patients to have accurate information on each patient's condition before anesthesia is administered and a surgical procedure is undertaken. HCFA thus proposes to require that a comprehensive assessment be performed before surgery and that "a preanesthesia evaluation be done by an individual qualified to administer anesthesia."

ASA would like to express in the strongest possible terms our opposition to HCFA's proposal to eliminate the requirement that a nurse anesthetist be supervised either by the operating practitioner or by an anesthesiologist. As is manifest from our prefatory description of anesthesia practice, anesthesia care involves the practice of medicine. Simply stated, a doctor of medicine must be responsible for the provision of all medical and surgical services, including anesthesia, and available anesthesia outcomes data clearly presents the evidence HCFA says is necessary for it to retain a process requirement.

A. The wisdom of HCFA's 1992 rejection of a proposal to eliminate physician supervision of nurse anesthetists

In 1992, HCFA rejected a proposal to eliminate physician supervision of nurse anesthetists—a proposal identical to the one that it is now advancing. 57 F.R. 33878. HCFA's rejection was based on two stated grounds:

"Regardless of whether some State laws allow CRNAs to practice independently, the laws of most States still require nonphysician anesthetists to administer anesthesia only under the supervision of a doctor of medicine or osteopathy. Moreover, the conditions of participation are intended to be minimum requirements that promote health and safety. We do not believe it would be practical to adopt as a national minimum standard for care a practice that is allowed in only some states."

"While some of the information [submitted to HCFA] supports the conclusion that similar results occur under each of the three sets of circumstances [CRNA alone, anesthesiologist alone, or the two providers together], we note that . . . existing studies of this issue do not account for the differences in outcomes caused by differences in age and in severity of illness among patients. We believe it would be wrong to conclude from the studies mentioned above that oversight by an anesthesiologist does not contribute significantly to the safety and quality of care. In view of the risks associated with anesthesia procedures, we believe it would not be appropriate to allow anesthesia administration by a non-physician anesthetist unless under supervision by either an anesthesiologist or the operating practitioner."

HCFA now proposes to reverse itself, on both these grounds, without offering a shred of evidence that developments since 1992 make the change appropriate, consistent with HCFA's obligation to protect the health and safety of Medicare and Medicaid patients. The fact is that the factors contributing to HCFA's 1992 conclusions have not changed at all since 1992, and if anything, there exists today even more compelling evidence to support the wisdom of HCFA's 1992 action.

First, there is no greater uniformity of state law on the subject than there was when HCFA rejected the elimination of physician supervision in 1992. The American Association of Nurse Anesthetists (AANA) widely trumpets its "data" that the nursing rules of 29 states permit nurse anesthetists to practice unsupervised. This disingenuous statement presents less than the whole truth. For one thing, the AANA claim is based on the assumption that the requirement of "collaboration" with a physician—articulated in the nursing rules of many of the 29 states—somehow may be equated with "unsupervised" care. There is no foundation for this conclusion, other than a semantic one.

More important, nursing rules comprise only one portion of the health and safety regulations of any given state; also of significance are the state's medical code, hospital regulations, and restrictions on the prescription of controlled substances. Attached hereto as Appendix IV are the results of an analysis of all state laws and regulations regarding the scope of practice of nurse anesthetists undertaken at ASA's request by a large private law firm. The analysis discloses the panoply and diversity of restraints on nurse anesthesia practice that currently exist in this country. Viewed in this context, it is difficult to understand how HCFA, in pursuing the proposed rule, could conclude that it was maintaining the "minimum standard of care" that it, in its 1992 statement quoted above, defines the COPs as representing.

Nor can HCFA find comfort or justification for its proposed action in comparative post-1992 anesthesia outcomes studies: There simply are no new studies showing or even suggesting that anesthesia is as safe, when provided by an unsupervised nurse anesthetist, as when it is performed by or under the direction of a physician. If anything has changed since HCFA's 1992 rule-making, it is the availability of more recent research indicating that patient outcomes are improved in hospitals staffed by adequate numbers of board-certified anesthesiologists. To the contrary, the one new anesthesia outcomes study since 1992, performed by Silber et al. at the University of Pennsylvania, demonstrates just the opposite.

J.P. Abenstein, M.D. of the Mayo Clinic, in his article noted above, states that intraoperative anesthesia-related deaths had declined from 1:1560 in the early 1950s to fewer than 1:244,000 in 1989. There has been a corresponding decline in morbidity related to anesthesia. Abenstein found that these improved outcomes could not be attributed to either pharmacological agents or technology, and that therefore the improvement must be attributable to anesthesia personnel. And the most notable change in anesthesia personnel over the last 50 years has been the explosion in the number of anesthesiologists: since 1967, that number has increased by 208 percent, while the number of nurse anesthetists has increased by only 78 percent.

In support of this conclusion, Abenstein summarized a study from the University of Pennsylvania. Jeffrey H. Silber, M.D. and colleagues reported, in 1992 after HCFA's ruling appeared in the Federal Register, on differences in patient outcomes related to patient and hospital attributes. The authors examined the outcome of 5972 patients undergoing elective surgery in 531 hospitals. After exhaustive examination of numerous factors relating to patients and medical facilities, only the proportion of board certified anesthesiologists was directly related to a decrease in mortality rate after elective surgery (i.e., the higher the proportion of board certified anesthesiologists, the lower the mortality rate). No other attribute, including those related to nursing, improved perioperative mortality. (Silber JH, Williams SV, et al. Hospital and patient characteristics associated with death after surgery. A study of adverse occurrence and failure to rescue. Med Care 1992;30:615–27.

To the same effect were two studies from 1981 and 1980. In the 1981 study (Bechtoldt AA Jr. Committee on anesthesia study. Anesthetic-related deaths: 1969–1976. NC Med J 1981;42:253–9), which reviewed more than 2 million anesthetics and analyzed the 90 anesthetic-related deaths in that sample, anesthesiologists personally providing anesthesia and anesthesiologists supervising nurse anesthetists had significantly better mortality rates than nurse anesthetists supervised by non-anesthesiologists—15 percent and 26 percent better, respectively. These results were surprising, since nurse anesthetists practicing alone generally undertake shorter procedures on healthier patients.

The 1980 study (Forrest WH. Outcome—the effect of the provider. In Hirsh RA, Forrest WH, et al, eds. Health care delivery in anesthesia. Philadelphia: George F. Stickley, 1980; 137–42) showed that nurse anesthetists had an 11% worse than ex-

pected outcomes while anesthesiologists had as much as a 20% better than expected outcomes—a 31 percent difference between provider groups.

Most importantly, however, researchers at the University of Pennsylvania (Silber et al) will publish next month a major Medicare outcomes study, disclosing significantly higher death rates when an anesthesiologist is not involved in the administration of anesthesia. This peer-reviewed study covers all Medicare general surgical and orthopedic cases in Pennsylvania over a recent four-year period. After factoring out variables based on patient condition and hospital characteristics, the study shows that when an anesthesiologist was not involved, there were 2.5 excess deaths per thousand Medicare general surgical and orthopedic cases without complications; when an anesthesiologist was not involved and there were post-operative complications, there were 6.9 excess failures to rescue (deaths) per thousand Medicare general surgical and orthopedic cases. Dr. Silber is a witness at this hearing, and his testimony speaks volumes about the regulatory insanity of HCFA's current proposal; if anything, it appears that HCFA should be tightening its supervision rule, not dismantling it.

Contrary to scientific data, the AANA has attempted to claim that anesthesia care delivered by a nurse anesthetist is safer than the care delivered by an anesthesiologist. The AANA touts the number of malpractice claims filed with the National Practitioner Data Bank against anesthesiologists versus those claims filed against nurse anesthetists as the only support for such claims. The reality is that most nurse anesthetists are employed by anesthesiologists within group practices. The group pays for the nurse anesthetists' insurance. Malpractice lawsuits are generally filed against the group or physician employer, not the individual nurse anesthetist. Most malpractice insurance companies do not write individual policies for nurse anesthetists when they are employed by a physician group practice. As such, when a lawsuit is filed, it is filed against the group practice, not the individual nurse anesthetist. Furthermore, it is important to point out that there is no obligation for nurse anesthetist malpractice claims to be reported to the National Practitioner Data Bank when that nurse anesthetist is employed by the institution or group practice. There is a reporting obligation for physicians. For these reasons, any attempt to compare doctor-to-nurse malpractice data as an indication of patient safety is inherently flawed and irrelevant.

There is a wealth of data demonstrating that the present COP requirement of physician involvement in the administration of every anesthetic contributes to patient safety and the quality of care. There are no studies that would indicate any patient benefit from the proposed change. To the contrary, to paraphrase HCFA's own words in the preamble to the proposed rule, this process requirement—that nurse anesthetists work under the supervision of a physician—is supported by clear evidence that it is "predictive of desired outcomes for patients". In 1992 HCFA stated, "we believe it would be wrong to conclude from the studies . . . that oversight by an anesthesiologist does not contribute significantly to the safety and quality of care." Today, there is even more compelling evidence to support the requirement of physician supervision of nurse anesthetists.

B. Evisceration of national standard of care for Medicare or Medicaid

The proposed change in the COPs would allow nurse anesthetists to practice unsupervised only where doing so is consistent with state law. Only one or two states currently permit nurse anesthetists to practice without physician supervision. As is apparent from even a casual review of the summary chart of state regulations appearing in Appendix IV, however, the state codes and regulations are replete with inconsistency. New Jersey, for example, requires an anesthesiologist to supervise a nurse anesthetist. Where collaboration is required instead of supervision, varying standards exist as to what collaboration means—ranging from an undefined nominal relationship to a clearly interactive one. Some hospital codes require physician supervision; others merely require that a physician oversee the anesthesia department. Even those states requiring physician supervision or direction define those terms differently.

As of March 2000, the practice acts of only about half the states required that a physician direct or supervise a nurse anesthetist in the administration of anesthesia, or otherwise issue a patient-specific order for such administration. Eighteen practice acts required mere "collaboration" between a physician and a nurse anesthetist; the remainder of the states were silent on the issue.

Most often, collaboration is defined as "a process involving two or more parties working together, each contributing his or her area of expertise to provide more comprehensive care than one alone can offer." There is rarely a requirement that the collaborating physician be specially trained in anesthesia or be present during administration of anesthesia by the nurse anesthetist. There are normally no limits

on the number of nurse anesthetists with whom a physician can collaborate. It is not uncommon in some states for the collaborating physician to be retired from active practice or located in a community remote from where the anesthesia is being administered.

Most state acts requiring physician supervision or direction do not require, as does the current federal rule, that the physician be immediately available during the course of anesthesia. Only one state practice act requires that such physician be credentialed in anesthesia.

Hospital regulations in half the states require that a physician direct or supervise the administration of anesthesia by a nurse anesthetist. In general, however, these tend to be the same states which require supervision or direction in the practice acts affecting nurse anesthetists.

While the vagaries of state law allow for varying standards of care, as a practical matter, hospitals do not distinguish between Medicare and non-Medicare patients; as such HCFA's objective of ensuring a national minimum requirement that promoted health and safety is met.

For better or worse, the Medicare program is the single most influential force in this country for establishing health care standards, and abandonment of the physician supervision requirement would not only throw Medicare and Medicaid patients into the existing complex of state regulation, but also send a powerful signal—its protestations to the contrary notwithstanding—of HCFA's view of the need for physician supervision. The elimination of this requirement will be used by the nurse anesthetists to continue the erosion of physician supervision and physician collaboration requirements until such time as they are permitted complete independent practice. Nurse anesthetist advocates are already telling state legislators and regulators that the federal government approves of unsupervised nurse anesthetist practice and are arguing that individual states should allow nurse anesthetists to practice independently. For years, nurse anesthetists have sought independent practice, including independent prescriptive authority for all controlled substances, at the state level for years. It is this effort that has led to the erosion of strong physician supervision standards in some states.

The bottom line is that adoption of the proposed rule will mean that Medicare and Medicaid patients will have available a differing minimum standard of anesthesia care dependent on where they undergo a procedure requiring that care. HCFA makes much in its proposed rule about the fact that hospitals are free to establish their own higher standards of care, but that is not the point: the point is that unless HCFA maintains a national minimum, Medicare and Medicaid patients will have no assurance that such a minimum exists.

C. The absence of cost incentives

There is no difference in cost to the Medicare beneficiary or the Medicare program, whether or not a physician supervises care provided by a nurse anesthetist. But there is evidence or greater cost efficiency, and resultant savings to the Medicare and Medicaid programs, when an anesthesiologist in involved. In a review article published in the New England Journal of Medicine on October 16, 1997 (Wiklund, RA, Rosenbaum, SH. Medical Progress: Anesthesiology. NEJM 1997;337:1132–1219), the authors noted the growing role of anesthesiologists in preoperative assessment of patients and cited research showing that: "requests for preoperative consultations are reduced by three quarters when the need for a consultation is determined by an anesthesiologist in a preoperative screening clinic rather than by a surgeon. Cancellations of operations due to unresolved medical or laboratory abnormalities are reduced by 88 percent, and the costs of laboratory tests are reduced by 59 percent, or $112 per patient."

Additionally, anesthesiologists may help to hold down the expenses of caring for patients post-operatively. Their ability as physicians to intervene when complex problems occur (e.g., treat heart failure) may save the Medicare and Medicaid programs the cost of caring for a catastrophically compromised patient. As noted above, the 1992 study by Silber et al. showed that the higher the ratio of anesthesiologists to other anesthesia providers, the greater the likelihood of patients recovering from adverse events. Also as noted, there have been no corresponding data indicating that the rate of anesthetic morbidity has declined at all for nurse anesthetists working alone during the decades that it has decreased twenty-five fold for anesthesiologists.

D. The misconception of access

Access to rural health care is not improved by the elimination of the physician supervision requirement. The existing rule permits supervision either by an anesthesiologist or by the operating practitioner. Although it is true that some of the smallest rural hospitals do not have an anesthesiologist on staff, there is always by definition an operating practitioner available to perform the required supervision.

This would suggest that if a rural access problem exists, it is due to a lack of availability of surgeons or other operating practitioners. Clearly, the proposed rule does not reach that access problem, if in fact one exists. Whether or not the surgeon supervises the anesthesia care will not affect the patient's access to surgery. In a recent survey of rural hospital administrators, Peter J. Dunbar, M.D. and colleagues found that 85 percent would not do more surgery if they had more anesthesia staff. (Dunbar PJ, Mayer JD, Fordyce, MA, Lishner, DM, Hagopian, A, Spanton, K, Hart, LG. Availability of Anesthesia Personnel in Rural Washington and Montana. Anesthesiology 1998;3:800–808).

Moreover, with the ongoing expansion of the number of anesthesiologists, which is predicted to continue into the next century (Abenstein, noted above), anesthesiologists will provide or supervise more and more of the anesthesia care delivered in rural settings. Dunbar noted that the numbers of anesthesiologists relative to the population had increased, between 1970 and 1993, in Colorado, Nevada, Arizona, Utah, New Mexico, Wyoming, and Montana. In Montana, the number had more than doubled, from fewer than five anesthesiologists per 100,000 population to eleven per 100,000.

The AANA recently has claimed that surgeons do not want to supervise CRNAs because of concerns related to increased liability for the nurse anesthestists' actions, and it is for this reason that access to care in the rural areas is compromised. The fallacy of this anecdotal information is revealed by the unanimous support for continued physician supervision of nurse anesthetists from medical and surgical specialty societies as demonstrated in a recent letter to HCFA. We would be remiss if we did not point out that the AANA had a different view regarding surgeon's willingness to supervise nurse anesthetists last year. The AANA argued in testimony last year before the House Judiciary Committee that "[t]he law governing the liability of a surgeon for the negligence of a nurse anesthetist is precisely the same as the law which governs the liability of a surgeon for the negligence of an anesthesiologist."

In short, there is simply no basis for the suggestion that independent nurse anesthesia practice is the solution to increasing access to health care in rural hospitals and surgical centers.

E. The inappropriateness of an outcomes approach

In its preamble to the NPRM, HCFA explained that it proposed to revise the COPs consistent with a new philosophical approach to quality that would focus on "patient-centered, outcomes oriented standards" rather than on "specific, process-oriented requirements for each hospital service or department."

ASA has followed the shift in emphasis in evaluating the quality of medical care, from process to outcomes measures, with great interest. We agree that outcomes are generally a better guage of performance than adherence to specific processes. It remains far easier, however, to establish processes of care that are expected to contribute to good results than to define and obtain appropriate outcomes data. HCFA acknowledged the ongoing importance of process requirements when it stated, in the preamble, that it proposed to include process-oriented requirements "where we believe that they remain highly predictive of ensuring desired outcomes or are necessary to deter or prevent fraud and abuse." At the very least, the 2000 Silber study demonstrated the need for more comprehensive analysis by HCFA, as called for by the Safe Seniors Assurance Study Act of 1999 (S. 818/H.R. 632), introduced in the Senate by Senators DeWine and Reid, and now enjoying wide bipartisan support in both Houses of Congress.

The requirement that an anesthesiologist or the operating practitioner supervise nurse anesthetists is one process-oriented standard that is highly predictive of ensuring desired outcomes. As we documented above, research has demonstrated that anesthesiologist involvement is the major cause of the dramatic drop in anesthesia mortality and morbidity rates. There are absolutely no data suggesting that unsupervised nurse anesthesia is as safe as medically-directed anesthesia has become. The outcomes here—discharging a living patient, promptly and with as little pain as possible, from the recovery room—are so important that we cannot afford to experiment on Medicare patients with widely varying state supervision requirements, as HCFA would have us do.

Accordingly, we respectfully submit that the benefits of continued involvement of an anesthesiologist or a surgeon in the anesthesia care provided to every Medicare or Medicaid beneficiary undergoing surgery far outweighs HCFA's desire to concentrate on outcomes measures.

F. Beneficiary support for retention of supervision

A strong majority of Medicare beneficiaries are unequivocal in their preference for continuance of the current supervision requirement. Surveys of senior citizens in 1998 and 1999 by the Tarrance Group disclosed that 80% opposed eliminating the rule as HCFA has proposed. (A survey last month by Luntz-Laszlo of all voting Americans reported that three-quarters of the respondents disfavored turning the supervision issue over to the individual states, as HCFA proposes).

In the absence of any countervailing benefit—there being no relative cost advantages or quality of care or access improvement—there would seem to be little reason to disregard beneficiaries' and all Americans voters' clear preference and to deprive beneficiaries of their right to obtain anesthesia care from or under the supervision of a physician.

III. CONCLUSION

HCFA's existing rule on physician supervision of nurse anesthetists is a clear example of a restraint on competition, legally authorized under the "state action" doctrine, maintained in HCFA's own words in 1992 that contributes "to the safety and quality of care" for Medicare beneficiaries. HCFA now proposes to dismantle that rule in the face of scientific data that the change will lessen, not improve, patient safety, and in the face of the clear preference of the American people. Why HCFA is unwilling at least to undertake a more definitive study, as called for in S. 818/H.R. 632 is beyond comprehension, and ASA intends to use every resource at its disposal to stop this clear denigration of anesthesia care.

ASA respectfully requests that a copy of this statement be included in the record of this hearing.

ANESTHESIA PATIENT SAFETY FOUNDATION,
Pittsburgh, PA, February 17, 1998.

NANCY-ANN MIN DEPARLE,
Administrator, Health Care Financing Administration,
HCFA–3745–P, Baltimore, MD.

DEAR MS. DEPARLE: The Executive Committee of the Anesthesia Patient Safety Foundation (APSF) wishes to most strongly express its collective opposition to the Health Care Financing Administration's (HCFA) proposed rule to eliminate physician supervision of nurse anesthetists. In 1992, HCFA publicly stated that "in consideration of the risks associated with anesthesia procedures, we believe it would not be appropriate to allow anesthesia administration by a non-physician anesthetist unless under the supervision of either an anesthesiologist or the operating practitioner." This practice of supervising non-physician anesthetists has evolved over many years directed toward optimizing patient safety. There are no data to judge the extent to which the current level of safety experienced by patients depends on this supervision.

A basic tenet of medicine is "first do no harm". Administration of anesthesia is a high risk activity. Prior to making any change in the existing supervision requirement, the burden of proof must be based on definitive evidence that this change is safe. No such evidence exists! If the proposed rule is enacted in the absence of evidence that the change in practice is safe, HCFA will have set a dangerous precedent by having shifted the burden of proof in the wrong direction.

Such a shift in the burden of proof was a key factor in the ill-fated decisions leading to the space shuttle Challenger disaster. Health care should learn from this catastrophe by demanding evidence that the safety of patients is preserved whenever substantive changes are introduced in systems with known risks of death and serious injury from medical interventions.

The Executive Committee of the APSF most strongly urges that HCFA not enact the proposed rule change.

Sincerely,

ROBERT K. STOELTING, M.D.,
President.

BURTON A. DOLE, Jr.,
Vice-President.

DAVID M. GABA, M.D.,
Secretary.

CASEY D. BLITT, M.D.,
Treasurer.

JEFFREY B. COOPER, Ph.D.,
Member at Large.

ROBERT A. CAPLAN, M.D.,
Member at Large.

ROBERT C. BLACK,
Member at Large.

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