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The accepted use of physical restraint in the medical care of patients is a rapidly evolving area of concern. Since elders are most likely to be involved in such circumstances, this is an issue of particular importance for those charged with the care and well-being of the aging. A look at the current status of and developing trends in use of restraint in general medical care and surgical facilities can assist caregivers in minimizing risk and liability.

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The use of physical restraints in hospitals in the United States is common, with prevalence rates estimated (not even counting bedrails/siderails) between 7 percent and 22 percent.[1] The elderly are the most likely group to be restrained in the hospital; chronological age over 65 is an independent risk factor in this regard.[2] However, the law regarding the use of restraints on hospitalized patients is rapidly evolving and, with the guidance of enlightened risk managers, is likely to bring about a sea of change in clinical behavior in its wake over the coming years.

Physical or mechanical restraints are any manual method or physical device, material, or equipment attached or adjacent to a patient's body that physically restricts that person's freedom of movement, physical activity, or normal access to his or her body. Physical restraints include leg and arm straps, hand mitts, soft ties, wheelchair safety bars, and gerichairs. Seclusion, the involuntary confinement of a person alone in a unit or room that the person is physically prevented from leaving, may be characterized as another form of restraint. Side rails are restraints if they restrict the freedom of movement by preventing a patient from getting out of bed when he or she wishes, regardless of the patient's ability to do this safely.[3]

Health care providers traditionally have sought to justify the extensive use of restraints under a variety of rationales,[4] most notably to prevent the patient from falling and to prevent the patient from disrupting needed therapies (e.g., to prevent self-extubation from ventilators).[5] One reason for employing restraints expressed frequently by providers and their risk management advisors is anxiety about potential personal exposure to litiga-

tion and legal liability in the event that unrestrained patients injure themselves and sue. This article addresses these concerns related to anxiety about legal consequences.

Extensive attention has been devoted lately to the use of physical restraints in a number of different kinds of health care settings and for diverse patient populations. The present article concentrates exclusively on the legal ramifications of using such restraints on adult patients within general medical and surgical units of acute care hospitals. Thus, restraint use for children,[6] as well as in nursing facilities,[7] psychiatric,[8] home,[9] and emergency department settings, is not specifically examined here. While valuable practice and policy lessons may be garnered from experiences in these areas, important distinctions exist between them and the delineated topic of analysis in this article. Also dealt with elsewhere are issues pertaining to chemical,[10] rather than physical, restraints.

Further, the focus of this article is primarily legal. There are, though, many interesting related ethical[11] implications, too. The central values of respect for persons,[12] preventing harm, and promoting positive outcomes often conflict with each other when physical restraints are used, especially when they take the place of proper medical evaluation, nursing care, and compassion.

Clinical Evidence Regarding Restraints and Risks

Evidence that restraints effectively accomplish the objective of preventing serious fall injuries or that removing restraints contributes to an increase in the rate of such injuries lies somewhere between scant and nonexistent.[13] The widely taken for granted benefits from the use of restraints are scientifically unproven. The preponderance of data suggests that restraints generally do not prevent either serious falls or the inadvertent or intentional removal of medical therapies.[14] Indeed, the incidence of patient falls actually increases, rather than decreases, among restrained patients.[15] In two studies, the incidence of self-extubations in restrained patients exceeded 60 percent,[16] undermining the prevalent mythology that restraints prevent such actions from taking place.

At the same time, there is substantial evidence that the use of physical restraints on older hospitalized patients exposes those patients to significant risks of physical injury (e.g., the natural outcome of being kept from moving, institution-acquired infections) and mental harm (e.g., confusion, agitation, fear, and embarrassment).[17] Injury or harm, of course, is an essential element of proof for a plaintiff in a malpractice or professional liability lawsuit based on a theory of negligence.[18]

Epidemiological studies conducted over the span of many years[19] establish that the likelihood of morbid results, including serious injurious falls, goes up significantly with the continued use of physical (and/or chemical)[20] restraints. The risk of patients injuring themselves, sometimes fatally,[21] while becoming agitated and trying to escape from their restraints is real. For instance, injuries occur with regularity[22] when patients try to climb over side rails to get out of bed.[23] Improperly applied restraints (such as vests that are placed on the patient backward) or restraints that staff neglect to monitor and adjust as needed at specific, timely intervals may cause strangulation and suffocation[24] or other loss of bodily control.

It has been estimated that 36,000 patients per year nationwide suffer significant adverse events as a result of falls while hospitalized. Many of these occur in elderly patients when they try to get out of bed, often to use the toilet at night, and must contend with a combination of disorienting drugs and physical restraints.[25]

There is a broad range of physical, cognitive, and emotional difficulties[26] associated with restraint use, especially when such devices are used for a lengthy period of time. This range includes problems with the skin, the gastrointestinal and genitourinary systems, respiration, blood circulation, musculoskeletal functioning, anxiety, confusion, panic, depression, and lethargy. For the physically immobilized patient, the risk of institution-acquired infection is tremendously magnified.[27]

Case Law

The case law regarding physical restraints in hospitals has been mixed. In light of the clinical evidence that many institution-acquired and physician-caused injuries actually are the result of reliance on restraints, there have been a number of legal judgments rendered and settlements negotiated on the basis of inappropriate ordering of restraints, failure to monitor and correct their negative effects on the patient, or errors in the way that the restraint was mechanically applied. Nonetheless, the author of one study of reported verdicts from 1980 through

1995 found enough case law seeming to be in the opposite direction to conclude that hospitals have some basis for a general concern about their potential legal liability exposure for failure to restrain adequately patients who are at risk of falling or otherwise injuring themselves.[28]

This interpretation of historical case law has an immediate and superficial plausibility. However, it inaccurately predicts the future shape of liability exposure related to physical restraints, and hence the correct risk management posture and behavior of hospitals, as standards of care in this arena undergo a process of rapid evolution. The reasons for this evolution are discussed next.

Moreover, in a number of cases courts have found a lack of duty to restrain patients on the hospital's part.[29] Courts have ruled that hospitals were not negligent in failing to restrain patients who fell even after receiving medication.[30]

Changing Standards of Care

Cases that are currently working their way through the civil justice (for actual claims) or institutional administrative (for threatened claims) processes, as well as restraint-related claims that are threatened or filed in the future, likely will be governed by a very different legal standard of care than the one used to adjudicate earlier claims based on the use or nonuse of restraints. Consequently, the resolution of such claims is likely to be quite different in the future than it has been in the past. Risk management advice and strategies regarding the use of restraints in hospitals must take account of the following important influences on the evolving standard of care in this arena.

Regulatory Initiatives

Relevant recent regulatory requirements push in the direction of physical restraint use reduction, even though individual states have not yet enacted legislation specifically pertaining to this issue. For instance, hospitals that operate nursing home units or "swing beds" must act in compliance with the restraint limitation sections of the Nursing Home Reform Act portion of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87)[31] and its implementing regulations.[32]

In addition, the federal Food and Drug Administration (FDA) now has turned its attention to the status of physical restraints as medical devices. On November 16, 1991, the FDA issued a medical bulletin entitled "Potential Hazards with Protective Restraint Devices," which was reissued on July 15, 1992 as an FDA Safety Alert to hospital administrators, nursing directors, and directors of emergency room services. On August 28, 1995, the FDA issued a Safety Alert (to, among other intended audiences, hospital administrators and risk managers) entitled "Entrapment Hazards with Hospital Bed Side Rails."

Since 1992, restraints must be labeled as "prescription-only" devices. On March 4, 1996, the FDA published a final rule[33] that ended restraint manufacturers' previous exemption from the requirement[34] to notify the FDA of the intent to market most restraint devices; effective September 3, 1996, these devices need FDA prior-approval for marketing and sale.

Perhaps most importantly, the FDA actively maintains complaint files concerning restraining devices. The information contained in those files is accessible from the FDA by members of the public, including plaintiffs' attorneys, on request under the federal Freedom of Information Act.[35] Under the Safe Medical Devices Act (SMDA), passed in 1990[36] and effective November 28, 1991, and its implementing regulations,[37] hospitals (as well as nursing homes, ambulatory surgical facilities, and outpatient treatment facilities) are obligated to report certain incidents to the FDA on Form 3500A within ten working days.[38] A medical device report must be submitted whenever the "user facility" receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device may have caused or contributed to either (a) the death of a patient or employee of the facility or (b) serious injury to a patient or facility employee.

"Caused or contributed" includes problems that arise because of device failure, malfunction, improper or inadequate design, manufacture defects, mislabeling, or (particularly relevant in the restraint context) user (i.e., hospital) error. "Serious injury" means an illness or injury that (a) is life-threatening, (b) results in permanent impairment of a body function or permanent damage to a body structure, or (c) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

If earlier problems involved in the use of specific devices have been made a matter of public

record, but a hospital nonetheless condones the use of those devices by its staff on its patients, and injuries occur for which the patient seeks compensation, the hospital's defense may be a very difficult one to make. The hospital would have the burden of persuading the trier of fact (ordinarily a jury in medical malpractice litigation) that restraint use was appropriate in the particular situation, even in the face of information that the hospital had or should have had about the reasonably foreseeable hazards associated with the use of the device.

Voluntary Accreditation Standards

Pertinent standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are a quasiregulatory force in restraint reduction for the more than 90 percent of hospitals that apply for JCAHO accreditation. By virtue of voluntarily agreeing to comply with JCAHO standards, and to undergo periodic JCAHO surveys to assure that compliance, hospitals may achieve financially important "deemed status" for Medicare participation purposes. Until relatively recently, requirements accompanying the use of restraints had been contained in JCAHO management and administrative services standards.[39]

In January 1996, the JCAHO published a new chapter of its standards for hospitals (Standard TX.7.1-TX.7.1.3.3.), effective July 1, 1996. This revision deals exclusively and specifically with the use of physical restraints and seclusion, containing requirements about detailed policies and procedures; staff, patient, and family education programs; and development of alternative prevention strategies and implementation programs.[40] The stated goal of this new standard is unequivocally to assist in "[l]imiting the use of restraint or seclusion to those situations with appropriate and adequate clinical justification. . . ." The JCAHO explicitly acknowledges that achieving this goal "requires clear policies and procedures, well-trained staff, and the support of the organization's leaders and culture."

An earlier set of voluntary standards on physical restraints was developed for hospital nurses by the Nurses Improving Care of the Hospitalized Elderly Project, sponsored by the John A. Hartford Foundation in New York. The standards emerging from this project embody the following themes: (a) physical restraint use is not a usual part of medical treatment; (b) physical restraint use does not promote a patient's independence; and (c) all reasonable alternatives must be exhausted before use of a physical restraint.[41]

The American Geriatrics Society approved a Clinical Practice Statement on "The Use of Restraints" in May 1991. That professional organization took the position that it "strongly advocates the elimination of all types of mechanical restraints and strongly encourages restraint-free environments in all health care settings."

The Alzheimer Society of Canada has adopted the following official position:

> It is recommended that no restraints be used. However, should there be a special reason for using restraints, the risk and benefits to the individual and those around him/her must be weighed. If a restraint is used, it should be only for a very limited time. There must be well defined goals and the individual should be closely monitored.[42]

There is an increasing tendency for the courts in personal injury actions to look to relevant government statutes and regulations, as well as to voluntary accreditation standards and major organizational positions, as evidence of the appropriate standard of care under the circumstances. Thus, compliance with those sources of guidance may be deemed minimally adequate conduct while deviation from them may be considered to constitute negligence *per se* (negligence in and of itself) or, at the very least, strong presumptive evidence of negligence.[43]

The federal laws, JCAHO standards, and organizational policy statements outlined above thus clearly ought to create a strong incentive against the use of physical restraints in hospitals. There is today a heavy burden of proof resting squarely on the hospital that uses restraints to justify its conduct as the least restrictive alternative available to meet the therapeutic needs of the particular patient. Facilities that do not move away from previous practices of routine restraint use toward a much more discriminating, individualized approach will find themselves at severe jeopardy not only in terms of maintaining desired accreditations, but in the context of trying to defend against civil actions brought by or on behalf of an injured, improperly restrained patient. Conversely, in lawsuits brought by or on behalf of unrestrained patients, the hospital may be able to introduce in its defense evidence

about its compliance with applicable regulatory, accreditation, and organizational standards and policies.

Changes In Customary Practice

The legal standard of care in professional liability cases is determined in large part by the customary practice of the relevant industry at a specific point in time.[44] The dynamic, evolutionary relationship between changing industry behavior and the recognition of that behavior through incorporation into common-law standards of care, which standards in turn motivate further refinements in professional behavior, is complex and imprecisely defined. In terms of constituting the acceptable legal standard of care for tort purposes, it is quite unclear how we can tell with confidence when enough credible data has been amassed for new forms of professional behavior to have progressed in status from experimentation to innovation to customary practice.

Changing physicians' practices is a complex dynamic. As one eminent practitioner described it:

> . . . many medical practices are not soundly based. They are sustained, as is true of other human pursuits, by an inertia supported by fashion, custom, and the word of authority. The security provided by a long-held belief system, even when poorly founded, is a strong impediment to progress. General acceptance of a practice becomes the proof of its validity, though it lacks all other merit.[45]

Nonetheless, American hospitals and the legal standards that govern them are now on the crest of a wave in terms of the use of physical restraints. As the practice of hospitals increasingly becomes one of reduced reliance on restraints (alternatives are discussed below), it will become easier for hospitals to justify nonuse of restraints in specific instances that might become the subject of litigation. At the same time, it will become harder for a hospital defending its use of restraints, in the context of a lawsuit where patient injury resulted from the restraints, to present persuasive evidence that the nonindividualized use of physical restraints is an acceptable practice to even a respectable minority of hospital industry leaders. Thus, as the customary practice of the industry continues to evolve, the legal standard of care in hospitals is likely to incorporate a strengthened presumption against the use of physical restraints unless and until less intrusive and restrictive alternatives have been honestly identified, investigated, and found impossible for a particular patient.

The recent case of *Gerard v. Sacred Heart Medical Center*[46] may be a harbinger. There, a patient sued a hospital for injuries sustained in a fall after the hospital removed physical restraints. The appellate court upheld a jury verdict for the defendant hospital, holding that a health care provider is not liable for a clinical judgment arrived at through the exercise of reasonable professional care and skill, which supported the decision to remove the restraints, and that "the decision to restrain a patient is not merely a matter of custodial security."

International attention to restraint reduction is longstanding.[47] In the United States, significant strides have been made mainly in the last several years in identifying and popularizing a broad range of less intrusive, restrictive alternatives to physical restraints to accomplish (often better) the stated objectives of restraints. The American Geriatrics Society's 1991 Clinical Practice Statement on "The Use of Restraints" asserts the following:

> Increasing numbers of acute and long-term care institutions report a completely restraint-free environment. Restraint-free environments acknowledge the importance of individualization of therapy through consideration of various alternative measures for meeting patient needs and preventing and managing behavioral symptoms. Measures such as positioning, cushions and pads, enhanced physical therapy and recreational activities, environmental changes, and increased staff education and attention to patient needs and behavioral symptoms, may successfully lessen such behaviors, prevent injury to patients and staff, and promote quality of life and high quality care.

Less intrusive and restrictive alternatives to the use of physical restraints might encompass physiologic care (for example, attention to comfort, pain relief, positioning, oral feedings in lieu of intravenous or tube-fed nutrition, and abdominal binders to limit the confused patient from accessing tubes); psychosocial care; activities (for example, exercise and planned recreation); environmental manipulation (for example, increased light, redesign of furniture, placement of patient near the

nursing station, accessible call light or other means of communication, beds close to the floor with no side rail); and administrative support (for example, emotional support for staff that work with patients who have behavioral disturbances and adequate or alternative staffing patterns and staff training).

Because a hospital's policies and practices concerning restraints directly affect the delivery of patient care, they should be thoroughly incorporated into the institution's overall quality assurance program.[48] Furthermore, the imposition of physical restraints (whether with or without apparent informed consent—see discussion below) for individual patients should be scrutinized for its necessity, appropriateness, and impact on quality of care under the hospital's standard utilization review[49] procedures.

Accordingly, it will grow increasingly difficult for any particular hospital to continue to claim that it absolutely needed (as opposed to the fact that it simply chose) to use restraints in specific circumstances in which those restraints caused patient injuries. At the same time, use of an established, field-tested alternative increasingly will be considered persuasive evidence of compliance with the applicable standard of care in those relatively unusual situations in which patient injuries occur in the absence of restraints; while a plaintiff may show that the defendant hospital should have been doing "something" to protect the patient from foreseeable harm, more and more that "something" required is a less intrusive intervention than restraints. Further, when restraints are used, the hospital will be expected to show how such use was minimized as much as possible and that proper application and monitoring of the restraints by trained staff took place to reduce potential associated dangers.

Informed Consent and Assumption of Risk

It is essential to educate and involve patients themselves (if decisionally capable of making and communicating autonomous treatment choices) and/or families[50] or other authorized surrogate decision makers in the process of informed, voluntary consent to, or refusal of, physical restraint use as a form of medical intervention. Medical and nursing staff need to explain to patients or their surrogates the various risk/benefit implications of different treatment strategies, including physical restraints, and their reasonable and less intrusive alternatives.

For example, the decision maker needs to understand that one conceivable consequence of refraining from all restraints in the acute setting may be the patient's removal, purposely or inadvertently, of tubes, needles, and other invasive, unpleasant technological means of supplying the patient with clinically indicated and ordered medication or food. In addition, the patient's removal of certain tubes or catheters may require reinsertion, entailing perhaps[51] some risks and more discomfort. Weighing these possible risks, on one hand, against the demonstrated risks of restraint-induced injuries and the benefit of greater freedom, on the other, is a matter within the prerogative of the patient or surrogate.

The patient's right to make informed choices about personal health care interventions derives from both common-law principles[52] and constitutional provisions.[53] If, as the U.S. Supreme Court[54] and a plethora of other judicial bodies[55] have held, an individual has a fundamental right to refuse even life-sustaining medical interventions, then surely the right to choose extends to decisions about the acceptance of physical restraints by a hospitalized patient.

The patient's or surrogate's accurate comprehension and acceptance or assumption of potential consequences and ramifications entailed in accepting or rejecting the use of restraints is an important part of a sound professional and institutional legal risk-minimization strategy. The affirmative defense against a malpractice claim that stems from the doctrine of assumption of risk means that a patient understands and accepts the possibility of foreseeable risks of untoward results of either intervention or its lack.[56] Courts should engage in a broad recognition of the legitimate scope of assumption of risk by the patient, since such recognition extends the patient's decision-making power.[57]

In a number of cases, hospital defendants have been relieved from liability for injuries sustained when patients fell, on the ground that the patients had knowingly and voluntarily assumed the risks that occurred in the absence of restraint use.[58] In an analogous case, a court recently found a retirement center not liable to a resident who had left his wheelchair outside a common dining room. The center had a common dining room available to all residents not in wheelchairs. A resident entered the dining room so that he could eat with the other residents. While attempting to enter the dining room

using his walker, he fell and suffered serious injuries. The court held that the resident had knowingly and voluntarily assumed the risk of the injuries he sustained.[59]

More directly, in *Marottoli v. Hospital of St. Raphael*[60] the plaintiff fell and broke his hip when he attempted to leave his bed to walk to the bathroom. In his suit against the hospital for negligence, the court held:

> It is . . . not unheard of for patients to decide to do without assistance things they are used to doing, even though they have been told not to do them post-surgically without help. A review of the testimony and the documentary evidence leads this court to the conclusion that Mr. Marottoli's fall and injury were not the result of negligence by the defendant but were caused by his own premature attempt to leave his bed unassisted.

The court found that leaving up only one, rather than two, bedrails was an "adequate precaution taken by the defendant to discourage the plaintiff from trying to leave his bed unassisted."

Conclusion

The key to an effective risk management strategy while reducing or eliminating hospitals' historic reliance on—bordering in many instances on addiction to—the routine use of physical restraints must be based on substituting something other than neglect for those restraints. Hospitals must help develop and implement less restrictive, especially preventative, alternatives to restraints based on a patient's individualized assessment and adequate communication and negotiation between the medical and nursing staffs and the patient and/or surrogate decision maker. In the words of one court:

> It should not be inferred . . . that the safe course for the hospital to take is always to impose severe restraints in order to avoid lawsuits. Undue severity, besides being a betrayal of the patient, may itself entail liability. The practice should be one of reason which takes account, as far as may be feasible, of the needs of individual patients.[61]

As a result of that creative process of individualized assessment and care, the hospital's multiple interests in regulatory compliance, voluntary accreditation, and the limitation of tort liability exposure will all be well served.

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44. Hall v. Hilbun, 466 So. 2d 856 (Miss. 1985); Holt v. Godsil, 447 So. 2d 191 (Ala. 1984); Senesac v. Associates in Obstetrics and Gynecology, 141 Vt. 310, 449 A.2d 900 (1982).

45. BERNARD LOWN, THE LOST ART OF HEALING 187 (1996).

46. 86 Wash. App. 387, 937 P.2d 1104 (1997), *rev. denied,* 133 Wash. 2d 1017, 948 P.2d 388 (1997).

47. *See, e.g.,* Jeffrey M. Levine, *Historical Notes on Restraint Reduction: The Legacy of Dr. Philippe Pinel,* 44 J. AM. GERIATRICS SOC'Y 1130 (1996); Shaun O'Keefe *et. al., supra* note 1.

48. Regarding quality assurance programs in hospitals, *see generally* 42 C.F.R. § 482.21.

49. Regarding utilization review in hospitals, *see generally* 42 C.F.R. § 482.30.

50. Genevieve W. Kanski, Linda M. Janelli, Helen M. Jones, & Mary C. Kennedy, *Family Reactions to Restraints in an Acute Care Setting,* 22 J. GERONT. NURS. 22 (1996).

51. *See* Mion, *supra* note 5, at 598 ("Complications after deliberate self-extubation are important to quantify. For example, nurses typically expect most self-extubation events to be life-threatening, yet few complications were reported after deliberate self-extubation.").

52. *See generally* RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT (1986).

53. Roe v. Wade, 93 S. Ct. 705, 410 U.S. 113 (1973).

54. Cruzan v. Director, Missouri Department of Health, 110 S. Ct. 2841 (1990). The right to refuse treatment was reaffirmed by the Court when it refused to recognize an affirmative constitutional right to physician-assisted suicide [*Vacco v. Quill,* 117 S. Ct. 2293 (1997); *Washington v. Glucksberg,* 117 S. Ct. 2258 (1997)].

55. *See generally* COORDINATING COUNCIL ON LIFE-SUSTAINING MEDICAL TREATMENT DECISION MAKING BY THE COURTS, GUIDELINES FOR STATE COURT DECISION MAKING IN LIFE-SUSTAINING MEDICAL TREATMENT CASES, 2d ed. (1992).

56. *See* M.L. Howard & L.B. Vogt, *Physician-Patient Relationship,* in LEGAL MEDICINE, 3d ed. 265,

286–87 (American College of Legal Medicine Textbook Committee, eds., 1995). For discussion of the related affirmative defense of contributory negligence in the hospital restraints context, *see Tobia v. Cooper Hospital University Medical Center,* 136 N.J. 335, 643 A.2d 1, 18 (Pollock, J., dissenting) (1994).

57. *See* Comment, *Contributory Negligence in Medical Malpractice: Are the Standards Changing to Reflect Society's Growing Health Care Consumerism?* 17 U. DAYTON L. REV. 151 (1991).

58. Browne v. Nash General Hospital, 65 N.C. App. 708, 309 S.E.2d 704 (1983); Polisso v. Saint Elizabeth Hospital, No. 74 C.A. 100, slip. Op. (Ohio Ct. App. March 12, 1975); Noble v. Insurance Company of North America, 248 So. 2d 12 (La. Ct. App.1971); DeBlanc v. Southern Baptist Hospital, 207 So. 2d 868 (La. Ct. App. 1968).

59. Morgan v. Retirement Unlimited, No. 139189 (Va. Cir. Ct. 1996).

60. No. 280860 Superior Ct. of Connecticut, Judicial District of New Haven, 1992 Conn. Super. LEXIS 2809 (Sept. 29, 1992).

61. Bennett v. Winthrop Community Hospital, 21 Mass. App. 979, 489 N.E.2d 1032 (1986).