# W. Liability Overview: New Theories and Challenges

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# I. INTRODUCTION

This paper is designed to provide an overview of selected significant decisions and an analysis of trends in litigation affecting providers.

## **II. MEGA TRENDS AND MONSTER VERDICTS**

#### **A. Medical Malpractice Verdicts**

## 1. Martin v. Childrens' Advanced Medical Institutes

In *Martin v. Children's Advanced Medical Institutes*, the jury awarded \$268.7 million dollars to the parents of fifteen year old Rachel Martin, a teenager stricken with cerebral palsy from birth.<sup>[1]</sup> Rachel was hospitalized at Medical City Dallas Hospital in March 1998 for surgery to repair a narrowing of the trachea caused by built-up scar tissue. Her surgery went well and she was expected to fully recover and return home, however, Rachel unexpectedly died two and one-half days after surgery.<sup>[2]</sup>

After surgery, the pediatrician, Dr. Robert Pryor, prescribed Propofol, a sedative that, although prescribed, is not recommended for extended use in pediatric cases. What is more, Dr. Pryor prescribed 40 times the proper dosage for Rachel.<sup>[3]</sup> In addition, two other physicians, Dr. James Matson and Dr. Michelle Papo, failed to spot or correct the medication error even after Rachel's urine changed from amber to tea to dark brown, and then finally to black.<sup>[4]</sup> Dr. Pyror had also prescribed morphine to control Rachel's pain, however, hospital staff failed to give Rachel the morphine. As a result, the Propofol overdose caused Rachel's organs to shut down completely. She could not tell anyone because of her cerebral palsy, and she had no morphine to stem the pain over the course of the next two days before her death.<sup>[5]</sup>

The Martins first assumed that Rachel died of an infection, and were not aware of the mistake with the Propofol until the autopsy report was returned. Neither the doctors nor the hospital explained what happened to Rachel, and did not apologize to the Martins. Mr. Martin repeatedly requested his daughter's medical records, but his requests went ignored. The Martins filed suit naming Dr. Robert Pryor, Dr. James Matson, Dr. Michelle Papo, the drug manufacturer (Xeneca), and Children's Advanced Medical Institutes. The three doctors settled their portion of the case for \$3 million dollars, and the drug manufacturer settled for a confidential amount. Thus, the hospital was the sole defendant at trial.

The Plaintiffs argued that the doctors were acting as agents of the

hospital based upon the contract between the hospital and the physicians, and therefore, the hospital was responsible for the physicians' conduct.<sup>[6]</sup> In addition, the Plaintiffs pled a violation of the penal code, which makes it a crime to knowingly cause injury to a disabled person or a child. The jury found that the doctors were acting as agents of the hospital, and that the defendants violated the penal code by recognizing the risks and then disregarding them and ignoring guidelines and Rachel's abnormal symptoms.<sup>[7]</sup> The jury apportioned negligence at 75% to the hospital, 15% to Dr. Robert Pryor, 5% to Dr. James Matson and 5% to Michelle Papo. The jury awarded more than \$130 million in compensatory damages to the Plaintiffs and \$137 million dollars in punitive damages.<sup>[8]</sup>

Texas law caps compensatory damages in this case at \$1.5 million dollars per defendant. Thus, the jury's finding that the doctors were acting as agents of the hospital meant that the hospital was responsible for its \$1.5 million dollars, plus \$1.5 million dollars for each of the three doctors. Further, by pleading the violation of the penal code, the Plaintiffs were able to eliminate the punitive damages cap, which, in this case, would have been approximately \$750,000 per defendant, or twice the economic portion of the compensatory damages.<sup>[9]</sup> Following the verdict, on November 3, 2000, the hospital settled for a confidential amount.<sup>[10]</sup>

## 2. One Hundred Million Dollar Verdict to Premature Baby

On October 20, 2000, a Pennsylvania jury awarded Alys Vlasny (now 5 years old), \$100 million for damages she sustained due to surgical errors that occurred soon after her premature birth.<sup>[11]</sup> Alys Vlasny was born at 26 weeks gestation and despite her premature birth, was neurologically fit and able to breath without a ventilator following the first few days of her birth. Alys however, suffered from ductus arteriosis which is a common problem among premature babies, wherein the arterial duct fails to close. Because of her condition, surgery was required to close the arterial duct. Dr. Nicholas Cavarocchi performed the surgery at St. Luke's Hospital in Bethlehem, Pennsylvania. Dr. Cavarocchi unsuccessfully searched for the duct for two hours during surgery and then ended the surgery with the duct still open.<sup>[12]</sup> During the operation, Dr. Cavarocchi damaged Alys' phrenic nerve. As a result of the damage to her phrenic nerve, Alys had to be placed on a ventilator. According to the plaintiff's lawyer, the rapid infusion of oxygen from the ventilator damaged her lungs which, in turn, led to Alys' brain damage.<sup>[13]</sup> After the surgery, Alys was transferred to St. Christopher's Hospital where the duct was successfully closed. However, a nurse at St. Christopher's placed an arterial line into the wrong artery where it stayed for ten days.<sup>[14]</sup> The mistake allegedly stopped the blood flow to Alvs' arm which eventually had to be amputated. Alys is now 5 years old, is profoundly retarded and has to be fed through a tube.

The plaintiffs sued Dr. Cavarocchi, his professional corporation, St.

Luke's Hospital, St. Christopher's Hospital for Children, and three neonatologists, Dr. Leonard Goldsmith, Dr. S. David Rubenstein, and Dr. Eileen Tyrala.<sup>[15]</sup> The lawsuit was initiated by Alys' birth mother who was 17 at the time of Alys' birth and who relinquished her parental rights in 1997. Mr. Mark Albright was appointed as guardian ad litem for Alys who was adopted by Dawn and Wendy Vlasny. The Vlasny's did not know that the lawsuit had ever been filed when they committed to taking Alys, and are not a party to the litigation.<sup>[16]</sup>

The defendants complained that their defense was hampered by the judge's decisions to exclude certain evidence, and the fact that the two groups of defendants (*St. Luke's vs. St. Christopher's*) were not granted separate trials. The \$100 million award was for compensatory damages for Alys' pain and suffering, emotional distress, disfigurement, loss of enjoyment of life's pleasures, loss of future earnings and life care costs for Alys.<sup>[17]</sup> Ninety million dollars of the award was rendered against Dr. Cavarocchi, his professional corporation and St. Luke's Hospital. The remaining \$10 million was against the St. Christopher's defendants for the loss of Alys' arm.<sup>[18]</sup> According to the plaintiff's lawyer, future life care costs and past and future medical costs and lost earnings totaled \$50 million. At last report, the verdict is being appealed and post-trial motions are pending.<sup>[19]</sup>

# 3. Romero v. Columbia/HCA Health Care Corp.

In *Romero v. Columbia/HCA Health Care Corp.*, a Texas jury awarded the plaintiff \$40.6 million in a medical malpractice lawsuit brought against a hospital and two doctors.<sup>[20]</sup> The plaintiff Dolores Romero filed the lawsuit on behalf of her husband, Ricardo Romero, who was left brain-damaged following a surgery to repair a herniated disk. During surgery, Mr. Romero suffered uncontrollable blood loss, and then endured cardiac arrest. His excessive blood loss, and the delay in receiving transfusions and the cardiac arrest left Mr. Romero incapacitated. The plaintiffs sued Columbia Kingwood Medical Center, Dr. Merrimon W. Baker, an orthopedic surgeon, and Dr. William Huie, an anesthesiologist, in Harris County. The plaintiff brought suit pursuant to Texas case law that provides a cause of action against a hospital for negligent credentialing upon a showing of malice.<sup>[21]</sup>

Ms. Romero alleged that Dr. Baker knew or should have known that he had a history of and a continuing problem with drug use and drug abuse that impaired or affected his medical judgment and his ability to perform surgery and other treatment. Dr. Baker had previously been sued 9 times for malpractice while employed by other hospitals and plaintiffs alleged that the hospital was aware of his alleged addiction to prescription pain killers. Ms. Romero claimed that Dr. Baker failed to terminate the surgery on her husband when an extensive amount of blood loss posed a serious threat to his safety. She also alleged that Dr. Baker failed to adequately communicate with the anesthesiologist and certified nurse anesthetist regarding the nature and degree of blood loss.

As against the hospital, the plaintiffs alleged gross negligence and malice and that the hospital was negligent by entrusting the operating room facilities to Dr. Baker at a time when it knew he was reckless and careless as a physician. The plaintiffs also alleged that the hospital erred in granting staff privileges at a time when the physician posed a threat to his patients and failed to deny or suspend his privileges at a time when the hospital knew the physician was reckless and posed a threat to his patients. In addition, the hospital allegedly failed to conduct supervised urine testing, conduct a background investigation, and allowed unsupervised urine samples to be taken knowing the doctor had a history of drug abuse that impaired his medical judgment. The plaintiffs sought \$18.5 million in actual and exemplary damages. Prior to trial, Dr. Baker agreed to a \$400,000 settlement, and Dr. Huie agreed to a \$1.8 million settlement.<sup>[22]</sup> The jury determined that the hospital was 40% negligent and found \$12 million in punitive damages. As of November 1998, Dr. Baker was no longer a member of the hospital staff.<sup>[23]</sup>

# 4. HCA, Inc. v. Miller

In 1992, the plaintiffs, Carla and Mark Miller, were awarded \$60 million against the hospital for the successful resucitation of their premature baby against their wishes and without their consent.<sup>[24]</sup> Carla Miller was admitted to Women's Hospital of Texas in August 1990 when she was approximately 23 weeks pregnant. At that time, she and her husband were told that if the fetus survived, it would suffer severe impairments. The Millers orally requested that no heroic measures be performed on the baby after birth. The request was recorded in the medical records by the neonatologist, and the obstetrician informed the nursing staff that no neonatologist would be needed at delivery. However, after further consultation, the obstetrician concluded that if the baby was born alive and weighed over 500 grams. the medical staff would be obligated by law and hospital policy to administer life-sustaining procedures even without the parents' consent.<sup>[25]</sup> The baby girl was born late in the night, and the attending neonatologist determined that she was viable and instituted resucitative measures. Although the baby survived, she suffers, as had been anticipated, from severe physical and mental impairments and will never be able to care for herself.

The Millers subsequently filed a lawsuit against HCA asserting vicarious liability for the actions of the hospital in treating the baby without consent, having a policy that mandated the resucitation of newborn infants weighing over 500 grams even in the absence of parental consent, and for direct liability for failing to have policies to prevent such treatment without consent.<sup>[26]</sup> The trial court entered judgment against the hospital in favor of the Millers for \$42 million in actual damages and \$17 million in punitive damages based upon the jury's findings of liability and damages.<sup>[27]</sup> On appeal, HCA challenged the imposition of tort liability on the grounds that it did not owe the Millers a duty and, in fact, were legally obligated to treat the

baby without consent because the Millers had no right to withhold lifesustaining medical treatment.

The Fourteenth Court of Appeals, noting that competing legal and policy interests were at play, reversed and rendered a take-nothing judgment concluding that HCA was not liable under the facts of the case.<sup>[28]</sup> The court reasoned that Texas law gives parents the right to refuse life-sustaining care for their children, however, only if they comply with state law, such as the Advanced Directives Act. Similarly, parents have a legal duty to provide needed medical care to their children, and the state has the right to protect the well-being of minors, "even where doing so requires limiting the freedom and authority of parents over their children."<sup>[29]</sup> In addition, the appellate court noted that there was no statutory or common law in Texas that allowed parents to withhold urgently needed life-sustaining medical treatment from a non-terminal child and further that by granting that right it would pose imponderable legal and policy issues such as a whether a right would apply to a healthy child with an abnormality.<sup>[30]</sup> The court concluded that there was no legal basis for finding that Texas law gave parents the right to withhold medical treatment urgently needed by their children unless they complied with state law governing the withholding of medical care for the terminally ill.<sup>[31]</sup> The court sustained HCA's contentions finding that "it did not owe the Millers a tort duty to: (a) refrain from resucitating [the baby]; (b) have no policy requiring resucitation of patients like [the baby] without consent; and (c) have policies prohibiting resucitation of patients like [the baby] without consent".[32]

The court added that a court order would not be required to override a parent's refusal to consent to urgently needed life-sustaining medical treatment for a child.<sup>[33]</sup>

# **B. Managed Care Organization Verdicts**

## 1. Chipps v. Humana Health Insurance Co. of Florida

In Chipps v. Humana Health Insurance Co. of Florida, after two days of deliberation, a Florida jury returned an \$80 million verdict against Humana for improperly terminating a 9 year old girl with cerebral palsy from a special treatment program for catastrophically-ill patients.<sup>[34]</sup> The case began in 1994, when Mark Chipps joined Humana's Preferred Provider Organization after the county sheriff's office, where he was a deputy, changed insureds. He was told at the time by a company representative that the plan would place his daughter in the medical management program because of her condition.<sup>[35]</sup> Chipps later received a letter from the company saving that his daughter no longer met the requirements of the program and that her care was being discontinued. The company explained that his daughter was receiving therapy at her public school and that they would not provide her with a prior level of benefits. Mr. Chipps took the matter to the State Department of Insurance and some of the benefits were restored, however, the company refused to pay \$28,000

in medical bills including bills for physician services, speech, rehabilitation, and occupational therapy.<sup>[36]</sup>

The girl was among 100 to 150 catastrophically-ill children allegedly systematically denied benefits from a medical case management program offered by Humana as part of is Preferred Provider Network coverage. Humana had allegedly set up a bonus incentive plan where they would pay doctors and nurses cash bonuses based upon arbitrary targets to reduce the number of children in the program and the number of days spent in a hospital.<sup>[37]</sup>

Plaintiffs brought suit against the subsidiary alleging claims of breach of insurance contract, fraud in the inducement, bad faith, intentional infliction of emotional distress, and promissory estoppel.<sup>[38]</sup> The trial court ruled, and an appellate court affirmed, that the company was in a default liability judgment of the allegations contained in the plaintiffs' complaint following several violations of court orders during the discovery phase of the case. The jury awarded more than \$1 million in compensatory damages for unpaid medical bills and intentional infliction of emotional distress, and \$78.5 million in punitive damages.<sup>[39]</sup>

# 2. Missouri Consolidated Health Care Plan v. Community Health Plan

A Missouri jury awarded \$14.5 million to a health maintenance organization on fraud and breach of contract claims raised against Missouri Consolidated Health Care Plan.<sup>[40]</sup> Missouri Consolidated Health Care Plan (MCHCP) sued Community Health Plan (CHP), a St. Joseph Missouri HMO, in July 1998, to enforce contracts it entered into from 1995 through 1997 to provide health care services for Northwestern Missouri. CHP was preliminarily enjoined from reducing its provider network or abandoning its contracts.<sup>[41]</sup> Thereafter, CHP filed a counter claim alleging that MCHCP breached the contracts. breached its covenant of good faith and fair dealing, and had induced CHP into entering the contracts through misrepresentation, and that it had lost more than \$21 million through the contracts.<sup>[42]</sup> CHP claimed that MCHCP mislead it and other bidders by claiming that information that would have better allowed for accurate premium projection was unavailable, when it actually was available. Had MCHCP provided the requested information, it would have revealed that the insured population at issue presented an abnormally adverse risk.<sup>[43]</sup>

The jury found for MCHCP on two counts of breach of contract.<sup>[44]</sup> The jury returned verdicts totalling \$14.5 million in favor of CHP, on its claims of misrepresentation and breach of faith and fair dealing.<sup>[45]</sup> MCHCP has appealed the verdicts and assert that the claims are subject to sovereign immunity.<sup>[46]</sup>

# **III. MANAGED CARE**

# **A. ERISA Preemption**

Driven by the need for cost containment, managed care has largely supplanted traditional fee-for-service medicine as the predominant model for the delivery of health care in America. Currently, some 85% of this country's insured workers receive coverage through managed care plans.<sup>[47]</sup> Under the traditional fee for service arrangement, the health care provider submitted a bill to the patient's insurance carrier after the treatment had been provided, thus making cost review entirely retrospective. Managed care, on the other hand, generally entails prospective review, analyzing the necessity for the recommended medical treatment before it's delivered. Hence, in a managed care environment, some of the responsibility for medical decision making is shifted from the actual health care provider to the managed care plan. Indeed, managed care has been defined as "a system that, in varying degrees, integrates the financing and delivery of medical care through contracts with selected physicians and hospitals that provide comprehensive services to enrolled members for a predetermined ... premium."<sup>[48]</sup> This convergence of coverage and care is what brings together state and medical malpractice claims and ERISA preemption.

Generally, cases considering the liability of managed care organizations for medical malpractice type claims have fallen into main categories: direct liability or "quantity of care" cases on the one hand, and vicarious liability or "quality of care" cases on the other. Courts consideing direct liability claims — such as neglience claims arising out of cost containment systems or utilization review — have generally held those claims to be preempted by ERISA because they challenge the administration of benefits and therefore "relate to" the plan.<sup>[49]</sup> The are "quantity of care" cases. On the other hand, the courts considering vicarious liability claims such as neglience claims arising out of treatment decisions made by managed care organizations have generally held such traditional state law claims are not preempted by ERISA.<sup>[50]</sup>

# 1. Quality of Care Cases.

Just recently, the Third Circuit addressed the issue of "complete preemption" in the context of a lawsuit claiming medical malpractice in In Re U.S. Health Care, Inc. <sup>[51]</sup> The plaintiffs brought suit in state court for damages arising from the death of the newborn daughter naming the pediatrician, the hospital and U.S. Health Care, Inc. (the HMO) asserting direct tort claims against the defendants and vicarious liability on the part of the hospital and the HMO. The defendants jointly removed the petition to federal court based on complete preemption under Section 502 of ERISA.<sup>[52]</sup> The HMO then moved for dismissal or in the alternative, for summary judgment on the ground that all of the plaintiff's claims were subject to express preemption under Section 514 (a) of ERISA. The District Court found complete preemption as to one count, dismissed the single count, and then declined to exercise supplemental jurisdiction over the remaining counts and remanded them to state court. U.S. Health Care petitioned for writ of mandamus and filed a Notice of Appeal and the plaintiffs

cross-appealed. The case began with the birth of plaintiff's daughter at Kennedy Hospital in New Jersey. In accordance with the health care benefits precertification provided by the HMO, Dr. Meneh, an independent health care provider contracting with the HMO, discharged the mother and newborn from the hospital after only 24 hours. One day after discharge, the infant became ill, whereupon the parents made numerous phone calls to the doctor who did not advise them to return to the hospital. The parents also contacted the HMO and requested an in-home visit by a pediatric nurse, but no such nruse was provided. The infant contracted a Group B strep infection that went undiagnosed and untreated, and developed into menangitis. The infant died that same day.<sup>[53]</sup>

On appeal, U.S. Health Care argued that by their complaint, plaintiffs were seeking recovery under state law for the HMO's denial of benefits under a health benefits plan governed by ERISA.<sup>[54]</sup> U.S. Health Care argued that because Section 502 creates a cause of action to recover such benefits and, because all the plaintiff's claims came within that section, they were completely preempted. In rendering its decision, the Third Circuit concluded that because the complaint did not raise a failure to "provide benefits due under the plan" the claim should not fall within ERISA's civil enforcement scheme.<sup>[55]</sup> The court noted that it was significant that none of the three counts as plead by the plaintiffs alleged a failure to provide or authorize benefits under the plan, and the plaintiffs could not claim that they were denied any of the benefits that were due under the plan.<sup>[56]</sup> The court ruled that the vicarious liability claims against U.S. Health Care for the doctor's malpractice did not fall within the scope of Section 502 and thus was not completely preempted.

U.S. Health Care was also recently involved in a case relating to quality of care under ERISA preemption and arising in the Third Circuit. A lawsuit was filed in state court by Mr. Lazorko, on behalf of his deceased wife, who had committed suicide in July of 1993.[57] She had attempted suicide in 1992, and had been hospitalized for months, however, following her discharge, her request for rehospitalization was denied by her doctor. Mr. Lazorko sought to hold U.S. Health Care, Inc., as the administrator of his health plan, "directly and vicariously liable" under state law for his wife's death because the HMO imposed financial disincentives on this wife's doctor that discouraged him from recommending her for additional treatment.<sup>[58]</sup> U.S. Health Care removed the case to Federal court arguing that the denial of the hospitalization request was completely preempted by ERISA under Section 502 (a) (1) (B), which gives a member of an ERISA plan an exclusive federal remedy for claims alleging the denial of benefits guaranteed by the plan. The District Court denied Mr. Lazorko's Motion for Remand construing his claims as falling under ERISA's complete preemption doctrine, and then dismissed the claims that were preempted by ERISA's civil remedy.

On appeal, the Third Circuit held that the claim involved the "quality of care" received rather than the "quantity of benefits" received, and

therefore was not necessarily federal in character as a claim alleging the denial of benefits under Section 502 of ERISA.<sup>[59]</sup> Citing its opinions in In Re U.S. Health Care, Inc., and Dukes v. U.S. Health Care, Inc., the court concluded that financial incentives that discouraged care did not deny plan benefits but instead affected the quality of care provided and thus decisions to deny a particular request in the course of providing treatment, as in Lazorko's case, is a claim about the quality not the quanitity of benefits provided. According to the court, Mr. Lazorko's claims against U.S. Health Care falls squarely within the line of reasoning that claims involving denial of treatment decisions are "akin to claims for medical malpractice" and thus fall outside of ERISA's complete preemption clause.<sup>[60]</sup> The court explained that to the extent that the mixed decision implicates the quality of care received by Ms. Lazorko, "Pegram does not foreclose direct claims against U.S. Health Care." The court concluded that Lazorko's case was not subject to complete preemption and therefore it was properly removed from state court and should be remanded.<sup>[61]</sup>

# 2. Quantity of Care Cases.

In *Thompson v. Gencare Health Systems, Inc.*, <sup>[62]</sup> the plan participant, Ms. Thompson, was suffering from breast cancer and after undergoing a Gencare precertified modified radical mastectomy, sought a more aggressive treatment procedure to cure the disease. After consulting with independent physicians, Gencare declined to precertify the more aggressive treatment.<sup>[63]</sup> After Ms. Thompson's death, her husband commenced an action in state court seeking damages for Gencare's alleged medical malpractice and refusing to "perform and/or provide high dose chemotherapy and/or bone marrow transplant procedures."<sup>[64]</sup> Gencare removed the action to federal court and moved for summary judgment arguing complete preemption by ERISA. The District Court denied Thompson's motion to remand and dismissed the complaint.

Citing U.S. Supreme Court and Eighth Circuit precedent, the Eighth Circuit stated that Gencare's only role in Ms. Thompson's cancer treatment was to make precertification benefit decisions on behalf of the plan, and therefore Thompsons' assertions of a tort claim for damages on account of Gencare's allegedly wrongful benefit decisions as plan administrator were completely preempted by ERISA's remedies.<sup>[65]</sup>

In *Thompkins v. United Health Care of New England, Inc.*, [66] the parents of a child suffering from Trisomy 13, a chromosomal disease, sued United alleging that the denial of benefits for treatment of their child violated the Americans With Disabilities Act and antidiscrimination statutes, and asserted state law claims for negligent and intentional infliction of emotional distress, misrepresentation and breach of contract. The Thompkins' daughter received treatment at the New England Medical Center that was preapproved and paid for by United. The Thompkins had received their insurance through Mr.

Thompkins' employer for a period for three years. They were offered a new United insurance policy through Ms. Thompkins' employer and switched to the new policy after receiving assurances from United representatives that changing employer providers would not alter their coverage. United soon began to deny payments, however, for treatment provided to their daughter at the New England Medical Center. The Thompkins were notified that their daughter's therapies would not longer be preapproved or paid for because she was to receive future treatment by United-covered physicians at less costly hospitals closer to home.[67]

The Thompkins appealed United's denial of coverage at New England Medical Center and its decision to transition their daughter to other hospitals for treatment. They ultimately obtained reversal of the earlier denial of benefits and an agreement from United to pay back costs for treatment already received and authorizing their daughter to obtain future treatments at New England Medical Center. Despite their successful appeal of denial of benefits, the Thompkins sued United for damages as a result of their efforts to reverse the denial of benefits. United moved to dismiss their claims on grounds that ERISA preempted the state's statutory and common law and that the ADA claims failed to state a cause of action. The district court held that the common law claims related to United's ERISA regulated health insurance plan within the meaning of ERISA preemption and that ERISA preempted all of the Thompkins' state law claims. In addition, the court ruled that the Thompkins could not state an ADA claim because the allegations did not show that United was a covered entity.[68]

The First Circuit affirmed the dismissal of the Thompkins' claims but relied upon different grounds because of the interrelationship between the ADA claims and the plaintiffs' and ERISA preemption. The court held that the only discriminatory conduct alleged in the complaint, which was United's initial decision to deny payment for the daughter's treatment at New England Medical Center, was fully readdressed through United's ERISA-mandated internal review process.[69] The court concluded that the Thompkins could recover the benefits that they claimed were wrongfully denied on the basis of discrimination by utilizing the internal administrative remedies available to them. Accordingly, the Thompkins did not suffer discrimination under the ADA as a result of United's initial decision to deny their daughter benefits based on her disability.

Further, the First Circuit held that because the plaintiffs did not contest the District Court's finding that their state claims "relate to" the United health benefit plan, and because the ADA's enforcement regime does not depend on the availability of the state's statutory claims, the state claims were subject to ERISA preemption.<sup>[70]</sup>

# **B.** State and Federal Initiatives to Hold Managed Care Organizations Liable for the Denial of Care

1. Texas Health Care Liability Act.

Effective September 1, 1997, Texas became the first state to allow an individual to sue a health insurance carrier, health maintenance organization, or other managed care entity for damages proximately caused by the entity's failure to exercise ordinary care when making a health care treatment decision.<sup>[71]</sup> Under the Texas Health Care Liability Act, (the "Act") these entities may be held liable for substandard health care treatment decisions made by their employees, agents or representatives.<sup>[72]</sup> The Act also establishes an independent review process for adverse benefit determinations and requires an insured or enrollee to submit his or her claim challenging an adverse benefit determination if such a review by an independent review organization if such a review is requested by the managed care entity.<sup>[73]</sup> Additional responsibilities for HMOs and further requirements concerning review of an adverse benefit determination by an independent review organization are also addressed by the Act.<sup>[74]</sup>

# 2. Corporate Health Ins., Inc. v. Texas Dept. of Insurance.

In *Corporate Health Ins., Inc. v. Texas Dept. of Ins.*,<sup>[75]</sup> plaintiffs Corporate Health Insurance, Inc., Aetna Health Plans of Texas, Inc., Aetna Health Plans of North Texas, Inc., and Aetna Life Insurance Company brought an action against Defendants the Texas Department of Insurance, the Commissioner of the Texas Department of Insurance, and Dan Morales, Attorney General of the State of Texas, in their official capacities, seeking a declaration that the Act is preempted by ERISA and by the Federal Employees Health Benefit Act ("FEHBA"). The plaintiff also sought to enjoin the enforcement of the Act as it relates to employee benefit plans covered by ERISA and FEHBA.

The defendants filed a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, arguing that while the Act regulates the quality of care provided by HMOs operating in Texas, ERISA and FEHBA, in contrast, govern what types of regulations may be placed on an employee benefit plan. The purpose of the Act, they reasoned, is to prevent health plans from escaping liability for the medical decisions they "make," "control" or "influence," not to regulate how HMO's make benefit or coverage determinations, nor to proscribe requirements governing the structure of a benefit plan. Accordingly, the defendants argued that the ERISA and FEHBA preemption clauses do not apply to the Act.

The plaintiffs, on the other hand, filed a motion for summary judgment, contending that the Act impermissibly interferes with the purpose, structure and balance of ERISA and FEHBA, thereby injecting state law into an area exclusively reserved for Congress. The plaintiffs contended that the language in the Act expressly "refers to" ERISA plans, and that the Act has a connection with ERISA plans because it purports to impose state law liability on ERISA entities and to mandate the structure of plan benefits and their administration. The plaintiffs also maintained that the Act wrongfully binds employers and plan administrators to particular choices and impermissibly creates an alternate enforcement mechanism. On September 18, 1998, the U.S. District Court for the Southern District of Texas held that the Act was partially preempted by ERISA. Because Texas law permits portions of a statute to be severed when the remainder does not violate the intention of the legislature, the district court severed the portion of the Act preempted by ERISA, while leaving the rest of the statute in place. Specifically, the district court upheld the portion of the Act that holds insurance carriers, health maintenance organizations and other managed care entities liable for substandard health care treatment decisions made by their employees, agents, or representatives, and severed the portion that would have established an independent review process for adverse benefit determinations.

Relying on the Fifth Circuit's decisions in *Corcoran v. United Health Care Inc.*, [76] and *Rodriguez v. Pacificare of Texas, Inc.*, [77] the plaintiffs argued that the Act improperly imposed state liability on ERISA entities. Interestingly, the district court predicted, given the Supreme Court's recent trend of narrowing the scope of ERISA preemption, that the Fifth Circuit might reach a different decision in *Corcoran* were it to review the case today. Nevertheless, the court distinguished *Corcoran* and *Rodriguez*, cases in which suits stemming from the decisions of managed care plans about benefits to be paid were held to be preempted by ERISA, from actions that might be brought pursuant to the Act. Under the Act, a plaintiff could, according to the district court, challenge the quality of benefits actually received without challenging a denial of benefits or the handling of a medical claim. Claims against an HMO for the poor arrangement of medical treatment, such as those examined in *Dukes v. U.S.* 

*Healthcare, Inc.*, <sup>[78]</sup> would be permitted by the Act. Hence, the Court appears to have decided the case based on the quality of care versus quantity of care analysis discussed in Section IV above.

Both Aetna and Texas appealed the decision of the district court. In its review, the Fifth Circuit returned to the traditional analysis of ERISA preemption under the trilogy of U.S. Supreme Court cases asking whether a state regulation frustrates the federal interest in uniformity.<sup>[79]</sup> The court then addressed each of the Senate Bill 386 provisions in turn, finding first that ERISA did not preempt the provisions allowing HMOs to be liable for physician negligence.<sup>[80]</sup> The court reasoned that the act allows suits for claims that a treating physician is negligent in delivering medical services, and imposes vicarious liability on managed care entities for that negligence. Further, the vicarious liability does not "relate to" the managed care provider's role as an ERISA plan administrator or affect the structure of the plans themselves so as to require preemption.<sup>[81]</sup> The court further explained that a suit for medical malpractice against a doctor is not preempted by ERISA simply because those services were arranged by an HMO and paid for by an ERISA plan.

The court next turned to the anti-retaliation and anti-indemnification provisions under the Act. The anti-retaliation provision forbids a managed care entity from dropping or refusing to renew a doctor or

health care provider for advocating medically necessary treatment.<sup>[82]</sup> The anti-indemnification provision prohibits a managed care entity from including an indemnification clause in its contracts with doctors or other health care providers that would hold it harmless for its own acts.<sup>[83]</sup> The court found that these provisions complement the Act's liability provisions by realigning the interests of managed care entities and their doctors, and together the provisions thus preserve the physician's independent judgment in the face of the managed care entity's incentives for cost containment. The court held that such a scheme is again the kind of quality of care regulation that has been left to the states.<sup>[84]</sup>

The independent review determinations by managed care entities were next reviewed by the court. The first set of provisions codified in Section 88 allow suit against an entity only after the patient has followed an independent review procedure.<sup>[85]</sup> The court found that these review provisions were not preempted because the provision describes the patient's complaint as the "claim" which refers back to the basis of the cause of action, and thus allows independent review only of claims for which the patient may bring suit under the liability provisions. The other set of provisions relating to independent review of determinations add procedures through which the patients may appeal "adverse determinations." Because adverse determinations include determinations by managed care entities as to coverage, not just negligent decisions by a physician, and the provisions allow the patient who has been denied coverage to appeal to an outside organization, they are coverage determinations and fall squarely within ERISA preemption. The Fifth Circuit further concluded that these provisions would not be saved under ERISA's savings clause, because the provisions create alternative mechanisms through which plan members may seek benefits due to them under the terms of the plan which are identical to relief under ERISA, and therefore, the independent review provisions conflict with ERISA's exclusive remedy. The Fifth Circuit also ruled that the provisions they held do not relate to ERISA plans similarly would not relate to any FEHBA plans because they do not concern coverage or benefits.

Finally, because the Fifth Circuit found some of the act's provisions preempted, they were compelled to consider whether such provisions were severable from the remainder of the statute. They examined whether the provisions were so independent that the legislature would have passed the remaining statute without the disallowed provisions. The Fifth Circuit found that the legislature would wish to give effect to those provisions targeting the quality of care, because after the district court's determination holding the IRO provisions preempted, the Texas Legislature passed a bill making those procedures optional as to the liability provisions.<sup>[86]</sup> The Fifth Circuit severed those portions of the act as preempted by ERISA.

The Texas Department of Insurance petitioned for a panel rehearing of the court's decision, however, that petition was denied. The department petitioned the court's ruling on the law's independent review

provisions, arguing that the Appeals Court had "factually misunderstood" the provision and that the U.S. Supreme Court's recent decision in *Pegram* "cast doubt" on the appellate court's ruling. In denying the petition, the Fifth Circuit said "our panel opinion does not hold or suggest that when implementing its police power, Texas cannot deploy an independent review mechanism to regulate the minimal quality level of medical care provided for covered conditions." The court added, "the law is clear that Texas cannot provide a supplementary claims process by binding the HMO to pay for the treatment that is simply a second opinion on medical necessity about which reasonable doctors might reach differing conclusions."[87] Texas Attorney John Cornyn filed a petition for review of the case to the U.S. Supreme Court, arguing that the decision by the U.S. Court of Appeals by the Fifth Circuit misinterpreted the law and Supreme Court precedent. According to the petition, the Fifth Circuit erred in striking down that part of the Texas law that established an independent review mechanism to challenge medical necessity decisions by health maintenance organizations. Further, according to the petition, the decision is part of a split federal appellate authority on an issue of "paramount importance" to many states.<sup>[88]</sup> According to the brief, the Fifth Circuit opinion directly conflicts with the Seventh Circuit's interpretation of Section 502 (a) of ERISA in Moran v. Rush Prudential HMO, Inc., infra.

The respondents assert that the Supreme Court should leave untouched the Fifth Circuit's decision that trumps portions of the Texas law and maintain that the opinion should not be reviewed. They argued that, because independent review laws fundamentally interfere with the allocation and payment of plan benefits to participants and beneficiaries, the Fifth Circuit's decision should be left intact.

The American Medical Association and 24 states have filed briefs in support of Texas.<sup>[89]</sup> The states argue that they have a strong interest in protecting state insurance laws from ERISA preemption, and have an interest in enforcing state insurance laws that directly impact their citizen's health under managed care. The AMA argued that the Texas external review provision "satisfies a pressing need in our health care system and should not be preempted by ERISA." On January 8, the U.S. Supreme Court invited the U.S. Solicitor General to state its position on whether states can mandate external reviews of challenged medical necessity decisions by health plans.<sup>[90]</sup>

# C. Other Issues Arising Under ERISA

## 1. Plan Fiduciary and Employer Liability in Benefits Administration.

In *Shea v. Esensten*, [91] the Eighth Circuit held that ERISA preempts the state law claims of the surviving spouse of a plan participant that a health maintenance organization engaged in fraudulent nondisclosure and misrepresentation in failing to disclose its physician compensation arrangement. After being hospitalized for severe chest pains during an overseas business trip, Patrick Shea made several visits to his long-

time family doctor, who refused referral to a cardiologist. Mr. Shea's doctor persuaded Mr. Shea, who was forty years old, that he was too young and did not have enough symptoms to justify a visit to a cardiologist. A few months later, Mr. Shea died of heart failure. Mr. Shea had been an employee of Seagate Technologies, Inc. for many years. Seagate provided health care benefits to its employees by contracting with a health maintenance organization (HMO) known as Medica. Before Mr. Shea could see a specialist, Medica required Mr. Shea to get a written referral from his primary care doctor. Unknown to Mr. Shea, Medica's contracts with its preferred doctors created financial incentives that were designed to minimize referrals. Specifically, the primary care doctors were rewarded for not making referrals to specialists, and were docked a portion of their fees if they made too many. The Court held that if a fiduciary's alleged ERISA violation caused a former employee to lose plan participant status, the former employee will nonetheless have standing to challenge a fiduciary violation. Accordingly, Mr. Shea's wife had standing to assert her husband's ERISA claims.

On May 6, 1997, the U.S. Court of Appeals for the Eighth Circuit denied requests to reconsider its earlier decision that a health maintenance organization has a fiduciary duty under ERISA to disclose physician financial incentives discouraging patient referrals to specialists.

The remanded state court action proceeded against the doctors and the clinic in state court. The surviving spouse moved to amend her complaint to add the corporation that owns and operates the clinic. The corporation removed the second amended complaint to federal court and moved for a partial dismissal. The district court dismissed the fraud and negligent misrepresentation claim as preempted by ERISA after concluding that the claim related to the ERISA plan because it involved an administrative denial of benefits, not a medical decision. The corporation then moved for and received a complete dismissal on statute of limitations grounds. On appeal, the Eighth Circuit concluded that in its analysis *Shea I* did not apply to the second appeal because the cause of action did not address the responsibilities of a plan fiduciary.<sup>[92]</sup> The Eighth Court held that a lawsuit to enforce an independent statute to create a duty to disclose on the part of physicians will not impact the structure, administration, or economics of the ERISA plan in any meaningful way, and therefore, ERISA did not preempt the negligent misrepresentation claim against the physicians.

On October 2, 2000, the U.S. Supreme Court denied review of *Shea* II, leaving intact the Eighth Circuit's decision.<sup>[93]</sup>

# 2. Liability of Insurance Professionals.

In *Cypress Fairbanks Medical Center, Inc. v. Pan American Life Ins. Co.*, [94] the Fifth Circuit held that ERISA does not preempt a hospital's state law claim that an insurer and its agent violated Article 21.21 of the Texas Insurance Code by misrepresenting that an employee was covered by a plan, when in fact, he was not. Following its prior opinion in *Memorial Hosp, Sys. v. Northbrook Life Ins. Co.* ,<sup>[95]</sup> the Court explained that although the employee was enrolled in the plan, he was not covered by the plan because coverage was rescinded prior to the time of the employee's hospitalization. Accordingly, the Fifth Circuit reasoned that the hospital's cause of action did not relate to ERISA, but rather, arose under state law, and therefore, was not preempted by ERISA.

Six other Circuits have heard cases nearly indistinguishable from *Cypress Fairbanks*. The Eighth,<sup>[96]</sup> Ninth,<sup>[97]</sup> Tenth,<sup>[98]</sup> and Eleventh<sup>[99]</sup> Circuits found that the state law claims were not preempted. The Fourth<sup>[100]</sup> and Sixth<sup>[101]</sup> Circuits found the state law claims preempted in two cases.

# 3. Pegram v. Herdrich.

In *Pegram v. Herdrich* <sup>[102]</sup>, the United States Supreme Court addressed whether treatment decisions made by a health maintenance organization, acting through its physician employees, are fiduciary acts within the meaning of ERISA. Herdrich was covered by Carle Health Insurance Management Co. ("Carle"), the HMO, through her husband's employer, State Farm Insurance Company. The Carle physician, Pegram, examined Herdrich and discovered an inflamed mass in her abdomen. Pegram did not order an ultrasound at the local hospital, but decided that Herdrich should wait eight more days for an ultrasound to be performed at a facility staffed by the HMO more than 50 miles away. Before the eight days were over, Herdrich's appendix ruptured, causing peritonitis.<sup>[103]</sup>

Herdrich sued the physician and Carle in state court for medical malpractice and state law fraud. The physician and Carle removed the case to federal court, alleging ERISA preemption, and then sought summary judgment on the state law fraud causes of action. Herdrich amended her petition in federal court alleging that the provision of medical services under the terms of the HMO rewarding its physician owners for limiting medical care, entailed an inherent or anticipatory breach of an ERISA fiduciary duty since the terms created an incentive to make decisions in the physician's self interest, rather than the exclusive interests of the plan participants. Carle then moved to dismiss the ERISA count for failure to state a claim, which the district court granted, holding that the HMO was not involved in the events as an ERISA fiduciary. After Herdrich prevailed on her original malpractice counts at trial, she appealed the dismissal of the ERISA claim to the Court of Appeals for the Seventh Circuit, which reversed.<sup>[104]</sup> The Seventh Circuit held that the HMO was acting as a fiduciary when its physicians made the challenged decisions and that Herdrich's allegations were sufficient to state a claim.<sup>[105]</sup> The Court of Appeals held "our decision does not stand for the proposition that the existence of incentives automatically gives rise to a breach of fiduciary duty. Rather, we hold that incentives can rise to the level of a

breach where, as pleaded here, the fiduciary trust between plan participants and plan fiduciaries no longer exists ... "[106] Justice Souter, delivering the unanimous opinion of the court, began with a review of the facts and law about HMO organizations and the meaning of Herdrich's allegations. <sup>[107]</sup> Herdrich argued that the particular incentive device of annually paying physician owners the profit resulting from their own decisions rationing care can distinguish Carle's organizations from HMOs generally, so that reviewing this decision under a fiduciary standard as pleaded in her complaint would not open the door to like claims about other HMO structures. The court declined to accept Herdrich's argument, stating that no HMO organization could survive without some incentive connecting physician reward with treatment rationing. [108] The Supreme Court further reasoned that courts are not in a position to derive a sound legal principle to differentiate an HMO like Carle from other HMOs. For that reason, the court proceeded on the assumption that the decisions listed in the plaintiff's complaint could not be subject to a claim that they violate fiduciary standards unless all such decisions by HMOs acting through their owner or employee physicians are to be judged by the same standards and subject to the same claims.<sup>[109]</sup>

After setting forth such assumptions, the Court turned to the fiduciary requirements under ERISA. Herdrich's ERISA count charged Carle with a breach of fiduciary duty in discharging its obligations under State Farm's medical plan. A fiduciary with respect to ERISA must be someone acting in the capacity of a manager, administrator, or financial advisor to a "plan".<sup>[110]</sup> Further, fiduciaries shall discharge their duties with respect to a plan "solely in the interest of the participants and beneficiaries for the exclusive purpose of (i) providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plan."<sup>[11]</sup>

Thus, in every case charging breach of ERISA fiduciary duty, the threshold question is not whether the actions of some person employed to provide services under a plan adversely affected a plan beneficiary's interests, but whether that person was acting as a fiduciary when taking the actions subject to complaint.<sup>[112]</sup> Here, Herdrich's complaint does not point to a particular act by any HMO physician owner as a breach. Rather, she claims that Carle, acting through its physician owners, breached its duty to act solely in the interest of beneficiaries by making decisions affecting medical treatment while influenced by the terms of the HMO scheme under which the physician owners ultimately profit from their own choices to minimize the medical services provided. Thus, she claims that when State Farm contracted with Carle, Carle became a fiduciary under the plan, acting through its physician, and as fiduciary administrator, was subject to such influence from the year end payout provision that its fiduciary capacity was necessarily compromised, and its readiness to act amounted to anticipatory breach of the fiduciary obligation.[113]

Considering Herdrich's claims, the Court distinguished between

physician decisions that are "eligibility decisions" and "treatment decisions." Eligibility decisions turn on the plan's coverage of a particular condition or medical procedure for its treatment, while treatment decisions are choices about how to go about diagnosing and treating a patient's condition. The court concluded that these decisions are often practically inextricable from one another, because a great many and possibly most coverage questions are not simple yes or no questions, but rather when and how questions.[114]

The Court held that the eligibility decision and the treatment decision made by Dr. Pegram were inextricably mixed, as they are in countless medical administrative decisions every day. The kinds of decisions mentioned in Herdrich's ERISA count and claimed to be fiduciary in character, are mixed eligibility and treatment decisions, such as: physician's conclusions about when to use diagnostic tests; about seeking consultations and making referrals to physicians in facilities other than Carle's; about proper standards of care, the experimental character of the proposed course of treatment, the reasonableness of a certain treatment, and the emergency character of a medical condition.[115]

# **D. Extending ERISA**

# 1. Zamora-Quezeda v. Health Texas Medical Group of San Antonio.

New avenues of litigation under ERISA are being paved by use of the Americans with Disabilities Act as shown in the case of Zamora-Quezeda v. Health Texas Medical Group of San Antonio .[116] In Zamora, two physicians alleged that six health plans violated the Americans with Disabilities Act by seeking to limit health care to disabled enrollees because it was too costly to treat their disabilities. The lawsuit alleged that the physicians operated, in violation of the ADA, under financial incentives that pressured them to deny care and that they were forced out of work at a medical clinic when they continued to provide care to their disabled patients. The defendants the action, including Humana Health Care of Texas, PacifiCare, Humana Gold Plus Medicare HMO, Secure Horizons Medicare HMO, Health Texas Medical Group of San Antonio, and Primary Care Net of Texas. The suit was originally filed in state court in 1997, but was removed to federal court on motion of the defendants. In 1998, Humana unsuccessfully moved to have the case dismissed from federal court.[117]

Trial of the case began on November 7, 2000 before Judge Fred Biery of the U.S. District Court for the Western District of Texas and was scheduled to proceed in two phases: 1) trial against the medical clinic and medical services organization; and 2) if the plaintiffs were successful, trial against the health maintenance organizations. Two weeks and three days into the jury trial, however, the parties reached a settlement for an undisclosed amount.<sup>[118]</sup>

2. Multiple Class Action Lawsuits Under ERISA.

Not unlike the tobacco litigation, a number of managed care organizations were hit by a wave of class actions in the year 2000. More than two dozen proposed class action lawsuits have been filed across the country asserting novel legal theories against several health plans, including Aetna, U.S. Health Care, CIGNA Health Care, United Health Care Corp., Prudential Health Plans, Physicians Health Services, and PacifiCare Health Systems. At least two thirds of the cases alleged violations of ERISA and RICO. Some of the cases allege violations of state consumer protection law, instead of or in addition to violations of the federal laws.<sup>[119]</sup> Several of the class action lawsuits were filed by the "REPAIR" team, a group of plaintiffs lawyers from across the country (Alabama, California, Florida, Mississippi, New Jersey and Pennsylvania) led by Mississippi attorney Richard Scruggs.<sup>[120]</sup> REPAIR is short for, RICO and ERISA prosecutors advocating for insurance industry reform. The REPAIR team, who once brought state lawsuits against the tobacco industry, has now turned to accusing HMOs of depriving enrollees of adequate treatment.

The lawsuits contain various allegations including that the health maintenance organizations engaged in misrepresentation, fraud, and extortion, and that the defendants have "engaged in a nationwide fraudulent scheme" by misrepresenting that coverage and treatment decisions are made on the basis of "medical necessity" when in fact they have "aggressively engaged in implementing systemic internal fraudulent and extortionate policies and practices designed to [or limit] claims and medical services."<sup>[121]</sup> The complaints challenge such practices as giving financial incentives to doctors and claims reviewers to limit treatment. The class actions seek compensatory damages, subject to tripling under the RICO statute, punitive damages, injunctions enjoining the defendants from pursuing fraudulent practices, and creation of trusts, to be administered by the court and funded by the "wrongful revenues" obtained by the defendants.

The class action lawsuits are in various stages of discovery and many were transferred to Federal Judge Federico A. Moreno of the U.S. District Court for the Southern District of Florida, under an order of the Judicial Panel on Multi-District litigation.<sup>[122]</sup> According to the panel, the lawsuits all involve common questions of fact concerning whether the defendants implemented certain policies, including utilization review processes, physician financial incentives and/or failure to pay clean claims in a timely manner, which unlawfully deprived subscribers of the health care for which they contracted for and/or unlawfully interfered with the health care providers with the delivery of that care.<sup>[123]</sup> The issues before Judge Moreno include motions to compel discovery, whether plaintiffs have legal standing to bring the claims under ERISA and RICO, exhaustion of administrative remedies before filing suit, and the impact of *Pegram*, statutes of limitation, arbitration clauses and state and common law claims.

# IV. MEDICATION ERRORS — SYSTEMS ON TRIAL

## A. To Err is Human: Building a Safer Health System

In June 1998, the Institute of Medicine initiated a project called "The Quality of Health Care in America" and was charged with developing a strategy that would result in a "threshold improvement in quality over the next ten years." The Quality of Health Care Committee was directed to:

Review and synthesize findings in a literature pertaining to the quality of care provided in the health care system;

Develop a communications strategy for raising the awareness of the general public and key stakeholders of quality care concerns and opportunities for improvement:

Articulate a policy framework that would provide positive incentives to improve quality and foster accountability;

Identify characteristics and factors that enable or encourage providers, health care organizations, health plans and communities to continuously improve the quality of care; and

Develop a research agenda in areas of continued uncertainty.[124]

The first report focused on patient safety in the health care environment and is entitled, To Err is Human: Building a Safer Health System. The report describes a serious concern in health care and focuses on the category of medical errors. According to the Chair of the Committee, William C. Richardson, Ph.d., the reasons for the focus are several: 1) errors are responsible for an immense burden of patient injury, suffering and death; 2) errors in the provision of health services, whether they result in injury or expose the patient to risk of injury, are the events that everyone agrees just should not happen; 3) errors are readily understandable to the American public; 4) there is a sizeable body of knowledge and very successful experiences in other injuries to draw upon in tackling the safety problems of the health care industry; and 5) the health care delivery system is rapidly evolving and undergoing substantial redesign, which may introduce improvements, but also new hazards.[125]

The report estimates that up to 98,000 Amercans die each year as a result of preventable medical errors. The report also states that the majority of these errors are the result of systemic problems, rather than poor performance by individual providers. The cost associated with the errors in lost income, disability, and health care costs, are estimated to be as much as \$29 billion annually. Further, the consequences of medical mistakes are often more severe than the consequences of mistakes in other industries underscoring the need for aggressive action in the health care area.[126]

The Committee on Quality of Health Care in America made summary recommendations for improving patient safety. The report recommends the establishment of a national goal of reducing the number of medical errors by 50% over five years. The recommendations include:

Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge based about safety;

• Identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;

• Raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and

• Creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all of the recommendations.<sup>[127]</sup>

The Committee noted that, although it is a national agenda, many activities are aimed at prompting responses at the state and local levels and within health care organizations and professional groups.<sup>[128]</sup>

# **B.** President's Proposal on Medical Errors

The Quality Interagency Coordination Task Force (QuIC) joined the IOM's call for action to reduce errors, implement a system of public accountability, develop a robust knowledge base about medical errors, and change the culture in health care organizations to promote the recognition of errors and improvement in patient safety. The QuIC also fully endorsed the IOM's goal of reducing the number of medical mistakes by 50% over five years and developed a strategy that built on the IOM recommendations.

Following release of the report, President Clinton directed the Quality Interagency Coordination Task Force to evaluate the recommendations in the report of the IOM, and to respond with a strategy to identify prevalent threats to patient's safety and reduce medical errors. The strategy, in part, includes apportionment of \$20 million in the fiscal year 2001 budget to support a center for quality improvement and patient safety; development of error reporting systems in all 50 states that have both mandatory and voluntary components; implementation of oversight activities for performance standards and expectations of safety; assistance to state or professional agencies to ensure a basic level of knowledge for health care providers on patient safety issues; new efforts to ensure that pharamceuticals are packaged and marketed in a manner that promotes patient safety; investment of \$64 million in the fiscal year 2001 to begin the implementation of a new computerized medical record; investment of \$75.1 million to complete the implementation of an automated order entry system in all of its health care facilities (along with a bar coding system for blood transfusions and medication administration); and a collaborative project to reduce errors in high hazard areas such as emergency rooms, operating rooms, intensive care units, and labor and delivery units.[129]

The QuIC proposed to take strong action on each and every one of the IOM recommendations to promote safer health care. The administration noted that, while some of the IOM recommendations could be addressed individually by specific agencies, the majority of

the proposed actions require joint effort.[130]

## **C. Medication Error Update**

# 1. Three Percent of Medication Errors in 56 Hospitals Resulted in Harm to Patients.

A new analysis of medication errors reports by 56 hospitals showed that three percent of the 6,224 reported medication errors or potential errors, resulted in harm to patients.<sup>[131]</sup> U.S. Pharmacopeia released a report that is based on reports by hospitals to its Internet database that was created in 1998.<sup>[132]</sup> Health care professionals anonymously report drug errors to the database and compare their hospitals to other to follow trends and pinpoint problem areas. Among the 187 instances where medication errors resulted in harm to the patient, 181 of those errors resulted in temporary harm to the patient, five errors caused permanent patient or a near death event, and one error resulted in patient death.<sup>[133]</sup> In 1999, the most frequently reported medication error types were dose omissions, improper dose or quantity and unauthorized drug errors, such as when the wrong drug is given to a patient.<sup>[134]</sup> The top three causes of medication errors were performance deficits (instances where the health care professional or professionals who erred despite the requisite training and education), failure to follow a procedure or protocol, and knowledge deficits.[135]

# 2. FDA Proposes Rule on Drug Labeling.

On December 22, 2000, the Food and Drug Administration (FDA) published a proposed rule that would amend regulations governing prescription drug labeling to make the use of such drugs safer and more effective.<sup>[136]</sup> The proposed rule follows an FDA study that found petitioners thought drug product labeling was lengthy, complex, and hard to use.<sup>[137]</sup> The drug labels at issue are the inserts that usually accompany a filled prescription. The proposed changes, according to the FDA, would simplfy drug product labels and reduce the potential for medication errors.<sup>[138]</sup>

Medical malpractice lawsuits and drug manufacturer wariness about product liability, have played a part in making labels more lengthy and complicated. According to the FDA, fear of lawsuits has caused manufacturers to become more cautious and include all known adverse event information on the labels, regardless of its importance or its plausible relationship to the drug.<sup>[139]</sup> In addition, the accelerated approval for certain drugs for serious or life-threatening illnesses has lead to the quick availability of products that require expanded information about benefits and risks necessary to help ensure safe and effective prescribing of the new drugs.<sup>[140]</sup>

"The proposed rule would require that labels for new and recently approved prescription drugs include a section containing highlights of prescribing information that practitioners most commonly refer to and find most important."<sup>[141]</sup> The proposed rule also requires:

• Drug makers to re-order currently required information and make minor changes to its contents;

• Establish minimum graphical requirements;

• Amend labeling requirements for older drugs to require that certain statements currently appearing in labels be removed if they are not sufficiently supported; and

• Eliminate certain unnecessary statements that currently must appear on prescription drug product labels.<sup>[142]</sup>

The changes contained in the proposed rule would likely render information on prescription drugs easier to find, read and use, and will hopefully enhance the safe and effective use of prescription drugs and reduce medical errors caused by inadequate communication.<sup>[143]</sup>

# V. OTHER SIGNIFICANT DEVELOPMENTS A. Recent Decisions Under EMTALA

Congress enacted EMTALA "to prevent 'patient dumping,' which is the practice of refusing to treat patients who are unable to pay."<sup>[144]</sup> EMTALA requires that participating hospitals provide the following care to an individual who presents for emergency medical care: 1) an appropriate medical screening; 2) stabilization of a known emergency medical condition; and 3) restrictions on transfer of an unstabilized individual to another medical facility.<sup>[145]</sup>

In the last year, federal courts across the United States have addressed varying issues under EMTALA including medical review panel requirements, standing to bring claims under EMTALA, disparate treatment, and patient screening and stabilization.

# 1. Bauman v. Tenet Health System Hospitals, Inc.

On August 24, 2000, the U.S. District Court for the Eastern District of Louisiana, denied the hospital's motion to dismiss and ruled that a plaintiff suing a hospital under the Emergency Medical Treatment and Active Labor Act (EMTALA) is not required to first have his claim reviewed by a state medical malpractice review panel.<sup>[146]</sup> The issue before the court was whether the plaintiff's claims amounted to medical malpractice and therefore under state law were required to be reviewed by a medical review panel. The court held that the plaintiff's lawsuit did not allege negligence, and therefore, did not need to conform to Louisiana's medical malpractice act. The court further found that the plaintiff alleged a patient dumping violation under EMTALA and therefore the medical review panel requirements contained in Louisiana's medical malpractice did not apply to his lawsuit.<sup>[147]</sup>

# 2. Harry v. Marchant

The Eleventh Circuit recently ruled that a Florida Hospital failed to stabilize and treat an emergency room patient in accordance with EMTALA.<sup>[148]</sup> On November 26, 1997, Lisa Normil was taken to the Aventura Hospital Emergency Room and was seen by Dr. Marchant,

who diagnosed her as suffering from pneumonia and possible sepsis or pulmonary embolism. Dr. Marchant then contacted the on-call attending physician to report the diagnosis and to request permission to admit Ms. Normil to the ICU.[149] The on-call attending physician did not immediately authorize the admission, but instead directed Dr. Marchant to obtain a VQ scan. However, the VQ scan was not performed because the hospital was not capable of performing the scan at that time. Subsequently, Dr. Marchant did not arrange to have Ms. Normil transferred to another facility, but contacted her primary care physician. The primary care physician did not see Ms. Normil until approximately five hours later while she was still in the emergency room. Ms. Normil was admitted to the ICU after having been in the emergency department for more than seven hours. Although antibiotics had been prescribed. Ms. Normil did not receive them while in the ICU. She lapsed into respiratory and cardiac failure after admission to the ICU, and attempts to resuscitate Ms. Normil were unsuccessful. and she died that day.

Ms. Normil's personal representative sued various physicians and the hospital, alleging, among other things, violations of EMTALA. The Plaintiff claimed that Ms. Normil did not receive an appropriate screening to determine if she was suffering from an emergency condition, and claimed that the hospital failed to stabilize and treat her condition.<sup>[150]</sup> The district court dismissed Plaintiff's claims brought under EMTALA, and Plaintiff appealed.

On appeal, the Eleventh Circuit reviewed Plaintiff's two claims under EMTALA, first addressing the medical screening violation.<sup>[151]</sup> The Court noted that there are limitations on EMTALA's requirement of a medical screening examination. EMTALA was not intended to substitute a state malpractice claim, and its purpose is to protect patients by eliminating the practice of hospitals simply discharging or transferring patients with an emergency medical condition without first providing a proper screening examination. In this case, the court held the facts revealed that the hospital did conduct an initial screening examination and determined that Ms. Normil had an emergency condition, notwithstanding the lack of a VQ scan.<sup>[152]</sup> The Court stated that while Ms. Normil may have had a valid malpractice claim with respect to the diagnosis, the allegations did not support a claim that the hospital did not conduct an initial screening examination to determine whether an emergency medical condition existed.

As to the stabilization violation, the Court reviewed whether the requirement applied to patients in situations in which the hospital releases or transfers the patient seeking emergency medical attention.<sup>[153]</sup> The Defendants argued that because Ms. Normil was eventually admitted as a patient and not transferred, the stabilization provision of EMTALA was not applicable. The Eleventh Circuit disagreed, holding that the hospital breached EMTALA by failing to stabilize Ms. Normil after determining that she had a medical condition.<sup>[154]</sup> The Court reviewed congressional intent and the purpose in adopting the statute, explaining that the language of the

statute does not condition the stabilizing treatment requirement upon transfer. The hospital must treat and stabilize the condition or transfer the patient to another facility that can provide the necessary treatment. The Court held that a reasonable and common sense reading of EMTALA indicates that a hospital has a duty to stabilize a patient once the hospital discovers an emergency medical condition.<sup>[155]</sup>

# 3. Battle v. Memorial Hospital at Gulf Port, Mississippi

In September 2000, the Fifth Circuit reversed a Mississippi district court's decision granting summary judgment in favor of Memorial Hospital on the Plaintiff's EMTALA claims, finding issues of fact on screening and stabilization violations under EMTALA.[156] In this case, 15 month old Daniel Battle was taken to Memorial Hospital and seen in the emergency room by Dr. Graves and Dr. Sheffield on December 22, 1994, with complaints of seizures, fever and twitching.[157] A lumbar puncture was performed and interpreted as normal. Daniel was diagnosed with febrile seizures, pneumonia and an ear infection and was discharged home with antibiotics.

On the afternoon of December 25, Daniel was continuing to have seizures, and Dr. Reeves instructed that his mother take him back to Memorial Hospital Emergency Room. On this second trip, Mrs. Battle put "self-pay" on the paperwork. The physician diagnosed Daniel with a seizure disorder and pneumonia and Mrs. Battle took Daniel home with a prescription for Dilantin. The physician, Dr. Aust, instructed Mrs. Battle to "not bring that child right back in here because Dilantin takes time to work."[158]

Daniel's seizures returned on December 26, and on that afternoon, Mrs. Battle called Dr. Reeves, who instructed her to take Daniel to Memorial Hospital to have him admitted. ACT scan was taken and read as negative, and an EEG was ordered. When the EEG was read seven days later, it was grossly abnormal. On the evening of December 26, Dr. Reeves saw Daniel and his condition continued to deteriorate. The following day, Dr. Reeves' partner, Dr. Akin, saw Daniel and diagnosed viral encephalitis, and initiated treatment. She arranged for a helicopter to transport the baby to Tulane Medical Center to receive care from an infectious disease specialist, and when he arrived, a lumbar puncture was performed and was read as grossly abnormal. All the tests taken at that time revealed abnormal results consistent with herpes simplex encephalitis. Daniel was eventually discharged from Tulane on February 1, 1995, in a near vegetative state, and will require 24 hour a day care for the rest of his life.<sup>[159]</sup>

The Plaintiffs filed medical malpractice claims against the physicians and the hospital, and after amending their complaint to allege EMTALA violations against the hospital, the case was removed to federal court.<sup>[160]</sup> Prior to trial, the district court granted summary judgment for the hospital on Plaintiff's state law claims, finding they were barred by the statute of limitations. The trial commenced before a different judge in January 1999, and at the close of the Plaintiff's case, judgment was granted for the hospital on the EMTALA claims, and

they were dismissed from the case with a finding by the court that there was no evidence of disparate treatement or failure to stabilize Daniel's condition.[161]

On appeal, the Fifth Circuit reviewed de novo the district court's dismissal of the EMTALA claims against the hospital. Citing Fifth Circuit precedent, the Court stated that "because hospitals can act and know things only vicariously through individuals, any EMTALA violation by ... a physician [who treat patients in fulfillment of their contractual duties with the hospital] is also a violation by the hospital."<sup>[162]</sup> The Court stated that a hospital's liability under EMTALA is not based on whether the physician misdiagnosed the medical condition or failed to adhere to the standard of care, but rather whether the hospital treated the Plaintiff differently from other patients with similar symptoms. The Court explained that "an appropriate medical screening examination is determined by whether it was performed equitably in comparison to other patients with similar symptoms, not by its proficiency in accurately diagnosing the patient's illness."<sup>[163]</sup> The Plaintiffs identified three parts of Daniel's medical records in support of their position that the EMTALA screening violation should have been submitted to the jury. They compared the screening performed on the child during his first emergency room visit, to his second and third visits to establish disparate treatment. Daniel was given a lumbar puncture on his first emergency room visit, however, not on his second visit after his mother revealed that she was "self-pay" and had no insurance for the boy.<sup>[164]</sup> The Court concluded that the failure to conduct the second lumbar puncture, while arguably an error in medical judgment, did not constitute disparate treatment under the Act.[165]

With respect to the nursing care rendered by the hospital, the Court found that evidence of a hospital's failure to follow its own screening procedures could support a finding of EMTALA liability for disparate treatment. The Court found that a jury could have concluded that Daniel was sent home sooner than other similarly situated patients, and that the hospital's policy may have been satisifed by further screening.<sup>[166]</sup> Further, the Court noted that the jury did hear evidence concerning the alleged motivation for the hospital's disparate treatment of Daniel because he was black, poor, uninsured and presented at the emergency room during the holidays.

On the issue of the stabilization violation, the Court found that there was evidence at the time of Daniel's second ER visit that the hospital released him even though the doctors knew he was suffering from seizures of an unknown etiology that had not been stabilized. The Court concluded that judgment as a matter of law was granted in error by the trial court on both the screening and stabilization prongs of Plaintiff's EMTALA claims, vacated the judgment as a matter of law for the Defendants on the EMTALA claims, and remanded for further proceedings.[167]

4. Drew v. University of Tennessee Regional Medical Center Hospital

The Sixth Circuit recently affirmed a district court's ruling that a state hospital was entitled to Eleventh Amendment immunity from allegations that the hospital violated EMTALA by allowing a patient to leave the hospital while his condition was worsening.<sup>[168]</sup> Mr. James Drew presented to the University of Tennessee Regional Medical Center on April 13, 1995, and was experiencing seizures resulting from chronic alcohol abuse and was diagnosed with hypertension, nausea, and cerebral atrophy. He was admitted to the hospital and prescribed Ativan and other medication to control his seizures and agitation. The following day, he was seen by the attending physician during rounds with a team that included medical students. The following morning, a medical student checked on Mr. Drew and then relayed to the attending physician that Mr. Drew refused to be examined and was upset about being in the hospital. The medical student remained on the floor and waited for the attending physician to arrive. When they went to Mr. Drew's room, however, he was gone and was never seen alive again. His body was discovered in a nearby lake a week later.<sup>[169]</sup>

Mr. Drew's family filed a complaint in federal district court alleging EMTALA violations, substantive due process and equal protection violations, and state law claims against the hospital and physicians. The district court granted summary judgment in favor of the physicians and dismissed the claims against the hospital on Eleventh Amendment grounds.[170]

On appeal, the Sixth Circuit held that the Plaintiff's EMTALA claim against the University of Tennessee Medical Center was properly dismissed by the district court because the University, as a state institution, is immune from suit in federal court pursuant to the Eleventh Amendment.<sup>[171]</sup> The Court rejected Plaintiff's argument that EMTALA has preempted the relevant field of hospital regulation, stating that "no such preemption would suffice to defeat an otherwise valid assertion of Eleventh Amendment immunity."<sup>[172]</sup>

## 5. Reynolds v. MaineGeneral Health

In *Reynolds v. MaineGeneral Health*, the First Circuit Court of Appeals found that the patient, Mr. Reynolds, did not exhibit symptoms that required screening under EMTALA, nor that he was unstable, and therefore, the hospital was not liable under the act for his death five days later.<sup>[173]</sup> On September 8, 1996, following a car accident, Mr. Reynolds arrived at MaineGeneral for treatment of various injuries, including several bone fractures.<sup>[174]</sup> After triage, the emergency room physician examined Mr. Reynolds, and ordered a series of tests, x-rays and a CT scan. The physician then determined that Mr. Reynolds suffered from multiple trauma to his lower right leg and possible fracture of his left foot. The emergency room physician then requested surgical and orthopedic consults, after which it was determined that the injuries to Mr. Reynolds' lower extremities required surgery.<sup>[175]</sup> Surgery was performed and Mr. Reynolds was subsequently admitted to the hospital where he was monitored and

began receiving physical therapy. Five days later, Mr. Reynolds returned to the operating room for closure of his right lower leg wound, and he was discharged the following day from the hospital. On September 19, 1996, Mr. Reynolds died of a massive pulmonary embolism that emanated from deep veinous thrombosis at the fracture site on his leg.[176]

Mr. Reynolds' widow subsequently filed a complaint in federal district court in Maine in her personal capacity and as the personal representative of the estate of her husband, the decedent. Mr. Reynolds' minor daughter was also a plaintiff. The complaint alleged that Mr. Reynolds presented to the emergency department at MaineGeneral with an emergency medical condition defined by EMTALA, and that the hospital failed to screen him appropriately for the deep veinous thrombosis as required under the statute, and that it failed to stabilize Mr. Revnolds for the deep veinous thrombosis before releasing him on September 14, 1996, all in violation of the requirements of EMTALA.<sup>[177]</sup> The Defendants moved for summary judgment, which was granted by the Court with a finding that the facts did not support a claim for failure to screen under EMTALA, even though they supported a state law claim for negligent diagnosis and treatment. In addition, the trial court held that Plaintiff's claims for failure to stabilize Mr. Reynolds failed as a matter of law because the hospital was not aware that Mr. Reynolds was suffering from deep veinous thrombosis.[178]

On appeal, the First Circuit addressed the issue of the "scope of a participating hospital's duty to screen for risks or related conditions associated with or aggravated by an emergency medical condition."<sup>[179]</sup> The parties all agreed that Mr. Reynolds presented to the emergency room with an emergency medical condition requiring appropriate screening and stablization; however, the parties disputed whether the increased risk of deep veinous thrombosis associated with that type of injury, combined with Mr. Reynolds' family history of blood clotting problems, triggered a duty to screen for deep veinous thrombosis.<sup>[180]</sup>

The First Circuit first engaged in an analysis of the meaning of "symptom" under the Act, and whether the patient's family history of blood clots was an emergency "symptom" that created a duty under EMTALA for the hospital to screen Mr. Reynolds. The Court found that Plaintiff's proposed interpretation of "symptoms" was contrary to ordinary usage and not supported by statutory text or purpose and not supported by case law.<sup>[181]</sup> The Court explained that information about family history, without any physical indications of a problem, did not rise to the level of an "acute symptom of sufficient severity" manifested by a medical condition as defined by EMTALA.<sup>[182]</sup>

The Court also addressed Plaintiff's contention that the hospital failed to stabilize Mr. Reynolds for deep veinous thrombosis before releasing him. The First Circuit quickly pointed out that the Plaintiffs failed to demonstrate that Mr. Reynolds had an emergency medical condition at the time of his discharge from MaineGeneral, and therefore, the predicates to the stabilization provision of EMTALA were not satisfied.<sup>[183]</sup> The Court concluded that the Plaintiffs failed to offer evidence sufficient to support a finding that Mr. Reynolds was symptomatic for deep veinous thrombosis when he arrived at the ER, within the meaning of EMTALA, and therefore, the hospital was not

required under the statute to screen for deep veinous thrombosis.<sup>[184]</sup>

# 6. Ingram v. Muskogee Regional Medical Center

The mother of a gun shot victim who died shortly after being transferred from Muskogee Regional Medical Center, brought a wrongful death cause of action against the hospital and several physicians, asserting claims for medical malpractice and violations of EMTALA.<sup>[185]</sup> The district court granted summary judgment for the hospital on the EMTALA claim and dismissed the plaintiff's remaining claims for lack of jurisdiction and the mother appealed. The Tenth Circuit Court of Appeals held that the mother was required to show that the treating physician violated existing procedure or requirements in providing treatment to her daughter prior to the transfer to another hospital, in order to establish that the transfer was not appropriate and constituted a violation of EMTALA.<sup>[186]</sup>

The case involves LaTasha Ingram who suffered a gun shot wound to the chest and was taken to the emergency room at Muskogee Regional Medical Center in Muskogee, Oklahoma. The emergency room physician initiated treatment and called the on-call surgeon who ordered, over the phone, that Ms. Ingram be transferred to the ICU. The on-call surgeon later determined at the hospital that she required cardiovascular surgery. The hospital, however, lacked the necessary surgeons and therefore the on-call surgeon arranged for Ms. Ingram to be transferred to St. Francis Hospital in Tulsa, Oklahoma. The risks were explained to Ms. Ingram's mother who requested the transfer in writing. LaTasha Ingram died shortly after she was transferred to St. Francis Hospital.

LaTahsa's mother sued Muskogee Regional Medical Center and three physicians and specifically alleged that the hospital inappropriately transferred LaTasha under EMTALA because they failed to first stabilize her condition and minimize the risk of transfer by inserting chest tubes.[187]

The Tenth Circuit examined the EMTALA provision that provides that a transfer is not appropriate unless the "transferring hospital provides the medical treatment within its capacity which minimizes the risk to the individual's health," and noted that it found "no cases from any jurisdiction interpreting § 1395dd(c)(2)(A)."<sup>[188]</sup> The Tenth Circuit noted that plaintiff did not allege medical screening violations under the Act. Rather plaintiff alleged that the hospital failed to stabilize Ms. Ingram's emergency medical condition and that the hospital may not transfer such an individual unless certain conditions are met under EMTALA.<sup>[189]</sup> One condition is that the individual or a responsible

person acting on his behalf, request a transfer in writing, or a physician determines that the risk of transfer are outweighed by the medical benefits reasonably expected to be provided at another medical facility, and that determination is documented. The Tenth Circuit found that the defendants had satisfied the written request and signed certification conditions for transfer and thus the conditions were met in this case.[190]

Under the Act, however, the transfer must be appropriate, which means that the "transferring hospital provides the medical treatment within its capacity which minimizes the risks to the individual's health."<sup>[191]</sup> Citing Tenth Circuit precedent, the Court concluded that "each hospital determines its own capabilities by establishing a standard procedure, which is all the hospital needs to follow to avoid liability under EMTALA."<sup>[192]</sup>

The Tenth Circuit found that the Muskogee Regional Medical Center's "capacity to provide medical treatment to minimize the risk of transfer should be measured by its standard practices," and to that end the plaintiff was required to produce evidence that the surgeon who treated LaTasha "violated an existing hospital procedure or requirement by failing to insert chest tubes in order to show that the transfer was not appropriate under § 1395dd(c)(2)(A)."<sup>[193]</sup>

# 7. Torres Otero v. Hospital General Menonita

In *Torres Otero v. Hospital General Menonita*, a case arising out of the district of Puerto Rico, the plaintiffs brought a cause of action under EMTALA asserting that the hospital and others failed to adequately screen and stabilize Torres Otero upon his arrival at the emergency room complaining of chest pain.<sup>[194]</sup> The district court granted defendants' motion for summary judgment finding that although the hospital violated EMTALA, there was no evidence of causation of injuries as a result of the violations.<sup>[195]</sup>

The case began on April 8, 1988, when Torres Otero arrived at the emergency room of the hospital complaining of chest discomfort, difficulty in breathing, and cramps in his left arm. He allegedly was under the influence of alcohol and smelled of alcohol on presentation to the ER. Because Torres Otero exhibited signs and symptoms of possible alcohol or drug intoxication, the hospital only partially followed its chest pain protocol.<sup>[196]</sup> Laboratory tests were performed and Torres Otero was administered nitroglycerine and other medications, and was admitted to the hospital. The following day additional tests were performed which were suggestive of a myocardial infarction. Later that evening, Torres Otero was transferred to the ICU, and administered heparin and then remained in the hospital under treatment for 8 days. Several days later Torres Otero was transferred to another medical center for heart surgery.

Torres Otero and his family sued the hospital and physicians, claiming total disability and asserting EMTALA and state causes of action. On defendants' motion for summary judgment, the court found that "in

light of the admission from the hospital that it only partially followed its own protocol for chest pain, and in the absence of evidence that such departure was standard procedure," a genuine issue of fact exists as to whether the hospital failed to conduct an appropriate screening of Torres Otero when he presented himself to the emergency room.<sup>[197]</sup> Despite raising a fact issue on the EMTALA violation, the court found that Torres Otero failed to show "the relationship of cause and effect between the harm suffered by Torres Otero, which flows from the myocardial infarction suffered on April 8, 1998, and the claim relating to the hospital's failure to screen."<sup>[198]</sup> The court concluded that "without evidence to establish the nexus between the delay and proper diagnosis allegedly caused by the failure to appropriately screen and the need for the heart surgery, the alleged total disability, and the emotional harm flowing therefrom," there was no issue for the jury to consider.<sup>[199]</sup>

# **B.** Termination of Independent Contractor Physicians

# 1. Potvin v. Metropolitan Life Insurance

The California Supreme Court recently held, in a split decision, that managed care organizations could not arbitrarily remove an individual physician from a provider network despite a contract that would allow terminations without cause.<sup>[200]</sup> The case arose out of Metropolitan's "deselection" of Louis E. Potvin, M.D. from its provider list without explanation and despite a physician contract that allowed for termination without cause.<sup>[201]</sup>

In September 1990, Dr. Potvin signed an agreement with two California-based health care networks managed by Metropolitan Life. The agreement contained a commonly used provision that allowed either party to terminate the agreement, with or without cause. In 1992, Dr. Potvin was deselected without explanation and after several attempts by Dr. Potvin to learn why he was deselected, Metropolitan Life responded that his malpractice history did not meet the insured's standards, and denied Dr. Potvin a hearing.<sup>[202]</sup> Dr. Potvin's malpractice record included four lawsuits, three of which were abandoned and the other was settled for \$713,000.<sup>[203]</sup> Metropolitan Life's policy was to remove physicians with more than two malpractice lawsuits or more than \$50,000 in judgments or settlements.

The trial court granted Metropolitan Life summary judgment and on appeal, the court held that Dr. Potvin did have a common law right to fair procedure before Metropolitan Life could terminate its membership in its health care provider networks.<sup>[204]</sup> The California Supreme Court agreed to review the appeal, and rendered its decision on May 8, 2000, holding that independent physicians can enjoy the common law right to fair hearings.<sup>[205]</sup> The court limited the scope of physician's rights to fair hearings to instances where the managed care organization wielded significant ecomonic power in a market. "The obligation to [provide a fair hearing] only arises when the insurer

possesses power so substantial that the removal significantly impairs the ability of an ordinary, competent physician to practice medicine or a medical specialty in a particular geographic area, thereby affecting an important, substantial economic interests."<sup>[206]</sup> The court reasoned that the provision of health care, especially through the relationship among an insurance company, its insureds, and the physicians who participate in the preferred provider network, substantially affects the public interest.<sup>[207]</sup> According to the majority, the law in California is that an insurer wielding significant power may terminate physicians only when the decision is "substantively rational and procedurally fair."<sup>[208]</sup>

The high court remanded the case on the issue of Metropolitan Life's economic power and exercise of that power in the area where Dr. Potvin practiced, gynecology and obstretrics. "Proof of these allegations might establish that, in terminating a physician's preferred provider status, Met Life wields power so substantial as to significiantly impair an ordinary, competent physician's ability to practice medicine or a medical specialty in a particular geographic area, thereby affecting an important, substantial economic interest."[209] If economic power by Metropolitan Life is found by the court, because the termination violated public policy and Dr. Potvin's common law right to a fair hearing, the Metropolitan Life contract provision allowing termination without cause, would be unenforceable.[210]

# 2. Grossman v. Columbine Medical Group

Contrary to *Potvin*, a Colorado Court of Appeals recently declined to find that a physician's termination without cause was void as against public policy. In 1992, Dr. Grossman joined an independent practice association and agreed to provide care to the health plans, FHP of Colorado, Inc., managed care patients. Dr. Grossman signed a contract that allowed either party to terminate the agreement without cause with 90 days notice. In 1994, Columbine Medical Group sent a letter of termination to Dr. Grossman. Dr. Grossman then filed suit asserting that "the termination without cause provision in the physician's service agreement is void as against public policy because of its negative impact on the physician-patient relationship and its disruption of the continuity of patient care." Dr. Grossman argued that he was at least entitled to a hearing to address the reasons for his termination. The health plan moved for summary judgment and Dr. Grossman appealed.

In a split decision, the Colorado Court of Appeals declined to grant relief and declined to adopt out of state precedent recognizing the public policy importance of the physician-patient relationship and overturning a de-selection proceeding.<sup>[211]</sup> The court relied upon a Colorado statute that expressly allows a health plan carrier to terminate a contract in accordance with the contract provisions and further stated that it is not for the courts to enunciate the public policy of the state if the general assembly has spoken on the issue.<sup>[212]</sup>

3. Wuchenich v. Shenandoah Memorial Hospital

In an unpublished per curiam opinion, the U.S. Court of Appeals for the Fourth Circuit held that an anesthesiologist who had lost his medical privileges after being recruited to a hospital could proceed with several claims, including breach of contract and civil conspiracy, against the hospital and three of its doctors.<sup>[213]</sup> In this case, Dr. John D. Wuchenich, an anesthesiologist, was recruited by Shenandoah Memorial Hospital in 1995, and signed a 12 month contract with the hospital. Dr. Wuchenich allegedly immediately clashed with hospital physicians and asserted that Dr. George Phillips, an anesthesiologist at the hospital, feared competition and told others that Dr. Wuchenich was not a very good anesthesiologist.<sup>[214]</sup> Dr. Wuchenich claimed that Dr. Phillips took steps to restrict his practice, such as requiring that all surgeons request a specific anesthesiologist, namely, Dr. Phillips. After the chief of anesthesiology resigned, the hospital refused to consider Dr. Wuchenich for the position. Instead, the hospital hired a third anesthesiologist, Dr. David Ciochetty, over Dr. Wuchenich's protests that there was not enough work for two full-time anesthesiologists. Dr. Ciochetty allegedly assigned most cases to himself or to his own CRNAs and told Dr. Wuchenich not to work full-time, despite his contract. Thereafter, Dr. Phillips resigned his medical privileges and Dr. Ciochetty recruited another anesthesiologist rather than offering more work to Dr. Wuchenich.[215]

At the same time, Dr. Robert Karmy, an obstetrician/gynecologist, was openly hostile to Dr. Wuchenich because he was allegedly threatened by the hospital's recruitment of Dr. Wuchenich's sister, who was also an OB/GYN. Dr. Karmy reported Dr. Wuchenich to the hospital peer review committee, claiming that Dr. Wuchenich may have committed two cases of malpractice.<sup>[216]</sup> The peer review committee found that Dr. Wuchenich met the appropriate standard of care in those cases, and that his care did not lead to adverse consequences, however, the committee recommended that Dr. Wuchenich's medical privileges be revoked.<sup>[217]</sup>

Dr. Wuchenich was not allowed to respond to the allegations, and his privileges were revoked. The revocation was reported to the State Board of Medical Examiners and filed with the National Practitioner Data Bank. After a hospital appeal and hearing, the suspension was voided in May 1997, and a further investigation by the State board of medicine led to Dr. Wuchenich's record being cleared.<sup>[218]</sup>

Thereafter, in June 1998, Dr. Wuchenich filed a lawsuit against Shenandoah Memorial Hospital, and Drs. Robert Karmy, David Ciochetty, and George Phillips, seeking \$1.12 million dollars in economic damages and \$500,000 in emotional distress and loss of reputation damages. Dr. Wuchenich specifically alleged breach of medical staff bylaws, breach of oral contract, civil conspiracy, common law conspiracy to breach contractual obligations, common law defamation, and tortious interference. The federal district court dismissed all his claims, and Dr. Wuchenich appealed.<sup>[219]</sup> The Fourth Circuit Court of Appeals reversed the dismissal of Dr. Wuchenich's breach of contract claim on the medical staff bylaws, finding that the complaint sufficiently alleged that the hospital owed the doctor a legal obligation to follow its bylaws.<sup>[220]</sup> The court partially reversed the ruling on Dr. Wuchenich's civil conspiracy claim, finding existence of the claim to the extent it alleged a conspiracy between the hospital, Dr. Phillips, and Dr. Ciochetty, to injure Dr. Wuchenich in his reputation and to injure his ability to engage in business, trade and profession by failing to assign him a fair number of patients.<sup>[221]</sup>

The court affirmed the district court's dismissal of the doctor's defamation claim and tortious interference with his employment contract; however, it did allow Dr. Wuchenich's claim that the defendants tortiously interfered with his expectation of entering into contracts with patients to survive.<sup>[222]</sup>

# VI. NEGLIGENT CREDENTIALING UPDATE

# A. The Corporate Negligence Doctrine

Several jurisdictions have held hospitals directly liable for plaintiffs' injuries under the theory of "corporate negligence" separate and apart from any basis of vicarious liability and in the absence of any negligence on the part of the treating physician.<sup>[223]</sup> Corporate negligence has developed in response to three basic factors. First, hospitals are no longer shielded from liability in malpractice claims with the abolition of charitable immunity.<sup>[224]</sup> Second, modern hospitals have increasingly injected themselves into the regulation of the medical treatment of the patient by requiring physicians to subject their work to consultation and review as a condition of obtaining staff

privileges. And third, by holding hospitals directly liable in malpractice cases, courts have added hospitals' assets to the pool of assets available for the payment of malpractice claims and increased plaintiffs' chances of recovery.[225]

Many jurisdictions in the United States do not have statutory causes of action for negligent credentialing and instead rely upon state common law to hold hospitals liable for negligence in its credentialing activities. Some of these jurisdictions include California, Louisiana, Missouri, Pennsylvania, and Texas. While some jurisdictions do not have a statutory cause of action for negligent credentialing, they have expressly adopted the doctrine of corporate negligence as a viable theory to hold hospitals liable for failure to select competent medical staff.

## 1. California

For instance, prior to 1982, California courts apply the doctrine of corporate hospital liability in malpractice cases. The doctrine provides that a hospital may be held liable for a physician's malpractice when the physician is employed by the hospital or is the ostensible agent of the hospital.<sup>[226]</sup> In 1982, the doctrine was extended by the *Elam* 

case to include that a hospital could be liable for negligent credentialing of medical staff based on a corporate negligence theory.<sup>[227]</sup> The Court held that "a hospital is accountable for negligently screening its medical staff to insure the adequacy of medical care rendered to patients at its facility."[228] The Elam Court reasoned that a hospital's established duty of reasonable care to protect patients from harm must, as a general principle, encompass the duty to insure the competence of its medical staff through careful selection and review.<sup>[229]</sup> Further, the Court contemplated that by imposing this duty of care upon hospitals, hospitals would have "a greater incentive to assure the competence of its medical staff and the quality of care rendered within its walls."<sup>[230]</sup> Thus, after *Elam*, the potential exposure under the doctrine of corporate hospital liability is no longer solely based on the malpractice of employee or ostensible agent physicians treating patients, but may also arise from the negligent acts of those charged with insuring competency of mere staff members. Following the *Elam* decision, another California appeals court held that a hospital's failure to follow its bylaws requiring physicians to carry malpractice insurance was relevant to a claim based on negligence in screening and evaluating a physician under the corporate negligence theory.<sup>[231]</sup> In *Brown*, the hospital failed to inquire whether a physician applying for privileges had malpractice coverage despite the fact that its bylaws required such coverage. The Court reasoned that this failure to inquire as to malpractice coverage demonstrated "a willingness [by the hospital] to ignore that the physician was not coverable for reasons that may go to the physician's medical competency."<sup>[232]</sup> Though the *Brown* Court did not ultimately pass on the issue, it did speculate that this failure "may indicate conduct contrary to the Hospital's duty under Elam."[233]

## 2. Louisiana

In Louisiana, the courts have traditionally accepted the concept of a hospital's duty of care in the selection retention of its staff and looked to theories of vicarious liability and respondeat superior when imposing liability.<sup>[234]</sup>

As the Louisiana Supreme Court has explained, in the absence of a statute, hospitals are subject to liability either vicariously on the basis of respondeat superior or independently on the basis of negligent hiring or training of professional staff members employed by the hospital.<sup>[235]</sup> The *Spradlin* court acknowledged that hospitals frequently avoid even these forms of liability by asserting the independent contractor status of their professional staff members.<sup>[236]</sup> Thus, while Louisiana case law contemplates a duty of care in the credentialing process, it appears that a plaintiff must show the existence of an employer-employee relationship between the hospital and physician in order to establish liability.

In *Garlington v. Kingsley*, <sup>[237]</sup> the plaintiff sued the charitable hospital where he underwent surgery for negligence in failing to

properly supervise, select and train its employees.<sup>[283]</sup> The court abolished the doctrine of charitable immunity in Louisiana and held that a hospital is not immune from suit in tort for negligent supervision, selection and training of its employees.<sup>[239]</sup> The court based its ruling on express provisions of its civil code that mandate that "[m]asters and employers are answerable for the damage occasioned by their servants and overseers, in the exercise of the functions in which they are employed."[240]

In *Sibley v. Supervisors of La. State Univ. & Mechanical College*, [241] the court declined to apply the doctrine of corporate negligence to state-owned health care facility. The *Sibley* court explained that the policy underlying the doctrine of corporate negligence as applied to hospitals is inconsistent with the policy of the Louisiana state statute limiting medical malpractice awards.[242]

Recent Louisiana case law, however, indicates a potential for filing negligent credentialing claims of non-employees.<sup>[243]</sup> In *Narcise*, the hospital defendant sought to uphold summary judgment and argued that it could not be liable under the doctrine of respondeat superior for the conduct of an emergency room physician who was an independent contractor.<sup>[244]</sup> The Court vacated summary judgment and held that, under appropriate factual circumstances, a hospital could be held liable for the negligence of a non-employee staff physician under theories other than respondeat superior.<sup>[245]</sup>

In *Fusilier*, the Court reviewed whether summary judgment was proper as to plaintiff's claims of liability on the part of the hospital for allowing a surgeon to perform a procedure for which he was not credentialed.<sup>[246]</sup> The appellate court held that the trial court did not err in finding, after review of expert deposition testimony, that the hospital was not negligent in its credentialing process and that there was no evidence of a causal connection between any negligent injury of the patient and the fact that the hospital board had not yet approved the physician to perform the surgical procedure.<sup>[247]</sup>

## 3. Missouri

Missouri does not impose a statutory duty upon hospitals to select competent medical staff members and has not expressly accepted the corporate negligence doctrine. Missouri common law does recognize that a hospital has an independent duty of ordinary care to its patients.

The notion of corporate negligence was introduced in the case of *Gridley v. Johnson*.<sup>[248]</sup> The plaintiffs in *Gridley* sued the hospital and physicians for damages resulting from the failure to perform a pregnancy test before doing a D&C and gall bladder operation on the plaintiff. The plaintiffs sought to hold the hospital liable by alleging that the hospital was equipped to perform diagnostic testing preoperatively to prevent the usage of its facilities for contraindicated major surgery and that it failed to use proper diagnostic techniques.<sup>[249]</sup> The Court noted that "the hospital takes an

increasingly active part in supplying and regulating the purely medical care which the patient receives ... and [e]very doctor using the hospital facilities is ordinarily required to comply with its standards and subject his work to staff consultation, review, and regulation, at pain of losing his staff privileges ... "[250] Specifically, the Court stated that "the fact that the defendant doctors were not employees of the defendant hospital does not necessarily mean the hospital cannot be held for adverse effects of treatment or surgery approved by the doctors."[251] In reversing the dismissal of the hospital from the case, the appellate court held that "modern hospitals do operate under definite rules and regulations and subject themselves to recognized accreditation standards."

In Manar v. Park Lane Medical Ctr., [252] the plaintiff asserted that the hospital was liable for the acts of the physicians because it extended staff privileges to the surgeon allowing him to render treatment for which he was not qualified.<sup>[253]</sup> Plaintiff further asserted that the hospital failed, through the negligence of the supervising surgeon, to insure a minimum standard of professional care to patients who relied on the hospital's representation that it had facilities and personnel trained and expert in the rendition of medical services.<sup>[254]</sup> The court relied on *Gridley* and stated that plaintiff's petition arguably fell within the category of cases wherein a hospital could be directly liable for permitting unqualified non-employee doctors to practice within the hospital.<sup>[255]</sup> The court, however, did not rule on the issue of corporate neligence and left the question for future resolution.<sup>[256]</sup> Following *Manar*, in 1994, a Missouri appeals court observed that if the hospital conduct involves nonmedical, administrative, ministerial or routine care, a hospital owes an obligation of ordinary care to its patients.<sup>[257]</sup> In *Poluski*, the plaintiffs sued a wheelchair transportation compnay for negligence in transporting the patient from the hospital to a long-term care facility and the company filed a thirdparty petition against the hospital.<sup>[258]</sup> The Court analyzed the question of duty presented by the facts of the case and remarked that a hospital owes a duty of care to its patients that is independent and apart from the duty of a physician, and that includes the duty of protection.<sup>[259]</sup> The *Poluski* court rejected the hospital's argument that it had no duty to the patient because the defendant was not its employee, but an independent contractor [260] The court held that the hospital's liability was based on its independent duty of ordinary care to its patients that included the duty of reasonable care to the patient until she left the premises of the hospital.[261]

Finally, in *Harrell v. Total Health Care, Inc.*, [262] the Missouri Supreme Court addressed the issue of corporate negligence in the "notfor-profit/health services corporation" context. In *Harrell*, the plaintiff sought to impose liability on Total Health Care, a health services corporation, on the theory of "corporate liability" based on the assertion that it was negligent in the selection of the specialist who

performed surgery on her who was alleged to be demonstrably incompetent.<sup>[263]</sup> Total Health Care moved for, and was granted, summary judgment based on a state statute that precluded liability for injuries resulting from neglect, misfeasance, malfeasance or malpractice on the part of any person, organization, agency or corporation rendering health services to the health services corporation's members and beneficiaries.<sup>[264]</sup> The Missouri Supreme Court affirmed the summary judgment and held that the statute operated to exempt Total Health Care from corporate liability as alleged by the plaintiff and that the statute was constitutional.<sup>[265]</sup> In so holding, the Court reasoned that, in enacting the statute, the legislature may have considered that plaintiffs had an adequate remedy against the persons actually guilty of malpractice, who are licensed physicians, and that plaintiffs did not need an additional source of remuneration from not-for-profit corporations.<sup>[266]</sup>

# 4. Pennsylvania

Like Missouri, Pennsylvania does not have a statutory cause of action for negligent credentialing. It has, however, joined many other jurisdictions in expressly adopting the doctrine of corporate negligence as a viable theory to hold hospitals liable for failure to select competent medical staff.[267]

The theory of corporate negligence was first recognized by the Pennsylvania Supreme Court in *Thompson v. Nason Hospital*, in 1991.<sup>[268]</sup> In *Thompson*, the Court held that a hospital owes some non-delegable duties *directly* to its patients, without requiring that the injured party establish the negligence of a third party.<sup>[269]</sup> The Supreme Court found four areas of duty owed by a hospital:

- 1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment;
- 2) a duty to select and retain only competent physicians;
- 3) a duty to oversee all persons who practice medicine within its walls as to patient care;
- 4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients.[270]

The Court held that in order to recover on a theory of corporate negligence, a plaintiff must prove: 1) the hospital had actual or constructive knowledge of the defect or procedures that created the harm; and 2) that the hospital's negligence was a substantial factor in bringing about the harm to the injured party.<sup>[271]</sup>

Following Thompson, in 1997, the Pennsylvania Supreme Court provided explicit guidance regarding the proof required to succeed on a claim based on corporate negligence.<sup>[272]</sup> Unless a hospital's negligence is obvious, a plaintiff must produce expert testimony to establish that the hospital deviated from an accepted standard of care and that the deviation was a substantial factor in causing the harm to

the plaintiff.<sup>[273]</sup> The *Welsh* opinion was careful to note that no "magic words" will be required of experts in these cases.<sup>[274]</sup> Rather, the inquiry should be whether the required deviation can be shown when the substance of the experts' testimony is considered.<sup>[275]</sup>

In *Corrigan v. Methodist Hosptial*, <sup>[276]</sup> the plaintiff sought to hold the Hospital liable for corporate negligence on the basis of negligent credentialing of two physicians who performed her back surgery.<sup>[277]</sup> The district court denied the hospital's motion for summary judgment on the issue of negligent credentialing but granted the motion on plaintiff's claims of negligence on an ostensible agency theory.

The plaintiff presented expert testimony on the issue of negligent credentialing that was based in part on peer review information and stated that the hospital failed in its duty to the patient by granting staff privileges to the surgeons when one physician had malpractice suits brought against him.<sup>[278]</sup> The *Corrigan* court held that credentialing doctors with knowledge of, or failure to learn of, their malpractice history could be negligent and, drawing inferences in favor of the non-moving party, summary judgment was not warranted.<sup>[279]</sup>

# 5. Texas

The Texas Medical Practice Act exempts from liability hospitals and individuals engaged in making credentialing decisions in the absence of malice.<sup>[280]</sup> The pertinent sections read as follows:

A cause of action does not accrue against the members, agents, or employees of a medical peer review committee or against the healthcare entity from any act, statement, determination or recommendation made, or act reported, **without malice**, in the course of peer review as defined by this Act.<sup>[281]</sup>

A person, health-care entity, or medical peer review committee, that, **without malice**, participates in medical peer review activity or furnishes records, information or assistance to a medical per review committee or the board is immune from any civil liability arising from such an act.<sup>[282]</sup>

In *St. Luke's Episcopal Hospital v. Agbor*, the Texas Supreme Court held that these sections apply to the process of credentialing a hospital's medical staff members.<sup>[283]</sup> The result of these statutes and their applicability to the credentialing process is a requirement that plaintiff's must make a threshold showing of malice to state a cause of action against a hospital for its credentialing activities.<sup>[284]</sup>

Assuming that a plaintiff could make the difficult showing of malice on the part of a hospital's credentialing body, there remains the important question of what theory, if any, will allow the plaintiff to hold the hospital liable. Texas has not followed the group of

jurisdictions that have fully embraced the increasingly popular corporate negligence doctrine as applicable to credentialing claims.

Two Texas Courts of Appeal have considered whether there exists a common law cause of action for "negligent credentialing" and have reached opposite results.<sup>[285]</sup> When it had occasion to consider this split of authority, the Texas Supreme Court declined to decide the issue because it was not necessary to the disposition of the case before the Court.<sup>[286]</sup> While it appears that the matter remains unresolved, just last year another appellate court stated that a hospital is under a duty of reasonable care in the selection and retention of physicians who are granted staff privileges.<sup>[287]</sup>

Finally, assuming that a plaintiff can make the required showing of malice and demonstrate a sufficient relationship between the hospital and the physician (if we assume for the time being that there is no negligent credentialing cause of action in Texas), a plaintiff must still prove that the credentialing activity was negligent by expert witness testimony.<sup>[288]</sup> In *Mills*, the Court reasoned that experts are necessary because the procedures ordinarily used by a hospital in evaluating applications for staff privileges are not within the realm of the ordinary experience of jurors.<sup>[289]</sup> However, the court noted that the expert "need not be a physician, but may be a witness who is familiar with the standard of care for credentialing because of his training and experience."<sup>[290]</sup>

# **B.** A Statutory Duty to Ensure Medical Staff Competency

## 1. Florida

Unlike California and several other states, Florida imposes a statutory duty upon hospitals to insure medical staff competency.<sup>[291]</sup> The relevant portion of the statute, which was enacted in October 1985, reads as follows:

- (1) All health care facilities, including hospitals and ambulatory surgical centers, as defined in chapter 395, have a duty to assure comprehensive risk management and the competence of their medical staff and personnel through careful selection and review, and are liable for a failure to exercise due care in fulfilling these duties. These duties shall include but not be limited to:
- (a) the adoption of written procedures for the selection of staff members and a periodic review of the medical care and treatment rendered to patients by each member of the medical staff;
- (b) the adoption of a comprehensive risk management program which fully complies with the substantive requirements of §395.041 as appropriate to such hospitals size, location, scope of services, physical configuration, and similar relevant factors;
- (c) the initiation and diligent administration of the medical review and risk management processes established in paragraphs (a) and (b) including the supervision of the medical staff and hospital personnel to the extent necessary to endure that such medical review and risk

management processes are being diligently carried out.

Prior to 1985, the corporate negligence doctrine had not been explicitly adopted in Florida.<sup>[292]</sup> The substantial weight of authority, however, supported the view that a private physician with hospital privileges was not considered a servant of the hospital because the hospital had no right to control the acts of a physician who was an independent contractor.<sup>[293]</sup> Consequently, the hospital would not be liable for the independent physician's negligence, and was not a guarantor of the physician's competence.<sup>[294]</sup>

The Supreme Court of Florida addressed the issue of the application of the corporate negligence doctrine in Florida in the case of Insinga v. LaBella, <sup>[295]</sup> Insinga involved a wrongful death claim that arose in 1981, prior to the 1985 enactment of the above statute. The case presented the issue of whether the State of Florida would "recognize the doctrine and adopt as a matter of public policy the principle that a hospital has an independent duty to its patients to assure the competence of its medical staff and personnel thought its selection and review processes."<sup>[296]</sup> The Court reasoned that public policy justified placing the expanded responsibility and duty of care on hospitals because of the present day view that a hospital is a multi-faceted health care facility that should be responsible for proper medical treatment on its premises and is the only entity that can realistically provide quality control.<sup>[297]</sup> The Court expressly adopted the corporate negligence doctrine independent of the statute and found that the enactment of the statute codified the doctrine.<sup>[298]</sup>

# 2. Applications of the Florida Statute

The statutory nature of Florida's negligent credentialing claims is significant in at least two areas, pre-suit requirements and limitations. The statute provides that certain presuit requirements must be met in cases involving "medical negligence" claims.<sup>[299]</sup> In 1999, it was held that a cause of action arising under Section 766.110, the corporate negligence statute, is a "medical negligence" claim and the presuit requirements set forth in Section 766 apply.<sup>[300]</sup> Similarly, two separate courts held that the two-year medical malpractice statute of limitations applies to negligent credentialing claims because such claims arise out of the breach of a duty imposed by the medical malpractice statue.<sup>[301]</sup>

Notably, Florida plaintiffs have argued, with mixed success, that a hospital's duty of care in the selection and retention of staff goes beyond an obligation to select medically competent staff members. In *O'Shea v. Phillips*, the Court held that Chapter 766 imposes a duty on hospitals to screen and monitor medical staff members to prevent sexual misconduct with patients.<sup>[302]</sup> Conversely, in *Beam v. University Hosp. Bldg., Inc.*, the court refused to expand a hospital's duty to encompass reviewing a physician to ensure that the physician is financially capable of compensating a patient for any malpractice the

physician might commit.[303]

- [1] <u>Natalie White</u>, Lawyers Avoid Punitive Damage Cap in \$268 Million Med-Mal Verdict
- [2] See id.
- [3] *See id.*
- [4] See id.
- [5] *See id.*
- [6] *See id.*
- [7] See id.
- [8] See id.
- [9] See id.
- [10] See id.
- [11] <u>Natalie White</u>, Monster Med Mal Verdict Feeds Tort Reform Debate
- [12] See id.
- [13] See id.
- [14] See id.
- [15] See id.
- [16] See id.
- [17] See id.
- [18] See id.
- [19] See id.
- [20] Hospital Guilty of Malice for Retaining Unqualified Staff Surgeon
- [21] See St. Luke's Episcopal Hospital v. Agbor, 952 S.W.2d 503, (Tex. 1997).
- [22] See Hospital Guilty of Malice for Retaining Unqualified Staff Surgeon
- [23] See id.

- [24] See HCA, Inc. v. Miller, No. 14-98-00582-CV, 2000 WL 1876775 (Tex. App. Houston [14 th Dist.] Dec. 28, 2000).
- [25] See id. at \*4.
- [26] *See id.*
- [27] See id.
- [28] *Id.* at \*5.
- [29] *Id.* at \*2.
- [30] See id. at \*3.
- [31] See id. at \*4.
- [32] *Id.*
- [33] *See id.*
- [34] Humana Hit With \$80 Million Verdict For Ending Child's Special Treatment
- [35] *See id.*
- [36] *See id.*
- [37] *See id.*
- [38] See id.
- [39] See id.

[40] State Employees' Insurer Appeals \$14.5 Million Jury Award to HMO For Fraud

- [41] *See id.*
- [42] See id.
- [43] *See id.*
- [44] MCHCP is a quasi-state agency that purchases health insurance coverage for approximately 165,000 state and municipal employees. *See id.*
- [45] See id. (citing Missouri Consolidated Health Care Plan v. Community Health Plan, Mo. Cir. Ct. No. CV-198-979CC, verdicts returned 4/12/00)).
- [46] *See id.*

- [47] *See* Ron Winslow, "Health Care Inflation Kept in Check Last Year
- [48] John K. Inglehart, "Health Policy Report Physicians and the Growth of Managed Care," 331 New Eng. J. Med. 1167, 1167–70 (1994).
- [49] See Jass v. Prudential Health Care Plan, Inc., 88 F.3d 1482 (7 th Cir. 1996); Tolton v. American Biodyne, Inc., 48 F.3d 937 (6 th Cir. 1995); Spain v. Aetna Life Ins. Co., 11 F.3d 129 (9 th Cir. 1993); Kuhl v. Lincoln Nat'l Health Plan of Kansas City, Inc., 999 F.2d 298 (8 th Cir. 1993); Rodriguez v. PacifiCare of Texas, Inc., 980 F.2d 1014 (5 th Cir. 1993); Corcoran v. United Health, Inc., 965 F.2d 1321 (5 th Cir. 1992).
- [50] See Rice v. Panchal, 65 F.3d 637, 639–40 (7 th Cir. 1995); Pacificare of Oklahoma, Inc. v. Burrage, 59 F.3d 151 (10 th Cir. 1995); Dukes v. U.S. Health Care, Inc., 57 F.3d 350, 355 (3rd Cir. 1995). Some federal district courts, however, have held that even vicarious liability claims are preempted by ERISA. See, e.g., Pomeroy v. Johns Hopkisn Med. Servs., Inc., 868 F.Supp. 110 (D. Md. 1994); Butler v. Wu, 853 F.Supp. 125 (D. N.J. 1994); Nealy v. U.S. Health Care HMO, 844 F.Supp. 966 (S.D.N.Y. 1994).
- [51] In Re U.S. Health Care, Inc., 193 F.3d 151 (3rd Cir. 1999), cert. denied, 120 S. ct. 2687 (2000).
- [52] *Id.* at 156.
- [53] *See id.*
- [54] *Id.* at 161.
- [55] *See id.*
- [56] *Id.* at 162.
- [57] *Lazorko v. Pennsylvania Hosp.*, Nos. 98-1776, 98-1777, 98-1790, 2000 WL 1886619 (3rd Cir., Dec. 26, 2000).
- [58] *Id.* at \*1.
- [59] *Id.*
- [60] See i d.
- [61] *Id.* at \*6.
- [62] Thompson v. Gencare Health Care Systems, Inc., 202 F.3d 1072 (8 th Cir. 2000).
- [63] *Id.* at 1073.

- [64] See i d.
- [65] *Id.* at 1074.
- [66] Thompkins v. United Health Care of New England, Inc., 203 F.3d 90 (1 st Cir. 2000).
- [67] *Id.* at 92.
- [68] *Id.* at 93.
- [69] See i d.
- [70] *Id.* at 97.
- [71] TEX. CIV. PRAC. & REM. CODE ANN. § 88.002(a)(West 1998).
- [72] *Id.* at § 88.002(b).
- [73] *Id.* at § 88.003(c).
- [74] See TEX. INS. CODE ANN. arts. 20A.09, 20A.12, 20A, 21.58A and 21.58C (West 1998).
- [75] Corporate Health Ins., Inc. v. Texas Dept. of Ins., 12 F.Supp.2d 597
  (S.D. Tex. 1998), aff'd in part, rev'd in part, 215 F. 3d 526 (5 th Cir. 2000).
- [76] See Corcoran, 965 F.2d 1321.
- [77] See Rodriguez, 980 F.2d 1014.
- [78] See Dukes, 57 F.3d 350.
- [79] Corporate Health Ins., Inc. v. Texas Dept. of Ins., 215 F.3d 526 (5 th Cir. 2000), reh'g denied, 220 F.3d 641 (5 th Cir. 2000), petition for cert. filed, Montemayor v. Corporate Health Ins., Inc., No. 00-665, 69 USLW 3317 (Oct. 24, 2000).
- [80] *Id.*, 215 F.3d 526.
- [81] *Id.*
- [82] See Tex.Civ.Prac. & Rem. Code §88.002 (f).
- [83] *Id.* at §88.002 (g).
- [84] *Corporate Health Ins.*, 215 F.3d 526.
- [85] *Id.*

- [86] *Id.* (citing Tex. S.B. 1884, 76 th Leg., R.S. (1999), Bill Analysis).
- [87] Corporate Health Ins., 220 F.3d at 645.
- [88] Montemayor, No. 00-665, 69 USLW 3317 (Oct. 24, 2000).
- [89] MCOs Don't Want Supreme Court Review, 5 Health Care Daily Rep. (BNA) No. 243, (Dec. 18, 2000).
- [90] Supreme Court Seeks Federal Position, 6 Health Care Daily Rep. (BNA) No. 6, (Jan. 9, 2001) (citing Montemayor v. Corporate Health Insurance, Inc., No. 00-665, <u>U.S.</u> (interim order January 8, 2001)).
- [91] Shea v. Esensten, 107 F.3d 625 (8 th Cir. 1997), cert. denied 118 S.Ct.
  297, 139 L.Ed.2d 229 (1997) (Shea I).
- [92] Shea v. Esensten, 208 F.3d 712 (8 th Cir. 2000) cert. denied, 121 S.Ct. 172 (2000).
- [93] *Esensten v. Shea*, 121 S.Ct. 172 (2000).
- [94] Cypress Fairbanks Med. Ctr. Inc. v. Pan Am. Life Ins. Co., 110 F.3d 280
  (5 th Cir. 1997), cert denied 118 S.Ct. 167, 139 L. Ed. 2d 110 (1997).
- [95] See Memorial Hosp. Sys. v. Northbrook Life Ins. Co., 904 F.2d 236 (5 th Cir. 1990).
- [96] See In HomeHealth, Inc. v. Prudential Ins. Co. of Am., 101 F.3d 600, 606–07 (8 th Cir. 1996).
- [97] See The Meadows v. Employers Health Ins., 47 F.3d 1006, 1011 (9 th Cir. 1995).
- [98] See Hospice of Metro Denver, Inc. v. Group Health Ins., 944 F.2d 752, 756 (10 th Cir. 1991).
- [99] See Lordmann Enterprises, Inc. v. Equicor, Inc., 32 F.3d 1529, 1534
  (11 th Cir. 1994).
- [100] See Healthsouth Rehabilitation Hosp. v. American Nat'l. Red Cross, 101 F.3d 1005, 1010 (4 th Cir. 1996). In *Healthsouth*, however, the plaintiff conceded its state law claims were preempted, so the issue was not squarely presented. 101 F.3d at 1010.
- [101] See Cromwell v. Equicor Equitbable HCA Corp., 944 F.2d 1272, 1276 (6 th Cir. 1991). In Cromwell, however, the complaint alleged promissory estoppel, breach of contract, negligent misrepresentation and breach of good faith as grounds of recovery of benefits under the plan. 944 F.2d at 1276.

- [102] Pegram v. Herdrich, 530 U.S. 211, 120 S.Ct. 2143 (2000).
- [103] *Id.*, 120 S.Ct. at 2146.
- [104] Herdrich v. Pegram, 154 F.3d 362 (7 th Cir. 1999), reversed, 530 U.S.
  211, 120 S. Ct. 2143, 147 L. Ed. 2d 164 (2000).
- [105] *Id.*, 154 F.3d at 373.
- [106] *See id.*
- [107] See Herdrich, 120 S.Ct. at 2148–50.
- [108] *Id.* at 2150.
- [109] *Id.* at 2151.
- [110] 29 U.S.C. §§ 1002(21)(a)(i)–(iii).
- [111] Id.  $\S$  1104(a)(1)(A).
- [112] See Herdrich, 120 S.Ct. at 2152–53.
- [113] *Id.* at 2153.
- [114] *Id.* at 2154.
- [115] *Id.* at 2155.
- [116] Zamora-Quezeda v. Health Texas Medical Group of San Antonio, No. SA-97-CA-726-FB (W.D.Tex. 1997, settlement Nov. 22, 2000).
- [117] Health Plans Settle Lawsuit Alleging Bias Against Members With Disabilities
- [118] See id.
- [119] Class Action Lawsuits Are Numerous But So Are Legal Hurdles
- [120] *See id.*
- [121] 'Repair Team' Files New Round of Class Action Against Five HMOs
- [122] Bulk of Managed Care Class Actions Transferred
- [123] See id.
- [124] To Err Is Human: Building a Safer Health System, Forward
- [125] To Err Is Human, Building a Safer Health System, Preface

- [126] See id.
- [127] See id. at recommendations.
- [128] See id.
- [129] President's Proposal on Medical Errors, Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact
- [130] See *id*.
- [131] Report Shows Three Percent of Medication Errors in 56 Hospitals Resulted In Harm To Patients
- [132] See id.
- [133] See id.
- [134] See id.
- [135] See id.
- [136] FDA Proposes Rule on Drug Labeling, Says Changes Would Curb Medication Errors, 10 Health Law Rep. (BNA) No. 1 (Jan. 4, 2001) (citing 65 Fed. Reg. 81081)).
- [137] See id.
- [138] See id.
- [139] See id.
- [140] See id.
- [141] See id.
- [142] See id.
- [143] See id.
- [144] Marshall v. East Carroll Parish Hosp., 134 F.3d 319, 322 (5 th Cir. 1998).
- [145] See 42 U.S.C. § 1395dd(a)–(c).
- [146] Bauman v. Tenant Health System Hospitals, Inc., No. 00-1176, 2000 WL1219151 (E.D. La., August 24, 2000).
- [147] See id.

- [148] Harry v. Marchant, No. 99-13205, 2001 WL 23199 (11 th Cir., Jan. 10, 2001).
- [149] See id.
- [150] See id.
- [151] See id. at \*3.
- [152] See id. at \*4.
- [153] See id. at \*5.
- [154] See id. at \*6.
- [155] *See id.*
- [156] See Battle v. Memorial Hosp. at Gulf Port, Miss., 228 F.3d 544, 558–59
  (5 th Cir. 2000) reh'g en banc denied, (Nov. 1, 2000).
- [157] See id. at 548.
- [158] *Id.*
- [159] See id. at 549.
- [160] *See id.*
- [161] See id. at 549–50.
- [162] Id. at 557 (quoting Burditt v. U.S. Dept. of Health and Human Services, 934 F.2d 1362, 1374 (5 th Cir. 1991)).
- [163] *Id.*
- [164] See id. at 557–58.
- [165] See id. at 558.
- [166] See id. at 559.
- [167] *See id.*
- [168] See Drew v. University of Tennessee Regional Medical Center Hospital, No. 99-5070, 2000 WL 572064 (6 th Cir. 2000).
- [169] See id. at \*2.
- [170] See id.

- [171] See id. at \*3.
- [172] *Id.*
- [173] See Reynolds v. MaineGeneral Health, 218 F.3d 78 (1 st Cir. 2000).
- [174] See id. at 79.
- [175] See id. at 80.
- [176] See id.
- [177] See id.
- [178] See id.
- [179] *Id.*
- [180] See id. at 81.
- [181] See id.
- [182] See id.
- [183] See id. at 84–85.
- [184] See id. at 85.
- [185] *Ingram v. Muskogee Regional Med. Center* No. 99-7126, 2000 WL 1847510 (10 th Cir. 2000).
- [186] See i *d*. at \*3–4.
- [187] See i *d*. at \*3.
- [188] *Id.* at 4–5.
- [189] See i d.
- [190] See id.
- [191] See i d. (citing § 1395dd(c)(2)).
- [192] See id. (citing Repp. v. Anadarko Municipal Hosp., 43 F 3d 519 (10 th Cir. 1994)).
- [193] *Id.* . at \*5.
- [194] Torres Otero v. Hospital General Menonita, 115 F. Supp. 2d 253 (D.P.R. 2000).

- [195] See id. at 261.
- [196] See id. at 256.
- [197] *Id.* at 259.
- [198] *Id.* at 260.
- [199] See id.
- [200] Potvin v. Metropolitan Life Ins. Co., 22 Cal. 4 th 1040, 997 P.2d 1153 (Cal. 2000).
- [201] See id. at 1063.
- [202] See id. at 1064.
- [203] See id.
- [204] See id. at 1065.
- [205] See id.
- [206] *Id* at 1071.
- [207] See id. at 1070.
- [208] See id. at 1072.
- [209] *Id.*
- [210] See id. at 1073.
- [211] Id. at 270–71 (citing Harper v. Health Source New Hampshire, Inc.,
  674 A. 2d 962 (N.H. 1996); Potvin, 63 Cal. Rptr. 2d 202 (Cal. Dist. Ct. App. 1997), petition for review granted, 941 P.2d 1121 (July 30, 1997).
- [212] *Id.*
- [213] See Wuchenich v. Shenandoah Memorial Hosp., No. 99-1273 (4 th Cir. 2000).
- [214] See id. at \*2.
- [215] See id. at \*3.
- [216] *See id.*
- [217] See id. at \*4.

- [218] See id.
- [219] See id. at \*6 \*7.
- [220] See id. at\*9.
- [221] See id. at \*13.
- [222] See id. at \* 17.
- [223] See Sibley v. Board of Supervisors of La. State Univ. & Mechanical College, 446 So.2d 760, 766 (La.App. 1 Cir. 1983).
- [224] See id.
- [225] *See id.*
- [226] See Elam v. College Park Hosp., 183 Cal.Rptr. 156, 159 (1982).
- [227] See id. at 161.
- [228] *Id.* at 165.
- [229] See id.
- [230] *Id.* at 164.
- [231] See Brown v. Superior Court, 214 Cal.Rptr. 266, 275 (1985).
- [232] *Id.* at 275.
- [233] *Id.*
- [234] See Garlington v. Kingsley, 289 So. 2d 88 (La. 1974).
- [235] See Spradlin v. Acadia-St. Landry Med. Found., 758 So.2d 116, 119 (La.2000).
- [236] *See id.*
- [237] See id. 289 So.2d 88.
- [283] See id. at 89.
- [239] See id. at 93.
- [240] See id. at 90 ( citing Civil Code Article 2320).
- [241] 446 So.2d 760, 767 (La. App. 1 Cir. 1983).

- [242] See id.
- [243] See Narcise v. Jo Ellen Smith Hosp., 729 So.2d 748 (La.App. 4 Cir. 1999); Fusilier v. Dauterive, 759 So.2d 821 (La. App. 3 2000), rev'd on other grounds, 764 So.2d 74 (La. 2000).
- [244] See id. at 753.
- [245] See id. at 754.
- [246] See Fusilier, 759 So.2d at 830.
- [247] See id. at 831.
- [248] Gridley v. Johnson , 476 S.W.2d 475 (Mo. 1972).
- [249] See id. at 483–84.
- [250] *Id.* at 484.
- [251] *Id.* at 485.
- [252] Manar v. Park Lane Medical Ctr., 753 S.W.2d 310 (Mo.App. W.D. 1988)
- [253] See id., at 311.
- [254] See Manar, 753 S.W.2d 311–12.
- [255] See id. at 314.
- [256] See id. at 315.
- [257] See Poluski v. St. Louis Univ. Med. Ctr., 877 S.W.2d 709, 713
  (Mo.App. E.D. 1994).
- [258] See id. at 711.
- [259] See id.
- [260] See id. at 714.
- [261] See id.
- [262] Harrell v. Total Health Care, Inc., 781 S.W.2d 58 (Mo. 1989).
- [263] See id. at 59–60.
- [264] See id. at 60.

- [265] See id. at 62–63.
- [266] See id. at 61.
- [267] See Thompson v. Nason Hosp., 591 A.2d 703 (Pa. 1991).
- [268] See id., 591 A.2d 703.
- [269] See id. at 707.
- [270] *Id.* at 707 (citations omitted).
- [271] See id. at 708.
- [272] See Welsh v. Bulger, 698 A.2d 581, 585 (Pa. 1997).
- [273] See id.
- [274] See id.
- [275] See id. at 586.
- [276] Corrigan v. Methodist Hosptial, 869 F.Supp. 1208 (E.D. Pa. 1994).
- [277] See id. at 1209–10.
- [278] See id. at 1211.
- [279] See id.
- [280] See Tex.Rev.Civ.Stat.Ann. art 4495b §§ 5.06(1) (m) (Vernon 2000).
- [281] Id. at § 5.06(1) ( emphasis added ).
- [282] Id. at § 5.06(m) ( emphasis added ).
- [283] St. Luke's Episcopal Hospital v. Agbor, 952 S.W.2d 503, 505 (Tex. 1997).
- [284] See id. at 509.
- [285] See Park North General Hosp. v. Hickman, 703 S.W.2d 262, 264–66 (Tex.App.—San Antonio 1985, writ ref'd n.r.e.) (holding that Texas does recognize a common law cause of action for negligent credentialing and that a hospital is under a duty to select competent staff); cf. Jeffcoat v. Phillips, 534 S.W.2d 168, 172–174 (Tex.Civ.App.—Houston [14 th Dist.] 1976, writ ref'd n.r.e.) (holding that absent an employer-employee, principal-agent, partnership, or joint venture relationship between a hospital and physician, a hospital is not liable for its recredentialing decisions where the patient chooses the physician).

- [286] See Agbor, 952 S.W.2d at 508.
- [287] *Mills v. Angel*, 995 S.W.2d 262 (Tex.App.—Texarkana 1999, no pet.).
- [288] See Mills, 995 S.W.2d at 268.
- [289] See id. at 275.
- [290] *Id.*
- [291] See § 766.110, Fla. Stat. (2000) (formerly Section 768.60, Florida Statutes (1985)).
- [292] See Insinga v. LaBella, 543 So.2d 209, 211 (Fla. 1989).
- [293] See id. at 212.
- [294] *See id.*
- [295] Insinga v. LaBella , 543 So.2d 209 (Fla. 1989).
- [296] *Id.* at 213.
- [297] See id. at 214.
- [298] See id.
- [299] See §§ 766.201–766.212, Fla. Stat. (2000).
- [300] See O'Shea v. Phillips, 746 So.2d 1105, 1108 (Fla. 4 th Dist. Ct. App. 1999).
- [301] See St. Anthony's Hosp., Inc. v. Lewis, 652 So.2d. 386, 387 (Fla. 2 nd Dist. Ct. App. 1995) and Martinez v. Lifemark Hosp. of Florida, Inc., 608 So.2d 855 (Fla. 3 rd Dist. Ct. App. 1992)
- [302] See O'Shea, 746 So.2d at 1107.
- [303] See Beam, 486 So.2d 672, 673 (Fla. 1 st Dist. Ct. App. 1986).