Summer is Over: Celebrate Fall by Writing for LMP

As the lazy days of summer have now drawn to a close and school begins again in earnest, LMP delivers on the promise in the last issue, by bringing the ACLM readership several of the June Supreme Court cases in more detail. The cases chosen for inclusion run the gamut from a child with educational special needs under the IDEA to a sexual harassment claim by a female forklift operator. Sandwiched between these cases, the Court took a moment to consider the insanity defense arising out of a criminal act in Arizona. Additionally, nestled amongst the Supreme Court Briefs in this issue are the typical offerings of health law case briefs and interesting news stories. Additionally, ACLM Fellow Victoria Green, MD, JD submitted a Colleagues’ Corner piece on physician countersuits, a topic which continues to garner significant attention when it is presented at national meetings. The current medical malpractice climate continues to be an issue meriting discussion. Physician countersuits clearly evolved out of the frustration that providers feel when on the receiving end of increased litigation by the plaintiff’s bar. However, all physicians have also observed sub-standard care provided by colleagues and thus plaintiffs must continue to be allowed their day in court. The role that such countersuits will assume in this landscape has yet to be determined.

Speaking of Colleagues’ Corner articles, LMP is actively soliciting articles from the ACLM membership for consideration of publication. Any member who presents a talk at a local, regional, or national meeting on a topic of health law, bioethics, or other area which would be of interest to the readership is encouraged to submit their article idea to LMP.

Typical pieces are 3,000 to 4,000 words, but smaller articles will also be considered. As LMP is intended to represent all members of ACLM, we are striving to broaden the number of contributors by calling on the wealth of experience of our membership. Ideas for contribution or potential articles can be electronically submitted to Chris White, MD, JD, FCLM the Editor of LMP via email to whitec@fammed.uc.edu.

Supreme Court Cases

In Arlington Central School District v. Murphy, 126 S.Ct.2455 (2006), the Supreme Court of the United States determined that the Individuals with Disabilities Education Act (“IDEA”) did not provide for reimbursement of expert fees for prevailing parties. The goal of the IDEA is to “ensure that all children with disabilities have available to them a free appropriate education.” Id. at 2463 (citing 20 U.S.C. § 1400(d)(1)(A)). In this case, Pearl and Theodore Murphy prevailed in their action under the Act against the Arlington Central School District demanding that the District Board of Education pay for their son’s private school tuition. As a prevailing party, the Murphys demanded reasonable attorneys’ fees and expert fees incurred during this litigation. Under this act, “a court ‘may award reasonable attorneys’ fees as part of the cost’ to parents who prevail in action brought under the Act.” The Southern District of New York and the Second Circuit determined that these costs included expert fees the Murphys had paid to a consultant during the litigation. Both courts ordered that the District Board of Education pay these fees. On certiorari, the Supreme Court of the United States determined that such fees could not be awarded to the Murphys. In the analysis of this case, the Supreme Court began by examining the IDEA’s authority. The IDEA was enacted by Congress under the Spending Clause of the United States Constitution. Id. at 2459 (citing U.S. Const. Art. I, § 8). As such, it serves as a type of contract between the state and federal governments. In essence, the state governments agree to feder-
ally imposed conditions in exchange for federal funds. Of note, such federally imposed conditions under the Spending Clause can only be imposed on states that “voluntarily and knowingly accept” such conditions. As such, a “state cannot knowingly accept conditions of which they are ‘unaware’ or which they are ‘unable to ascertain.’” The Court reasoned that it needed to determine “whether the IDEA furnishes clear notice regarding the liability at issue in this case.” Of course, this liability was whether the costs of expert fees were clearly provided for in the IDEA.

To aid in this determination, the Court looked at the unambiguous language of the statute providing for the reimbursement of costs to a prevailing party. It provides that:

[I]n an action or proceeding brought under this section, the court, in its discretion, may award reasonable attorneys’ fees as part of the costs to the parents of child with a disability who is the prevailing party. Id. at 2459 (citing 20 U.S.C. § 1415(i)(3)(B)).

First, the Court noted that “costs,” as a term of art, does not include expert fees. Further, the Court stated that costs were specifically defined by the U.S. code in 28 U.S.C. § 1920 and 1821. This list of allowable costs in the Code does not include expert fees. As a result, the Supreme Court concluded that “the text of 20 U.S.C. 1415(i)(3)(B) does not authorize an award of any additional expert fees, and [ ] certainly fails to provide the clear notice that is required under the Spending Clause.” Of note, the Court recognized that the legislative history of this act actually did state that “the conferees intend that the term ‘attorneys’ fees as part of the costs’ include reasonable expenses and fees of expert witnesses…” However, the Court stated that in light of the past precedent regarding the interpretation of costs and the clear language of the disputed statute, it could not “say that the legislative history on which respondents rely is sufficient to prove the requisite fair notice.” Accordingly, the Court reversed and remanded this case.

Editors’ Comments: Of note, this case may have significant effect on the future interpretation of the IDEA. Here, in spite of clear legislative history to the contrary, the Court refused to interpret costs as inclusive of expert fees and favored the unambiguous language of the statute as determinative. Accordingly, in the future the Court may rely more on the clear language of IDEA and less on the legislative history of the Act in interpreting the federally imposed conditions states have agreed to.

In Burlington Northern v. White, 126 S.Ct. 2405 (2006), the Supreme Court of the United States considered the scope of prohibited retaliatory behavior under Title VII of the Civil Rights Act of 1964. This Act forbids “discrimination against ‘any individual’ based on the individual’s ‘race, color, religion, sex, or national origin.’” In a separate section of this Act termed the anti-retaliation provision, it “forbids an employer from ‘discriminating against’ an employee or job applicant because that individual ‘opposed any practice’ made unlawful by Title VII or ‘made a charge, testified, assisted or participated in’ a Title VII proceeding or investigation.” Id. (citing 42 U.S.C. §2000e-3(a)). The Court found that the anti-retaliation provision does “not confine the actions and harms it forbids to those that are related to employment or occur at the workplace.” Rather, the Court concluded “that the provision covers those employer actions that would have been materially adverse to reasonable employee or job applicant.”

In this case, Sheila White asserted a cause of action against Burlington Northern & Santa Fe Railway Company asserting that this company had violated the anti-retaliation provision. Ms. White was employed with this company as a “track laborer” and ran the forklift. In September 1997, Ms. White complained about sexual harassment on the part of her immediate supervisor, Bill Joiner. As a result of this complaint, Mr. Joiner was investigated by the company, suspended for 10 days and ordered to attend sexual-harassment training. Subsequently, Ms. White was reassigned from her forklift duties, a coveted position, to more menial labor. Additionally, Ms. White was later suspended for 37 days without pay for alleged insubordination. This suspension was later reversed by the company upon a finding that Ms. White had not been insubordinate. After pursuing administrative remedies, Ms. White filed a Title VII action in federal district court in Tennessee claiming that her reassignment and suspension were unlawful retaliations for her initial reporting of Joiner’s sexual harassment. A jury found for Ms. White and awarded compensatory damages. On appeal, the Sixth Circuit reversed. However, the Sixth Circuit then vacated this decision and affirmed the district court ruling en banc.

The Court took this case on certiorari to settle a circuit split regarding what constitutes retaliatory action under Title VII. The Sixth Circuit has held that retaliatory acts, like discriminatory acts under Title VII, should be limited to actions that “result in adverse effect on the term, condition, or benefits of employment.” The Fifth and Eighth Circuit had an even more restrictive view limiting retaliatory acts to conduct such as “hiring, granting leave, discharging, promoting, and compensating.” In contrast, the Seventh Circuit and District of Columbia Circuits have said that the plaintiff must simply show that the “employer’s challenged action would have been material to a reasonable employee” and would have dissuaded a reasonable employee from making or supporting a charge of discrimination.

The Court determined that the anti-retaliation provision was meant to be broader than the discrimination provision of Title VII. As such, the Court concluded:

Plainly, effective enforcement could thus only be expected if employees felt free to approach officials with their grievances. Interpreting the anti-retaliation provision to provide broad protection from retaliation helps assure the cooperation upon which accomplishment of the Act’s primary objective depends. For these reasons, we conclude that Title VII’s substantive provision and its anti-retaliation provision are not coterminous. The scope of the anti-retaliation provision extends beyond workplace-related or employment-related retaliatory acts and harm. We therefore reject the standards applied in the Courts of Appeals that have treated the anti-retaliation provision as forbidding the same conduct prohibited by the anti-discrimination provision… Id. at 2414.

The Court agreed with Seventh Circuit and District of Columbia Circuits’ interpretation of the anti-retaliation provision. This interpretation states that a plaintiff must show that a reasonable employee would find a disputed action “materially adverse.” This means that such behavior “might have dissuaded a reasonable worker from making or supporting a charge of discrimination.” In the current matter, the Court affirmed the district court’s decision finding that Ms. White’s suspension and reassignment was materially adverse and a violation of the anti-retaliation provision of Title VII.

Editors’ Comments: This case serves to broaden the federal prohibi-
tion of retaliatory actions under Title VII. As such, it may serve to encourage compliance with the Act by employers and potentially increase the number of suits brought under this provision in the future.

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Physician Countersuits: Is the Bark Worse than the Bite?

Medical malpractice is an important aspect of medical practice and is on everyone’s lips. Fear of malpractice may lead physicians to order more care than necessary and refer patients to specialists more often than needed. Amongst 736 doctors surveyed by the Wall Street Journal, 72% indicated they viewed patients as potential adversaries because of the malpractice environment. In addition, nearly 40% had limited services and moreover, half of medical students surveyed indicated that medical liability was a factor in their specialty choice and are less eager to practice medicine than before. See 105 Obstetrics & Gynecology 1287-95 (2005); Rachel Silverman, “Doctors take the offensive”, Wall Street Journal (March 23, 2004). Multimillion-dollar awards are routine. Even President George Bush has addressed the issue in his 2004 State of the Union address by establishing the need to “eliminate wasteful and frivolous medical lawsuits in order to protect the doctor-patient relationship and keep good doctors doing good work.” Although most lawsuits are dropped or dismissed, litigation costs doctors’ insurance companies more than $16,000 in legal costs on average according to the Physicians Insurers Association of America. Thus, as a strategy to combat what practitioners believe to be frivolous medical malpractice suits, some physicians are turning to counterclaims. Interestingly, whether this strategy has been successful is debatable. Although the absolute number of medical malpractice claims has increased dramatically in recent years, there has been a conspicuous lack of a concomitant increase in the number of successful physician countersuits. Courts tend to recognize a strong public policy interest in ensuring injured parties have free and open access to the judicial system, and are extremely reluctant to allow countersuits, as they believe this would have a chilling effect on a party's ability to seek legal redress.

The American Medical Association supports the use of countersuits to discourage frivolous lawsuits in an October 20, 2004 resolution. Although an appealing recourse, litigating counterclaims is expensive and time consuming. Many strategies have been tried but all have been largely unsuccessful, including defamation, negligence theories and the intentional torts of invasion of privacy and infliction of emotional distress. Defamation is committed when an oral or written false statement is made to a third party about another person and is damaging to that person’s reputation and or good name. These have been unsuccessful as counterclaims as there is an underlying privilege covering oral and written statements made in the course of judicial proceedings. This privilege immunizes patients and their attorneys from liability for any reasonable communication made in the course of a lawsuit. The purpose of the privilege is to permit free expression of facts and opinions as are necessary to decide the merits of the case. Even the mere threat of a defamation lawsuit may have a chilling effect on access to courts and the honesty of the participants. Moreover, it would be contrary to public interest and the free and independent operation of the courts. Despite the public policy argument, there was a successful defamation case in a California intermediate appellate court in 1963. See Hanley v Lund, 32 Cal Rptr 733 (1963). The defendant was sued for defamation and the plaintiff physician prevailed on appeal. However, the fact pattern is unusual and subsequent decisions have criticized the court's ruling. In the initial case, the court held that statements made by the patient's attorney to the media were not made in pursuit of the underlying malpractice litigation and although the attorney was made aware of the fact that the statements were false, he failed to retract them when given the opportunity. Thus, a defamation claim may be a viable form of action in countersuits in which erroneous and unsubstantiated statements are made outside of the usual judicial proceedings where the privilege covering judicial proceedings may not protect the individuals.

Negligence theories have been unsuccessful since courts would have to find that the defendant unreasonably brought an unfounded lawsuit against the physician. However, negligence law would require that the plaintiff’s attorney owed a duty to the defendant, which is counterintuitive as attorneys are to zealously advocate for and defend their clients (the patient) and thus, owe no duty to the defendant (other than those implicit in rules of conduct discussed infra). Thus, no physician has prevailed with a countersuit based on negligence at the appellate level. Barratry is the offense of persistently instigating lawsuits, typically groundless ones. It is less used (and also little known), but is also an unsuccessful strategy for counterclaims.

A few options are emerging which may protect the physician’s interest in not being subjected to unwarranted judicial proceedings. Three related tort actions include abuse of process, malicious prosecution and wrongful institution of civil proceedings. An additional resource is seeking redress against the plaintiff’s expert witnesses when there is delivery or makes the prosecution more likely, this would likely be held to
be sufficient. The “terminated in favor” requirement is met not only where there is an acquittal, but also where the prosecutor ultimately decides not to prosecute because he doesn’t believe the case to have merits, or where a grand jury refuses to indict or any other disposition that signifies the weakness of the case. Lack of probable cause is likely the physician’s biggest hurdle, as the defendant is held to have probable cause if they correctly or reasonably believed the plaintiff committed certain acts and that these acts constituted the crime charged. The defendant may have been mistaken as to the facts of the case or as to the law, as long as the mistake is reasonable. Erroaneous lay belief as to whether the acts constitute a crime may be held to be unreasonable if consultations with an attorney are not received. However, once consultation is received and assurances made that these facts constitute a crime, probable cause is present, assuming the defendant has made a full disclosure of the facts as known to her. Additionally, the outcome of a criminal proceeding may or may not affect the existence of probable cause. If convicted, then probable cause is present, but if the complaint is dismissed, most courts will hold that probable cause is lacking. As only reasonable doubt is necessary for an acquittal in a criminal case, this does not establish prima facie evidence of lack of probable cause.


One must also show that the defendant acted out of malice or some other purpose rather than bringing the offender to justice or securing adjudication of the claim. The prosecutor is almost always immune. Additionally, other professionals have been held to be immune including police officers. Usually the plaintiff does not have to prove actual pecuniary loss. However, presumed damages for harm to reputation, in absence of actual showing of such harm may be unconstitutional. Thus, a showing of actual harm to reputation, emotional distress, lost income, etc., stemming from the proceedings, would bolster the case.

The tort of malicious prosecution formally relates only to unwarranted criminal proceedings. However, most states have granted a similar tort action for wrongful institution of civil proceedings, although many continue to use the terms synonymously. As there is less severe hardship imposed on the person defending the civil action and a lowered burden of proof, less certain knowledge of the facts suffice as compared to malicious prosecution. Moreover, the institution of a civil proceeding is less harshly penalized for a mistake of law, such that it is enough if she reasonably (though mistakenly) believed there was a respectable chance (though less than 50%) that she would be able to convince a court or jury as to the legal merits of her claim. A nuisance suit, where the plaintiff believes they have no real chance of succeeding, and is brought solely for the purpose of extorting a settlement or a counterclaim brought solely for the purpose of delaying the proceedings, is considered an improper purpose.

Dr. John Guarnaschelli, a Kentucky neurosurgeon, was successful in bringing a claim against the attorney that sued him for malpractice. The facts of the case begin in 1995 when the client presented to Dr. Guarnaschelli complaining of severe back and leg pain after involvement in a motor vehicle accident. The client was admitted to the hospital where imaging studies including Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) myelogram were performed to rule out a possible herniated disc. Based on the normal results, conservative treatment and steroid epidural injections were recommended to relieve the patient’s pain. The patient was involved in a second car accident approximately 10 days after the second steroid injection. She was admitted to the emergency room complaining of headache thus, a spinal tap was performed to rule out the possibility of infection. The consulting infectious disease specialist diagnosed the patient with non-infectious meningitis, which he later attributed to the prior epidural blocks performed by Dr. Guarnaschelli. Alternatively, Dr. Guarnaschelli thought the spinal tap result was secondary to a delayed reaction to the myelogram dye. The patient quickly improved and was discharged seven days later in no apparent distress. A malpractice suit was filed, alleging negligent diagnosis and treatment resulting in meningitis, great physical and mental anguish and various unsundy complications.

The initial malpractice claim was dismissed on summary judgment and Guarnaschelli filed a claim for wrongful institution of civil proceedings alleging Mr. Radolovich (the attorney) had produced no evidence or expert opinion to support his client’s allegations and that he did not conduct a reasonable investigation into the veracity of the facts alleged. He sought compensatory damages for humiliation and loss of reputation and punitive damages on the grounds that Mr. Radolovich’s actions were reckless, grossly negligent and malicious. Mr. Radolovich countered, indicating he was only vigorously pursuing the client’s best interest in good faith and had a reasonable belief that the case had merit.

Mr. Radolovich highlights the downfalls of his case in the lack of documentation. Although there was no economic loss of provable damage to his reputation, Guarnaschelli stated the lawsuit affected his practice and made him question his clinical day-to-day decisions. Additionally, he had to report the case to the state medical board, Health Maintenance Organizations (HMOs) with which he contracted, and hospitals. He was able to show lost time from his practice responding to interrogatories and attending depositions. Mr. Radolovich indicated that he had a reasonable belief that the case had merit but only had access to the limited medical records the patient had initially provided. Moreover, he indicated he had spoken with the specialty physicians in the elevator while at the hospital for a different case to confirm their opinions before filing the claim. Both specialists denied this conversation; moreover it was not plausible that they would speak to him without provocation. Additionally, Radolovich indicated that the specialists were willing to testify on his client’s behalf which was again denied by the physicians. Actually, at the time of dismissal, the physicians denied any evidence of negligence on Guarnaschelli’s part and denied ever telling anyone that they had suspected malpractice. In fact, one had written the treatment provided by the neurosurgeon was “entirely proper and appropriate.” Mr. Radolovich also related he had advised his client to drop the case after he learned the specialists did not support the negligence claim, but she had refused. His client never confirmed that account. However, his professional relationship with the client was now tainted by the fact that he was also representing her in a separate case resulting from yet another auto accident that had occurred on her way home from his office. Moreover, for over a year, Radolovich refused the neurosurgeon’s request to drop the suit. Dr. Guarnaschelli was successful as he was able to prove that Mr. Radolovich did not obtain the full medical record, nor speak with the expert witnesses that were supposed to support his client’s testimony. Moreover, there was no documentation on Mr. Radolovich’s part as to any conversations either with the client to drop the case or with the supporting experts.

Jurors awarded compensatory and punitive damages causing Radolovich to state that he would never take another malpractice case unless “they leave the scalpel in the chest and it’s showing through the skin.” The case has been appealed. Thus one must realize, despite
initial success in this case, countersuits take a cautionary level of time and effort. In many cases it may be difficult to find an attorney willing to bring a case against a colleague (not unlike the physician community). Even if successful, the legal expenses could easily exceed any amount of recovery.

Another successful counterclaim was litigated under the Ohio frivolous conduct statute where, although the plaintiff’s own expert did not support any negligence on the part of the defendant physician when queried nearly 9 months prior to the trial, he was not dismissed from the suit until after the trial commenced.

Now, of course, it is not just physicians that are interested in stemming the tide of frivolous lawsuits. The legal profession has for centuries had guidelines and rules that address this specific issue, including rule 3.4 in the American Bar Association Model Rules of Professional Conduct where a lawyer shall not “allude to any matter that the lawyer does not reasonably believe is relevant or that will not be supported by admissible evidence.” See American Bar Association Model Rules of Professional Conduct, Rule 3.4 e.

An additional option in combating frivolous medical malpractice suits is seeking redress against false or exaggerated expert witness testimony. Again, the legal profession has addressed this issue where a lawyer shall not “counsel or assist a witness to testify falsely,” and should “respect the independence of the expert and should not seek to dictate the formation of the expert’s opinion on the subject.” See American Bar Association Model Rules of Professional Conduct, Rule 3.4 b; American Bar Association Standards Relating to the Administration of Criminal Justice 3d edition approved Feb 3, 1992. Moreover, medical organizations, including the American College of Obstetrics and Gynecology, American Association of Pediatrics and the American Association of Neurosurgeons, have developed guidelines for expert witness testimony which suggest experts testify solely in accordance with one’s judgment, does not impugn performance that falls within accepted standards, does not support obviously deficient practices, and exercises care to ensure the standards promoted do not narrowly reflect the experts’ views. See American Academy of Pediatrics, Guidelines for expert witness testimony in medical liability cases (1994).

Varying theories have been met with differing levels of success. A defamation claim against an expert witness has been met with little success as decreed in the case of Kabn v. Burman, 673 F Supp 210 (E.D. Mich. 1987), where the court held “In most, if not all, American jurisdictions… statements made in the court of judicial proceedings which are relevant and pertinent to the issues are absolutely privileged, which are relevant and pertinent to the issues are absolutely privileged, and therefore cannot be used as basis for a libel action for damages. This is true even if the statements are known to be false or even malicious. It is said that the policy underlying this rule is that access to judicial process, freedom to institute an action, or defend, or participate without fear of the burden of being sued for defamation, is vital and necessary to the integrity of the judicial system and it must be made paramount to the right of an individual to a legal remedy where he or she has been wronged thereby.”

Conversely, professional medical societies in recent years have begun to express interest in the activities of their members, especially in the arena of expert witness testimony. Especially, as expert witness membership in a professional society is often used to bolster their credibility. Implications for members sanctioned by their professional organization can be considerable including suspension of membership, expulsion (both of which must be reported to the National Practitioner Data Bank), reprimands and censures. Although reprimands and censures are not reported, they are discoverable during the litigation process. Thus, litigation counsel will look unfavorably upon a potential expert witness who has been sanctioned or reprimanded by his or her professional society.

The importance of this came to light in the case of Austin v. American Association of Neurologic Surgeons, 253 F.3d 967 (2001), where Dr. Austin testified that the “majority of neurosurgeons” concur that the defendant’s performance of the procedure was careless and negligent based on articles he had reviewed by an important contributor to the procedure who indicated that “serious complications are avoidable/prevented by surgeon adhering strictly to the surgical technique described.” The 7th circuit court of appeals disagreed that the articles supported Dr. Austin’s testimony and reviewed not only the internet for additional information but also the association’s code of ethics holding that the dismissal of Dr. Austin was unquestionably correct and without bad faith. They went further to state that collaboration between the courts and the professional societies further the cause of justice and is in the best interest of the association and the community. Although judges screen expert testimony according to Danbert, “judges are not experts in any field except law.”

Other novel approaches are addressed by many organizations including Medical Justice, which provides a proactive strategy of the threat of a countersuit to mitigate frivolous malpractice suits and better protect physicians. Additionally, their early intervention program is designed to get frivolous suits dropped. Under their strategy, patients are asked to sign forms and waivers promising not to sue for frivolous reasons.

Doctors for medical liability reform purport another creative approach to frivolous lawsuits on their website Protectpatientsnow.org. DoctorKnowUs.com was a website which tracked litigious patients, plaintiff lawyers and expert witnesses. This ignited a firestorm of controversy resulting in its voluntary shut down.

Ultimately, perhaps one editorial stated it best when its author declared, “Sure, ordinary folks need access to the courts to deal with harm inflicted on them by incompetent doctors— or, for that matter, incompetent lawyers. But access to the courts can be abused. Doctors, lawyers, businesses, motorists—all of us— deserve protection from frivolous or malicious lawsuits… It’s a sad paradox that, in our overly litigious society, it takes a lawsuit to fight groundless lawsuits.”

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In Clark v. Arizona, 126 S.Ct. 2709 (2006), the Supreme Court of the United States evaluated a criminal defendant’s claim that their due process rights, under the federal constitution, had been violated by the State of Arizona’s law regarding criminal insanity defenses. Further, the defendant, on appeal, claimed that the Supreme Court of Arizona’s evidentiary ruling under State v. Mott, 931 P.2d 1046 (Az 1997), had violated his due process rights by preventing the consideration of psychiatric testimony with respect to deliberation of the mens rea of accused crime of first degree murder. The Supreme Court found that the Arizona statute regarding the affirmative defense of insanity did not violate the defendant’s due process rights under the federal constitution. Additionally, the Court found that the State of Arizona could limit psychiatric evidence with respect to the consideration of mens rea in this murder case. The Court affirmed the Supreme Court of Arizona’s ruling.
On June 21, 2000, officer Jeffery Moritz, of the Flagstaff Police Department, responded to a complaint that a pickup truck was circling the block of a residential area and playing loud rock music. Officer Moritz identified the suspect vehicle, turned the emergency lights of his police cruiser on and proceeded to pull over the suspect, Eric Clark. Officer Moritz was in a marked police car and wearing his issued uniform. Minutes later, Clark shot the officer and fled the scene on foot. The dying officer contacted the dispatch operator and requested assistance, but later died because of his wound. Clark was apprehended later that day and tested positive for a gunshot residue. The weapon used to kill officer Moritz was also recovered. Clark was charged with first degree murder under Ariz. Rev. Stat. Ann. 13-1105(A)(5)(2006). This statute states:

A person commits first degree murder if . . . intending or knowing that the person's conduct will cause death to a law enforcement officer, the person causes the death of a law enforcement officer who is in the line of duty. Id. at 2716 n.1 (emphasis added).

Clark, a paranoid schizophrenic, did not deny the shooting but claimed insanity as an affirmative defense. He suffered from delusions and believed that Flagstaff was inhabited by aliens, many of whom were public officials and police, and believed that these aliens were trying to kill him. Clark claimed that he was insane at the time of the shooting and should be excused for the murder. Additionally, Clark asserted that his mental incapacity and pathology served to disprove the mens rea requirement that he acted “inten[itionally] or knowing[ly] to ‘cause death to a law enforcement officer.” Id. at 2716. At a bench trial, Clark was found guilty. On appeal, Clark claimed that Arizona’s formulation of the insanity defense denied due process to him. Further, Clark claimed that the bar in Arizona, under Mott, of consideration of expert testimony regarding mens rea, was also a violation of due process rights. The Supreme Court of Arizona denied both these arguments and affirmed the trial court’s ruling. Subsequently, the Supreme Court of the United States heard the appeal.

On appeal, the Supreme Court considered each of Clark’s points of error in turn. First, the Court considered whether Arizona’s formulation of the insanity defense violated due process under the federal constitution. Under Arizona law, amended in 1993, an insanity defense could only be based on “moral incapacity.” Accordingly, “[u]nder current Arizona law, a defendant will not be adjudged insane unless he demonstrates that ‘at the time of the commission of the criminal act [he] was afflicted with a mental disease or defect of such severity that [he] did not know the criminal act was wrong.” Id. (Quoting Ariz. Rev. Stat. Ann. 13-502(A) (2001)) (emphasis added).

Previously, the Arizona statute included both “cognitive and moral incapacity.” The statute prior to the 1993 amendment read:

A person is not responsible for criminal conduct if at the time of such conduct the person was suffering from such a mental disease or defect as not to know the nature and quality of the act or, if such person did know, that such person did not know that what he was doing was wrong. Id. at 2719 (Quoting Ariz. Rev. Stat. Ann. 13-502 (1978)).

Clark claimed that the narrowing of this statute to only consider whether a defendant understood an act was wrong and unconstitutionally limited the insanity defense. It also violated his due process rights. The Supreme Court denied this argument for several reasons.

First, the Court recognized the inherent power of the state to determine affirmative defenses under their respective penal codes. Second, the Court reviewed the insanity defense definitions and laws among the states in order to determine if there was some consistent minimum standard under due process. The Court cited numerous different formulations and definitions of the insanity defense dictated by different states. As such, the Court reasoned that this diversity of definitions argued against a constitutional minimum standard which was required to satisfy due process.

With this varied background, it is clear that no particular formulation has evolved into a baseline for due process, and that the insanity rule, like the conceptualization of criminal offenses, is substantially open to state choice. Id. at 2722.

Third, the Court pointed out that so called “cognitive capacity” considerations (i.e. whether a defendant appreciates the nature and quality of their actions) is part of a moral incapacity evaluation. The Court reasoned that a person who does not understand the “nature and quality” of their actions also would not understand that what he was doing was wrong. As such, the amended Arizona statute implicitly included the cognitive capacity consideration under the old statute.

In practical terms, if a defendant did not know what he was doing when he acted, he could not have known that he was performing the wrongful act charged as a crime. Indeed, when the two-part rule was still in effect, the Supreme Court of Arizona held that a jury instruction on insanity containing the moral incapacity part, but not a full recitation of the cognitive incapacity part, was fine, as the cognitive incapacity part might be “treated as adding nothing to the requirement that the accused know his act was wrong.” Id. at 2722-23.

For the above reasons, the Court found that the Arizona law did not violate due process under the federal constitution.

Fourth, the Court considered whether barring expert opinion testimony in the consideration of mens rea violated the defendant’s due process rights. Under the Mott decision, the Supreme Court of Arizona determined that expert opinion testimony regarding a type of psychopathology could not be proffered in consideration of defendant’s mens rea at the time of a crime. However, this decision allowed expert testimony regarding direct observations made by a psychiatrist or psychologist of a defendant’s behavior. The subtle difference between these types of testimony is that experts could recount specific observed characteristics of the defendant, but could not generally speak about what a specific type of patient with the defendant’s diagnosis would be thinking.

The Supreme Court found that the Mott decision did not violate the due process rights of the defendant. First, the Court noted that no specific example of evidence barred under Mott was pointed out in the record. As a result, the Court stated the issue was not before the Court. In sum, the trial court’s ruling, with its uncertain edges, may have restricted observation evidence admissible on mens rea to the insanity defense alone, but we cannot be sure. But because a due process challenge to such a restriction of observation evidence was, by our measure, neither pressed nor passed upon in the Arizona Court of Appeals, we do not consider it. Id. at 2728.

In spite of this, the Court considered whether barring evidence of diminished capacity is a violation of due process. In other words, whether barring expert testimony regarding psychopathology in considering mens rea, violates due process by preventing the presentation of evidence of diminished capacity. The Court stated that a state has a right to limit evidence for good reason.

[1] The right to introduce relevant evidence can be curtailed if there is a good reason for doing that. While the Constitution . . . prohibits the exclusion of defense evidence under rules that serve no legitimate purpose or that are disproportionate to the ends that they are asserted to promote, well-established rules of evidence permit trial judges to exclude evidence if its probative value is outweighed by certain other factors such as unfair prejudice, confusion of the issues, or potential to mislead the jury.” Id. at 2731 (citation omitted).

The Court noted that Arizona limits such expert testimony for good reason consistent with the “standard of fundamental fairness that due
process requires." The Court further reasoned that Arizona does not recognize the defense of diminished capacity. As such, the state may limit expert testimony regarding mens rea in order to prevent the factfinder from essentially creating a diminished capacity defense. Further, the Court noted the uncertainty and changing landscape of the psychiatric field and potential influence expert opinions may have on the factfinders justifying such testimony in the consideration of mens rea.

Arizona’s rule serves to preserve the State’s chosen standard for recognizing insanity as a defense and to avoid confusion and misunderstanding on the part of jurors. For these reasons, there is no violation of due process … and no cause to claim that channeling evidence on mental disease and capacity offends any “principle of justice so rooted in the traditions and conscience of our people as to be ranked as fundamental…” Id. at 2737 (citation omitted).

**Pharmacy Liability**

*Rite Aid Corp. v. Levy-Gray*, 894 A. 2d 563 (Md. Ct. of App. 2006) examines pharmacy liability for dispensing patient package inserts. Ms. Levy-Gray was diagnosed with Lyme disease on October 25, 2000 and given a prescription for doxycycline by Dr. Ronald Geckler. Dr. Geckler instructed Ms. Levy-Gray to discontinue nursing her son while taking the medication, but provided no further details as to how to take the medication. The prescription was filled at Rite Aid Pharmacy #4465 in Timonium, Maryland. Ms. Levy-Gray received an instruction and information packet known as a “patient package insert” (PPI), entitled “Rite Advice” with the prescription. She followed the package instructions to take the drug with food or milk if it caused an upset stomach. She received no alleviation of her symptoms of Lyme disease and developed post-Lyme syndrome. The question before the court was whether the pharmacy can be held liable under the Uniform Commercial Code for dispensing a PPI as an express warranty of a prescription drug.

An express warranty is a representation about a product by the seller to a buyer when the buyer relies upon the representation in purchasing the product. No particular words are necessary to create an express warranty. The PPI stated on its cover page: “Inside is everything you need to know about your prescription. It covers everything in writing from dosage to side effect. If you have any questions just ask your pharmacist.” Further the instructions in question provide: “How to take this medication: take each dose with a full glass of water (4 oz. or 120 ml) or more. Do not lie down for at least 1 hour after taking this drug. Take with food or milk if stomach upset occurs unless your doctor directs otherwise.” Ms. Levy-Gray alleged that this instruction indicated an express warranty from Rite Aid that she may take the medication with milk or other dairy products without any harmful affects, including rendering the medicine ineffective.

An affirmation of fact must become “part of the basis of the bargain” for the statement to be considered an express warranty. Rite Aid argued that to be a part of the bargain, the terms must be handed over during the negotiation process before the actual sale of goods. The terms were given to Ms. Levy-Gray by the pharmacy along with her prescription. However, if this interpretation was applied to most modern commercial transactions it would render almost all warranties today null and void. Most warranties today are not viewed before the payment transaction takes place, but typically come with a purchase. The court decided that while the warranty was technically handed over after Ms. Levy-Gray paid the purchase price, the proximity of the warranty’s availability to the delivery of the goods ensured it was a part of the bargain.

Rite Aid relied on the learned intermediary doctrine to absolve it of liability on the theory that patients rely on their physicians when purchasing a prescription drug because a pharmacist merely fills the prescription as ordered by the physician and does not give express warranties. Many courts agree with this general theory. This case is distinguishable from this general proposition because the pharmacy did in fact disseminate information to Ms. Levy-Gray concerning “everything you need to know about your prescription” in a packet titled “Rite Advice.” These statements seem to indicate Rite Aid’s affirmative decision to distribute information in its PPI on behalf of the pharmacy. The court found that this PPI did in fact constitute an express warranty from Rite Aid that Ms. Levy-Gray relied upon when she consumed milk and other dairy products with her medication, which caused it to become ineffective and led to further medical complications.

**HIV Trial**

Libya is currently seeking to impose the death penalty on five Bulgarian nurses and a Palestinian physician during a second trial based on accusations that the group infected hundreds of Libyan children with HIV. The workers were first arrested in 1999 and then convicted of infecting 426 children with the AIDS virus. Although this trial introduced evidence of confessions by two of the nurses during subsequent courtroom testimony, the nurses claimed coercion by torture. This first trial resulted in convictions and sentences of death by firing squad, however, this verdict was overturned on appeal. The second trial commenced following the European Unions’ and the United States’ unsuccessful attempts to garner release of the workers via establishment of a fund which holds several million dollars aimed at covering the costs of medical care for the children. Although Libyan medical authorities claim the virus was intentionally passed on to the children, multiple international HIV
Malpractice Screening Panels

A challenge to the constitutionality of pre-litigation screening was litigated in Smith et al. v. Hawthorne, M.D., 892 A.2d 433 (Me. 2006). Following several corrective operations, James Smith and his wife filed a notice of claim against Mr. Smith's original treating physician, Dr. Catherine Hawthorne. Mr. Smith's fractured ankle did not heal correctly after an infection remained untreated by Dr. Hawthorne. The notice of claim triggered Maine’s pre-litigation screening panel process, which is governed by 24 M.R.S. §§ 2851-2859 (2005).

The screening panel is required in medical malpractice actions brought in Maine courts absent an agreement by all parties to bypass the process. The process serves to distinguish claims of professional negligence, which merit compensation, from non-meritorious claims and further encourages early resolution of disputes. Under the statute, when a medical malpractice claimant files a notice of claim, the Maine Court appoints a chair for the panel that in turn chooses the two other members; one must be a health care practitioner and the other an attorney. A hearing is held after the parties begin discovery. The rules of evidence do not apply at the hearing; however, the burden is on the claimant to prove negligence and proximate causation by a preponderance of the evidence. If attempted mediation by the panel chair fails, then the panel makes findings by answering three standard questions: (1) whether the acts or omissions complained of constitute a deviation from the applicable standard of care by the health care practitioner or health care provider charged with that care; (2) whether the acts or omissions complained of proximately caused the injury complained of; and (3) if negligence on the part of the health care practitioner or health care provider is found, whether any negligence on the part of the patient was equal to or greater than the negligence on the part of the practitioner or provider.

Once the panel answers these questions, the findings are admissible in a subsequent action. Under the relevant statute, if the panel findings as to both the first and the second questions are unanimous and unfavorable to the person accused, the findings are admissible in any subsequent court action on those facts. If the panel findings are unanimous on all questions and unfavorable to the claimant, the findings are admissible in any subsequent court action on those facts against the same accused. If the answers to the first two questions are unanimous and affirmative then the accused must enter into negotiations. If the answers to those two questions are negative, the claimant must either release the claim or be subject to the admissibility of the findings of question two. This final statute requirement was at issue here, where a hearing was held and findings were issued. The panel found that the acts/omissions complained of by the Smiths constituted a deviation from the applicable standard of care by Dr. Hawthorne. However, the panel found that the acts/omissions complained of did not proximately cause the injury to Mr. Smith. As noted above, under 24 M.R.S. § 2857 (2005), only findings of the second question could be presented to the jury. The Smiths filed a medical malpractice complaint and moved to admit the panel’s previous findings on the basis that the relevant statutory provision was unconstitutional as it denied them their right to a trial by jury.

The court denied the motion and ruled that the provision was constitutional. Following a mistrial, a second trial was conducted and the panel findings regarding the lack of proximate cause were presented to the jury. The jury found for Dr. Hawthorne and the Smiths appealed to the Supreme Judicial Court of Maine.

In making its decision, the Court reviewed its earlier decision from the case of Irish v. Gimbel, 1997 ME 50, 691 A.2d. 664 (Me. 1997). Under the statute, all deliberations of the panel are confidential and privileged. A previous version of the confidentiality provision provided that when the findings were admissible they had to be presented to the jury without explanation; meaning that there could be no explanation of the panel deliberations or proceedings. In Irish, this requirement was challenged and the Court found that withholding information from the jury regarding the context of the panel proceedings in the face of highly prejudicial findings invited unprincipled evaluation and could only result in juror confusion. Thus, the statute was unconstitutional until it was later amended to remove the “without explanation” language.

The Court found Irish and the Smith cases comparable. In Smith, there were findings favorable to both the Smiths and Dr. Hawthorne, yet only the finding favorable to Dr. Hawthorne would be allowed, thereby distorting the jury’s fact-finding role. The Court further found that the evidentiary rule of completeness would be ignored if only one finding was allowed. The Court also noted the elements of the prima facie case for the cause of action, negligence and causation, were both relevant to the jury’s deliberations. Given only the lack of causation finding, the jury could be misled into believing the panel found Dr. Hawthorne to be not negligent, even though the panel unanimously found that she was. Both the admission of the panel’s findings without explanation in Irish and the partial admission of the panel’s findings in Smith invited unprincipled juror evaluation of the evidence that could only result in confusion. Thus, the application of subsections 2857(1)(B) and (C), which denied the Smith’s request to admit the panel’s findings on
negligence and comparative negligence and allowed in only evidence of
the findings on causation, was unconstitutional. Accordingly, the case
was remanded for further proceedings.

Poisoned Popcorn

Consumer advocates and workplace safety organizations have
aligned to challenge governmental agencies charged with over-
seeing a chemical added to microwave popcorn as a butter
flavoring. The groups allege that the chemical in question, diacetyl, has been linked to the pulmonary disease bronchioliti-
sis obliterans which eventually destroys the lung tissue. The
linkage first appeared in 2000 when workers at a microwave
popcorn plant developed this rare disease. The National Insti-
tute for Occupational Safety and Health tracked the linkage to
several other microwave popcorn factories and concluded that
diacetyl butter flavoring additive gave off toxic vapors when
heated. The workers in the quality-control areas of the factories
who are charged with popping and sampling the popcorn as it
comes off the line appeared to have the highest incidence of the
disease. Since then advocacy groups claim that OSHA, the FDA
and EPA have not enacted any new standards aimed at protect-
ing workers or the public exposed to microwave popcorn.
Congress may be taking note of the alleged linkage as Repre-
sentative Henry Waxman has been quoted suggesting that the
agencies may have passed the buck. Regardless of the relative
governmental inaction the plaintiff’s bar has moved quickly
and numerous lawsuits alleging damages on behalf of the work-
ers have been filed against the Flavoring companies. See
Schneider, Potential hazards to consumers from flavoring agent
unchecked, Baltimore Sun (August 30, 2006).

Paramedic Negligence

The alleged negligence of paramedics who triaged a patient but did
not transport was the topic raised in Lemann & Lemann v. Essen Lane
Daiquiris, Inc, 923 So. 2d 627 (La. 2006). On March 30, 2002,
Parker Lemann visited the French Quarter Daiquiris Bar in Baton Rouge,
Louisiana. During the night, a fight ensued between Mr. Lemann and
Freddie Paul. Two Baton Rouge police officers were called to the park-
ing lot where they found Mr. Lemann seated in his pickup truck. After
assessing the situation, the officers called for paramedics. Mr. Lemann
appeared to have cut himself as he had a blood-soaked t-shirt wrapped
around his left hand. Subsequently, two paramedics and an EMT arrived
at the bar and examined Mr. Lemann. The paramedics performed a physical
and visual assessment of Mr. Lemann and found only the injury to the
hand. One of the paramedics observed no indication that he had a serious
head injury. The paramedics performed a physical and visual assessment of Mr.
Lemann and found only the injury to the hand. One of the paramedics
even examined Mr. Lemann’s head and felt it for injuries. The court
denied the motion for summary judgment and the appellate court de-
nied a writ, which this Court granted.

The Court’s analysis centered on the elements required to state a
claim for negligence: (1) the defendant’s duty to conform his conduct
to a specific standard; (2) the defendant’s conduct failed to conform to
that standard; (3) the defendant’s conduct was a cause in fact of the
plaintiff’s injuries; and (4) damages. The focus was on the first element
and whether there was a law to support the claim that the paramedics
owed him a duty. The court recognized that the duty of a paramedic is to
render appropriate medical care based on the situation. The Plaintiffs
argued based on expert testimony, that the paramedics breached this
duty by not taking Mr. Lemann to a hospital. The expert testified that a
closed head injury, undetectable to the paramedics could have resulted
in Mr. Lemann’s condition and subsequent death. The Plaintiffs argued
that because Mr. Lemann had been in an altercation, the absence of an
obvious head injury should not keep the paramedics from examining
further. In addition, the paramedics failed to follow their own protocol
for head injuries, which would require them to transport Mr. Lemann
to a hospital. The court responded saying that the protocol for head inju-
rises was not relevant because on the night they saw Mr. Lemann the
paramedics observed no indication that he had a serious head injury.

Plaintiffs further contended that the differences in the officers’ and
the paramedics’ description of Mr. Lemann’s condition was material to
bar summary judgment. One officer testified that he wrote in the police
report that Mr. Lemann had “slurred speech” and was “very incoherent”
and made “erratic body movements.” The paramedics, on the other
hand, found Mr. Lemann to be alert and oriented. The court concluded
that the officers were under the impression that Mr. Lemann’s condition
was caused by intoxication, and not by a head injury. In ruling on the
motion, the court decided that the differences in the officers’ and the
paramedics’ observations were not material. They noted that there was
no evidence the officers told the paramedics about Mr. Lemann’s behav-
ior and at no time was evidence of head trauma revealed to them. The
court held that there was no duty on the part of the paramedics to
conduct an investigation beyond examining Mr. Lemann. There was no
obligation on their part to force Mr. Lemann to a hospital. Further,
under Louisiana law, adults have the right to refuse medical treatment,
which Mr. Lemann did. The court declined to hold paramedics liable
for respecting an adult’s right to refuse treatment and thus, their motion
for summary judgment was granted.
Physician Misconduct

Public Citizen, a watchdog group based in Washington, has issued a report claiming that physicians often receive minimal punishment from state and federal medical boards when convicted of crimes. The group examined the cases of some 2,247 physicians disciplined between 1990 and 1999. Study authors claim physicians in the following groups received relatively minor punishments such as fines, reprimands, or mandatory educational programs: 36% of physicians involved in prescription-controlled substances violations; 67% of physicians involved in insurance fraud, and 6% of physicians convicted of sexual related offenses. From this data the authors conclude that medical boards typically composed of predominantly physicians are too lenient with physicians who have broken the law. However, critics quickly point out that very few physicians are involved in criminal activity and the medical boards are strictest when the crime charged involved potential harm to a patient. The complete study was published in Health Matrix and interested members are encouraged to read the study in its entirety. See Kornblum, Bad doctors get slapped on the wrist, USA Today (August 30, 2006).

Controlled Substance Crimes

U.S. v. Prejean, 429 F. Supp. 2d 782 (E.D. La. 2006) involved numerous evidentiary objections filed by a nurse charged with controlled substance violations, including one based on destruction of evidence by hurricane Katrina. In September 2000, Ms. Prejean was arrested for illegally transporting scheduled substances without a license after a traffic stop revealed she was carrying approximately 1,659 dosage units of prescription drugs from her home to a clinic in a personal vehicle. Nothing came of this arrest. Then, in November 2004, Ms. Prejean agreed to a Consent Judgment with the Louisiana State Nursing Board. In the Consent Judgment, she admitted to the unauthorized transport of prescription drugs, failure to report her September 2000 arrest to the Nurse Practice board, failure to keep proper inventory of prescription drugs in her clinic, failure to provide safety measures to prevent drug abuse by patients, and failure to ensure the physician working for her had enough time to properly counsel and assess patients. As a result, Ms. Prejean was fined and threatened with suspension of her nursing license as of June 2005. During Hurricane Katrina, the government stored Ms. Prejean’s patient files and business records in a building used by the Drug Enforcement Agency in Metairie, Louisiana. The building sustained damage during the storm and some of the patient files were lost. Ms. Prejean, through eight pretrial motions, moved the court to make evidentiary rulings, restrict the scope of the charges and determine legal standards for the upcoming trial.

The first motion sought to exclude evidence of the September 2000 arrest as irrelevant and unduly prejudicial. Under Rule 609 of the Federal Rules of Evidence (FRE), typically evidence of convictions is allowed to discredit witnesses. However, FRE 404(b) allows evidence of arrests only when trying to prove intent, so long as notice is provided. Additionally, FRE 403 allows criminal activity that occurs during the timeframe of the charged act to be considered intrinsic and therefore, admissible, if the probative value outweighs the prejudice created by the evidence. The Court concluded that the arrest itself would be unduly prejudicial, but the circumstances and findings of the traffic stop were admissible as related to the other drug charges.

The second motion sought to exclude evidence of the Consent Judgment as reaching a legal conclusion, and therefore, usurping the power of the jury. The government argued that the Judgment was admissible as an admission under FRE 801(d)(2), was intrinsic under FRE 404, and demonstrated Ms. Prejean’s knowledge that the way she ran her clinics violated the law. The Court agreed and allowed evidence of the Consent Judgment to be presented at trial.

The final exclusionary motion moved to exclude evidence of the suspension of Ms. Prejean’s nursing license in June 2005. As this suspension was the direct result of the present offense and the government did not address the issue, the Court ruled this evidence would be prejudicial and outside the scope of the conspiracy, and as such, was excluded from evidence.

The next motion sought to require the government to produce testimony from any patient whose patient file would be used by the government as evidence during the trial. Ms. Prejean argued that the government’s use of statistical evidence from a random sampling of the patient files violates FRE 403, FRE 1006 and the Confrontation Clause of the United States Constitution. The Confrontation Clause prevents testimonial statements from being entered by witnesses who are unable to be cross-examined. Statements made in circumstances that would lead an objective observer to reasonably believe the statement could be used at a later trial are considered testimonial. Moreover, FRE 803(4) specifically excepts “statements made for purposes of medical diagnosis or treatment” from the hearsay rule and FRE 803(6) makes a hearsay exception for business records. In light of these rules, the Court ruled the medical records to be admissible as non-testimonial statements if the government used the evidence to prove factual information about the operation of the clinic but inadmissible as testimonial statements as used to describe the medical condition of a patient or the medical necessity of a particular treatment. Any testimonial statements will have to be backed up with evidence from a patient that will be available for cross-examination. The determination about whether individual statements are testimonial or non-testimonial was reserved until trial.

The next motion sought to limit the government’s use of the clinic’s records because Hurricane Katrina destroyed several of the records. Ms. Prejean argued that if the government stored the records in bad faith, it would violate the due process rights of the defendants, and if the government was simply negligent, the records should be suppressed as unduly prejudicial or as a sanction for the negligent conduct of the government. The Court, finding that the documents were not destroyed by the bad faith actions of the government, determined that there was not a due process violation and turned to the argument that the evidence was unduly prejudicial and should be removed as a sanction. The Court noted that the jury is permitted to draw adverse inferences from the destruction of evidence, as well as the availability of a jury instruction limiting the inferences the jury may draw and Ms. Prejean’s ability to argue the incompleteness of the record. In light of this, the Court
denied the motion to suppress the evidence, instead allowing the incomplete records into the trial so long as Ms. Prejean may challenge the evidence as incomplete at trial.

Ms. Prejean next moved the Court to strike surpluses from the Superseding Indictment as prejudicial and unnecessary. The Court noted that the Superseding Indictment would not be read at trial and that the information in the surpluses was relevant to demonstrate criminal liability in this case. As such, the Court ruled to leave the Superseding Indictment in tack.

Ms. Prejean’s next motion sought to dismiss Count One of the Superseding Indictment because it charges her and the clinics with two separate conspiracies in a single count, where the first conspiracy should be barred as untimely. The Superseding Indictment charges one conspiracy under 21 U.S.C. § 841 running from 1998 to 2005, with Ms. Prejean’s employment of various physicians as the continuous link. Ms. Prejean and the clinics argued that there was no conspiracy from 2000 to 2004 because there was no physician or DEA registrant identified as a part of the conspiracy during that period, and thus no violation of 21 U.S.C. § 841 during that time. The following elements are used to distinguish a single conspiracy from multiple conspiracies: 1) the time involved; 2) the persons acting as co-conspirators; 3) the offenses charged in the indictment; 4) the nature and scope of the criminal activity; 5) the locations of the alleged conspiracy. The Court noted that the clinics, although expanding during the timeframe, provided a centralized location as well as legitimacy and continuity throughout the conspiracy period. Although the physicians changed during the conspiracy period, the clinics and Ms. Prejean remained constant. While a non-physician must conspire with someone authorized to write prescriptions in order to violate 21 U.S.C. § 841, the Court found that Ms. Prejean’s employment of at least one doctor able to prescribe medications throughout the period was sufficient to make her the pivotal figure of the conspiracy. As Ms. Prejean employed physicians from 2000 to 2004, the Court ruled that only one conspiracy was charged, and thus, the motion to dismiss was denied.

Ms. Prejean and the clinics then asked the Court to find that the state medical regulations are not relevant in determining what constitutes “professional practice” or “legitimate medical purpose,” but rather to apply a nation-wide standard for these terms. While the federal government regulates and prosecutes the distribution of controlled substances, the practice of medicine is regulated predominantly and with a wide degree of variation, by the states. Violations of generally accepted medical practices, including state regulations, have usually been held relevant to prove criminal liability under 21 U.S.C. § 841. Since there is no nation-wide standard created by Congress for either “professional practice” or “legitimate medical purpose,” the state standard remains in effect. While violation of a state regulation for medical practice does not automatically make a person guilty of a federal offense, the violation is persuasive and relevant. Therefore, the Court ruled to follow a state-standard and allow evidence of state medical regulations into the trial. Ms. Prejean and the clinics also motioned for a requirement that the government demonstrate in an evidentiary hearing that the new standard has been met. Since the motion was not clear under what rule the government would now be required to provide an evidentiary hearing, the Court considered several possible rationales and denied them each in turn. Under rule 12(b)(3)(B) of the Federal Rules of Criminal Procedure, challenging the sufficiency of the information in the indictment, there is no requirement for an evidentiary hearing on this type of motion before a court. The Court may deny any hearing whose true purpose is to conduct discovery. Moreover, the Court noted that even if there were a new standard, the Superseding Indictment meets the heightened standard. As such, the evidentiary hearing was denied.

The final motion asked the Court to dismiss the entire Superseding Indictment for failure to state a claim. Ms. Prejean and the clinics argued that 21 U.S.C. § 841 does not apply to them because they are not registered with the DEA to dispense controlled substances. Alternatively, they argued that the statute is void for vagueness. 21 U.S.C. § 841 provides that: “Except as authorized by this subchapter, it shall be unlawful for any person knowingly and intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.” The statute has been interpreted to apply to “any person,” not just physicians and DEA registrants. As such, the Court held that Ms. Prejean and her clinics could be charged under 21 U.S.C. § 841 even though neither are physicians or DEA registrants. The Court then turned to the argument that the statute is void for vagueness for not creating a clear, nation-wide standard for “legitimate medical purpose.” Although the term has no clear definition so that physicians may use their professional judgment and discretion, the Court found that the statute prevents physicians from acting as drug-pushers and thus, is not standardless. Moreover, the repeated violations of state regulations were sufficient to provide notice to the accused. The Court noted that if the charge was simply over-prescription, the ruling might be different, but in light of the current case, the statute will stand.

Physician-Owned Hospitals

Recent changes to federal regulations regarding funding for physician-owned specialty hospitals may promote a substantial increase in the number of these enterprises but not without the larger general hospitals and some watchdog groups crying foul. These specialty hospitals proliferated rapidly in the 1990’s as physicians realized that certain procedures could be completed at these centers quite profitably. The next logical step was for physicians to open such facilities as a way of guarding against the ever decreasing amount of reimbursement from governmental payers. The hospitals typically focus on the better reimbursing orthopedic and cardiac procedures. However, the growth of these facilities was arrested in 2003 when federal regulators imposed a funding ban until now. Critics charge that physician ownership creates an inherent conflict of interest and leads to increasing numbers of self referrals for procedures which may be unnecessary or could be performed at larger general hospitals. However, strict financial disclosure laws exist resulting in fines of up $10,000 per day for failure to file the necessary disclosures. There is also disagreement on the outcome data as patients treated at these facilities tend to have fewer complications but are generally healthier overall thereby confounding the data. In fact the general hospitals claim that the specialty hospitals essentially cherry-pick the profitable health patients, leaving the public health care system to absorb the costs of treating the increasing burden of the underinsured patients. However, advocates of the specialty hospital system point to patient popularity and greater efficiency as major factors in the
The next issue was whether the alleged defect in the properties of Angio-Seal would have been a primary cause of Mrs. Gomez’s injuries. The two sides presented expert testimony on whether this was possible. The appellate court determined that issue also should have gone to a jury, as it was inferable that the alleged defect in Angio-Seal caused the injuries. The appellate court decided to remand this issue to the district court for a new trial.

**Emergency Contraception**

Although Barr Pharmaceuticals recently earned approval from the FDA to sell its emergency contraception pill, “Plan B,” over the counter the three year debate is far from over. Originally the company requested approval in 2003 to market the drug OTC to all age groups. This proposal was agreed to by the advisory panel but stopped by senior staff in the agency. A modified proposal seeking approval to sell the medication to those 16 and older was then submitted by the company. Following hearings this issue was placed on hold by the FDA citing a need for public hearings. Barr’s most recent approval allows the sale of Plan B to only those over 18 years of age and restricts the product to pharmacies in order to ensure age verification. Although a partial win for the company, many groups claim that the age restriction should be lifted and litigation aimed at accomplishing what is currently pending. This issue has become a sticking point for the Bush administration as several senators have stated their intention to block confirmation of the President’s nominee to head the FDA until the issue had been resolved. The recent announcement removes this roadblock.

Plan B is composed of hormonal derivatives similar to those found in birth control pills and consists of a first dose taken within 72 hours of unprotected sex and the second dose taken 12 hours later. The earlier it is taken the more effective the medication is, and can reduce pregnancy rates by up to 89%. However, if the woman is already pregnant the medication will have no effect. Prior to the FDA’s announcement, nine states already allowed pharmacies to provide Plan B without a physician’s prescription to women of any age. In these states minors will continue to be able to obtain the medication without a physician’s prescription. Although the final pricing information is not available, the company currently generates in excess of $30 million from the sale of Plan B, which sells for $25-$40 per packet. As part of the approval, Barr plans to have the product available by the end of the year and is required to monitor pharmacies for compliance with the age restriction via the use of “secret shoppers.”

**FMLA**

*Edwards v. Dialysis Clinic, Inc.*, 423 F. Supp. 2d 789 (Ohio 2006) explores an alleged employer’s interference with the rights protected by the Family and Medical Leave Act (FMLA), 29 U.S.C. § 2615, and the Ohio Civil Rights Act (OCRA), Ohio Rev. Code Ann. § 4112.02(A). Deirdre Chabot began working as a receptionist for Dialysis Clinic, Inc. (DCI) in February 2002. Subsequently, Chabot also began to perform some of the functions of a ward clerk, such as filing patient charts and providing assistance during crisis situations. Around the time of Cabot’s initial hire by DCI, her physician diagnosed her with bipolar disorder,
anxiety and anorexia. Chabot immediately informed a DCI supervisor of the diagnosis, but also admitted the diagnosed conditions did not prevent her from performing any aspect of her work with DCI.

In November 2004, Chabot's outpatient therapist recommended that she admit herself to a twenty-four hour a day treatment center, which required a minimum of one month's stay, based upon Chabot's deteriorated condition of anorexia. In response, Chabot informed a DCI supervisor that she was strongly considering admitting herself into the treatment center, and needed to know if she would be able evoke the FMLA regarding her absence from DCI. Mr. Salisbury, a DCI supervisor, responded by stating that Chabot would have to use her personal vacation days as part of her approved FMLA leave. Ultimately, Chabot decided against admitting herself to the treatment center because she did not want to use all of her vacation time.

Subsequently, in December 2004, Mr. Salisbury contacted Chabot's physician with concerns that she was possibly suicidal and demanded certain information regarding Chabot for the purpose of maintaining workplace safety. Thereafter, several DCI officials summoned Chabot for a meeting to discuss certain comments and actions of Chabot that raised workplace safety concerns among some of her co-workers. Chabot argues that the DCI officials mandated that she stay at her office and not speak to anyone, which forced her to resign from her position. Conversely, DCI claims that the officials merely instructed Chabot to not discuss her problems with staff members in a manner that raised safety concerns. Further, DCI argues several attempts were made to clarify the meaning of the meeting and there was no intent for Chabot to resign. Cabot then filed a complaint against DCI for (1) interference with FMLA rights, (2) disability discrimination pursuant to OCRA, (3) intentional infliction of emotional distress, and (4) invasion of privacy. Subsequently, DCI filed a motion for summary judgment and dismissal of the action.

The court analyzed the first claim by setting forth the necessary elements for an interference claim pursuant to the FMLA. The plaintiff must establish that (1) he or she is an eligible employee, (2) the defendant is an employer, (3) the employee was entitled to leave under FMLA, (4) the employee gave the employer notice of an intention to take FMLA leave, and (5) the employer denied the employee benefits to which he or she was entitled. Hodge v. Honda of Am. Mfg., Inc., 384 E3d 238, 244 (6th Cir. 2004). One major purpose of the FMLA is to prohibit employers from interfering with or restraining any rights provided to employees under its provisions. 29 U.S.C. § 2615(a). The court ultimately agreed with DCI that Chabot's interference claim failed because she did not provide notice of her intention to take FMLA leave and because DCI did not deny Chabot benefits, which she was entitled. Although the court recognized that Chabot did in fact express her consideration of a FMLA leave to a DCI official, this statement merely provided notice that she was considering a leave. Specifically, Chabot never formally requested a leave pursuant to the FMLA, and she ultimately decided not to take the leave. The court also determined that there was no evidence that DCI denied Chabot benefits to which she was entitled by DCI, specifically the use of earned vacation days. In fact, Chabot failed to identify any DCI employee that was not required to use earned vacation time as a part of his or her FMLA leave.

Next, in analyzing the second claim, the court outlined the relevant elements needed to establish a claim under the OCRA. In order to establish a claim for disability discrimination, one must claim (1) he or she is disabled within the meaning of the OCRA, (2) the employer took an adverse employment action, and (3) he or she could substantially perform the essential functions of the employment position. House v. Kirkland Capital Partners, 814 N.E.2d 65, 75 (Ohio Ct. App. 2004). The ORCA defines a person as disabled if “she has a physical or mental impairment, which substantially limits one or more major life activities, has a record of such impairment, or is regarded by her employer as having such impairment.” Id. Specifically, an employee is not disabled when diagnosed with a certain condition; rather, the employee is disabled when the condition “substantially limits a major life activity.” Toyota Moto Mfg., Ky., Inc. v. Williams, 534 U.S. 184, 195 (2002). The court determined that the record did not establish Chabot as disabled pursuant to the OCRA, and in fact, Chabot admitted in her deposition that her impairments did not impose any limitations on her ability to perform her duties with DCI. In addition, the court held that DCI did not regard Chabot as disabled because although DCI knew of the impairments, they did not regard them as substantial. In fact, DCI increased Chabot's job responsibilities, and gave her consistently good job performance reviews. Finally, the court ruled that because none of Chabot's complained incidents of unwarranted treatment by DCI resulted in any loss or tangible consequence, they were not adverse employment actions.

After establishing that Chabot did not have a viable claim pursuant to the FMLA or the OCRA, the court shifted its focus to the claim of intentional infliction of emotional distress. The court recognized that the judiciary only finds liability for such a claim when “the conduct has been so outrageous in character and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community. Yeager v. Local Union 20, 453 N.E.2d 666, 671 (Ohio 1983). In the case at bar, the court found that even if they held DCI's conduct as discriminatory, which they did not, the conduct was not atrocious or utterly intolerable as a matter of law.

Finally, the court examined the invasion of privacy claim regarding DCI's inquiry into Chabot's condition from her physician. The court recognized that under Ohio law, “an actionable invasion of the right of privacy is the...wrongful intrusion into ones private activities in such a manner as to cause outrage or cause mental suffering, shame or humiliation to a person of ordinary sensibilities.” Sustin v. Fee, N.E.2d 992, 993 (Ohio 1982). One of the over-riding purposes of the tort of invasion of privacy is to protect persons from having their medical information released without their consent. Rothstein v. Montefiore Home, 689 N.E.2d 108, 111-112 (Ohio Ct. App. 1996). Here, the court opined that there was no evidence on the record that Chabot's physician provided any information to DCI, and the court had not discovered any case in which liability was imposed where there was no actual disclosure of the patient's medical information. Simply contacting a physician regarding specific concerns about a patient's safety, even if accompanied with a demand for information, does not in itself warrant liability. Therefore, the court ultimately ruled in favor of DCI's motion for summary judgment on all of Chabot's claims, which the court dismissed with prejudice.
Prisoner Research Subjects

A new report prepared by the Institute of Medicine of the National Academy of Sciences suggests easing the current restrictions on utilizing prisoners as human subjects in research. However, prisoner advocates and some bioethicists, have claimed that the history of prior abuses is so strong and recent that the proposal raises significant concerns. Prior to the 1970s, about 90% of pharmaceutical research was conducted on inmates. However, this declined substantially when revelations about research abuses and ethical questions about coercion led to restrictions being enacted for researchers dealing with this protected class of subjects. Currently, prisoners can only be enrolled if the study poses no more than minimal risk. Under the proposal participation by prisoners would be broadened to include projects which had greater risk provided the potential to benefit the prisoners outweighed the risks. Additional safeguards such as independent review by a panel containing prisoner advocates, a requirement that the studies be those occurring later (and generally safer) phase of FDA approval, and a requirement that at least half of the subjects enrolled be nonprisoners are also recommended by the panels’ report. However, critics claim the significant financial pressures facing researchers today are too great to open the door even slightly without risking a return to prior abuses. They cite the entire cottage industry of contract research which has sprung up to provide scientists with the much need number of subjects. The prison population would provide a significant pool to draw from as it has quadrupled over the past 30 years to 2.3 million. Research proponents state that excluding prisoners from research may deprive them of the benefits of medical research as the prison population suffers disproportionately from HIV and hepatitis. See Urbina, Panel Suggests Using Inmates in Drug Trials, The New York Times (August 13, 2006).

Class Action

The New Jersey superior court reversed a trial court’s class certification for a group of hospital patients who were filmed for a reality show, and then claimed privacy rights violations in Castro v. NYT TV, 895 A.2d 1173 (N.J. Super. 2006). In a case of first impression in New Jersey, a state trial court certified a class of hospital patients who claimed that their right to privacy was violated when a television production company filmed them as part of a reality television show on emergency room health care. The statewide class consisted of all patients treated in the emergency room of the Jersey Shore Medical Center (JSMC) in Neptune, New Jersey, from June 26, 2001, to July 27, 2001, while New York Times Television (NYT TV) was filming for The Learning Channel’s “Trauma: Life in the ER.” The statewide class included more than 5,000 patients. In granting statewide class action status, the trial court found the case met the class action criteria of numerosity, typicality, commonality and adequacy of representation. NYT TV’s contention that problems of individual proofs should preclude a finding of commonality, to deny certification of a class action, was held to be without merit. NYT TV had filmed patients at 35 hospitals in 22 states over five years; however, the trial court limited the certified class to New Jersey and rejected the patients’ request for national scope. The trial court found that such a class would be unmanageable because it would involve analysis of invasion of privacy laws in each state. The patients who signed NYT TV’s consent forms claimed they were misled about the purpose of filming or were unable to make sound decisions because of their medical condition or medication. Claiming the television producers had fraudulently obtained their consent to film their injuries, the patients sued NYT TV, Discovery Communications Inc. (owner of The Learning Channel), and JSMC. The named plaintiffs are, Michael Castro, who was stabbed by his girlfriend, and Julio Trinidad Costa, whose hand was severed in an accident at work.

The suit alleges a common-law invasion of privacy claim. The appellate court listed the elements of invasion of privacy by unreasonable intrusion upon seclusion, as follows: One who intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns, is subject to liability to the other for invasion of his privacy, if the intrusion would be highly offensive to a reasonable person. Furthermore, to establish liability for this tort, a plaintiff must show that the interference with the plaintiff’s seclusion is a substantial one, of a kind that would be highly offensive to the ordinary reasonable man, as the result of conduct to which the reasonable man would strongly object.

Mr. Castro and Mr. Costa claimed the hospital gave the television crew the same clothing and identification badges worn by hospital staff. Mr. Castro also claimed that the producer violated an oral agreement not to disclose on television that his injury stemmed from domestic violence, while Mr. Costa, who spoke limited English, thought that even the cameramen were hospital employees. They allege that the hospital and the show’s producers told patients the filming was to be used for doctor training when it was actually free material for a shock cable TV show. As a result, the patients’ consent was allegedly obtained under false pretenses. Furthermore, they argue that the TV show has grossed hundreds of millions of dollars by exploiting emergency room hospital patients who are typically vulnerable and who are paid nothing for being subjected to intrusions into their private affairs.

Mr. Costa and Mr. Castro argued that a class action was required because thousands of patients may have been filmed for the show, too numerous a group to file as individuals, yet all subject to common legal issues. According to the patients, the variances in proofs would not be a problem, and a class basis was a more structured, efficient way to handle the claim on the part of the people affected. NYT TV argued that there was no way to try the case as a class action, because the issue on every claim would necessarily depend on the validity of the consent and there was no way to make that determination on a class-wide basis. They also argued that the composition of the class was never clearly defined, with the complaint identifying it as people filmed for the television program, while being described in subsequent pleadings as people filmed or observed by the producers. NYT TV claimed that while the original complaint was in time to meet the two-year statute of limitations, the expansion of the class was not, and should be barred.

The appellate court held that because the circumstances of the filming of the patients varied greatly, as did the circumstances under which they signed consent forms, liability and damage issues would have to be resolved on a case-by-case basis. Thus, the trial court erred by certifying any class, as issues of law or fact common to the putative class did not predominate over issues affecting only individual members. Therefore, it was proper to affirm the denial of certification of a nationwide class consisting of every patient videotaped or observed by the company in
any U.S. hospital. However, the case was remanded to the trial court. Consequently, patients may explore bringing class action suits in other states.

**Off-Label Talks**

The federal government has recently charged a psychiatrist with conspiring with a pharmaceutical company to illegally market a drug for off-label uses. Jazz Pharmaceuticals manufactures Xyrem that contains, as its active ingredient, GHB, which gained notoriety in the press as a date-rape drug, and is approved by the FDA for the treatment of narcolepsy. Dr. Peter Gleason began using the medication for the treatment of insomnia, depression, and fibromyalgia in his psychiatric practice after it was approved. Based on his high use the company approached him and inquired whether he would be interested speaking to other physicians about the medication. The FDA has strict rules prohibiting the drug's manufacturer from discussing off-label uses but these rules do not apply to physicians, including those hired by the company.

The evidence suggests Dr. Gleason was paid up to $3,000 per day for giving talks suggesting the off-label use of Xyrem and allegedly promoting the medication’s safety. Over the next few years these manufacturer-paid talks become a primary source of income, yielding more than $100,000 per year. Following one such talk, Dr. Gleason was arrested and handcuffed. The government prosecutor apparently asked Dr. Gleason to cooperate by assisting in the investigation of Jazz Pharmaceuticals. However, Dr. Gleason declined and was subsequently charged with conspiracy.

Apparently, the pharmaceutical company has severed its ties with Dr. Gleason, as he has retained his own attorney to represent him. Some have suggested that in a cruel twist of fate, the company may be cooperating with investigators with the charges against Dr. Gleason. Although FDA rules allow physicians to prescribe medications for any purpose, including those not listed on the product's label, many commentators state that physicians who do so should base their decision on evidence demonstrating positive benefit and not just anecdotal evidence of effects. Some claim the government is overreaching and fear that such actions may have a chilling effect on the discourse among physicians at CME meetings where innovative approaches to medications and treatments are often discussed. However, others point to the checkered past of Xyrem’s active ingredient as perhaps the primary impetus behind the investigation. The outcome of this test case will undoubtedly be watched by all pharmaceutical companies and should be required reading for those clinicians who continue to derive part of their income from giving industry sponsored talks. See Berenson, Indictment of Doctor Tests Drug Marketing Rules, *The New York Times* (July 22, 2006).
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If one watches the evening news, food safety litigation appears to be one of the growing areas of health-related litigation. This used to be limited to “mad cow” disease concerns or claims about a finger or some other contaminant found in some commercial chili. However, this past year has generated two significant outbreaks of E. coli contamination in the food system and the litigators have already begun to file their missives on the court. Several people died in a multistate recall of contaminated spinach and bulk salad mixes. Then, more recently, a large fast food chain was forced to recall its green onions after concerns over contamination with fecal bacteria. With all the potentially tortuous drivers on the road distracted by their cell phones, who would have thought that the greatest threat to your health comes from the salad or value menu purchase on the passenger seat next to you.

LMP readers will recall the news brief in a prior issue about the medical personnel charged with infecting Libyan children with HIV and facing an appeal after previously being convicted and sentenced to death. Researchers have come forward recently claiming that their analysis of DNA samples demonstrates that the HIV virus appears to come from a single outbreak of a type common in west Africa, which existed before the workers arrived. As previously mentioned, these researchers concluded that the ongoing infection was related to a systems problem of improper sterilization techniques. The court is scheduled to issue its verdict on December 19, 2006.

Continuing with the theme of updating prior news brief stories, the NIH Alzheimer’s scientist who was investigated after allegations of an improper relationship with industry surfaced was formally charged with engaging in a criminal conflict of interest by federal prosecutors. The crux of the charge stems from his failure to obtain approval for his consulting work with the pharmaceutical company and did not properly report his more than $250,000 in consulting fees. A few days later Dr. Trey Sunderland pled guilty under an agreement and if accepted will be placed on probation for 2 years and fined $300,000.

Finally, on the abortion front, the Supreme Court in November heard oral argument on the multiple challenges to the partial birth abortion ban enacted by President Bush. This decision is anxiously awaited by constitutional scholars as a potential window into how the new conservative composition of the Court will affect decisions on hot button issues such as abortion. When the Court faced a Nebraska statute with almost identical language it was declared invalid by a 5-4 vote. However, the judicial system is not the only arena in which abortion continues to be a topic of interest. During the recent election cycle the South Dakota electorate rejected their state’s previously enacted ban on abortion. This saga had been laid out in a former issue of LMP and has been very divisive for the citizens. Additionally voters in California and Oregon rejected provisions that would have required teenagers contemplating abortions to get parental approval prior to undergoing the procedure.
Organ Donation

Carey v. New England Organ Bank, 843 N.E.2d 1070 (Mass. 2006) examined whether an organ bank acted in good faith in connection with an anatomical gift and thus had immunity under the Uniform Anatomical Gift Act. Organ donation is a very sensitive and personal issue that can have great ramifications on the grief and well-being of surviving family members. Organ banks obtain consent for organ donations at moments when individuals are in shock at the death of a loved one. The Massachusetts Supreme Court recently had the opportunity to address the issue of whether the New England Organ Bank complied with the provisions of the Uniform Anatomical Gift Act, and whether this organ bank was immunized against judgment by the “good faith” provision of the statute.

On September 16, 2000, Adam Carey, the sixteen-year-old son of Richard Carey, was mortally injured in a vehicle crash. Adam received emergency treatment, but passed away one hour after the crash. The hospital staff discussed anatomical donations with Adam’s family, which resulted in a conversation between Mr. Carey and the New England Organ Bank. This conversation concluded with Mr. Carey completing a “Consent for Organ and Tissue Donation” form. However, moments before the organ bank completed the consent form, a nurse from the hospital reported that Adam’s tissues would not be suitable for human transplantation. Despite this information, the organ bank completed the Carey’s consent form. Following an inaccurate recording of Mr. Carey’s wishes about which of Adam’s tissues would be donated for transplantation, the organ bank harvested Adam’s tissues. During the next few days, the organ bank noted that the harvested tissues were unsuitable for transplantation, yet despite this, the organ bank erroneously reported a successful transplant to Mr. Carey. Although the organ bank subsequently apologized, Mr. Carey was unable to acquire Adam’s remains for internment, as they had already been discarded.

Mr. and Mrs. Carey filed suit against the New England Organ Bank and the New England Eye & Tissue Transplant Bank, as well as the Eye & Tissue Bank’s parent organization, Tissue Banks International. The trial court granted summary judgment to the organ banks after determining that the “good faith” provision of the Massachusetts version of the Uniform Anatomical Gift Act (UAGA) provided them with immunity.

The UAGA was intended to encourage the making of anatomical gifts by eliminating uncertainty as to the legal liability of those authorizing and receiving anatomical gifts. The Careys contend that the organ banks did not adhere to the statute in several respects.

The Careys’ first argument was that Massachusetts General Laws c. 113, § 8(b) prohibited the organ bank from soliciting the Careys’ consent for anatomical decisions. General Laws c. 113 § 8(b) requires that a hospital or its “designated representative” inform certain individuals of the opportunity to donate gifts for transplantation. Yet, the Massachusetts Supreme Court concluded there was no indication in the record that showed these organ banks were designated representatives of the hospital within the meaning of the statute. Even if the organ banks were the hospital’s representatives, however, the court reasoned that § 8(b) neither obliged nor prohibited a discussion of the opportunity to make an anatomical gift. The duty to inform where certain conditions are present does not imply a prohibition in the absence of those circumstances.

The Careys’ second argument was that the organ bank must inform those authorizing anatomical donations of any circumstances affecting the organ’s usability for human transplantation. However, the court observed that the statute does not suggest any limitation with respect to

the disclosure of risk factors for unsuitability. Importing such a disclosure requirement would raise the specter of litigation whenever a donated organ later proved unsuitable for transplantation.

Third, the Careys argued that the organ bank failed to “record” consent as required by General Laws c. 113, § 10(e). General Laws c. 113, § 10(e) specifies that any gift shall be made by documents signed by a person, or made by his telegraphic, recorded telephonic or other recorded message. Consent here was made by telephone, and § 10(e) requires that such communications be recorded. No recording existed in this case. Therefore, the defendant organ banks violated this provision.

With the identification of an act or omission within the scope of the statute, the court next examined whether the organ bank nevertheless acted in good faith, thus making the organization immune. The court defined good faith, as an honest belief, the absence of malice or the absence of a design to defraud or to seek an unconscionable advantage over another. When the defendant seeks a summary judgment on an area of good faith, the plaintiff has the burden of providing evidence on the defendant’s lack of good faith. The plaintiffs proffered three arguments for which the defendant organ bank did not act in good faith.

First, the Careys argued that the organ bank’s non-compliance was egregious. The court disagreed, stating that incorrectly interpreting the statute was not an egregious error. Second, the Careys contend that the subsequent letter, with misinformation regarding Adam’s gifts, showed lack of good faith. However, the court points out that the Careys failed to show the errors were more than a common administrative inaccuracy, which does not lead to a lack of good faith. Finally, the Careys maintain that the financial relationship between the organ bank and other entities displays a lack of good faith. Yet, the court noted that the Careys failed to show any significant connection between the financial relationships, initiated well after the organ bank destroyed Adam’s donated tissues and organs and any failure to adhere to the statute in this case. Therefore, the Massachusetts Supreme Court held that The New England Organ Bank acted in good faith in connection with anatomical gifts and thus had immunity under the Uniform Anatomical Gift Act.

Medicare

The Second Circuit determined that the Medicare statute authorizes the use of metropolitan geographic statistical to determine reimbursement. Bellevue Hospital Center v. Leavitt, 443 F.3d 163 (2nd Cir. 2006). Seventy-six hospitals challenged the Department of Health and Human Services’ (HHS) implementation of a statutory requirement concerning Medicare reimbursements. The hospitals objected to manner in which an agency payment scale that utilized differences in hospital wage levels across geographic areas was applied to Manhattan hospitals. Under the current Medicare payment scheme, hospitals are not reimbursed for their actual costs, but are instead paid fixed rates for providing specific kinds of treatment. Separate rates are set for hospitals in urban and rural areas. The HHS Secretary is required to adjust the prospective payment rates for area differences in hospital wage levels by a factor established by the Secretary, which reflects the relative hospital wage level in the geographic area of the hospital compared to the national average wage level. The Secretary must compute a wage factor for each hospital, which reflects the relative wage level in that hospital’s geographic area, and then apply that factor to the base rate that is

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Thrombolysis (Tissue Plasminogen Activator) in Stroke

Acute ischemic stroke is a leading cause of death and disability in the United States. One-third of patients who experience stroke die within 1 year. It has been estimated that ~600,000 new cases occur yearly. In 1995, 624 patients were randomized in the National Institute of Neurological Diseases in Stroke (NINDS) study demonstrating that intravenous recombinant tissue plasminogen activator (rtPA, alteplase) produced clinical and statistical benefit over placebo for patients treated within 3 hours of evaluation. National Institute of Neurological Disorders and Stroke. Tissue Plasminogen Activator for Acute Ischemic Stroke. 333 N Engl J Med. 1581-1587 (1995). The benefits also appear to be long-lasting at 3 months and 1 year as well as cost-effective, thus generating a great deal of enthusiasm. Specifically, it was stated that if the guidelines for eligible patients were followed within a 3-hour time period then there was at least 30% more likely to have minimal or no disability at 3 months and a 30-month mortality of 17%. There was a 6.4% risk of intracerebral hemorrhage. Id.; NINDS rtPA Stroke Study Group, Intracerebral Hemorrhage after Intravenous tPA Therapy for ischemic Stroke. 28 Stroke 2109-2118 (1997). On the basis of these results, alteplase (rtPA) was approved in the United States for use within 3 hours of onset of symptoms. However, closer scrutiny of this study raised methodologic concerns that there was an imbalance in stroke severity scores between groups from 90 to 180 minutes. Specifically, the placebo-treated group had more severe strokes than the tPA-treatment groups, and thus the results favored the mild stroke groups. Hoffman J. IV tPA Interventional Therapy for Acute Stroke Patients: Negative Position. Stroke Interventionalist. 2002;11:6-10; Solomon R, Hoffman J. tPA for Acute Ischemic Stroke: The Standard of Care? ACEP News. 2001; 10; Mac; Lenzer J. Alteplase for stroke: money and optimistic claims buttress the “brain attack” campaign. BMJ. 2002;324:723–726. Others felt that chance could explain the benefits. A prior European multicentered trial (ECASS I) of 620 patients used a maximum interval from onset to treatment of 1.1 mg/kg with 6-hour window. Hacke W et al. Intravenous thrombolysis with recombinant tissue plasminogen activator for acute hemispheric stroke: The European Cooperative Acute Stroke Study (ECASS). JAMA. 1995;274:1017–1025. This was a higher dose than used in the NINDS trial and resulted in a negative study with no difference between treatment and placebo groups. A high degree of protocol violations were also noted. Mortality was increased 33% as well as increased intracerebral hemorrhage in the treatment group of 40%. A follow-up study ECASS II of 800 patients was subsequently designed with a lower dose of alteplase (0.9 mg/kg) which was identical to NINDS criteria given IV within 6 hours of onset. Hacke W et al. Randomized, double-blind, placebo-controlled trial of thrombolytic therapy with intravenous Alteplase in acute ischemic stroke (ECASS II). Second European-Australasian Acute Stroke Study Investigators. Lancet. 1998;352:1245–1251. Stricter criteria were followed as well as CT eligibility and blood pressure control parameters. The results indicated that mortality was not increased and supported the use of dose of 0.9 mg/kg within 3 hours of stroke onset. However, there was a 2-to-5-fold increase in symptomatic intracerebral hemorrhage.


A disturbing community study from the Cleveland area’s experience revealed that 2% of admitted patients with acute ischemic stroke received intravenous tPA. There was a 50% incidence of protocol deviation from national treatment guidelines. In-hospital mortality was higher among treated patients (16%) compared with placebo (5%) and there was a 16% rate of intracerebral hemorrhage with a 55% mortality in this group. These findings significantly differed from the NINDS trial. Katzan IL et al. Use of Tissue-type Plasminogen Activator for Acute Ischemic Stroke: The Cleveland Area Experience. JAMA. 2000;283:1151–1158.

In August 2000, the American Heart Association upgraded its recommendation of tPA for stroke from optional (Class IIb) to definitely recommended (Class I) despite safety and efficacy concerns from the treatment. Several national groups made position articles contrary to the above. Of note, all major emergency medicine organizations in North America, i.e. the American College of Emergency Physicians (ACEP), the American Academy of Emergency Medicine (AAEM), the Society for Academic Emergency Medicine (SAEM), and the Canadian Association of Emergency Physicians (CAEP) have explicitly refused to endorse tPA as standard of care in their position papers. These organi-
zations represent over 40,000 emergency physicians who are at the forefront of care and this fact cannot be ignored by the AHA/ASA and needs to be addressed. Further, the Canadian Association of Emergency Physicians (CAEP) has stated that “further evidence is necessary to support the wide-spread application of stroke thrombolysis outside of research settings.” CAEP COMMITTEE ON THROMBOLYTIC THERAPY FOR ACUTE ISCHEMIC STROKE. POSITION STATEMENT ON THROMBOLYTIC THERAPY FOR ACUTE ISCHEMIC STROKE. CANADIAN ASSOCIATION OF EMERGENCY PHYSICIANS. CJEM 2001;3:8–12. AVAILABLE AT: WWW.CAEP.CA/002.POLICIES/00202.GUIDELINES/THROMBOLYTIC.HTM. Also, the American Academy of Emergency Medicine reached a similar conclusion and has stated that: “objective evidence regarding the efficacy, safety, and applicability of tPA for acute ischemic stroke is insufficient to warrant its classification as standard of care.” AAEM WORK GROUP ON THROMBOLYTIC THERAPY IN STROKE. POSITION STATEMENT OF THE AMERICAN ACADEMY OF EMERGENCY MEDICINE ON THE USE OF INTRAVENTOUS THERAPY IN THE TREATMENT OF STROKE. AVAILABLE AT: WWW.AAEM.ORG/POSITIONSTATEMENTS/THROMBOLYTICTHERAPY.HTML. Critics of the AHA's approval based only on 1 NINDS study led to further investigation demonstrating that in the minutes of AHA Board of Directors meeting of October 18, 1991, Genentech contributed $2.5 million to build the Dallas headquarters of AHA, and subsequent contributions to AHA have totaled $11 million. LENZER J. ALTEPLASE FOR STROKE: MONEY AND OPTIMISTIC CLAIMS BUTTRESS THE “BRAIN ATTACK” CAMPAIGN. BMJ. 2002;324:723–726. A panel of nine was responsible for the guidelines and 1 investigator noted that six out of eight panelists who supported alteplase for stroke as a Class I recommendation had ties to the manufacturer. The specific decision, however, to approve could have been reflective of scientific analysis of the data rather than the alleged taint of financial conflict. Two panelists who supported the upgraded classification had no ties to the manufacturer and one physician dissented from the recommendations.

Currently, there is a major disconnect between advocates who believe the AHA position has sufficient data to justify Class I position contrasted by critics who do not believe tPA should represent the standard of care in acute ischemic stroke. Though industry participation was acknowledged in the NINDS study, the AHA has never acknowledged any conflict of interest of its panelists and continues to hold financial “disclosures” secret. The implication of financial tint as well as refusal to release the NINDS raw data under the Freedom of Information Act to the British Medical Journal has only fueled this controversy. Further, there has been growing skepticism regarding industry-sponsored studies and this has been recently addressed in editorials in Neurology as well as JAMA.


Current Catalyst

Despite the debate regarding efficacy and safety of tPA in acute ischemic stroke, there has been significant pressure exerted on physicians and hospitals to expand its use. In 2000, the Brain Attack Coalition (BAC) proposed numerous specific criteria for developing academic primary stroke centers so that a standardized treatment would prevail which would facilitate early treatment. None of the 11 BAC recommendations was associated with the reduction of inhospital mortality or an increased frequency of discharge to home. ALBERTS MJ ET AL. RECOMMENDATIONS FOR THE ESTABLISHMENT OF PRIMARY STROKE CENTERS. BRAIN ATTACK COALITION. JAMA. 2000;283:3102–3109; DOUGLAS VC, TONG DC, GILLUM LA, ZHENG S, BRASS LM, DOSTAL J, JOHNSTON SL. DO THE BRAIN ATTACK COALITION’S CRITERIA FOR STROKE CENTERS IMPROVE CARE FOR ISCHEMIC STROKE? NEUROLOGY. 2005;64:422–427.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) began certifying primary stroke centers in 2005 using guidelines based on the American Stroke Association and BAC. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS. PRIMARY STROKE CENTERS. JULY 13, 2004. AVAILABLE AT: HTTP://WWW.JCAHO.ORG/ISO/psc/index.htm. Several states’ health departments (New York, California, North Carolina) have been active in trying to create community stroke centers. New York State has compelled emergency medical services to divert appropriate stroke patients past a closer hospital to a state designated stroke center within 2 hours. CAMILO O, GOLDSMITH LB. STATEWIDE ASSESSMENT OF HOSPITAL-BASED STROKE PREVENTION AND TREATMENT SERVICES IN NORTH CAROLINA. STROKE. 2003;34: 2945–2950; CALIFORNIA ACUTE STROKE PILOT REGISTRY (CASPR) INV. PRIORITY INTERVENTIONS TO IMPROVE RATES OF THROMBOLYSIS FOR ISCHEMIC STROKE. NEUROLOGY. 2005;64:654–659.

Medicare has now created a new DRG 559 code for “acute ischemic stroke with use of thrombolytic agent” which pays about $6,000 more than the previous DRG 014. TONG D. STROKE CERTIFICATION AND YOU: WHAT DOES THE FUTURE HOLD. PRACTICAL NEUROLOGY. 2005;21–23.

Current Standard of Care

It is clear that currently there is no universal standard of care. SOLOMON R, HOFFMAN J. tPA FOR ACUTE ISCHEMIC STROKE: THE STANDARD OF CARE? ACEP NEWS 2001;MAY. Less than 2% of community hospitals use tPA. The anticipation that this number will increase is attributable to the direction of Board of Health, JCAHO and Medicare. It is also clear that there are strong advocates and critics as well as cautious, concerned clinicians and the practicing physician and patient are in the middle of a quagmire. CAPLAN LR. THROMBOYSIS 2004: THE GOOD, THE BAD AND THE UGLY. REV NEUROL DIS. 2004;1:16 –26; CAPLAN LR. EVIDENCE-BASED MEDICINE: CONCERNS OF A CLINICAL NEUROLOGIST. J NEUROL NEUROSURG PSYCH. 2001;71:569 –576; CAPLAN LR. TREATMENT OF ACUTE STROKE. STILL STRUGGLING. JAMA. 2004;292: 1883–1885.

What is the correct decision? This is currently not known from the literature, yet this has not stopped the generation of civil (medical malpractice) lawsuits for both the use and nonuse of tPA. McINTYRE K. MEDICAL LEGAL IMPLICATIONS OF THE CONSENSUS CONFERENCE: CHIEN, 2001;11:357S–3438; PHYSICIANS RECIPROCAL INSURERS. DOCUMENTATION OF MEDICAL REASONING/JUDGEMENT. ALERT: 2006;1. There has been a shift in court thinking to accept “community care” rather than standard of care (nationwide). Thus, if neighboring hospitals are designated stroke centers, individuals may be held to an elevated criterion.

Definitions

“Malpractice” is defined as any medical treatment that fails to conform to the standard of care within the profession and that proximately results in injury to the patient. Plaintiffs have the burden of proving their case by a preponderance of the credible evidence (51%). They must show that there was a departure from standard and accepted medical practice and that this departure caused or was a substantial contributing factor causing the alleged injuries. Current tort law requires a physician-expert statement of deviation and negligence in order to initiate a lawsuit. In many states, any licensed physician can testify as an expert. Expert witness testimony is often indispensable in medical malpractice outcomes with opinions offered on behalf of both plaintiffs and defendants. Guidelines exist as to the qualifications in many specialty organizations.
In the United States, physicians and hospitals are involved in lawsuits whether they use or do not use tPA. Although all medical malpractice claims measure a physician's actions against a standard of care, how does one address this issue in controversial and evolving standards of care? “Maloccurrence” is defined as a negative outcome based on the natural history of the condition. There is often a fine line between negligent medicine and poor quality of care or inherent risks of disease. Persuaded by partisan expert witnesses, the jury often cannot tell the difference between medical malpractice and maloccurrence, standard of care and evolving standard of care. These issues are of paramount importance because there is a major thrust by national organizations to expand the number of stroke centers in the United States. It is clear that physicians in hospitals are faced with increased malpractice risk in dealing with stroke and thrombolysis.

**Elements of a Malpractice Claim**

Currently, there is a marked increase in the number of lawsuits regarding stroke and tPA. Physicians are currently being sued if they treat or do not treat with tPA. This topic is somewhat complex but usually revolves around several issues relating to documentation, informed consent, etc. Inherent in this is the fact that there are protocol deviations noted with absence of National Institutes of Health Stroke Scale (NIHSS) in 84%, and a recent retrospective analysis study revealed that one major protocol deviation in 67% and 97% had combined major and minor protocol deviations. When protocol deviations arise, there is increased mortality and morbidity. Deng YZ et al. IV tissue plasminogen activator use in acute stroke. Experience from a statewide registry. Neurology. 2006;16;306 –312; Brown DM, Kim N, Concato J, Krumholz HM, Brass LM. Thrombolysis for acute stroke in routine clinical practice. Arch Int Med. 2002;162; 1994–2001.

The Locality Rule, which calls for physicians to be judged according to the standards of practice in their communities, has been in decline because of the explosion of information on the Internet, etc. The current burgeoning of local stroke centers in the community has now produced a change from “nationwide standard of care” to “standard of community care.”

“Competence (testamentary capacity)” is the threshold element of informed consent because only a competent person can give valid consent to treatment or treatment refusal. Physicians are obligated and must make an assessment of the individuals capacity or lack of capacity before accepting a patient’s consent or refusal as being informed. Thor v. The Superior Court of Solano County, 855 P.2d. 375, 381 (Cal. 1993). Under emergency situations where the patients lack testamentary capacity, the physician should turn to a family member for consent if time and circumstances permit. It is noteworthy that a recent study found a substantial percentage of patients who received tPA for stroke had no consent documented. Surrogates often provided consent (63%) despite patients having capacity. Additionally, patients with diminished capacity sometimes provided their own consent. In one study 16%, of stroke patients treated with tPA had no documented informed consent. Rosenbaum JR, Brantza DM, Concato J, Brass LM, Kim N, Fried TR. Informed consent for thrombolytic therapy for patients with acute ischemic stroke treated in routine clinical practice. Stroke. 2004;35;353–355.

“Informed consent” refers to the legal principle that patients have the right to make an informed judgment as to their care after receiving the pertinent facts regarding a proposed treatment option rather than the appropriateness of the treatment. Informed consent should include statements regarding the condition being treated with its associated morbidity and mortality and if a specific treatment is being offered, describe state of current knowledge, i.e., accepted standard of care or controversial therapy as well as risks associated, and specifically describe hemorrhage into the brain, spinal cord and death. Because of the critical 3-hour time window, physicians must offer a timely transfer and this must be documented to both the patient and/or family (surrogate). Failure to do so may result in liability.

**Documentation**

This issue is critical to the success or failure of a lawsuit. Despite all allegations, legible documentation remains the key factor that leads to success or failure of a claim in a significant number of cases. In the time of the trial is often years later, an accurate memory for the events can be reflected only by the records. Physicians need to adopt good habits of documentation to be aware of their obligations. A number of malpractice cases have been reported to a large malpractice insurer and were found to be “difficult to defend, not because of the medical care, but because the physicians did not document their thought processes in the medical records.” Physicians Reciprocal Insurers. Documentation and informed consent. Neurologic Clinics of North America. In: Weinerbraub MI, ed. Medical and Legal Aspects of Neurology. Philadelphia, PA: W.B. Saunders, 1999, 371–381.

**Methodology**

A legal search of Jury Verdict Reporter (JVR) in Lexis and Westlaw regarding thrombolysis (tPA) and malpractice produced various case reports related to the heart, peripheral arterial and venous disease and stroke. The following cases were selected to illustrate and represent the types of malpractice lawsuits generated that should be of concern to neurologists, emergency room physicians and hospitals. It does not represent a selection bias and I hereby affirm that I personally do not know or have any relationship with any of the individual parties or their attorneys.

As will be noted, these vignettes are inconsistent in detail from venue to venue and were submitted not by physicians but by the involved successful attorney to JVR which may also have edited the vignette. Hospital records, deposition or trial testimony transcripts were not personally reviewed for more detailed clinical information. However, the Courts and Arbitration panels in each of these cited cases accepted the alleged damages as representing “stroke.”

**A. Failure to Use tPA. Absence of a Specific Hospital Protocol**

Reed v. Grandbury Hospital, 117 S.W.3d 404 (Tex. App.— Ft. Worth 2003)

Plaintiff experienced stroke-like symptoms and was taken to a local hospital 10 minutes away. His wife (nurse) wanted tPA to be used but Emergency Room physician (defendant) did not choose this option and wife transferred him to local Fort Worth Hospital for specific tPA.
treatment. He arrived outside the 3-hour window and did not receive treatment. The original defendant hospital did have tPA available and had a written protocol for administering only to cardiac patients. The Trial Court determined that both of the Plaintiffs’ experts were not qualified to opine on the standard of care for the hospital defendant with respect to tPA protocols. Id. at 408. As a result, the Court granted no evidence summary judgment for the defendants with respect to the hospital’s negligence. Id. at 408. Despite plaintiff’s expert, the Court stated that there was no showing that a common or universal standard of care for administering tPA to stroke patients applied to both physicians and hospitals or even to all physicians. The case was appealed and the Court of Appeals affirmed the Trial Court’s decision.

B. Failure to Offer tPA or Promptly Transfer to Another Hospital

Mei v. Kaiser Permanente South San Francisco Medical Center

In 2001, 45-year-old woman (plaintiff) experienced a stroke while driving. An ambulance took her to local hospital (defendant). The Emergency Room doctor diagnosed her with “depression and stress” for her symptoms of aphasia, inability to walk and facial weakness. A neurologist did not see her for a total of 6 hours. An arbitrator found negligence.

Lane v. TH Allied Services IC

In 1996, plaintiff experienced a stroke after an endoscopy procedure at Boone City Hospital (defendants). An emergency CAT scan was ordered and performed revealing findings compatible with ischemic stroke. The attending physician recommended transfer to the Intensive Care Unit (ICU) and emergency treatment with tPA. However, the orders for transfer and administration of treatment of tPA were not carried out. A Neurology consultation was called to determine whether anything else could be done after 5 hours. She then started tPA 6 hours and a half hours after the onset of symptoms. There was no benefit and the patient had residual dysphasia and hemiparesis. There was a plaintiff’s settlement of $500,000.

Herbert Paige and Annette Paige vs HCA Health Service of Florida, Inc. d/b/a Blake Medical Center: Robert C Gessner MD, and Steven A Norris, M.D. Manatee County (Fl), Circuit Court. Case No 2000 CA-1895.

Plaintiff experienced an ischemic stroke in February 1998 and was brought to Blake Medical Center (defendant) where he was evaluated by Emergency Room physician (defendant). The on-call neurologist (defendant) examined the patient and spoke with patient and physician son regarding treatment options and they decided on heparin. A second neurological opinion was sought and it was later determined that plaintiff was a candidate for tPA treatment. Defendant neurologist stated that this was untrue because symptoms were improving. Because of residual damages, the patient and his wife filed a lawsuit against defendant medical center and all involved physicians for failure to recommend tPA. A settlement of $50,000 was reached with defendant hospital. The claims against defendant Emergency Room physician were dismissed before trial. A defense verdict was returned for defendant neurologist.

C. Stroke Misdiagnosis as Vertigo and Loss of Chance


Fifty-seven year-old male (plaintiff) with prior history of stroke complained of sudden headache, blurred vision, dizziness and weakness. He went to the local hospital (defendant) Emergency Room where Emergency Room physician (defendant) diagnosed vertigo and sent him home. He was on clopidogrel (Plavix) for prior stroke prophylaxis. He returned several times to the Emergency Room and ultimately was admitted with stroke symptoms of slurred speech, right facial numbness and inability to walk. A lawsuit ensued for failure to diagnose stroke and loss of opportunity to give tPA, because it was alleged that this intervention could have significantly improved outcome. Verdict: $5 million to plaintiff.

D. Complications of Therapy/Failure of Informed Consent

Brooks v. SSM HealthCare and Fernando DeCastro, MD 73 S.W.3d 686 (Mo. Ct. App. 2002).

The plaintiff brought actions against the doctor and hospital for negligently administering tPA, which rendered the patient quadriplegic secondary to cervical epidural hematoma. She required two surgeries and was left with permanent incontinence of bowel/bladder, flaccid quadriplegia and wobbly head. A jury awards plaintiff $315,000 but defendant requested a new trial, which was granted by the Trial Courts, a decision that was reviewed by the Court of Appeals. While defendant cardiologist was using the drug for a cardiac condition, he did not specifically mention bleeding and also used higher amounts of tPA. Defendant cardiologist contested the plaintiff’s neurology expert’s qualifications in his rendering of the opinion because he did not have a knowledge of tPA as it applied to the heart rather than the brain. The Court of Appeals reversed the Trial Court’s decision to grant a new trial and reinstated the jury verdict.

E. Hemorrhagic Stroke After tPA/Informed Consent

Wilma Harris and Philip Harris vs Oak Valley Hospital District, Mohammed S. Al-Husan MD, Stanislaus County (CA) Superior Court, Case # 387697.

Plaintiff was a 65 year-old female who presented to the Emergency Room with stroke-like symptoms and hypertension. A CAT scan revealed an ischemic stroke and tPA was started. She subsequently developed an intracerebral hemorrhage producing permanent damages of dysphasia and walking difficulties and started a malpractice suit alleging that the tPA should not have been given and that her blood pressure was not adequately controlled and that her symptoms were rapidly resolving before the inappropriate administration of tPA. The defense argued that the patient and family received appropriate informed consent and that her blood pressure was in the appropriate range and under good control. A defense verdict was reached.

Expert Witness Testimony

The following 2 cases illustrate the influence of expert witness testimony in failure to offer tPA or transfer to local stroke center.


The patient was brought to local hospital with sudden paralysis. Stroke work-up was concluded 2 hours after onset but tPA was not given and residual damages occurred generating a lawsuit for allegations of loss of chance, failure to transfer and failure to treat. Dr. S. Levine, a stroke neurologist expert for plaintiff, admitted that he could not say how much the patient’s condition would have been expected to improve in this last available hour of window but that “it was more likely than not that there would be “some improvement.” He also acknowledged that there was a “20% spontaneous improvement without tPA.” The Trial Court approved summary judgment for the defense but the patient appealed. The Court of Appeals felt that plaintiff neurological expert’s testimony was “speculative” and that the patient could not show that opportunity to achieve better results exceeded 50% had tPA been given by ER within 3 hours. The decision was affirmed.
Wojcicki v. Caragher, MD, 849 N.E.2d 1258 (Mass. 2006)

The patient (plaintiff) was brought to Emergency Room of Addison Gilbert Hospital (defendant) after experiencing a “severe stroke.” Dr. Caragher (defendant) decided not to treat with tPA or transfer to another hospital. The patient had acute breast cancer with lymph node metastases, a falling hematocrit and was receiving chemotherapy. The defendant’s expert witness, Dr. Fred Hochberg, a well-known neuro-oncologist at Massachusetts General Hospital, stated that he was familiar with an NINDS study published in December 1995. He stated that there were no patients with breast cancer in the NINDS study. He also stated that no patients in the NINDS study had cancer. He never reviewed the CD-Rom disk of the study, which led to the defendant’s verdict, based on his testimony. The plaintiffs appealed, stating that defendant neurological expert gave “false and misleading testimony” and provided an affidavit from Dr. John Marler, the NIH coordinator for the NINDS study, which indicated that 59 of the 624 patients in the study responded affirmatively to a question on the baseline history form about malignancy. Another affidavit by Dr. Barbara Tilley, the lead Biostatistician for the study, confirmed that 59 patients responded positively to the questionnaire relating to diagnosis of malignancy. In Dr. Hochberg’s deposition on 01/25/04, he strenuously defended his trial testimony. He also stated that he spoke personally with Dr. Tilley 2 weeks before the trial and she said that the patient would not be a candidate for tPA. He also testified that he spoke with a secretary of Dr. Marler who suggested that he call Dr. Tilley. He made the calls from his office at Massachusetts General Hospital. Telephone records were ultimately retrieved showing a 30-second call to Dr. Tilley’s office in Charleston, South Carolina on November 17, 2003 (first day of trial) and a 6-minute telephone call to Dr. Marler’s office in Bethesda, Maryland. Dr. Tilley reiterated that she never spoke with him and that she was in San Francisco attending a meeting of the American Public Health Association at that time.

The Court found that Dr. Hochberg’s testimony was not credible and that he perpetrated a “fraud on the Court.” He intentionally and deliberately misled the Court and the jury and was responsible for a second “fraud on the Court.” He intentionally and deliber-ately misled the Court and the jury and was responsible for a second “fraud on the Court.”

The Court ordered a new trial and ordered Dr. Hochberg to pay reasonable Court costs as well as attorney costs totaling $20,305 in sanctions for deceiving jurors as an expert in a malpractice case. Id. at 1265 n.13. On review, the Supreme Judicial Court of Massachusetts reversed the Trial Court’s order for a new trial and its sanctions against Dr. Hochberg. Id. at 1271. Though the Supreme Judicial Court found that Dr. Hochberg’s testimony was misleading, it was not found to constitute a fraud on the Court or to be completely false. Id. at 1266-1268. Further, the Court found that the disclosure for 59 patients with a history of cancer in the NINDS study did not constitute new evidence warranting a new trial. The Court considered that such evidence could have been obtained by the plaintiffs at trial and was thus not newly discovered. Id. at 1268-1269. As Dr. Hochberg’s sanctions were contingent on the Court’s order for a new trial, these sanctions were vacated. Id. at 1271.

Comments

Neurologists and emergency room physicians stand at the forefront of stroke management and are at increased liability risk if they use or do not use tPA. Regardless of one’s personal view regarding the efficacy and safety of tPA, it is essential to discuss and document with patient and family (surrogate) all treatment options. By maintaining legible, detailed and timely documentation as to time of onset, examination findings and informed consent why patients should or should not receive tPA should substantially reduce the threat of legal action. If patient or family wish to receive tPA and physician disagrees with this approach, then a second opinion with another stroke physician is necessary or alternatively offering a timely transfer to a nearby stroke facility may also avoid litigation. However, this issue will not disappear as long as there is controversy regarding standard of care. The current guidelines are outdated and do not even include the benefit of MRI and diffusion-weighted imaging as well as the increased mortality associated with older age and large infarcts, etc. CAPLAN LR. TREATMENT OF ACUTE STROKE. STILL STRUGGLING. JAMA. 2004;292: 1883–1885. Therapeutic decisions for treatment of acute stroke need to be current and precise, yet the current FDA guidelines which physicians are using are too imprecise and controversial. Currently, tPA is not used universally and thus it is not a standard of care across the United States but rather is becoming a local community health care standard. However, the public’s demand for acute treatment and high expectations only fuels this controversy. We need to reestablish trust and confidence in our professional societies which can only occur with a definitive new trial and updated protocol. Because the Class I status for ischemic stroke treatment with tPA is controversial, a moratorium on this designation may be warranted. Such an action may serve to reduce the amount of litigation over this issue pending the resolution of the proper standard of care.

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attributable to labor costs. Since 1985, the Centers for Medicare and Medicaid Services (CMS) have grouped hospitals into geographic areas by adopting the Metropolitan Statistical Areas (MSA) developed by the Office of Management and Budget (OMB) for use throughout the federal government. The New York City MSA was slightly expanded to include certain additional hospitals in northern New Jersey. Because the New Jersey hospitals’ wages are somewhat lower, the average wage level in the MSA dropped, along with the wage adjustment for hospitals in that MSA. Wages in Manhattan were 38 percent higher than those in the outlying counties that are included in the New York City MSA. The New York hospitals argued that hospitals in the New Jersey counties had much lower wages and should not be included in the New York City MSA. The New York hospitals claim that the inclusion of the New Jersey hospitals would trim their wage index from 136 percent of the national average to 133 percent, cutting into their reimbursements at a time when New York City hospitals were struggling financially for other reasons. Congress also instructed the Secretary of HHS to provide for the collection of data every three years on occupational mix for employees of each covered hospital in order to construct an occupational mix adjustment in the hospital wage index. The Secretary must adjust payment rates for the relative labor costs in each hospital’s geographic area. CMS surveyed hospitals and collected data, but lacked full confidence in that data. Furthermore, CMS did not meet the September 30, 2003 Congressional deadline for the compilation of this information. In light of its lack of confidence in its data, CMS decided to apply the occupational mix adjustment to only ten percent of the wage index for 2005. The following year, rather than conduct a new survey, CMS used largely the same data. It continued to apply the occupational mix adjustment to only ten percent of the wage index. On November 1, 2004, the New York hospitals filed an action in the Southern District of New York pursuant to the Administrative Procedure Act as well as the judicial review provision of the Medicare Act.
The New York hospitals challenged CMS’s adoption of the new MSAs and its decision to implement the occupational mix adjustment at only ten-percent effectiveness. On March 1, 2005, the district court granted HHS’s summary judgment with respect to the MSA issue, finding that the use of MSAs to represent geographic areas was reasonable. The district court then granted the New York Hospitals summary judgment with respect to the occupational mix adjustment issue, finding Congress had unambiguously mandated that the agency implement the adjustment in full by October 1, 2004. The New York hospitals appealed, and HHS cross-appealed with respect to the occupational mix adjustment. The Court found that an MSA, while not designed for the statutory scheme and inevitably not perfectly tailored for it, generally coincides with the statutory purposes and is thus, a reasonable proxy for the geographic area that the statute charges CMS with defining. The court also found that the agency’s continued use of MSAs was not arbitrary or capricious. The agency was in violation of Congress’s direction regarding the collection of data. The district court’s decision to apply the occupational mix adjustment in full, based on CMS’s questionable data, was not consistent with Congressional intent. The court held that immediate application of the adjustment using flawed data would result in irrational policy and would contravene Congress’s purpose. The Court ordered the agency to collect data sufficiently robust in order to permit full application of the occupational mix adjustment.

Informed Consent

The Nebraska Supreme Court in Curran v. Buser, 711 N.W. 2d 562 (2006) examined the standard for physician disclosure in informed consent actions. After an ultrasound revealed abnormalities in Matthew Curran’s gallbladder, Dr. Kerrey B. Buser diagnosed Mr. Curran as having an inflamed gallbladder. Dr. Buser informed Mr. Curran that he needed to remove the gallbladder as soon as possible. Later on that date, Dr. Buser performed a surgery on Mr. Curran removing his gallbladder. Mr. Curran experienced complications after the surgery and had to undergo numerous corrective surgeries. As a result of the complications from the surgery, Mr. Curran experienced prolonged pain, fatigue, nausea and depression.

Mr. Curran and his wife, Emily Curran, sued Dr. Buser for medical malpractice, claiming that Dr. Buser negligently performed the surgery and failed to obtain informed consent. The Currans sought to introduce evidence of Dr. Buser’s disciplinary history, in which Dr. Buser had been disciplined for unprofessional conduct and had his surgical privileges restricted for the previous year. Dr. Buser filed a motion in limine, prohibiting mention of his disciplinary issues. The trial court granted Dr. Buser’s motion in limine and the jury found for Dr. Buser on the negligence issue. The Currans appealed the trial court’s ruling on the motion in limine. The court looked at the Nebraska Legislature’s adoption of a Professional Theory in interpreting the proper standard of care. Citing Neb.Rev.Stat. §§ 44-2816 and 44-2820, the court found that “informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar localities.” Furthermore, the court found that a plaintiff must establish by a preponderance of the evidence that a reasonably prudent person in the plaintiff’s position would not have undergone the treatment had they been properly informed and that the lack of informed consent was the proximate cause of the injury. The Currans first had to establish a standard of care, prove that the surgeon deviated from that standard of care and show that a reasonable person in their situation would have refused the surgery if the surgeon had properly informed them under the standard. Further, the Currans had to demonstrate that the lack of information proximately caused the injury sustained and damages alleged.

The court held that the Currans failed to prove that the standard of care required Dr. Buser to disclose his disciplinary history. The court refused to adopt the personal standard of care theory that would require Dr. Buser to disclose his disciplinary history even though Dr. Buser personally felt that he should disclose it, because it “would discourage doctors from exceeding the community standard and encourage blind conformity.” Therefore, the court held that the Currans failed to show through expert testimony that the standard of care in similar communities required a physician to disclose his disciplinary history. The trial court did not abuse its discretion in granting Dr. Buser’s motion in limine.

ADA

In Josephs v. Pacific Bell, 443 F.3d 1050 (9th Cir. 2006) the Ninth Circuit declared that a discriminatory refusal to reinstate is separately actionable from a claim of discriminatory discharge under the American with Disabilities Act. Pacific Bell (PacBell) terminated Mr. Josephs’ employment as a service technician in April 1998, based on fraudulent application entries in which Mr. Josephs denied ever being convicted of a felony or misdemeanor. In 1982, Mr. Josephs was charged with attempted murder and misdemeanor battery. Having been found not guilty by reason of insanity on the attempted murder charge, Mr. Josephs was committed to a California mental hospital and was eventually paroled in 1986. Mr. Josephs was convicted on the misdemeanor battery charge in 1985. Prior to being hired by PacBell in January 1998, Mr. Josephs had worked for Cox Communications as a service technician...
for ten years. Mr. Josephs unavailing filed a grievance seeking reinstatement. Forming the basis for denial of reinstatement, PacBell employees relied on the fact that Mr. Josephs spent time in a mental ward. In November 1998, Mr. Josephs contacted the Equal Employment Opportunity Commission (EEOC) and completed paperwork to file a discrimination charge, but was informed that retention of counsel was required. After retaining counsel, an EEOC complaint charging unlawful termination was filed, as well as a comparable state claim. Although both claims focused on wrongful termination based on a perceived mental disability, neither expressly charged discriminatory reinstatement practices. In an attached affidavit to the EEOC complaint, however, Mr. Josephs did describe PacBell's refusal to reinstate him. Receiving right-to-sue letters on both the federal and state claims, Mr. Josephs filed suit in district court claiming unlawful termination and unlawful refusal to reinstate in violation of the Americans with Disabilities Act of 1990 (ADA). 42 U.S.C. § 12101 et seq. (2000). The jury returned a verdict finding that PacBell’s termination of employment was not discriminatory, but that PacBell’s refusal to reinstate violated the ADA because PacBell regarded Mr. Josephs as mentally disabled. PacBell appealed the district court’s refusal to enter judgment notwithstanding the verdict or order a new trial.

Despite Mr. Josephs’ failing to timely file his EEOC claim within 300 days of the claimed event of discrimination, see 42 U.S.C. § 2000e-5(e), the Ninth Circuit affirmed the district court’s creation of an equitable exception because the EEOC representative misled Mr. Josephs on the requirement of retaining counsel in order to file the claim. See Rodriguez v. Airborne Express, 265 F.3d 890, 901-02 (9th Cir. 2001). Likewise, PacBell’s claim that Mr. Josephs failed to exhaust his reinstatement claims was rejected. Although the reinstatement claim was distinct from the wrongful termination claim, the court found the refusal-to-reinstate claim was related to the termination claim because both arose out of the same discriminatory basis. See Couveau v. American Airlines, Inc., 218 F.3d 1078, 1082 (9th Cir. 2000). Next, the court disposed of PacBell’s challenge to the sufficiency of the evidence supporting the jury’s findings that Mr. Josephs’ condition was covered by the ADA and that he was qualified for the service technician position. Under the ADA, an employee is considered disabled if he is regarded by his employer as having a physical or mental impairment that substantially limits one or more major life activities. 42 U.S.C. § 12102(2) (A) & (G). A mental impairment includes “[a]ny mental or physiological disorder, such as . . . emotional or mental illness.” 29 C.F.R. § 1630.2(g)(2) & (b)(2) (2005). An employee is considered disabled even where the employer mistakenly believes that the employee has a physical or mental impairment substantially limiting a major life activity. Sutton v. United Air Lines, Inc., 527 U.S. 471, 489 (1999). The Court noted that the California court’s prior determination that Mr. Josephs was legally insane does not equate to an impairment under the ADA. The statements by PacBell employees about Mr. Josephs’ time in a mental ward, constituted sufficient evidence that PacBell regarded Mr. Josephs as having a mental impairment. Moreover, because PacBell refused to consider other positions without customer contact, the evidence was sufficient for the jury to find that Mr. Josephs’ perceived mental impairment substantially limited his major life activity of working.

Finally, PacBell challenged the sufficiency of the jury’s finding that Mr. Josephs was a qualified service technician. Under the ADA, an employer can adopt job requirement that an employee not pose a direct threat to the health or safety of others in the workplace. See 42 U.S.C. § 12113(b); 29 C.F.R. § 1630.2(r). The court emphasized the jury was instructed that PacBell may take into account the past violence of Mr. Josephs. However, the finding that Mr. Josephs was qualified was supported by the fact that his past violent acts were 16 years prior to working for PacBell and that before working for PacBell, Mr. Josephs had successfully worked for Cox Communications for a decade performing a similar job. Moreover, Mr. Josephs’ PacBell supervisor testified that Mr. Josephs was performing well and was considered an asset. Thus, PacBell was unreasonable in believing Mr. Josephs to be dangerous. The Ninth Circuit summarily disposed of PacBell’s evidentiary challenge to the admission of employee statements made during the grievance process and its contention that the jury was erroneously charged. Normally, statements made during settlement or compromise negotiations of a disputed claim are inadmissible. Fed. R. Evid. 408. Failing to find an abuse of discretion, the court upheld the district court’s admission of this evidence because the statements did not concern Mr. Josephs’ discrimination claim which had yet to be filed. Claiming that its decision to discharge Mr. Josephs included legitimate motives, PacBell charged error with the district court’s failure to issue the second part of a mixed motive instruction. Specifically, PacBell would have terminated Mr. Josephs for other reasons apart from his perceived mental impairment. In mixed motive cases, the Supreme Court has expressly rejected the requirement that a plaintiff must show “but-for” causation. Further, the Court afforded defendants an affirmative defense if it can be shown the same decision would have been made for permissible reasons. Price Waterhouse v. Hopkins, 490 U.S. 228, 244-45 (1989). Refusing to find error in the district court’s incorrect instructions, the court affirmed the jury’s verdict on the basis that the instructions given required Mr. Josephs to actually meet the higher “but-for” burden.

Noneconomic Damage Caps

Challenges to the constitutionality of noneconomic damage caps gave rise to the litigation in Hughes v. PeaceHealth, 131 P.3d 798 (Or. Ct. App. 2006). In a wrongful death action brought against PeaceHealth, the personal representative of her daughter’s estate (Hughes) appealed a judgment of the Lane County Circuit Court, Oregon, in her favor following a jury trial. The jury found PeaceHealth negligent and awarded economic damages of $100,000 and noneconomic damages of $1 million. PeaceHealth moved to reduce noneconomic damages to $500,000 pursuant to ORE. REV. STAT. § 31.710(1) (2005). The court granted PeaceHealth’s motion, ultimately awarding Ms. Hughes $100,000 in economic damages and $500,000 in noneconomic damages and set the interest rate “at the rate of the lesser of 5% or 3% above the Federal Reserve Bank discount rate for Oregon,” ORE. REV. STAT. § 82.010(2)(f) (2005).

The constitutionality of the noneconomic damage cap found in ORE. REV. STAT. § 31.710(1) (2005) was challenged based on Oregon’s constitutional provisions for the right to a full and complete remedy and the right to trial by jury. Turning first to the Remedies Clause challenge, the court noted the Oregon Supreme Court’s decision in Grieb v. Phillips, 906 P.2d 789 (Or. 1995), held that the statutory application of the noneconomic damage cap in a wrongful death actions was within constitutional limits. The statutory cap on noneconomic damages was upheld.
The second issue raised on appeal involved the interest rate entered on the lower court’s monetary judgment. Ms. Hughes alleged that because ORE. REV. STAT. § 82.010(2)(f) (2005) sets the interest rates applicable to civil action judgments for “injuries” and does not specifically include “deaths,” the statutory limit was inapplicable to her case. The court ultimately found this argument unpersuasive because the word “injury” extends beyond physical injuries and includes “a violation of another’s rights for which the law allows recovery,” clearly implicating wrongful death actions. WEBSTER’S THIRD INT’L DICTIONARY 1164 (2002 ed.). Ms. Hughes’ final argument against application of ORE. REV. STAT. § 82.010(2)(f) to her judgment alleged that the wrongful death statute applied only to negligence by licensed health care providers and not judgments entered against corporate entities on a vicarious liability theory. The court held that the plain language of the wrongful death statute shows that the reduced interest rate is triggered by the negligent individual and does not specify application to health care providers. The ultimate liability of the corporate entity for a physician’s negligence does not remove the wrongful death action from this reduced interest rate provision.

**Product Liability**

*Cummins v. McIntosh, 845 N.E.2d 1097 (Ind. Ct. App. 2006)* involved a product liability allegation against the manufacturer of an intermedullary nail. Joe Cummins broke his right femur and hip while deer hunting in October of 1992. Subsequently, Dr. Brent McIntosh performed surgery on Mr. Cummins and inserted an intermedullary nail in his femur. Mr. Cummins was released to work in late April 1993. In June 1993, the intermedullary nail broke. Dr. McIntosh removed the nail and replaced it with a larger one. Following this second surgery, a third surgery was performed by yet another doctor to remove a wedge from Mr. Cummins’ femur in an effort to correct bone misalignment. Yet another doctor found that the bones were still not healing properly and placed a plate, secured with screws, outside of the femur.

In June 1995, Mr. Cummins filed a complaint in Circuit Court against Smith & Nephew, alleging that the intermedullary nail was negligently designed, sold and manufactured, as well as “defective and unreasonably dangerous.” As part of the settlement of that case, Mr. Cummins signed a “Release of All Claims.” In May 1999, Mr. Cummins filed a complaint against Dr. McIntosh alleging that the doctor was negligent in allowing him “to return to work and place weight on his fractured leg [and] in removing the broken nail at the time of surgical replacement.” *Id.* at 1101. In 2002, Dr. McIntosh became aware of the release that Mr. Cummins had signed in the Smith & Nephew proceeding. He then filed a motion for summary judgment, asserting that Mr. Cummins “had barred himself from pursuing any and all claims against any and all persons that purport to arise from the occurrence in question.” *Id.*

Mr. Cummins’ response to the motion for summary judgment included his own affidavit in which he averred that it was not his intent in signing the release, to release Dr. McIntosh from liability. The trial court entered summary judgment for Dr. McIntosh. On appeal, the judgment was remanded to the trial court due to a procedural defect in the order. On remand, the trial court issued an order stating, among other things, that a release should be interpreted according to the standard rules of contract law, meaning that “a release executed in exchange for proper consideration works to release only those parties to the agreement unless it is clear from the document that others are to be released as well.”

Id. at 1103. The trial court then granted summary judgment for Dr. McIntosh and Mr. Cummins took this appeal. Mr. Cummins argued that the trial court erred in holding that the execution of the release in the federal case released Dr. McIntosh of liability. Mr. Cummins claimed that the release was unambiguous and did not release Dr. McIntosh of liability. The appellate court first noted in its opinion that joint tortfeasors combine to form a single injury, while successive tortfeasors act separately from one another and produce different injuries. The Indiana Supreme Court had recently decided to follow the rule that a release of one tortfeasor from liability for harm does not discharge others liable for the same harm, unless it is agreed that the release would discharge them. *Huffman v. Monroe County Cnty. Sch. Corp.*, 588 N.E.2d 1264 (Ind. 1992). As for successive tortfeasors, the Indiana Supreme Court had held that a release of an original tortfeasor did not bar the claim asserted by a plaintiff against a subsequent tortfeasor. *Wecker v. Klimer*, 294 N.E.2d 132 (Ind. 1973).

Next, the court noted that the intent of the parties in an unambiguous contract is determined by looking at the document itself. If the language is ambiguous, then extrinsic evidence may be used to determine the intent of the parties. Mr. Cummins contended that the terms of the release were clear because it referred to injuries occurring on a specific date in June 1993; i.e. the date that the nail broke, not the date in April 1993 that Dr. McIntosh’s negligence was alleged to have occurred. Dr. McIntosh claimed that the terms of the release included him because it was to release “all persons… of and from all claims… for all known and unknown, foreseen and unforeseen, anticipated and unanticipated… injuries… resulting or to result from an incident which occurred on or about June 9, 1993, when the Recon Nail… failed.” *Id.* at 1105. The court cites two cases in which it had recently held that a release of one joint tortfeasor releasing “all other persons [liable or who might be liable] worked to prohibit later claims against the other joint tortfeasors.” *Dobson v. Citizens Gas and Coke Util.*, 634 N.E.2d 1343 (Ind. Ct. App. 1994); *Stemm v. Estate of Dunlap*, 717 N.E.2d 971 (Ind. Ct. App. 1999).

Because successor tortfeasors do not create the same injury, the Indiana courts had held that a release of all other persons involved with an injury might release joint tortfeasors, but not successor tortfeasors who work to exacerbate the original injury. *Arnold v. Burton*, 651 N.E.2d 1202 (Ind. Ct. App. 1995); *Dejew v. Burke*, 786 N.E.2d 1144 (Ind. Ct. App. 2003). In this case, Smith & Nephew and Dr. McIntosh were alleged to be successive tortfeasors, while Dr. McIntosh argued that he and Smith & Nephew were joint tortfeasors. The court held that when there are successive tortfeasors, the question of whether the parties to a release intended to release other tortfeasors is a question of fact to be determined by a jury after considering relevant evidence. In addition, when there are joint tortfeasors, it had been held that contradictory references in a release “cloud[s] the intent of the document” and necessitate a factual determination. *Id.* at 1107. The court felt that because the two litigations were ongoing at the time that the release with Smith & Nephew was signed, the intent to release Dr. McIntosh would have been included more specifically in the release. Because of the need for factual determination of the intent of the release, summary judgment was improper due to the factual issues needing resolution.
Agency by Estoppel

The issue of agency by estoppel was litigated in Musick v. Dutta, 2006 Ohio App. LEXIS 1607 (Ohio App. Mar. 29, 2006). A patient and his wife filed a medical malpractice suit asking for loss of consortium against the attending doctor, the doctor’s medical practice and the hospital. The hospital filed a motion for summary judgment claiming that it was not liable under the agency by estoppel doctrine. The court granted summary judgment for the hospital. The patient, Mr. Musick, appealed.

In June 2002, Mr. Musick went to the emergency room at Holzer Medical Center (“Holzer”) with apparent complications from a surgery performed the previous month. After the emergency room physician’s initial assessment, the physician contacted Dr. Dutta, who was on call, to discuss Mr. Musick’s condition. Dr. Dutta had Mr. Musick admitted as a patient in the hospital. Neither Mr. Musick nor his wife contacted Dr. Dutta themselves. ER doctors discussed options with Mrs. Musick, who was given the choice between two treating physicians for her husband. She chose Dr. Dutta because he had treated her mother at some time in the 1980’s. Mr. Musick stayed at Holzer for six days under the care of Dr. Dutta, and then was transferred to another hospital where surgery was performed to drain a lumbar abscess that had developed at the site of his previous surgery. After the surgery, Mrs. Musick was informed that Mr. Musick had a staph infection that could render him unable to walk, and that the problem could have been avoided had Dr. Dutta treated it properly at Holzer.

In 2003 Mr. and Mrs. Musick filed a medical malpractice complaint against Dr. Dutta and Holzer. Holzer argued that it could not be held liable for Dr. Dutta’s negligence under the agency by estoppel doctrine. Under this doctrine “a hospital may be held liable . . . for the negligence of independent medical practitioners practicing in the hospital when: (1) it holds itself out to the public as a provider of medical services; and (2) in the absence of notice or knowledge to the contrary, the patient looks to the hospital, as opposed to the individual practitioner, to provide competent medical care.” Clark v. Southview Hosp. & Family Health Ctr., 628 N.E.2d 46 (Ohio 1994).

Mr. Musick claimed that Holzer held itself out to the public as a provider of medical services and that he looked to the hospital, not Dr. Dutta, to provide medical treatment. Holzer’s response was an affidavit of Dr. Dutta, which effectively stated that he was an independent medical physician whose actions with respect to Mr. Musick were not controlled or directed by Holzer. On the basis of Dr. Dutta’s affidavit and the fact that Mr. Musick failed to present evidence to rebut the affidavit, the trial court granted summary judgment in Holzer’s favor because both criteria for the agency by estoppel doctrine were not satisfied.

On review, however, Mr. Musick argued that there still remained genuine issues of material fact with respect to both criteria. The Appellate Court first held that it was so obvious that Holzer held itself out to the public as a provider of medical services that no discussion was warranted. The Court stated the issue as whether the hospital provided Dr. Musick with the treating physician, or whether Mr. Musick sought out the doctor, and the doctor chose the hospital as the site of the treatment.

The Court held that the hospital, after giving Mr. and Mrs. Musick the choice between two doctors, assigned a doctor that Mr. Musick had never met. The Court held that the choice between two doctors that Holzer offered to Mr. Musick showed that Mr. Musick did not look to an individual physician, but instead looked to the hospital to provide him with competent medical care. Therefore, Holzer could be held liable for Dr. Dutta’s negligence under the agency by estoppel doctrine.

Sexual Orientation Discrimination

Another case defining the border of assisted fertility when it intersects with sexual orientation is North Coast Women’s Care Medical Group, Inc. v. Superior Court of San Diego, 40 Cal. Rptr. 3d 636 (Cal. Ct. App. 2006). North Coast Women’s Care Medical Group (“North Coast”) began providing fertility treatments to Guadalupe Benitez, a lesbian who hoped to become pregnant through artificial insemination. After a series of diagnostic tests and an initial course of treatment failed to help Ms. Benitez become pregnant, North Coast’s physicians recommended that Ms. Benitez undergo intrauterine insemination (IUI). Although North Coast’s physicians recommended this procedure, they ultimately referred Ms. Benitez to an outside physician to have the procedure performed. In early trial court action, the parties disagreed strongly about the rationale for the outside physician referral. According to North Coast, Ms. Benitez was referred because a North Coast physician believed that Benitez intended the IUI to be performed with live donor sperm. North Coast claimed that Ms. Benitez was referred to another physician because it lacked the licenses necessary to perform that procedure. Ms. Benitez, on the other hand, alleged that she was referred to the outside physician because it offended the North Coast physicians’ religious sensibilities to perform an IUI on an unmarried, lesbian woman. In 2001, Ms. Benitez filed suit against North Coast, claiming that North Coast had violated the Unruh Act (Cal. Civ. Code §51) by discriminating against her on the basis of her sexual orientation. As an affirmative defense, the North Coast physicians claimed that their alleged misconduct was protected by the United States and California constitutions’ protection of religious freedom. Subsequently, Ms. Benitez moved to have North Coast’s affirmative defense set aside. The trial court granted her motion. In the present case, North Coast sought and was ultimately granted an order from the appellate court compelling the lower court to vacate its order setting aside North Coast’s affirmative defense.

The appellate court began its analysis by finding a triable issue of fact as to whether North Coast’s referral was based on Ms. Benitez’s sexual orientation and/or her marital status. The court pointed out that this finding was significant because at the time that Ms. Benitez’s case accrued, the Unruh Act prevented discrimination based upon sexual orientation, but not discrimination based upon marital status. As an aside, the appellate court recognized that the California Supreme Court had in Koebke v. Bernardo Heights Country Club, 115 P.3d 1212 (Cal. 2005) extended the Unruh Act to bar marital status discrimination. The appellate court also acknowledged that typically such a decision would be given retroactive effect. However, the appellate court asserted that when a judicial decision changes a settled rule of law that decision will not, as a matter of public policy, be given retroactive effect if the parties have reasonably relied on the former rule. Here, the appellate court contended that during pleading and litigation the parties relied on the pre-Koebke interpretation of the Unruh Act, so that interpretation, the court said, is decisive.

Next, the appellate court concluded that the California Legislature’s amendment of the Unruh Act (Assem. Bill 1400 (2005-2006 Reg. Sess.) § 2(c)), which affirmed the Act’s prohibition of marital status discrimination did not apply to actions occurring prior to the
amendment’s enactment. The appellate court indicated that an amendment that “clarifies” rather than “changes” existing law does not act retrospectively, but an amendment that changes existing law may be applied retroactively. Here, the appellate court determined that the 2005 amendment changed the law because prior to the amendment California courts had held the Unruh Act inapplicable to marital status discrimination. Nevertheless, the appellate court found that the amendment was not retroactive because there was no clear evidence that the legislature intended to impose after-the-fact liability. Finally, the court held that North Coast was entitled to assert its constitutional right to free exercise of religion as an affirmative defense. Here, the appellate court reasoned that the North Coast physicians have a right to assert the free exercise of religion as an affirmative defense because marital status discrimination was not prohibited by the Unruh Act. The appellate court held that the physicians simply had the right to present testimony that their decision to deny the IUI procedure to Ms. Benitez was based on her marital status.

**Failure to Warn**

*Laisure-Radke v. PAR Pharmaceuticals*, 426 F. Supp. 2d 1163 (W.D. Wash. 2006) explored a pharmaceutical manufacturer’s liability for failure to warn under product liability theories for an adverse outcome. Ms. Laisure-Radke’s husband committed suicide while under the influence of fluoxetine, a generic substitute for the widely prescribed selective serotonin reuptake inhibitor (SSRI) Prozac. Although the prescription carried suicide-related warnings, Ms. Laisure-Radke claimed that those warnings were not effectively communicated to her husband’s physician. Subsequently, Ms. Laisure-Radke filed suit against fluoxetine’s manufacturer, PAR Pharmaceuticals (PAR), claiming that PAR: (1) was liable for marketing a defective product with inadequate and/or legally defective labeling; (2) was negligent because it failed to warn of or to test for an association between fluoxetine and suicidality that was the proximate cause of Mr. Radke’s death; and (3) manufactured a defective and potentially harmful product and did not provide consumers with adequate warnings of the products risks.

The Court began its analysis by determining that the Washington Product Liability Act (WPLA) preempted any common law product liability claim by Ms. Laisure-Radke. Next, the court examined PAR’s liability under the negligence and strict liability provisions of the WPLA. The court quickly decided not to apply the WPLA’s strict liability provision, *RCW 7.72.030(2)*, because Ms. Laisure-Radke had failed to plead a breach of warranty. However, before beginning its analysis under the WPLA’s less demanding negligence standard, *RCW 7.72.030(1)*, the court discussed the State of Washington’s evolving product liability standard for pharmaceutical manufacturers. For a number of years, Washington had applied the strict liability standard in all failure to warn cases brought under *7.72.030(1)(b).*

However, this court pointed to the Washington Court of Appeals decision in *Estate of LaMontaigne v. Bristol Meyers Squibb, et al.*, 111 P.3d 857 (Wash. Ct. App. 2005) as evidence of a developing consensus under Washington law that prescription drugs are a uniquely beneficial consumer product and that their manufacturers should be held to a negligence standard of liability. To discern whether PAR’s warning was sufficient under this lower standard, the court asked whether it had provided adequate and detailed information about the risks of using the drug. The court reasoned that “adequate information” was provided when a warning was accurate, clear and portrayed the risks involved in taking the drug. The court also pointed out that because the State of Washington has adopted the learned intermediary rule, a warning is sufficient when communicated to the physician. There is no need to communicate those warnings directly to patients.

Turning to the facts of the instant case, the court first concluded that the warning could not be deemed adequate as a matter of law, since Ms. Laisure-Radke had raised a genuine issue of material fact as to whether PAR knew of an increased incidence of suicide among its users and had failed to incorporate that knowledge in its warnings. The court then addressed the issue of proximate causation. First, the court pointed out that causation in fact is typically a question for the jury. Nevertheless, PAR had argued that Ms. Laisure-Radke, as a matter of law, could not claim that the warning was defective because the prescribing physician, Dr. Moore, knew of fluoxetine’s risks and would have still prescribed the drug. The court disagreed with PAR’s characterization of the prescribing physician’s testimony and reasoned that Dr. Moore may very well have chosen not to prescribe the drug if there had been a better warning.

Next, the court examined the legal causation element. Though PAR argued that attaching liability was against sound public policy, the court disagreed, reasoning, “Washington case law… supports imposing a duty of manufacturers of generic prescription drugs . . . if a fact finder determined that [the manufacturer] had failed to adequately warn physicians of a particular risk of harm to their patients.” For the above reasons, the court denied PAR’s motion for summary judgment.

**Retaliatory Discharge**

In *Wendeln v. Beatrice Manor, Inc.*, 712 N.W.2d 226 (Neb. 2006), the Supreme Court of Nebraska determined whether the Nebraska Adult Protective Services Act created a cause of action for a retaliatory discharge of an at-will employee. Beatrice Manor, Inc. hired Rebecca Wendeln, a certified nursing assistant, as a staffing coordinator in May 2000. In December 2001, a medical aide informed Ms. Wendeln that a wheelchair-bound patient had been moved contrary to procedure, resulting in injury from a fall. The aide had reported the incident to the administrator and the director of nursing, but believed neither had reported it. A licensed practical nurse at Beatrice Manor, who was a relative of the injured patient also indicated that the incident had not been handled properly. Ms. Wendeln confirmed the incident after interviewing another aid who had been summoned to assist the injured patient off the floor. Pursuant to statutory mandate, Ms. Wendeln contacted the Nebraska Department of Health and Human Services (NDHHS) and reported the incident after being informed no report had been made. After learning of the report to NDHHS, Ms. Wendeln’s supervisor became angry and approached her in a “very aggressive” manner. Scared and intimidated, Ms. Wendeln was granted some time off work. Upon her return, Ms. Wendeln discovered the locks to her office had been changed and her supervisor asked her to resign. Unwilling to resign, Ms. Wendeln’s supervisor fired her on January 2, 2002.

On January 27, 2003, Ms. Wendeln filed suit under the whistleblower provisions of the Nebraska Fair Employment Practice Act (NF EPA), Nues. Rev. Stat. § 48-1101 et seq. (1998). After filing an amended complaint alleging wrongful termination in contravention of public policy pursuant to the APSA, Ms. Wendeln dismissed her first cause of action under the NF EPA. Following a jury verdict awarding $4,000 in economic damages and $75,000 non-economic damages, Beatrice Manor’s motions
for remittitur and new trial were denied. On appeal to the Nebraska Supreme Court, Beatrice Manor assigns error, *inter alia*, on the grounds (1) that Ms. Wendeln’s alleged employment discrimination claims sounded in contract under the NFPEA, thereby making the 300 day limitation in § 48-1118(2) applicable, not the general four year limitation for torts, as well as making non-economic damages non-compensable as a matter of law (or alternatively, excessive in light of the evidence) and (2) that the jury was not instructed that Ms. Wendeln had to prove that she exercised good faith in making her report to the NDHHS.

In rejecting Beatrice Manor’s claim that the 300 day limitation period under NFPEA applied, the Nebraska Supreme Court articulated the three statutory bases for an employment discrimination claim: (1) opposition to any practice made unlawful by NFPEA, (2) making a charge, testifying, assisting, or participating in any charge, investigation, proceeding, or hearing under NFPEA, or (3) opposing any practice or refusing to carry out any unlawful action. Because Ms. Wendeln did not allege she was discharged for opposing any unlawful employment practice, participating in a proceeding under NFPEA, or opposing or refusing to carry out an unlawful act, she did not state a claim for employment discrimination. Instead, Ms. Wendeln alleged she was terminated for complying with her affirmative duty to report abuse pursuant to § 28-372(1) of the APSA. Moreover, as a matter of first impression, the court found Ms. Wendeln’s retaliatory discharge claim sounded in tort. Generally, breach of a contract is premised on a duty arising from the agreement itself whereas a tort involves a duty imposed by law, wholly independent of any contract. Thus, the general four-year limitation for torts applied to Ms. Wendeln’s claim. In recognizing a public policy exception for retaliatory discharge under the ASPA, the court relied on a similar exception it created when an employee is terminated for filing workers’ compensation benefits. *Jackson v. Morris Commc’ns Corp.*, 657 N.W.2d 634, 640 (Neb. 2003). According to the court, without a public policy exception, the substantive rights of the workers’ compensation act could be circumvented by an employer’s threat of termination for filing for benefits.

Likewise, the court found the Wisconsin Supreme Court case of *Hausman v. St. Croix Care Center*, 571 N.W.2d 393 (Wis. 1997), involving an abuse reporting statute persuasive. The Wisconsin statute provided criminal penalties for failing to report abuse. As a result, the Wisconsin Supreme Court concluded that the statute created an affirmative obligation to report abuse. The Court reasoned that a public policy exception was justified to avoid an employee being faced with choosing between reporting an abuse and being terminated or not reporting the abuse and being criminally prosecuted. Therefore, because the APSA provides for criminal sanction for not reporting an abuse, the Court reasoned that a public policy exception for a retaliatory discharge was necessary. Rejecting Beatrice Manor’s claim that the jury should have been instructed that Ms. Wendeln was required to prove good faith in reporting this abuse, the court relied on the plain language of the statute. Section 28-372 requires reporting of abuse when an employee has “reasonable cause to believe that a vulnerable adult has been subjected to abuse or observes such adult being subjected to conditions or circumstances which reasonably would result in abuse.” Because § 28-372 makes no mention of good faith, the court refused to create an additional requirement beyond that of reasonable cause. Further, the court determined that Ms. Wendeln’s claim sounded in tort. As such, the court disagreed with Beatrice Manor’s contention that this action was one of breach of contract and barred non-economic damages. As the court determined that the wrongful discharge claim was a public policy tort action, mental suffering was compensable. The Iowa Supreme Court has noted that humiliation and wounded pride may result in emotional harm casually connected to a wrongful discharge, and fairness requires an employee to be able to recover for the entire injury. *Niblo v. Parr Mfg., Inc.*, 445 N.W.2d 351, 355 (Iowa 1989).

The Nebraska Supreme Court also rejected Beatrice Manor’s assertion that the evidence was insufficient to support the non-economic damage award. In *Kant v. Allayar*, 270 Neb. 501, 506 (Neb. 2005), the court distinguished the proof requirements in negligent or intentional infliction of emotional distress actions from other actions seeking damages for torts independent of emotional distress. Unlike negligent or intentional infliction of emotional distress, severe emotional distress is not an element of a tortous retaliatory discharge in contravention of public policy. Concerning the sufficiency of the evidence, Nebraska courts deferred to the fact finder because the law provides no precise measurement for mental anguish. *Brandon v. County of Richardson*, 653 N.W.2d 829 (Neb. 2002). At trial, Ms. Wendeln presented evidence of the manner in which her supervisor reprimanded and subsequently fired her. This included feeling intimidated, scared and extremely upset, which lasted from before her termination to a long period thereafter. Thus, the jury’s verdict was reasonably related to and supported by the evidence.

**Child Abuse**

Liability for the failure to report suspected child abuse was litigated in *Grimm v. Summit County Children Services Board*, 2006 Ohio 2411 (Ohio 2006). On August 30, 2002, Shenna Grimm filed a personal injury complaint against Summa Health System; Akron City Hospital; Summit County Children Services Board (“CSB”); CSB’s executive director, John Goff; and CSB employees Mark Cernoia, Lori Testa and Sabrina Sypherd. The complaint alleged a failure to report suspected child abuse of Ms. Grimm by Mr. Goff. Ms. Grimm subsequently amended her complaint and dismissed this action against Mr. Goff. In the civil action, all motions for summary judgment were denied. Then, the court directed a verdict for CSB and its employees and dismissed the case with prejudice. On March 18, 2005, the jury found in favor of Ms. Grimm and against Summa Health System and awarded damages in the amount of $224,000. Summa Health System then filed a motion for judgment notwithstanding the verdict, or in the alternative a new trial. The trial court denied Summa Health System’s motion. On appeal, both Summa Health System and Ms. Grimm asserted error. Summa Health System appealed from the trial court’s denial of its motion for judgment notwithstanding the verdict, while Ms. Grimm appealed the trial court’s order granting directed verdicts for CSB and its employees.

1. **Summa Health System’s assignments of error**

Summa Health System raised, *inter alia*, three main assignments of error; alleging: 1) Ms. Grimm’s expert failed to identify the standard of care, any breach, or any resulting damages; 2) the jury’s award of $224,000 was unsupported by the evidence; and 3) Ohio’s child abuse reporting statute does not apply to corporations, and Summa Health System could not be held liable under the doctrine of respondeat superior because Ms. Grimm did not establish that any Summa Health System employee had violated the statute. The court disagreed with Summa Health System on all three contentions.
As to the first contention, the court stated that expert witness testimony was not needed because Ms. Grimm’s claim was grounded in ordinary negligence, and not on medical malpractice. To show actionable negligence, Ms. Grimm only needed show that a duty existed, there was a breach of that duty and as a proximate cause of the breach, damages were sustained. 

The defenses contained in § 2744.03. immunity can be reinstated if the political subdivision can raise any of the exceptions to the so-called sovereign immunity statute, the court affirmed the trial court’s ruling. First, establish immunity under the sovereign immunity statute, the court affirmed the trial court’s ruling. Immunity can be reinstated if the political subdivision can raise any of the exceptions to sovereign immunity. Next, Ms. Grimm argued that CSB fell within one exception, causing by an act or omission of the political subdivision or an employee of the political subdivision.

There are, however, several exceptions to the statute which sets forth specific duties constitutes negligence per se. The court held that the abuse reporting statute does not expressly impose liability for failure to investigate reports of child abuse. Having found no applicable exception to the so-called sovereign immunity statute, the court affirmed the trial court’s ruling.

Summa Health System next argued that the child reporting statute is a criminal statute and, as such, applies only to individuals. Ohio law holds that an employee’s negligence can be imputed to an employer through respondeat superior. The court held that an employee’s liability for failure to report may be imputed against the employer under the doctrine of respondeat superior. Evidence adduced at trial indicated that Summa Health System employees had articulable suspicions that Ms. Grimm was an abused child. These suspicions rose to the level by which Summa Health System employees should have reported under the statute. Thus, the trial court decision was affirmed and Summa Health System was held liable under respondeat superior. In sum, the court overruled all three of Summa’s points of error.

Ms. Grimm also raised three points of error. She alleged the trial court erred by: 1) granting CSB’s motion for directed verdict; 2) granting a directed verdict to CSB’s employees and 3) argued that the Political Subdivision Tort Liability Act (“PSTLA”) was unconstitutional. The court overruled all three of Ms. Grimm’s assignments of error.

In her first assignment of error, Ms. Grimm argued the conduct of CSB’s employees negated CSB’s enjoyment of sovereign immunity. PSTLA provides political subdivisions immunity from liability in civil actions caused by an act or omission of the political subdivision or an employee of the political subdivision. See, e.g., Ohio Rev. Code Ann. § 2744.02 (A)(1) (LEXIS 2006). There are, however, several exceptions to the rule. Id. at § 2744.02 (B)(1)-(5). The court employed a three-step analysis to determine immunity. First, establish immunity under the statute; second, determine if any of the five exceptions apply; and finally, immunity can be reinstated if the political subdivision can raise any of the defenses contained in § 2744.03. Cater v. Cleveland, 697 N.E.2d 610 (Ohio 1998).

The court held that CSB was clearly a political subdivision subject to immunity. Next, Ms. Grimm argued that CSB fell within one exception, namely that a political subdivision is liable when civil liability is expressly imposed by the statute. The court held that the abuse reporting statute does not expressly impose liability for failure to investigate reports of child abuse. Having found no applicable exception to the sovereign immunity statute, the court affirmed the trial court’s ruling.

Ms. Grimm next argued that an employee of a political subdivision may lose his immunity if he acts with malicious purpose, in bad faith, or in a wanton or reckless manner. The court held that those behaviors are jury questions, and the standard for demonstrating such conduct is high. Shadoan v. Summit Cty. Children Serv Bd., 2003 Ohio 5775 (Ohio O. App. 1994). Evidence during trial suggested that the employees may have acted negligently, but the negligence did not rise to the level of malicious purpose, bad faith or wanton or reckless behavior. Thus, the court affirmed the trial court’s holding.

Ms. Grimm’s final argument was that the PSTLA is unconstitutional because it violates a citizen’s right to a jury trial, to a remedy, to due process of law and to equal protection of law. The court held that legislative enactments enjoy a presumption of validity and constitutionality. Thus, a statute is void only where it is proved unconstitutional beyond a reasonable doubt. The same court had decided the issue in a previous case and, thus, declined to revisit the issue on Ms. Grimm’s appeal.

**Jury Prejudice**

Manke v. Physicians Insurance Company of Wisconsin, Inc., 712 N.W.2d 40 (Wis. 2006) determined that the dictionary definition of ‘negligent’ was extraneous prejudicial information to a jury considering a medical malpractice verdict. When seventeen-year-old Johanna Manke jumped into her friend’s swimming pool, she felt a sudden onset of pain. Accordingly, she sought aid at an emergency room where she received treatment from Dr. David Hendrickson. Together with her mother, Ms. Manke filed suit against the medical center and Dr. Hendrickson alleging they were both negligent and their negligence caused Ms. Manke’s injuries. The case proceeded to a jury trial on the issues of negligence, causation and damages. The jury returned a verdict in favor of Ms. Manke and awarded damages that totaled nearly one million dollars.

Approximately three weeks after the commencement of the trial, Dr. Hendrickson filed a motion, along with a paralegal’s affidavit asking the trial court to set aside the verdict and order a new trial on the ground that the jury had been prejudiced by inappropriate material brought into the jury room. Specifically, Dr. Hendrickson alleged the jury was prejudiced when a juror had photocopied the definition of ‘neglect’ from an unknown dictionary and brought it to the jury room to show other jurors.

Ms. Manke opposed the motion and submitted an affidavit from another juror who stated that eleven members of the jury had already found Dr. Hendrickson negligent before the definition was presented to the jury. At a subsequent evidentiary hearing, the jurors were examined by the parties. None disputed that the definition was brought into the jury room. When defense counsel inquired what the vote had been before the definition was presented, what discussion had occurred about the definition and how the definition had affected their views, Ms. Manke objected on the grounds of jury incompetence. The court overruled and allowed the jurors to answer. The circuit court required Dr. Hendrickson to show extraneous information must have somehow prejudiced the jury. The court found Dr. Hendrickson had met this burden, but Dr. Hendrickson had met this burden, and had met actual prejudice because at least one juror member had testified that the information had changed his mind about the negligence of the physician. Furthermore, the court ruled the dictionary definition of ‘neglect’ was not identical to the technical usage of the term as used in medical malpractice actions. Consequently, a new trial was granted on the issues of both causation...
and negligence. The Wisconsin Court of Appeals granted Ms. Manke’s request for appeal.

Ms. Manke contended the circuit court had erred in setting aside the verdict because: 1) Dr. Hendrickson did not make a sufficient showing at the preliminary hearing to entitle him to an evidentiary hearing; 2) the court relied on incompetent testimony under Wis. Stat. § 906.06(2) (2003); and 3) the standard for prejudice was not met.

If the court's decision depends on the testimony of a juror, the juror must be competent to testify under Wis. Stat. § 906.06(2) (2003). In short, the statute does not allow jurors to testify about the jury's deliberations, except that jurors may testify as to whether extraneous information had been presented to them. To satisfy the exception to the statute, the moving party must establish that: 1) the juror's testimony concerns only whether extraneous information was presented to the jury and not the deliberative processes of the jurors, 2) the extraneous information was improperly brought to the jury's attention, and 3) the extraneous information was potentially prejudicial.

The Appeals Court then went on to answer each one of Ms. Manke's contentions. In order for Dr. Hendrickson to be entitled to an evidentiary hearing, he must make a preliminary showing of competency through affidavits or non-juror evidence that the subject matter of the hearing is within the exception of the statute. Here, the court ruled ‘extraneous information’ is information not within the general knowledge and accumulated life experiences the court expects jurors to possess. The court then concluded that a specific dictionary definition is not within the general knowledge and accumulated life experiences of jurors. Thus, the dictionary definition of ‘neglect’ that was brought to the jury room and read aloud was ‘extraneous information,’ and because of this, an evidentiary hearing was warranted. However, because the lower court did not refer to these statements in rendering its decision to allow an evidentiary hearing, the Appeals Court affirmed the decision.

Next, the court examined the competency of the juror testimony at the evidentiary hearing. Ms. Manke asserts that Dr. Hendrickson should not have been allowed to question the jurors as to what effect the definition had on them, and that the lower court erred when relying on the testimony in making its decision of prejudice. The appeals court agreed with Ms. Manke because Wis. Stat. § 906.06(2) does not allow jury testimony on the effect of extraneous information. However, the court did not agree this warranted a reversal of the lower court's decision to grant a new trial because the court also relied upon competent testimony to render its decision. Thus, the court held that the competent testimony in and of itself was enough to satisfy the clear and convincing standard.

Ms. Manke's final contention was that the dictionary definition brought to the attention of the jurors would not affect the average hypothetical juror. A comparison of the two definitions revealed the dictionary definition was more expansive than the technical jury instruction. The court held an average juror could use the dictionary definition of negligence instead of the malpractice instruction because it is less complicated and easier to understand. Furthermore, a juror using the dictionary definition would be lead to apply a standard far more restrictive than what Dr. Hendrickson is held to in the medical community. Thus, it would be far easier to find him negligent with the dictionary definition. As such, the court affirmed the decision of the lower court to grant a new trial even though it had relied upon incompetent testimony.
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New Year, Same ‘ole Lawsuits.

Although the digital calendars in our computers have advanced to 2007, the courts of this country continue to wrestle with topics that have been making headlines for the past decade. This issue of LMP highlights some of these cases in an effort to provide the readership with a quick survey of some of the interesting health law decisions. Additionally, some news briefs are included to give your minds a break between the more dense case summaries as you read this issue cover to cover.

On the topic of what is old is new, a recent Boston Globe article discussed the increasing trend to opt for silicone for breast implants since the FDA allowed them back on the general market in November of 2006. The plastic surgeons quoted in the article estimate that the current division between saline and silicone is about 50-50. Apparently, patients tend to select the silicone for its more realistic feel and shape while saline’s primary advantages are its obvious safety and lower cost. Although Dow-Corning, which went bankrupt in 1998 when it had to cough up more than $3 billion to settle silicon related lawsuits is certainly turning over in its corporate grave, today’s silicone implant is a distant cousin to those involved in litigation. The older products contained a very oily mixture which leaked when ruptured, while the modern version’s silicone has a gel consistency which does not leak. Consumer advocates still express concern over the safety of silicone which was accused of being linked to all sorts of diseases in women although follow up science has cast doubt on these conclusions.

The often debated role of physicians in state executions will soon generate a Circuit Court opinion. The 8th Circuit recently heard argument on a case out of Missouri. The appeal was prompted after a district court judge ordered that an anesthesiologist must attend the execution on a case out of Missouri. The appeal was prompted after a district court judge ordered that an anesthesiologist must attend the execution.

Assisted reproductive technologies continue to stimulate litigation as courts grapple with definitions of parenthood. The resulting patchwork quilt approach is all but certain to make this a fertile area for litigation for generations yet to come. The Kansas Supreme Court is expected to issue an opinion in February on the question of whether a known sperm donor can exert parental rights. In the case, a woman used sperm from a known associate to conceive a child, and following the birth, the man raised a claim of fatherhood despite an apparent intent prior to conception not to be involved with the child. Kansas has a law on the books which states a sperm donor cannot be the father unless the mother and donor agree to it with the child. Kansas has a law on the books which states a sperm donor cannot be the father unless the mother and donor agree to it with the child. The resulting patchwork quilt approach is all but certain to make this a fertile area for litigation for generations yet to come. The Kansas Supreme Court is expected to issue an opinion in February on the question of whether a known sperm donor can exert parental rights. In the case, a woman used sperm from a known associate to conceive a child, and following the birth, the man raised a claim of fatherhood despite an apparent intent prior to conception not to be involved with the child. Kansas has a law on the books which states a sperm donor cannot be the father unless the mother and donor agree to it with the child. Kansas has a law on the books which states a sperm donor cannot be the father unless the mother and donor agree to it with the child. Kansas has a law on the books which states a sperm donor cannot be the father unless the mother and donor agree to it with the child. Kansas has a law on the books which states a sperm donor cannot be the father unless the mother and donor agree to it with the child. Kansas has a law on the books which states a sperm donor cannot be the father unless the mother and donor agree to it with the child.
As always we will strive to keep you updated on these and other conflicts at the interface of law and medicine as they become available. Our New Year’s resolution is to make this publication even more useful to you the reader. To that end if you ever come across a significant case or perhaps even participate in one and feel the rest of the membership would benefit from a discussion of it, please do not hesitate to send the citation or opinion via email to the LMP Editor whose email appears on the back of every issue. We continue to welcome your opinions (either pro or con) regarding our case discussions and coverage topics.

Failure to Report HIV Results
The duty of care to third parties within a class of reasonably foreseeable individuals threatened by an undisclosed HIV result was litigated in C.W. v. Cooper Health Sys., 906 A. 2d 440 (N.J. Super. 2006). The patient, C.W., was admitted to Cooper Hospital complaining of confusion, changes in mental status and progressive lethargy. He was immediately admitted to the intensive care unit. An HIV test was ordered by Dr. Gerber, the treating physician. C.W.'s mother signed the HIV consent form which stated that he would be offered counseling about HIV and the meaning of the results. Three days after the authorized HIV test, C.W. was discharged from Cooper Hospital. SmithKline performed the HIV test and sent Cooper Hospital a report indicating that he had tested positive for HIV. C.W. was never informed of the positive HIV test results. Subsequently, C.W. and E.Y. became sexually involved with one another. Their daughter, J.W., was born. C.W. was later treated for medical problems and tested again for HIV. These test results showed that C.W. was HIV positive. Shortly thereafter, E.Y. also tested positive for HIV while their child, J.W., tested negative for HIV.

C.W., E.Y., and their child filed a complaint in the Superior Court of New Jersey Law Division against Cooper Hospital claiming it breached a duty of care and was negligent in failing to inform C.W. of his positive HIV test results. The hospital moved for summary judgment. C.W., E.Y., and their child presented reports and deposition testimony of three physicians. The depositions appeared to indicate that the hospital acted negligently and failed to act in accordance with the required standards of care and conduct. The lower court entered judgment dismissing the complaints of the girlfriend and minor child.

On review, the appellate court sought to determine whether a hospital could be held civilly liable to an individual who contracted HIV from a former patient who was not informed of the positive HIV test results ordered by the physicians responsible for the patient’s care. In Olivo v. Owens-Illinois, Inc., 186 N.J. 394, 398-99, 895 A.2d 1143 (2006), the court held that when a company had a duty to protect its workers from the known consequences of exposure to asbestos in the work place, this duty extended to spouses handling the workers’ unprotected work clothing because there was a foreseeable risk of exposure from asbestos borne home on contaminated clothing. Similarly, this court held that the duty of care of the hospital extended to the girlfriend because she was within the class of reasonably foreseeable individuals whose health was likely to have been threatened by the patient’s ignorance of his own health status. Cooper Hospital should have made an effort to contact C.W. directly with his positive HIV test results. It was entirely foreseeable that C.W. would likely be sexually active and it was the hospital’s responsibility to advise him of his positive condition and the steps he needed to take to avoid transmitting the virus to other individuals. A health care provider, who orders an HIV test for a patient has a duty to take reasonable measures to notify that patient of the results of the test. The duty of care extends to a third party if they are within a class of reasonably foreseeable individuals whose health is likely to be threatened by the patient’s ignorance of his own health status.

While the court reversed the trial court’s judgment dismissing E.Y.’s complaint against Cooper Hospital, the court affirmed the dismissal of the claim of J.W., the daughter of C.W. and E.Y. The court held the daughter may have no present claim because she was born without the HIV virus.

Editors’ Comments: This court reaffirmed the notion that when extending liability to third parties; foreseeability is the key. It is foreseeable that a patient who tested positive for HIV may be sexually active and a failure to inform that patient of the positive test results will result in the transmission of the disease to a third party partner. While the court extended this duty of care to a third party, it would not extend the duty to a child born of the two partners who had not contracted the disease. The court may be ignoring the fact that although the child did not currently test positive for HIV, she may develop health problems related to her exposure in the future and thus may have a claim for damages at some time in the future. Failure to follow up on ordered lab results is a fertile source of litigation. In the short stays of modern hospital practice, it is all too common that individuals are discharged with pending lab results. Hospitals need to have a reliable method of notifying ordering physicians and the patient’s follow up providers the later released lab results. Additionally, with labs for certain communicable diseases, mandatory reporting statutes are often in place so the public health department can follow up with identified patients to ensure treatment.

Research Animal Ethics
The Cleveland Clinic and one of its neurosurgeons found themselves in PETA’s sights recently when it was revealed that a mix breed large dog was improperly used in a medical device sales marketing demonstration. After the dog was placed under anesthesia, the neurosurgeon caused an aneurysm and then allowed about two dozen sales representatives from the device manufacturer’s company to attempt to place a coil. About 27,000 people will suffer a ruptured aneurysm in the coming year and the device being demonstrated is a coil method aimed at treating the condition prior to rupture. The use of animals in experiments requires an ethical board review similar to the IRB experience for studies involving humans. In this case, although the clinic and physician appear not to have completed the required review, reportedly the planned procedure was submitted to the committee. Moreover, spokespersons for the committee soundly indicated that such a sales demonstration would never have passed muster. Dogs and cats account for less than 1% of all lab animals used in this country. It appears the animal was purchased from licensed lab animal vendors despite an old statute in Ohio which allows shelters to sell unclaimed impounded dogs for $3 to nonprofits engaged in research. The incident is now being reported to the U.S. Department of Agriculture which is tasked with regulating animal welfare. See Sarah Treffinger, Dog Killed at Clinic in Demo of Device, The Plain Dealer (January 12, 2007).

Respondentate Superior
The Supreme Court of Michigan, in Zsigo v. Hurley Medical Ctr., 716 N.W. 2d 220 (Mich. 2006), declined to adopt an exception to the
doctrine of respondeat superior. On July 9, 1998, Marian Zsigo was brought to the emergency room at Hurley Medical Center suffering from a manic-depressive episode. Upon arrival, Ms. Zsigo was kicking, screaming, and had to be placed in restraints. After being treated, she was left alone in the room with a nursing assistant; who asked her to release her from the restraints. When the nursing assistant refused to release her, Ms. Zsigo began making sexually explicit comments and at one point asked him to have sex with her. She claimed she made these remarks because she felt “he was a very powerful person in the hospital” who could release her. With no resistance from Ms. Zsigo, the nursing assistant engaged in oral and digital sex with her and left the room without releasing her. Three days later, Ms Zsigo reported the incident when she spoke with a social worker.

Ms. Zsigo filed a complaint against Hurley Medical Center, alleging assault, battery and intentional infliction of emotional distress. At the initial trial, a jury found in her favor and awarded damages, which were reduced by the court to the amount of $1,147,247.42. On appeal, the case was remanded to the trial court, but the Supreme Court granted Ms. Zsigo’s application for leave to appeal. Before the court was the issue of respondeat superior. The general rule of respondeat superior is that an employer is not responsible for the intentional or reckless actions of its employees when those actions are not within the scope of the employer’s business. There are several exceptions to this general rule and the court looked specifically at one of them. The relevant exception in this case states that an employer can be responsible for an employee’s actions when the victim of these actions (in this case, Ms. Zsigo) relied on the authority of the employee, or the employee was aided in harming the victim by the agency relationship that exists between the employee and employer.

The Supreme Court of Michigan declined to adopt this exception to the rule of respondeat superior for fear it would make employers responsible for virtually anything an employee does. In essence, the court felt the rule of respondeat superior would no longer exist. Every employee action would fall under this exception because of the relationship between the employer and the employee is constant. The existence of the employer/employee relationship could always be seen as “aiding in harming” the victim. Since the court declined to adopt this exception, Ms. Zsigo could not hold Hurley Medical Center responsible for the actions of the nursing assistant.

Justice Kelly dissented, asserting that the exception to respondeat superior should have been adopted because it ensures that an employer is responsible for granting authority to an employee. As such, when an employee abuses the power given to him by the employer, the employer is responsible for the abuse. Furthermore, the exception would not destroy the rule of respondeat superior because the existence of a relationship, by itself, is not enough to hold the employer responsible; the employee must have committed some negative conduct before the court would look to the exception. The exception would only apply where (1) the opportunity was created by the relationship; (2) the powerlessness of the victim to resist the perpetrator and prevent the unwanted contact existed; and (3) the opportunity to prevent and guard against the conduct is properly balanced.

Resident Physicians
Denzel Mensah, ppa Vida Amankwaa, et al. v. Jennifer Goedken, M.D., 2006 Mass. Super. Lexis 185 (2006), examines whether residents and staff members of the University of Massachusetts Medical School (UMMS) were “public employees” of the Commonwealth and thus immune from liability pursuant to the Massachusetts Tort Claims act (MTCA). Denzel Mensah suffered a brachial plexus injury allegedly occurring during a difficult delivery. The physicians’ motion for summary judgment was denied as plaintiffs argued that the material facts were unclear as to the circumstances surrounding the alleged negligence of each physician and further, a recent merger complicated a determination of the status of the medical center specifically in relation to the MTCA. The MTCA renders public employees immune from liability, while placing the liability on the shoulders of the public employer for any negligent or wrongful act or omission if committed while the employee was acting within the scope of his employment. (Mass. Gen. Laws Ch. 258, § 2.) There was no question that the UMMS was deemed to be a public employer within the meaning of the law whose employees are considered state employees rather; the dispositive issue, determining whether an individual is a “public employee,” requires an assertion that the person was subject to the direction and control of the public employer. Because the medical profession is distinct and requires a high level of skill and training, courts have considered physician’s functioning using independent judgment and thus similar to an independent contractor rather than a public employee, Kelley v. Rossi, 395 Mass. 659, 662, 481 N.E.2d 1340 (1985) thus it is not an automatic presumption that all employees are public employees even through the institution is considered a public entity.

Although the public employer may pay his/her salary, provides a retirement fund or manages a vacation schedule is not dispositive as to the “public” nature of the employment relationship. Williams v. Hartman, 413 Mass. 398, 400, 597 N.E.2d 1024 (1992). In defining the “public employee” status of a resident, courts consider whether the public employer (1) assigns the residents duties; (2) regulates the residents work schedule; (3) controls which patients the resident treats; (4) has assigned the resident to the particular department where the care and treatment at issue was provided; (5) has the authority to dismiss the resident from the residency program; (6) pays the resident a salary, health benefits, and life insurance benefits; (7) whether the resident is required to follow the regulations and policies of the public employer in the course of his residency; (8) whether the resident has admitting privileges to the hospital; and (9) whether the resident is authorized to discharge a patient without the consent of the supervising attending physician. McNamara v. Honeyman, 406 Mass. 43, 46, 546 N.E.2d 139 (1989).

The faculty group practice plan (UMMC) merged with Memorial Health Care, Inc, a private nonprofit corporation, to create two new private, nonprofit corporations. UMass Memorial Health Care, Inc. and UMass Memorial Medical Center, Inc (MC). The MC was established to operate the consolidated activities of UMMC and the Memorial Hospital. Prior to the merger, the University, UMass Memorial and the MC executed an Academic Affiliation and Support Agreement, which made the Medical School the exclusive academic and clinical teaching affiliate of the MC, intended in part to ensure that University residents would continue to have access to clinical training sites and research opportunities and programs following the merger. The merger specifically provided that resident physicians would remain employees of the University. According to the agreement, the university was 1) to control decisions regarding academic issues and medical education and training, for its residents, including rotation and work assignments, 2) be responsible for supervision, direction, and control of all residents, 3) implement personnel and institutional policies and 4) establish an annual stipend to be paid to the residents. Moreover, resident evaluations were to be
completed on University forms.

Allegations of negligence were brought against the physicians claiming negligence in failing to appropriately diagnose the size/weight of the baby during prenatal visits and failing to order an ultrasound at delivery to determine the baby’s actual weight/size thereby providing an opportunity for a cesarean section. Based on these issues of material fact, summary judgment was not granted and the case was remanded for further proceedings.

Obesity Drug

In a sign that the rush to develop successful obesity pharmacologic agents has truly gone to the dogs, the FDA has recently approved Pfizer’s canine obesity drug called Slentrol. Apparently modern day life (lots of quick junk food + little or no exercise) which has been linked to a dramatic increase in human obesity is also affecting man’s best friend. Studies suggest about a third of dogs are obese or overweight. The new medication is a selective microsomal triglyceride transfer protein inhibitor which prevents key steps in the lipoprotein pathway. Although the exact mechanism of weight loss in dogs is not fully understood, Pfizer reports up to 50% of dogs on the medication lost about 11% of their body weight. Veterinarians note this is significant because like their masters, the overweight dogs are developing weight related complications such as arthritis and diabetes. The medication is estimated to cost one to two dollars per day. In acknowledgment of the certain use of the medication by humans seeking to have a slimmer figure, the FDA has imposed special warnings about its side effects when improperly consumed by humans. For now, the medication is only approved for dogs so husky cats, horses, and humans will have to wait. See Peggy Peck, Slentrol (dirilatapide) Goes to the Dogs, MedPage Today (January 5, 2007); Rob Stein, Something for the Dog That Eats Everything: A Diet Pill, Washingtonpost.com (January 6, 2007).

Peer Review / Expert Witnesses

John Fullerton M.D. v. The Florida Medical Association, Inc, 938 So. 2d 587 (Fla. App. Ct. 2006) examines whether the Federal Health Care Quality Improvement Act, 42 U.S.C. §§ 11101-11152 (HCQIA) and the Florida peer review statutes immunize peer review defendants from liability when acting to evaluate the testimony of a medical expert given in a medical malpractice action. Dr. Fullerton brought a claim for violation of Florida’s RICO act against the Florida Medical Association (FMA) and counts of defamation, tortuous interference with an advantageous business relationship, and conspiracy through abuse of economic power; and witness intimidation against Drs. Warach, Zala and Krebs (defendants). The lower court held that section 766.101, Florida statutes (2003), and the Federal Health Care Quality Improvement Act, 42 U.S.C. §§ 11101-11152 (HCQIA) immunized the defendants, however on appeal the court dismissed the final judgments and remanded the case for further consistent proceedings.

Dr. Fullerton testified against defendant doctors in a medical malpractice action where the judgment exonerated defendant doctors from liability. Subsequently, defendant doctors forwarded a letter to the FMA complaining that Dr. Fullerton’s testimony was false and fell below a reasonable professional standard, and thus the lawsuit was frivolous and propagated solely for financial gain. Additionally, the letter requested disciplinary action in order “to prevent the Medical profession from being terrorized by similar experts.” Dr. Fullerton countered, arguing the statements in the letter were false and that the FMA’s Expert Witness Committee (EWC) of FMA’s Council on Ethical and Judicial Affairs (CEJA) was organized to intimidate persons from appearing as expert witnesses, thereby depriving injured plaintiffs of their ability to seek redress. As a result, Dr. Fullerton had suffered damages including irreparable harm to his reputation and income. Motions to dismiss were filed by defendants stating the claim was barred by the Florida peer review and HCQIA immunity statutes. The court agreed the claim was barred in the absence of allegations of intentional fraud however, granting the motions to dismiss without prejudice for Dr. Fullerton to amend his complaint. Plaintiff did not amend the complaint against the individual physicians, thus a final judgment of dismissal with prejudice was entered. Ultimately, Dr. Fullerton filed an amended complaint against the FMA asserting defamation specifically alleging extrinsic evidence of intentional fraud, which the court dismissed and this appeal ensued.

In reviewing the Florida peer review immunity statute 766.101 (3) (a), which provides for immunity for any member of a medical review committee if performed without intentional fraud, the high court held that neither the Florida peer review statutes nor the HCQIA clearly and unambiguously expresses the legislative intent that expert witness testimony should be scrutinized by peer review and thus the immunity provisions did not apply. Defendants argued that provision of expert witness testimony was “provision of health care” by a health care provider, and was therefore appropriate subject matter for a medical review committee, which is established for the purpose of reviewing standards of care. They continued that unprofessional expert medical testimony should be subject to peer review as it threatens the quality of health care by forcing physicians to practice defensive medicine thus supporting the legislative intent of improving the quality of health care.

The court disagreed indicating that their interpretation conflicted with common law that provides absolute privilege to statements made in the course of judicial proceedings. No matter how false or malicious the statements may be. Moreover, the court held the peer review applied to services rendered by providers, which would include the diagnosis, treatment operation or prescription for any disease.

The court also held that HCQIA did not apply; as to be entitled to immunity the body must be engaged in a professional review action, which encompasses the review of the professional conduct of a physician that might affect a patient’s health. The court found no provision that empowered the professional body to review a physician’s testimony. Although, the court cited Austin v. American Association of Neurological Surgeons, 253 F.3d 967 (7th Cir. 2001) where the court implied that HCQIA’s provision included the authorization of a professional body to review the quality of a physician’s testimony in a malpractice action. Here the court took issue with the ruling and found several distinguishing facts in Austin from those at bar, where most notably Dr. Fullerton, unlike Dr. Austin, was not a member of the professional association that entertained a complaint to discipline him, thus even if the statutes could be interpreted as permitting peer review of a member physician’s malpractice testimony, the FMA had no cause under the circumstances to subject Dr. Fullerton to its discipline.

Patent Law

The patent marking statute applies to a pharmaceutical drug even though the claim pertains only to method patent was the holding in Merck & Co., v. Mediplan Health Consulting, Inc., 434 E Supp. 2d
257 (2006). Merck & Co. is a pharmaceutical company that patented “Antihypercholesterolemic Compounds” (U.S. Patent No. 4,444,784, “the ’784 patent”) on April 24, 1984. The patent was later assigned to MSD Technology L.P., a Merck subsidiary. The ’784 patent protects Zocor, a medication that lowers cholesterol and fatty-substances in the blood. Simvastatin is Zocor’s active ingredient. Merck has the exclusive right by patent law and the U.S. Food and Drug Administration (“FDA”) to sell simvastatin in the United States. Merck did not provide written notice on the Zocor package of its patent on simvastatin. Instead, Merck listed the ’784 patent in the FDA Orange Book. The Orange Book is used to decide patent disputes between patent holders and generic product manufacturers. The book is over 1,000 pages of patent listings. Mediplan Health Consulting operates a Canadian online pharmacy that sells generic drugs, including simvastatin, to U.S. consumers. Mediplan’s sale of simvastatin in the U.S. is not approved by the FDA.

On April 8, 2005, Merck filed a federal lawsuit against Mediplan in the Southern District of New York for infringement on its simvastatin patent, unfair competition, and trademark infringement. Mediplan moved to dismiss the claims on the grounds that Merck failed to provide patent protection notice under 35 U.S.C. § 287(a), the patent marking statute, before bringing its claim against Mediplan. Mediplan also argued that no damages could be awarded for any alleged infringement after Merck’s patent expired on December 23, 2005. Mediplan was partially successful in its motion to dismiss.

The law provides that where a patent is strictly for a method, not a physical entity, the marking statute does not apply if there is no physical item to mark with the patent notice. However, as this court found, if a tangible item exists, the marking statute requires notice posted on the item, regardless of whether the patent is for a method or product. If a court finds that one company has accelerated its entry into the market by infringing on another’s patent, the patent holder may recover damages after the patent’s expiration under the “accelerated market entry” theory. The court in this case held that Merck’s listing of its patent in the FDA Orange Book did not provide adequate notice to Mediplan of Merck’s patent on simvastatin. Furthermore, the court found that Mediplan’s knowledge of the patent did not eliminate Merck’s duty to firmly communicate the patent infringement. The court did not grant Merck’s request for injunctive relief or damages for any use of simvastatin after the expiration of the patent because an expired patent cannot be infringed. Merck was allowed to move forward with its “accelerated market theory” claim and may be entitled to damages for the benefit Mediplan enjoyed for its pre-expiration infringement.

With respect to the marking statute, Merck argued that it was exempt from compliance. Although its patent contains method and product claims, Merck argued that because only the method claim in simvastatin was asserted in the lawsuit, the marking of the product is not required. Mediplan countered that Merck cannot avoid its duty to mark the Zocor package with a notice of the patent simply because it chose only to assert the method claim. The court agreed with Mediplan, using the purpose of the state as support for its finding. The court identifies three purposes of the statute: to provide notice to the public of the patent, to avoid innocent infringement, and to encourage the patentee to provide adequate public notice. The court cites another federal case requiring a company to provide a physical notice of the patent where the company “distributed tangible items created by the [patent] methods and by which [it] could have given notice.” Halliburton Services v. Smith Int’l Inc., 317 F.Supp. 2d 719, 725 (2004).

Editors’ Comments: The court’s finding in this case is consistent with all but one federal court that has dealt with the method infringe-ment and the marking of an available tangible item. In 2004, the Northern District of Georgia held that the marking statute only applies when there is a physical item to mark, and the party suing has brought claims for both method and product infringement under the same patent. Coca-Cola Co. v. PepsiCo, Inc., No. 02 Civ. 2887 (KRS), slip op. at 4 (2004). This court found that this reasoning undermines the purpose of the statute. Other federal courts that have dealt with this question have held that a company is required to abide by the marking statute. The question of whether the listing in the Orange Book provides adequate notice was one of first impression for the court. Without any prior authority, the court found that the mere listing of a patent in the Orange Book is not sufficient notice.

Blood Substitutes

Prior issues of LMP have outlined some of the issues surrounding the ongoing rush to study and achieve approval for a blood substitute. A blood substitute is needed because unlike saline which restores volume and thus blood pressure the substitute would also provide needed oxygen carrying capacity. Unlike natural blood, the substitutes would minimize risks of contamination and also have improved shelf lives. Two products are currently seeking to conduct the needed trials to obtain FDA approval. Northfield Laboratories has been conducting research studies with its product Polyheme since 2004. The FDA recently blocked Biopure Corporation’s competing product Hemopure from proceeding with advanced trials. Hemopure is manufactured from bovine hemoglobin and, unlike Polyheme, apparently has the added advantage of not requiring refrigeration. This has piqued the Navy’s interest; on the battlefield more than 2/3 of the soldiers who die from traumatic injuries suffer significant blood loss prior to arriving at the hospital. The Navy had been proposing to study Hemopure on civilian trauma victims without their informed consent. The panel voted 11-8 that the proposed risks are not outweighed by the benefits. In some earlier trials, there appeared to be an increased risk of heart attacks and strokes with the blood substitute. The panel proponents have attempted to differentiate these studies as coming from elderly patients receiving transfusions associated with elective orthopedic procedures as opposed to the proposed trauma population which is primarily young and healthy. The European Union has given similar studies the green light and Hemopure is already commercially available in South Africa. Although the FDA is not bound by its advisory committee’s decision, it typically adheres to the recommendation and this most recent vote marks the fourth time the proposed study has been rejected by the government despite the Navy’s urging. See Andrew Bridges, FDA: Blood Substitute Test Shouldn’t Go On, Associated Press (December 15, 2006); Marisa Taylor, Bad Blood from the FDA, Red Herring (December 15, 2006).

Peer Review

Whether hospital peer review hearings will give rise to anti-SLAPP motions was decided in Kibler v. Northern Inyo County Local Hosp. Dist. 39 Cal.4th 192 (2006). Dr. George Kibler was a staff surgeon for Inyo County Local Hospital District. In December 2001, the hospital district responded to a series of violent encounters between Dr. Kibler and the hospital staff. The hospital brought an action against him seek-
An injunction against workplace violence. The hospital’s review board subsequently suspended Dr. Kibler. In January 2002, he was readmitted to the hospital staff subject to an injunction, which required his attendance at anger management classes and barred him from bringing a firearm to the hospital.

In December 2002, Dr. Kibler sued the hospital district under various theories including, defamation, abuse of process, and interference with his practice of medicine. The hospital responded by moving to strike the suit pursuant to §425.16 of the Strategic Lawsuits Against Public Participation statute (SLAPP), which creates a procedure for striking complaints in harassment lawsuits. The trial court considered the hospital’s motion specially and determined that, while Dr. Kibler’s lawsuit arose out of the informal hospital peer review proceedings, those proceedings were an “official proceeding” for the purposes of the statute. Accordingly, the trial court struck the complaint and dismissed his lawsuit. The Court of Appeals affirmed. Dr. Kibler appealed to the California Supreme Court, which also affirmed.

The court arrived at its decision by applying California Code of Civil Procedure §425.16, which creates a mechanism for a party (the hospital district) to strike a lawsuit brought by another party (Dr. Kibler) if that second suit is frivolous and brought only to coerce the original party to drop the first suit. This anti-SLAPP statute can be applied to strike any lawsuit in response to either: (1) a writing or statement made before a legislative, executive, judicial proceeding or any other official proceeding under law; or (2) a writing or statement made in connection with an issue under consideration or review by a legislative, executive, judicial proceeding or any other official proceeding under law.

In this case, the court questioned whether the hospital district’s physician review board was “any other official proceeding under law” for purposes of the anti-SLAPP statute. By looking at the legislative intent of the California legislature, the court concluded that the statute was to be read broadly. Also, according to the California Business and Professional Code §809.8, all hospitals’ peer review decisions are subject to judicial review. Based on this reasoning, the court found that statements, like Dr. Kibler’s, which arise out of a hospital peer review board’s decisions, could be struck using the anti-SLAPP statute.

Editors’ Comments: This case stands for a broadening of California’s anti-SLAPP statute, §425.16, to include official meetings in quasi-judicial settings like the peer-review board of a hospital district. While amicus briefs for Dr. Kibler argued that the statute should be reserved for actions arising out of governmental proceedings, the court was not persuaded. Instead, it found that limiting the number of harassing lawsuits directed towards hospitals was not only an overriding public interest, but also one of the intentional legislative purposes of the statute.

**Duty to Warn**

*Munstermann v. Alegent Health – Immanuel Med. Ctr.*, 716 N.W.2d 73 (Neb. 2006), examined a psychiatrist’s duty to warn third parties. Dr. Hudson Hsieh, a psychiatrist at Alegent Health-Immanuel Medical Center (The Medical Center), was treating Marty Nuzum for depression. Mr. Nuzum killed his girlfriend, Jodi Rowe, after having alluded to Dr. Hsieh that he “wanted her to feel the same pain that he was feeling.” Carol Munstermann, personal representative of Ms. Rowe’s estate, sued the Medical Center and Dr. Hsieh. The issue here was whether a psychiatrist is under a duty to warn potential victims of violence when patients disclose in confidentiality their intent to harm others. In particular, the appeal focuses on whether psychiatrists are included within the Nebraska statute concerning the duty to warn, not whether this particular psychiatrist breached his duty to warn. The trial court failed to obtain a jury verdict and declared a mistrial.

On appeal, the Medical Center and Dr. Hsieh asserted that the trial court failed to award a judgment notwithstanding the verdict, on grounds that Ms. Munstermann failed to prove that they proximately caused Ms. Rowe’s death. The Nebraska Supreme Court reversed and remanded the case to the trial court. It affirmed the trial court’s denial of a judgment notwithstanding the verdict because it could not say that no reasonable jury could reach a verdict against the Medical Center or Dr. Hsieh. The court found that the Nebraska statute, limiting the liability for failure to warn to “mental health practitioners,” applies to psychiatrists as well. Under certain circumstances, a psychiatrist can be held liable for failure to warn a reasonably identifiable victim, so long as that psychiatrist has reason to believe the threat is both physical and legitimate. The failure of the statute to specifically list psychiatrists as affected mental health practitioners does not defeat the legislative intent for the statute to reach those health care professionals who, via confidential communications with patients, are alerted to a real threat of violence to third parties. The court, in hearing the appeal, was only required to decide whether the trial court had erred in failing to grant a motion for judgment notwithstanding the verdict because only one reasonable conclusion can be drawn from the facts presented. The case demonstrates that a high standard is required to overturn the denial of a motion for judgment notwithstanding the verdict, which no reasonable jury could have found as this particular jury did.

Editors’ Comments: The case clearly identifies the standards of duty and causation in these types of duty to warn cases. The court refused to believe that the Nebraska statute served to limit liability for failure to warn reasonably identifiable third parties of serious threats. The case does not discuss whether this particular psychiatrist or medical center breached a duty to warn the decedent of impending physical harm, such deliberations are appropriate for the jury, on remand.

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**A-fib Medical Device**

University of Cincinnati surgeon Randall Wolf received a note from the FDA recently that no one ever wants to get. The letter accused him of questionable record keeping and failure to properly disclose financial interests. Dr. Wolf had conducted the two studies in question in an attempt to get a medical device manufactured by AtriCure approved before the FDA. The device, called a bipolar ablation system, uses electrical impulses to block the heart’s erratic conduction wave in atrial fibrillation. After investigating the allegations, the University has ordered the physician to attend some remedial courses in research record keeping. Dr. Wolf disclosed that he receives $200,000 per year from the company in royalties in addition to having the company finance at least one of the studies. He has subsequently stepped down from heading up the research study, which is still ongoing, and a colleague has taken over the reins. As if this news was not bad enough, during the same week the company was hit with a shareholder class action lawsuit which claims the company also failed to disclose financial relationships with Cleveland Clinic physicians who also apparently owned a stake in the company. See Peggy O’Farrell, UC Doctor’s Research Under Review, The Enquirer (December 15, 2006); Greg Paeth, UC Heart Surgeon & FDA Tangle, The Cincinnati Post (December 15, 2006); AtriCure Hit with Shareholder Lawsuits, Business Courier (December 15, 2006).
Evidence / Manner of Death

The theory of “homicide by heart attack” was deemed admissible under Daubert in the opinion of Baraka v. Commw. of Kentucky, 194 S.W.3d 313 (Ky. 2006). Binta Maryam Baraka engaged in a physical and verbal altercation with her father, Brutus Price, who subsequently died. Ms. Baraka was indicted for his murder when the Commonwealth alleged that stress from the altercation caused Mr. Price’s fatal heart attack. Ms. Baraka requested a Daubert hearing concerning the testimony of the Commonwealth’s medical examiner, Dr. Cristin Rolf, M.D. Dr. Rolf concluded that Mr. Price’s cause of death was heart attack and the manner of death was homicide. Ms. Baraka entered conditional guilty pleas to second-degree manslaughter and to being a persistent felony offender in the second degree. She was sentenced to ten years imprisonment.

Ms. Baraka had motioned to suppress Dr. Rolf’s opinion that Mr. Price’s death was a homicide by heart attack. However, the trial court determined that Dr. Rolf’s opinion was admissible pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). The Court of Appeals affirmed and the Supreme Court of Kentucky granted discretionary review. Ms. Baraka argued that Dr. Rolf’s opinion was unreliable and did not assist the trier of fact. The test is whether the trial judge’s decision was arbitrary, unreasonable, unfair or unsupported by sound legal principles. The reliability factor is examined for clear error, while determining whether testimony assists the trier of fact is examined for abuse of discretion. The Court affirmed the trial court’s decision.

The reliability factor was assessed using Dr. Rolf’s testimony that homicide by heart attack was not a new or unique theory and was widely accepted in the scientific community. Dr. Rolf was unaware of any colleagues who did not accept the theory and she introduced several articles on the subject. She also testified to her educational background and that she had done over 500 autopsies on heart attack victims. The court determined that in the light of such testimony there was no clear error in the trial court’s determination. Ms. Baraka argued that Dr. Rolf’s opinion was based on disputed information given to her by the police. However, the court pointed out that facts, data, and information regarding the circumstances of a victim’s death provided by investigating officers is the customary information relied on by medical examiners. Further, determining the cause and manner of death is scientific in nature and outside the common knowledge of a juror. In a case such as this, medical testimony is critical because the cause of death is not clear from the physical evidence. The court determined that the trial court’s decision was reasonable in spite of the fact that Dr. Rolf’s testimony included an opinion that a criminal act was committed. Conversely, medical examiners make these determinations every day when they indicate on a death certificate that the death was natural, accidental, suicidal, homicidal or undetermined.

The concurring opinion noted every jurisdiction considering the issue has held that a homicide conviction can be based on the theory that it was death by heart attack so long as the prosecution proves cause and effect. A qualified expert can offer an opinion that the cause of death was homicide, but not that the homicide was intentional, wanton, reckless, or accidental. An expert cannot base an opinion on facts that a juror can easily understand. It would not be apparent in this case that Mr. Price’s heart attack was caused by the altercation with his daughter. Dr. Rolf stated only that the heart attack was homicide not that it was the intention of Ms. Baraka to kill Mr. Price, nor that Ms. Baraka wantonly, recklessly, or accidentally killed Mr. Price. Dr. Rolf did not know if Mr. Price had started the altercation, but if he had, it would change her determination that Ms. Baraka’s actions were criminal.

The dissenting opinion sets out a four part test that must be met in order to admit expert testimony: (1) the expert witness must be qualified; (2) the subject matter must satisfy the requirements of Daubert; (3) the subject matter must satisfy the test of relevancy set forth in FRE 401, subject to the prejudicial versus probative balancing test required by FRE 403; and (4) the testimony must assist the trier of fact. The dissenting opinion concludes that the requirements of this test have not been met. The dissenting justice concluded that the testimony of Dr. Rolf did not assist the trier of fact in understanding the evidence or in determining a fact in issue.

Editors’ Comments: Causation was at issue in this case because Ms. Baraka was charged with homicide. Therefore, Dr. Rolf could have testified that Mr. Price had cardiac disease, that he died of a sudden cardiac arrhythmia and that his body had numerous abrasions and contusions indicative of a struggle. However, allowing her to testify that Mr. Price died of homicide by heart attack was improper because the opinion was outside her expertise and unnecessary for the jury’s understanding of the evidence. The jury did not need expert testimony to determine the altercation was highly emotional because the police and 911 tapes were sufficient. Further, a juror’s common sense and knowledge would have been enough to determine that Mr. Price perceived a threat to his safety. Finally, Dr. Rolf’s determination that Ms. Baraka’s actions were criminal was outside her area of expertise. Therefore, her opinions were inadmissible as expert testimony because they neither helped the jury in understanding evidence, nor determined a fact in issue. Dr. Rolf’s autopsy confirmed that Mr. Price died of a heart attack, as her own interpretations and opinions of police reports and 911 tapes led to her conclusion that it was death by homicide. This was improper expert testimony because it was based on non-professional opinions; these inferences from testimony should be left to the jury. The jury should never have been told what conclusions to draw from the 911 tapes and police reports. Personal and common sense opinions of an expert are not admissible as expert testimony.

Child Abuse

Rees v. Department of Health and Welfare, 137 P.3d 397 (Idaho 2006), stands for the idea that the Idaho Department of Health and Welfare and its employees can be liable for negligence. In September of 2001, Justin Rees picked up his son Tegan from his ex-wife’s apartment where Tegan was living with his mother and her boyfriend. Mr. Rees noticed Tegan had bruises and other injuries on his head and face. Mr. Rees notified the sheriff’s office, which subsequently sent a deputy to interview Tegan’s mother and boyfriend. Tegan was sent to live with his day care provider while the investigation was conducted. The sheriff’s office referred the case to the Department of Health and Welfare (The Department). The Department sent their employee Nicole Ott to conduct an immediate risk assessment regarding Tegan. Ms. Ott interviewed Tegan’s parents, his mother’s boyfriend, Tegan’s day care provider and neighbors. Ms. Ott also attended a doctor’s appointment with Tegan at his pediatrician’s office. Based on her investigation, Ott concluded Tegan was not at risk and returned him to his mother’s care. She told Mr. Rees that after speaking with witnesses and with Tegan’s doctor she had found this was an invalid case of reported abuse. Less than two months later, in November of 2001, Tegan died as the result of abuse inflicted by his mother’s boyfriend. Mr. Rees then sued his wife, his wife’s boyfriend, the
The Department argued that recovery under tort law was impossible since they owed Tegan no duty of care. Mr. Rees argued the Idaho Child Protection Act (ICPA) creates in the Department an affirmative duty to competently investigate reports of child abuse. The court premised its analysis on Minnesota law concerning whether a statute alone could create a special duty of care. There, the court noted that under Minnesota law a statute alone could not create a special duty; rather there must be additional indicia that the governmental unit “has undertaken the responsibility of protecting a particular class of harm.” It then considered four non-exhaustive factors to determine if the government assumed responsibility for protecting reportedly abused and neglected children: (1) whether the governmental unit had actual knowledge of dangerous condition; (2) whether there was reasonable reliance by persons on the governmental unit’s representations and conduct (such reliance must be based on specific actions or representations which cause the persons to forego other alternatives of protecting themselves); (3) whether an ordinance or statute set forth mandatory acts clearly for the protection of a particular class of person rather than the public as a whole; and (4) whether the governmental unit used due care to avoid increasing the risk of harm.” Radke v. County of Freeborn, 694 N.W.2d 788 (Minn. 2005).

On the first factor, the Court ruled that the Department and Ms. Ott did have actual knowledge of the dangerous condition because Mr. Rees reported suspected abuse and there was no question that the Department knew about the danger to Tegan in his mother’s home. On the second factor, the Court ruled that is was reasonable for Mr. Rees to have relied on the Department since the deputy told Mr. Rees he would make sure Tegan was protected. Additionally, the Department removed Tegan from both Mr. Rees and his mother so an investigation into the reported abuse could be conducted. On the third factor, the Court found that the ICPA did set forth mandatory acts clearly for the protection of a particular class of person because the legislature had made clear that health and safety of reportedly abused children was its focus. This was not a general duty, rather it was a duty running to a narrow class of persons; abused and neglected children who are particularly vulnerable because they allegedly suffer abuse in the privacy of their homes and cannot protect themselves. Finally, on the fourth factor the Court ruled that whether the Department used due care to avoid future harm to Tegan was a genuine issue of material fact. Based on all four factors, the Court ruled the Department did have a special duty to Tegan to competently investigate the reported child abuse because of the special relationship created once the report of the suspected abuse was received. Therefore, the trial court erred in granting the Department’s motion for summary judgment.

**Insulin Wars**

Insulin has been in use for a long time, but despite this extended experience, generic versions are not readily available. With the increasing burden of diabetes on health care budgets, 11 state governors from both parties have requested the FDA to take some action to ease the burden of producing generic versions of biologicals. From just state Medicaid budgets, insulin cost more than $500 million in 2005. It is not unusual for patients to spend around $100 per month of their insulin regimens. Insulin is currently a battleground between large pharmaceutical companies seeking to maintain their cash cow and generic manufacturers seeking to enter the market. The FDA has become the battleground because of its delays in issuing regulatory guidelines despite announcing the commencement of guidelines back in 2001. The pharmacy industry is lobbying the FDA to prevent the generics from riding their coattails by using their clinical safety studies on insulin and merely demonstrating bioequivalence. Although this is the road to generic medication manufacturing, insulin is a biological agent and thus may not be entirely analogous. In other words insulin and human growth hormone type agents are not made from merely following a chemical recipe but rather represent products obtained from cultures of living material. This may be significant because there is an increased risk of allergic reactions if even slight changes are made in the manufacturing process. The current insulin market represents a $3.3 billion dollar expenditure per year and thus the fight will likely continue for some time despite the recent action by state governors and some comments by Congress expressing an interest in the matter as a means of cost containment. Several generic manufacturers, which currently market their product in India, are expected to seek European Union approval in 2007 because the EU has issued guidelines for the approval of generic biologic agents. See Stephanie Saul, Bridling at Insulin’s Cost, States Push for Generics, The New York Times (January 11, 2007).

**Insurance Benefits Assignment**

The result in Chamberlain v. Farm Bureau Mut. Ins. Co., Inc., 137 P.3d 1081 (Kan. Ct. App. 2006), was that when an insured settles with a tortfeasor, assignee along with the insured loses the right to pursue personal injury protection benefits. Lisa Chamberlain had an auto insurance policy that provided Personal Injury Protection (PIP) benefits. After an auto accident, she assigned to Dr. Vito Carabetta her rights to any insurance payments for medical services. Her insurance company made a partial payment more than 60 days after receipt of the medical bill, claimed the balance of the bill exceeded the usual and customary charges, and instructed that Ms. Chamberlain be billed for the remaining balance. Ms. Chamberlain filed suit against her insurance company including claims for denying PIP benefits and discounting physician charges on PIP claims. She amended her petition to assert herself as a representative of a class of insureds and requested declaratory and injunctive relief regarding the practice of denying and discounting PIP claims.

Ms. Chamberlain also brought a tort action against the driver of the other vehicle. They executed a settlement agreement that provided her with recovery of medical expenses, lost wages and released the other driver and his insurance carrier from further liability. After learning of the settlement agreement, Ms. Chamberlain’s insurance company moved for summary judgment and Dr. Carabetta moved to intervene. The district court denied the motion for summary judgment and granted Dr. Carabetta’s motion to intervene. Dr. Carabetta then filed a class action petition seeking relief for himself for his unpaid bill, interest
and attorney fees as well as declaratory and injunctive relief as a representative of a class of health care providers.

Class certification was granted to both Ms. Chamberlain and Dr. Carabetta, but then both the individual and class action claims for PIP benefits were dismissed. Ms. Chamberlain and Dr. Carabetta filed an appeal challenging the district court’s dismissal of their individual and class action claims for PIP benefits against the insurer. The Kansas Automobile Injury Reparations Act (KAIRA) requires liability insurance for all automobiles driven on Kansas highways. KAIRA also requires that all liability insurance policies include, among other benefits, PIP benefits to cover medical and rehabilitation expenses. Reimbursement to the PIP insurance carrier for paid PIP benefits can occur one of two ways: the insured reaches a settlement or obtains judgment against the tortfeasor that includes payment of damages already covered by payment of the PIP carrier or the PIP carrier brings an action against the tortfeasor for benefits already paid.

In this case, Ms. Chamberlain reached a settlement agreement for her total claim of medical expenses and lost wages and released the tortfeasor from any further liability. Thus the settlement, as a matter of law, duplicated the medical bills the insurance carrier had already paid to her physicians. Her insurance carrier was therefore entitled to reimbursement from the settlement proceeds for the PIP benefits it had already paid and not responsible to make further payments. Ms. Chamberlain lost her entitlement to PIP benefits when she settled with the tortfeasor. Since she does not have standing to sue for the PIP claims, she cannot be a representative plaintiff for the class-action claims.

KAIRA does not allow for a direct action by a health care provider against the PIP carrier of their patient. A basic contract principle recognized by Kansas law is that an assignee steps into the shoes of the assignor at the time of the assignment. The assignor no longer has any title, interest or right to the matter that is assigned. However, the district court found that Dr. Carabetta’s claim came from Ms. Chamberlain’s claim and therefore when she settled, his claim became moot. The Court of Appeals of Kansas determined that the general rule that an “assignee is ordinarily subject only to setoffs and defenses that existed at the time of the assignment” did not apply to this case. OXY USA, Inc. v. Colorado Interstate Gas Co., 20 Kan. App. 2d 69 (1994).

Editors’ Comments: To apply this general rule would allow for double recovery and undermine the intent of the Kansas legislature in enacting KAIRA. The court noted that Dr. Carabetta was not without recourse as he could receive his due funds from Ms. Chamberlain’s settlement. The court of appeals of Kansas affirmed the district court’s dismissal of Ms. Chamberlain and Dr. Carabetta’s claims for PIP benefits. The current case modified the fundamental contract principle of assignment. Because KAIRA does not expressly provide for a physician to have a direct action for PIP benefits against the PIP carrier of the patient, even when the patient and health care provider independently execute a valid assignment, it will not be enforced if the patient has settled with the tortfeasor.

Pharmaceutical Liability

The court in Bickel v. Pfizer, Inc., 431 F.Supp.2d 918 (2006) held that the expert testimony in question by a patient’s treating physician lacked reliable scientific methodology. In October 2001, Janet Bickel was prescribed Lipitor by her primary care physician for the treatment of hyperlipidemia. Shortly after using Lipitor, Bickel began experiencing body and joint pain along with swelling of the eyes. She contacted her physician and he advised her to discontinue the drug. Bickel stopped using Lipitor and her symptoms subsided. However, on March 1, 2002, she awoke from her sleep with blurriness and partial vision loss in her right eye. Bickel was initially diagnosed with anterior ischemic optic neuropathy (AION) and was subsequently diagnosed with bilateral AION after she complained of fuzziness in her left eye. Bickel was referred to Dr. Valerie Purvin, a neuro-ophtalmologist, for further examination and treatment. Dr. Purvin performed research to determine if an immune complex disease or other form of vasculitis was induced by the Lipitor and could have contributed to Bickel’s ischemic optic neuropathy.

In 2003, Bickel filed a complaint in federal court against Pfizer and Parke-Davis for several causes of action including strict product liability, negligence, and punitive damages. The complaint included Dr. Purvin’s expert report regarding causation. Pfizer and Parke-Davis filed a motion to exclude this opinion as inadmissible evidence. In addition, the companies argued that a motion for summary judgment should be granted because Bickel lacked any admissible evidence on the issue of causation.

In order for expert testimony to be admissible, it must be relevant and reliable as required by Federal Rules of Evidence 702. A witness qualified as an expert by knowledge, skill, experience, training, or education, may testify in the form of an opinion if the testimony is based on sufficient facts or data, the testimony is the product of reliable principles and methods, and the witness has applied the principles and methods reliably to the facts of the case. Fed.R.Evid. 702. The Supreme
Court held that Rule 702 requires district courts to perform a “gatekeeping function” before admitting expert scientific testimony to ensure relevance and reliability. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589. *Daubert* listed four factors in order to determine if the scientific evidence is reliable: 1) whether the theory or technique can be or has been tested, 2) whether the theory or technique has been subjected to peer review and publication, 3) whether there are standards controlling the operation of the technique and its known or potential rate of error, and 4) whether the theory or technique has gained widespread acceptance in the relevant scientific community. However, this is not an exhaustive list and courts may consider other factors in order to determine expert reliability.

The court held that Dr. Purvin’s expert opinion lacked reliable scientific methodology. Dr. Purvin did not rely on valid methodology, such as epidemiology, in forming her opinion. Epidemiologic studies are the primary, generally accepted methodology for demonstrating a causal relation between a chemical and a set of symptoms or a disease. *Conde v. Velsicol Chemical Corp.*, 804 F.Supp. 972, 1025-26 (S.D. Ohio 1992). Dr. Purvin did not conduct any scientific experiments or clinical studies to support her theory that statins can cause AION. In addition, Dr. Purvin did not rely on any studies to verify her conclusions. The medical literature Dr. Purvin cited in her report only “proposed” a connection between statin drugs and vasculitis and did not mention a relationship to AION. Furthermore, her theory is not generally accepted in the scientific community. However, this is not an exhaustive list and courts may consider other factors in order to determine expert reliability.

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**Editors’ Comments:** The court as gatekeeper applied the *Daubert* factor test to exclude the expert opinion. Nonetheless, the court did recognize Bickel’s argument that she would be barred from having her day in court simply because medical literature showing a connection between her condition and Lipitor does not yet exist. The court stressed that it was not the novelty of Dr. Purvin’s theory that led to its exclusion, but the fact that she did not provide any evidence that forthcoming literature would show a connection between Lipitor and AION.

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The adequacy of the Trimox warning label was challenged in *Ames v. Apothecan, Inc.*, 431 F.Supp. 2d 566 (2006). In February 2001, Dr. Alvaro Ramos diagnosed six-year old Catherine Shea Welch with strep throat and prescribed a ten-day regimen of amoxicillin. The pharmacist filled the prescription with Trimox, a generic version of amoxicillin. One day after Shea Welch completed the ten-day regimen, she contracted a fever and developed a rash on her back and chest. A pediatric infectious disease specialist diagnosed Shea Welch with Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN). The rash continued to spread over her extremities, including her mouth and eyes, and eventually developed into lesions. Shea Welch developed scarring of her skin and corneas and as a result, she is now blind.

Shea Welch brought suit against Apothecon, the manufacturer of Trimox, and Apothecon’s parent corporation Bristol-Meyers Squibb Co. alleging failure to warn Dr. Ramos of the connection between amoxicillin and TEN. She alleged that the “Warnings” section of the Trimox package insert did not properly advise doctors of the symptoms of early SJS/TEN and the incidence rate of the adverse reaction. Further, she argued that the adverse reactions of SJS/TEN should be listed in the Warnings section (rather than in the Adverse Reactions section) where it would be more likely to be noticed and heeded. Apothecon filed a motion to dismiss on the grounds that there was no failure to warn because the medical community in general and Dr. Ramos in particular were fully aware of the risk of TEN associated with amoxicillin.

The court, applying Maryland law, granted the motion to dismiss because it found that the risks were adequately disclosed. Maryland law recognizes the “learned intermediary” doctrine, which provides that manufacturers only need to warn the prescribing physician and not the patient directly. *Lee v. Baxter Healthcare Corp.*, 721 F.Supp. 89, 94-95 (D.Md., 1989). Even if a label’s warning is inadequate, this doctrine protects a manufacturer from liability provided that the physician has been sufficiently warned from other sources. In this case, the court found that Dr. Ramos was a learned intermediary because he was fully warned of the risk of TEN from his medical training and by reading the warning label for another amoxicillin product, which by law is identical to all amoxicillin brands.

Furthermore, the court declared that changes advocated by Shea Welch would not have materially improved the warning. The present structure between the Adverse Reaction section and the Warnings section is not unreasonable simply because it requires a reader to make a cross-reference. Dr. Ramos testified that the warnings advocated by Shea Welch would not have changed his decision to prescribe amoxicillin. In fact, Dr. Ramos has permitted his own daughter to take amoxicillin. In addition, the court stated that warnings must be brief and focused in order to be effective. These warnings are intended to be read by learned intermediaries who have the ability to access medical literature if they require additional information.

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**FTC Targets Diet Pills**

The Federal Trade Commission (FTC) recently announced it had collected more than $25 million in settlements/fines from the makers of several diet pills. Although the products were not charged with being unsafe and thus remain on the shelf, they were charged with false or misleading advertising in touting their weight loss claims. Bayer was fined more than $3 million for violating a previous FTC order in marketing its One-A-Day brand vitamins. It had advertised a version of these for weight loss with insufficient evidence supporting the claim. The makers of TrimSpa, which gained notoriety when endorsed by Anna Nicole Smith, agreed to pay $1.5 million. Finally the makers of Xenadrine and CortiSlim agreed to pay more than $10 million each. The Bayer penalty will go to the US Treasury, however, the remaining monies will go into a fund to possibly reimburse consumers who purchased the products. Details on the funds and how to submit claims will eventually be posted on the agencies website. The FTC urged the mainstream media, which often makes significant advertising revenue from these and other similar products, to adopt stricter policies in deciding when to air such advertisements. Although with weight loss products constituting more than a billion per year industry, expect more consumers jumping to purchase the latest snake oil concoction promising rapid weight loss simply from taking the pill. See Edward Iwata, Diet Pill Sellers Fined $25M, USA Today (January 5, 2007); Annys Shin, A Bitter Pill to Swallow, Washingtonpost.com (January 4, 2007); Peggy Peck, FTC Fines Diet Pill Makers Millions for Bogus Claims, Medpage Today (January 4, 2007).
Expert Witnesses

Issues pertaining to the use of expert testimony to establish the appropriate standard of care was litigated in Cleveland v. United States, 457 F.3d 397 (5th Cir. 2006). Samuel Cleveland, through his provisional curator, Bobbie Jean Cleveland, appeals evidentiary rulings made by the district court in regard to his medical malpractice claim. The events leading to his claim began when he sought admission to the emergency room at Bayne Jones Army Community Hospital (BJACH). He was seen by a triage nurse, who took his medical history and classified him as a low priority patient. Next, he was examined by physician assistant George Eubanks (Eubanks) who diagnosed the patient with an upper respiratory infection, bronchitis, and sinusitis. Eubanks prescribed a variety of medications, discharged him, and concluded he did not need a chest X-ray or other further tests. Samuel did not indicate his medical history of congestive heart failure to any hospital employee, nor did any employee review his history until one hour after he was discharged. Eubanks then reviewed the file and determined there was no reason for Samuel to return to the emergency room.

Two days later, Samuel returned to the emergency room. At that time, he was diagnosed with pneumonia resulting from congestive heart failure. He then went into respiratory and cardiac arrest, became comatose, and remained so until his death several years later. Samuel’s wife brought a medical malpractice suit; alleging that BJACH employees, specifically Eubanks, misdiagnosed and mistreated Samuel, and could have prevented his deterioration. At trial, her claim failed on the merits, based on the fact that she failed to prove that the defendant’s conduct fell below the requisite standard of care. To prove the standard of care, she offered four expert witnesses.

Wanda Poret, a certified legal nurse consultant, testified that the physician assistant failed to diagnose Samuel, deviating from an acceptable standard of care. This testimony was excluded because under Louisiana law a nurse must not testify against a physician. In this case, it was not a physician, but a physician assistant against whom the nurse testified. The court decided that because physician assistants like Eubanks were delegated many tasks without direct supervision, they stand in the place of physicians for the purpose of the aforementioned rule. Here, the nurse was prohibited from testifying against Eubanks because he was a physician assistant.

Dr. Piland, an expert in internal medicine, treated Samuel after he slipped into a coma. He testified to his opinion of the emergency room standard of care for someone in Samuel’s condition. For an expert’s testimony to be admitted against a specialist in a medical malpractice action, the expert must show either that he practices the same specialty as the one in question or if he practices in a different specialty that the standard of care used in both fields is identical. In this case, the court found that emergency room medicine is a specialty and has a different standard of care than that of other specialties, including internal medicine. As Dr. Piland is an expert in internal medicine, not emergency room medicine, his testimony was excluded by the district court.

The testimony of Dr. Rankin, an expert in radiology, and Dr. Cuenca, another internal medicine expert were excluded for similar reasons. Even though X-rays were a part of Samuel’s treatment, the court opined that since Dr. Rankin was an X-ray expert, not an emergency room specialist, he could not testify to the standard of care used in emergency rooms. Dr. Cuenca, while having some emergency room experience, was not an emergency room specialist and could not speak to typical emergency room procedures regarding the use of medical records and a patient’s medical history.

The final witness whose expert testimony was in question before the appellate court was Dr. McMillan, a practitioner in the specialty of emergency medicine for 18 years. His testimony concerned whether it was within the standard of care for a physician assistant in an emergency room to prescribe medications to patients. He testified that the practice varied from emergency room to emergency room. In fact, Samuel attempted to argue that this expert’s testimony, although offered by his opponent, established that the physician assistant’s conduct fell below the required standard of care. However, Louisiana law permits a physician assistant to prescribe medications to patients. Therefore, the court held that the physician assistant Eubanks did not violate the standard of care in prescribing medications to patient Samuel.

Due to the exclusion of all of Samuel’s experts offered to establish the standard of care, as none of his experts were specialists in the field of emergency room medicine, the appellate court affirmed the district court’s finding that he failed to carry his burden of proof. Thus, Samuel’s claim failed.

HIV Litigation

John B. v. Superior Court, 45 Cal. Rptr. 3d 316 (2006), examines some of the potential claims arising from partner transmission of HIV. Bridget, who was infected with HIV, alleged that her husband John became infected with HIV first, as a result of engaging in unprotected sex with other men before and during their marriage, and that he then knowingly and negligently transmitted HIV to her. According to Bridget, it was John who insisted on not using protection during sexual intercourse. Shortly after this, Bridget tested positive for HIV, the precursor to AIDS. John’s reaction was to blame Bridget for introducing HIV into their marriage; depressed and ashamed, Bridget allowed John to tell friends and family that it was she who caused his HIV infection. Within a year of having been diagnosed, John’s HIV turned into full-blown AIDS. Alarmed and suspicious at the unexplainable acceleration of the disease in her husband, Bridget began to ask questions. In court documents, Bridget alleged her husband had unprotected sex with other men before they dated, after they dated, after the engagement and while they were married. Moreover, Bridget alleges her husband knew or should have known he was infected when he suggested ending the use of condoms when the couple had sex.

Bridget had four claims upon which she sought relief: intentional infliction of emotional distress, negligent infliction of emotional distress, false representation of being in good health before the wedding, and negligent transmission of HIV. In connection with her claims, Bridget requested broad discovery orders which included but not limited to, requesting John to provide the names, addresses and phone numbers of all of the men he had had sex with before they dated, after they dated, while they were engaged, and during and after their marriage. Additionally, she subpoenaded his medical records in order to prove that he knew or should have known he was infected much earlier than he alleged. John responded that Bridget infected him and provided a negative HIV test result that supported his allegations. John argued: (1) California did not recognize a cause of action for negligent transmission of HIV; (2) Only in cases in which a person who has received a positive test result, knew they had HIV and still has sex without notifying the partner should be liable in negligence; (3) The discovery requests violate his state and constitutional rights to privacy; (4) The discovery requests
rather than on intelligible principles of law and fault. Standards of liability based on the history and experience of minority groups are unworkable and would require courts to determine standards that have historically been marginalized based on the disease. This is an able but still allow a cause of action for their negligent transmission.

Finally, the standard should be higher because certain minority groups should be 'does know based on the results of a HIV test.' The problem with this argument is that a number of other STDs can also be undetectable with this argument is that a number of other STDs can also be undetectable with the other spouse and the other spouse becomes infected with HIV, the spouse who was not told has a civil right to sue the spouse who had reason to know that he/she was infected. Further, the spouse who was not notified can discover the other spouse's sex history and medical records, if the spouse who had reason to know claims it was in fact the other spouse who infected him/her. Also, this aligns California with the majority of states that have considered the issue of whether the state recognizes a civil action for negligent transmission of sexually transmitted diseases (STDs) including HIV/AIDS.

The dissent argued that the law should not be changed or the standard should be higher. First, HIV is a deadly disease unlike other STDs. Second, because HIV can be undetected the 'reason to know' standard should be 'does know based on the results of a HIV test.' The problem with this argument is that a number of other STDs can also be undetectable but still allow a cause of action for their negligent transmission. Finally, the standard should be higher because certain minority groups have historically been marginalized based on the disease. This is an unworkable suggestion that would require courts to determine standards of liability based on the history and experience of minority groups rather than on intelligible principles of law and fault.

Antipsychotics & Diabetes Litigation

Eli Lilly & Company recently settled some 18,000 claims stemming from allegations that the company failed to adequately warn patients of the increased risk of diabetes / hyperglycemia from consuming their antipsychotic Zyprexa. Although exact terms of the settlement were not disclosed, the company did indicate it expected to take a charge of $500 million related to the settlement. This translates into a smaller amount per plaintiff than the $700 million paid to 10,000 patients in 2005 based on similar allegations. The decreased amount is likely due to the defense that the company changed its label in 2003 to better reflect the hyperglycemia / weight gain risk of the medication. Additionally, plaintiff's attorneys generally bring the stronger cases earlier. Despite now settling with nearly 30,000 plaintiffs, there remain at least some 1,200 cases which did not participate in the settlement which the company plans to take to trial. Perhaps even worse news for the company is the growing list of state attorneys investigating the company for its alleged marketing of Zyprexa to physicians in a systematic way to minimize the portrayal of diabetes risk despite internal studies indicating a very real danger. Following on the heels of these investigations are some third-party payors now tasked with providing care for patients with weight-related complications such as diabetes. However, before one sheds too many tears for big pharma it should be noted that Zyprexa is still a moneymaker for the company bringing in more than $4 billion during 2005. This pot of cash certainly looks to be at the end of a rainbow for members of the trial bar who continue to air ads on television recruiting patients who were prescribed Zyprexa. See Avery Johnson, Lilly Settlements, USA Today (January 5, 2007); Rick Callahan, Eli Lilly Settles More Zyprexa Lawsuits, washingtonpost.com (January 5, 2007); and Greg Toppo, Zyprexa Maker Minimized Possible Risks, USA Today (December 17, 2006).

Drug Warning & FDCA Preemption

A Pennsylvania Federal District Court, in Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D.Pa. 2006), decided to dismiss pharmaceutical failure-to-warn allegations based on implied pre-emption and deference to FDA prescription drug labeling requirements. Over the last few years, pharmaceutical companies have argued that the Food, Drug, and Cosmetic Act (FDCA) impliedly pre-empts state-law actions brought by patients injured by prescription drugs. Colacicco v. Apotex was the first district court decision on this issue since the U.S. Food and Drug Administration (FDA) reversed its longstanding position against pre-emption. Ultimately, the U.S. District Court for the Eastern District of Pennsylvania held that a plaintiff's state tort claims against manufacturers of prescription medication were impliedly pre-empted by the FDCA. The case involved Lois Colacicco, a woman who committed suicide after taking a generic version of Paxil (paroxetine hydrochloride), a selective serotonin reuptake inhibitor (SSRI). Her husband, Joseph, filed suit against Apotex, the manufacturer of the generic anti-depressant she had taken, and GlaxoSmithKline, the manufacturer of the brand-name version (Paxil), which she never took. He argued that both companies were liable under Pennsylvania state law for failing to warn his wife, or her doctor, of the increased risk of suicide associated with the medication. Conversely, the FDA argued that prior to Mrs. Colocicco's death in October 2003, it specifically and repeatedly rejected claims that adult use of anti-depression drugs increased the risk of suicide. They asserted that any warnings regarding a possible association between suicide and Paxil and/or its generic equivalent would have been false or misleading and in violation of the FDA's regulations.

While the FDA submitted an amicus brief at the court's request, the court also examined the FDA Preamble to the Rule regarding "Requirements on Content & Format of Labeling for Human Prescription Drug & Biologic Products." 71 Fed. Reg. 3922-3997 (Jan. 24, 2006). The Preamble to the drug labeling regulations stated the FDA's view that the FDCA pre-empts state tort claims of inadequate labeling. The court concluded that the preamble was an "interpretive rule" that merely clarified existing law rather than creating new law and, therefore, it could be applied "retroactively" to Mr. Colacccio's claims, even though his wife died in October 2003. Thus, it seems clear that the court deferred to the Preamble as well as the amicus brief.

The court rejected Mr. Colacicco's argument, one previously em-
braced by courts rejecting pre-emption, that FDA approval of pharma-
caceutical labeling constituted simply “minimum standards.” They did so
because in the Preamble, the FDA took the position that the FDACA
established “both a floor and a ceiling” with respect to pharmaceutical
labeling. Central to the pre-emption arguments advanced by both Apotex
and the FDA in its amicus brief was the fact that Mrs. Colacicco had
taken a generic drug. They contended that a pharmaceutical manufac-
turer is prohibited from strengthening warnings on a product label
without FDA approval. The court agreed, deferring to the FDA’s interpre-
tation of its regulations that a generic manufacturer operating under an
FDA abbreviated new drug application (ANDA) must provide labeling
and warnings identical to that of the brand name drug, and may not add
a warning or caution to the label without prior approval from the FDA.
Therefore, Mr. Colacicco’s failure-to-warn claims “inherently conflicted”
with federal law.

The decision in Colacicco treated the FDA’s views on pre-emption as
“dispositive.” The court based this pre-emption decision in large part
upon the position expressed by the FDA itself, observing, “fundamen-
tally, a series of Supreme Court decisions point this court in the direc-
tion of deference” to the FDA. In reaching this conclusion, the Colacicco
court relied heavily on Chevron U.S.A., Inc. v. Natural Resources
Defense Council, Inc., 467 U.S. 837 (1984), and Hillsborough County
mandates such deference to a federal agency’s interpretation of its own
regulations. Hillsborough applied Chevron, and also treated an FDA
statement on pre-emption as “dispositive.” Mr. Colacicco argued that
the position of the FDA had changed over time. The court found that
although the FDA’s position with respect to pre-emption had not been
entirely consistent, “there is no longer any justification for not giving
dereference to an agency’s interpretation of law merely because it is not
the agency’s longstanding position.” As such, the court concluded that
it was still obliged to defer to the FDA because it would be inappropriate
“to substitute its judgment for the FDA’s about these medical issues.”

Although the court also dismissed Mr. Colacicco’s claims against
GlaxoSmithKline on pre-emption grounds, it went on to analyze various
alternative Pennsylvania state tort claims. In another issue of first
impression, the court held that a name brand drug manufacturer does not
owe a duty under Pennsylvania common law to a user of the generic
version of the name brand drug. The court also held that Mr. Colacicco’s
state claims under the New York Consumer Protection Law were pre-
cluded by the “learned intermediary” doctrine, which is followed in
both Pennsylvania and New York. Mr. Colacicco alleged that the defen-
dants aimed deceptive, misleading marketing practices at consumer-
patients. However, the court found the learned intermediary doctrine
dictates that all pharmaceutical information is directed at physicians,
not consumer-patients.

Editors’ Comments: The Colacicco decision is not binding on any
court other than the Eastern District of Pennsylvania, and it will likely be
appealed to the Third Circuit. Nonetheless, it is significant because of
the court’s comprehensive pre-emption analysis. Therefore, it can be
expected that defense attorneys will use the decision vigorously in ef-
forts to dismiss future cases. Furthermore, while Colacicco involved a
prescription drug, depending upon how other courts view the analysis,
the decision to grant deference to the FDA’s views on pre-emption may
be useful precedent in product liability cases against medical device
companies as well. If other federal courts are forced to consider it,
Colacicco might prove to be an important turning point in pharmaceuti-
cal litigation.

Medicaid Fraud

In United States of America v. Davis, 471 F. 3d 783 (7th Cir. 2006),
the United States Court of Appeals for the Seventh Circuit considered
the appeal of a criminal conviction against an Indiana psychologist for
health care fraud for violations under 18 U.S.C. § 1347. This federal
code section states that it is a crime to “knowingly and willfully ex-
cute[, or attempt[.] to execute, a scheme…to defraud any health care
benefit program….” In this case, Dr. Davis was indicted for violation of
this statute by using “several methods to entice Indiana Medicaid to pay
claims that it would not otherwise have paid.”

Specifically, the indictment alleged that Dr. Davis billed for services
that required pre-approval. Further, it stated that Dr. Davis used un-
qualified staff to administer and interpret tests and then collected fees
for such services in contravention of the applicable Indiana billing
statute. At trial, Dr. Davis claimed that he believed that his billing
practices were in compliance with the applicable Indiana Medicaid
laws and, thus, he stated that he did not “knowingly and willfully”
vie these rules. Accordingly, he argued that he should not be con-
victed as he did not have the required mens rea to violate the federal
statute. At trial, the jury convicted Dr. Davis and he filed an appeal to
the Seventh Circuit.

On appeal, Dr. Davis claimed that (1) his billing for staff service
was legal under the Indiana Medicaid billing code, (2) that the admis-
sion of the prosecution’s Medicaid expert testimony was in error, (3)
that exclusion of an unpublished manuscript concerning billing prac-
tices was in error and (4) that the asserted charges were duplicative.
On review, the appellate court denied each of these assertions of errors
and affirmed the trial court’s conviction.

A. Billing by Staff

Dr. Davis had submitted billing to Indiana Medicaid for procedures
performed by his office staff. On appeal, he asserted that the Indiana
Medicaid statute allows such billing practices. In order to determine
this issue of first impression, the Court reviewed the plain language of
the relevant statute. Under 405, Indiana Administrative Code 5-20-8,
“Medicaid reimbursement is available for outpatient mental health ser-
"vices provided by psychologists endorsed as a health service provider in
psychology.” Dr. Davis argued that he “provided the substitute-billed
services that his staff conducted because—that even though the tests were
administered by other people—he paid the rent and utilities, trained
the staff, and acquired the various licenses under which the clinic oper-
ated.” On review, the Court found that the plain meaning of the statute
dictated that a health services provider in psychology “must be the
person who is actually engaged in the conduct of performing the tests.
Any other reading would ‘lead to absurd results.’” Further, the Court
noted that even if the services were provided by other approved indi-
viduals under the statute, Dr. Davis’s staff members were not such quali-
"fied individuals and such billing would require pre-approval under the
applicable law. Accordingly, Dr. Davis’s appeal regarding this issue was
denied.

B. Admission of the Medicaid Expert Testimony

Dr. Davis also claimed that the prosecution’s expert witness testimony
was admitted in error. Specifically, he stated that the prosecution’s
expert, who was an employee of Indiana Medicaid, opined on legal
interpretations of the governing rules and, thus, invaded the province of
the jury. The Court disagreed. Rather, the Court found that the expert
had simply stated the Indiana Medicaid interpretation and enforcement
of the governing code and its method of informing care providers. Of note, the Court stated that such administrators are allowed to opine on an agencies interpretation of the Medicaid Code and that such testi-
momy does not constitute a legal conclusion. “Experts are permitted to testify regarding how their government agency applies rules as long as the testimony does not incorrectly state the law or opinion on certain ultimate legal issues in the case.” Therefore the Court refused to find that the trial court had committed error by admitting this testimony.

C. Exclusion of the Unpublished Manuscript

Further, Dr. Davis claimed that the trial court erred by excluding the admission of an unpublished course-pack form a psychology class during the Winter of 1987-1988. Dr. Davis claimed that this packet was vital to his mens rea defense as it demonstrated that he thought it was the best practice to delegate certain testing to his office staff. The Court stated that the “photocopied, unsigned, fifteen-year old report could have been misinterpreted by the jury to imply that this was some sort of learned treatise or standard of care within the field.” As such, the Court determined that “balancing the probative and prejudicial nature of the evidence does not rise to the level of abuse of discretion.”

D. Duplicity of the Indictment

The Court found that the indictment was not duplicative. It found that there was one single count of health care fraud asserted in the indict-
mant that was asserted to have been carried out through three separate schemes. As such, it was not duplicative. As a result, the Court refused to find error in the indictment.

Editors’ Comments: The above case is of concern to medical practitioners as it demonstrates that billing standards, dictated by a respective jurisdiction’s reimbursement requirements or codes, may be strictly enforced. Further, such violations are enforceable through criminal federal prosecution. This case may serve as a warming to clinicians to carefully review terms of Medicaid billing in their respective practice jurisdictions in order to avoid potential criminal prosecution.

**Mandatory HPV Vaccine**

Human papillomavirus, which about 80% of women will have been exposed to by the time they are 50, has been identified as the causative agent in cervical cancer. Approximately 10,000 women are diagnosed with cervical cancer each year with about 1/3 of these women dying from the disease. Fortunately, the FDA approved this year a Merck vaccine against 4 of the potential dozens of strains of HPV. Researchers feel the strains targeted by the vaccine cause approximately 70% of all cervical cancers. The vaccine has been approved for patients from 9 to 26 years old. However, this vaccine has now found itself in a swirl of controversy at least a dozen state legislatures currently have legislation pending which would make this vaccine mandatory for school aged children at age 11 or 12. Although the language varies among the measures typically the students will not be denied entry to school like those who lack MMR and some other key vaccines. Some of the bills also contain language allowing exemptions for religious, medical or philosophical justifications. These proposals have generated sharp criticism from groups who cite concerns over infringing on parent’s authority or fears about encourage early sexual behavior. Still others who are opposed to vaccines in general are joining in and citing the limited experience with the HPV product. Finally, opponents may turn to the proposed cost of the three shot series needed to obtain immunity as a potential barrier. However, vaccine proponents cite the disproportionate of low income patients afflicted with cervical cancer and its associated costs as justification for mandating state based coverage. Additionally, the vaccine discussion can focus on minimizing cancer risk without involving detailed discussions of reproductive issues which can be then left for individual families to complete. See Lisa Rein & Ovetta Wiggins, Many in Senate Back Mandatory HPV Vaccination, Washington Post (January 19, 2007); AP Senators Propose New Vaccination for Girls, Chicago Tribune (January 18, 2007).

**Physician’s Liens**

The Oklahoma Supreme Court declared that a statutory physician’s lien attaches to the proceeds of a patient’s uninsured motorist coverage in *Broadway Clinic v. Liberty Mutual Insurance Co.*, 139 P.3d 873 (Oklahoma 2006). In September 2001, Tijuana Johnson was injured in an automobile accident. The Broadway Clinic provided Johnson with medical treatment after the accident. After providing treatment, Broad-
way Clinic filed a physician’s lien, under 42 O.S. 2001 § 46(B), against any payment Johnson should receive from either the tortfeasor or an insurer. Johnson asserted a claim against her insurance company, Liberty Mutual Insurance Company, for benefits under the medical pay-
ments and uninsured/underinsured (UM) motorist coverage of her policy. By April 2002, Liberty Mutual had paid Broadway Clinic $1,000.00 under the medical payments coverage of Johnson’s policy. Liberty Mu-

tual then issued Johnson a check in the amount of $4,200.00 under the UM coverage of Johnson’s policy. In July of 2002, Broadway Clinic was informed by Liberty Mutual that Johnson’s claims had been settled and that funds had been disbursed to Johnson.

Broadway Clinic filed a claim against Liberty Mutual seeking a decla-
ration that its lien attached to the UM coverage of Johnson’s policy. The issue before the judge was whether a 42 O.S. 2001 § 46(B) physician’s lien was enforceable against UM indemnity. The judge ruled a physician’s lien is not enforceable against UM indemnity. Broadway Clinic ap-
ppealed. The appeal was heard by the Supreme Court of Oklahoma. The issue before the court was whether a statutory physician’s lien is enforceable against UM indemnity. The court noted that when reviewing the findings of the trial court de novo, the appellate court exercises non-deferential authority. *Kluver v. Weatherford Hospit. Auth.*, 859 P.2d 1081,1084 (1993).

Liberty Mutual argued that when 42 O.S. 2001 § 46(B) is read in conjunction with § 46(A) of the same statute, it is clear the legislature intended § 46(B) to only apply to the tortfeasor’s insurer rather than the insurance purchased by the patient. Liberty Mutual also argued that according to Oklahoma case law, lienholders are denied access to funds received under UM coverage. Liberty Mutual further maintained that if a court construes the words “an insurer” in § 46(B) to include any insurer and not just the insurer of the tortfeasor, the result would be absurd because any insurance available to the patient could be used for the physician’s lien. Liberty Mutual finally argued that under 31 O.S. 2001 § 1.A.21, an exemption from attachment is created “for a person’s interest in a claim for personal bodily injury in an amount not to exceed $50,000.00.” Thus, Broadway Clinic cannot touch the UM benefits of Johnson.

Broadway Clinic argued the language of 42 O.S. 2001 § 46(B) is
unambiguous and does not suggest the legislature intended § 46(B) to apply only to the tortfeasor’s insurer. Since there is no language to suggest § 46(B) only applies to the insurer of the tortfeasor, the plain language of the statute must be said to apply to any insurer, including the patient’s carrier. Broadway Clinic stated the intent of the statute was to encourage physicians to offer medical treatment to any patient regardless of whether they could pay. If § 46 (B) does not allow UM funds to be used as payment for medical services, the purpose of the statute is thwarted.

According to the Supreme Court of Oklahoma, a statutory lien is in derogation of common law. Therefore, it owes its existence to legislative enactment and the language of the statute is the measure of the rights and remedies created. When the language of a statute is unambiguous and there is no conflict with another statute, a court must use the plain language of the statute when applying it. In this case the language of § 46(B) is unambiguous and is not in conflict with another statute. The Supreme Court of Oklahoma found that the plain language of the statute includes UM benefits.

The Supreme Court of Oklahoma believed that to declare UM benefits off limits to a § 46(B) physician’s lien would thwart the intent of the legislature. The intent of the legislature in enacting § 46(B) was to make insurance, which compensates a patient, available to compensate the physician who provides medical services to that patient. UM benefits are not a windfall for the injured party. Further, if the legislature had wanted to confine § 46(B) to only the tortfeasor’s insurance, the limitation would be included in the statute. The court relied on the statutory construction argument that when a word or phrase is not included in a statute, the absence is intentional. Furthermore, the court stated that the language of § 46(A) and § 46(B) are set apart in separate subsections and therefore the language of one has no effect on the meaning of the other. The two sections create two different liens that do not have a limiting effect on the other.

The Supreme Court of Oklahoma also rejected the argument of Liberty Mutual that “tortfeasor” in § 46(A) created a specific class that the general language “an insurer” from § 46(B) should be defined by. Liberty Mutual would have changed “an insurer” to the words “the tortfeasor’s insurer” by using the statutory principle of ejusdem generis. Ejusdem generis is a statutory construction argument which suggests that when general words follow specific words, the general words are not a windfall for the injured party. Further, if the legislature had wanted to confine § 46(B) to only the tortfeasor’s insurance, the limitation would be included in the statute. The court relied on the statutory construction argument that when a word or phrase is not included in a statute, the absence is intentional. Furthermore, the court stated that the language of § 46(A) and § 46(B) are set apart in separate subsections and therefore the language of one has no effect on the meaning of the other. The two sections create two different liens that do not have a limiting effect on the other.

The court also found that statutes 42 O.S. 2001 § 43 and 42 O.S. 2001 § 46(B) are far too dissimilar to say that a hospital lien does not attach to UM benefits. The language of § 43 is expressly limited to proceeds from a “claim against another for damages.” UM benefits are not received because of a claim against another for damages, thus the court held that UM benefits do not fall under a hospital lien.

The final argument rejected by the court was that the exemption from attachment under 31 O.S. 2001 § 1.A.21, excluded Broadway Clinic’s lien against Johnson’s UM benefits. The court refused to apply the exemption from attachment under 31 O.S. 2001 § 1.A.21 to exclude the lien because to do so would suggest the legislature enacted legislation that is nullified by another statute. The court construed the exemption under 31 O.S. 2001 § 1.A.21 to apply to personal injury proceeds of less than $50,000.00, except in cases in which a statutory physician’s lien is claimed.

A physician’s lien under 42 O.S. 2001 § 46(B) allows a physician to place a lien on proceeds received from a patient’s claim against an insurer. The language of the statute is plain on its face and therefore the court will not add words to the statute which might alter its meaning. The dissent argued that the language “an insurer” in § 46(B) is ambiguous and must be interpreted in a manner that best harmonizes with the rest of the statute. Because the statute is ambiguous the dissent would have the court, not the legislature, determine the reach of the lien. The dissent would apply the language in § 46(A), “the sums an injured patient recovers from his claim against a person, the tortfeasor or other third party at fault for his injury[,]” to § 46(B). The dissent further argued that when general words follow specific words, the general words apply only to “things of the same general character, kind, nature or class enumerated, and cannot include wholly different things.” Therefore, a physician’s lien attaches to benefits the patient recovers form the insurer of the tortfeasor or other third party.

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**Maryland Wal-Mart Law Invalid**

Rising health care costs are forcing many state legislatures to develop ways of countering the increases by limiting services or seeking out revenue sources. Against this backdrop there has been considerable press about Wal-Mart’s salaries and its employees utilization of Medicaid. Some statistics place the number of Wal-Mart employees on the Medicaid roster or uninsured at nearly 40%. In 2006 a democratic majority in Maryland overruled the Republican Governor’s veto and enacted the Maryland Fair Share Health Care Act. This law required nongovernmental employers with more than 10,000 employees to contribute 8% of payroll on health benefits or pay a penalty to the state’s Medicaid program. In Maryland, Wal-Mart was the only employer affected which was clear in the legislative intent. It was quickly challenged in federal court as violating ERISA by subjecting the company to a potential patchwork quilt of laws about employee health plans in violation of ERISA’s preemption provision. The disctric court agreed and overturned the statute which Maryland then appealed to the Fourth Circuit. A divided three judge panel recently affirmed the lower court’s decision based on ERISA. Maryland is weighing its option to appeal this ruling to the full court as legislators vow to go back to drawing board. With most states facing a similar crisis, new proposals seeking to accomplish similar results, but this time avoiding ERISA, will likely be proposed in the near future. See Alex Dominguez, Dismissal Upheld of Md. Wal-Mart Law, CBS News (January 17, 2007); Ylan Mui, Appeals Court Upholds Wal-Mart Health Benefits Decision, Washingtonpost.com (January 17, 2007); Jen Haberkorn, Court Upholds Killing of “Wal-Mart Bill”, Washington Times (January 18, 2007).
ACLM publishes materials and sponsors programs for medicolegal education for its members and for medical and legal professionals. **JOURNAL OF LEGAL MEDICINE** a scholarly journal published quarterly, offering in-depth discussion of topics of interest in legal medicine, health law and policy, professional liability, hospital law, food and drug law, medicolegal research and education, and a broad range of other related topics. **OTHER PUBLICATIONS** including **Legal Medicine Perspectives** and **Legal Medicine Q & A** offering information of current medicolegal interest, as well as news and information about upcoming ACLM programs. **ANNUAL MEETING** devoted to comprehensive consideration of recent developments in legal medicine and other important health law issues. **MIDYEAR MEETING** and other scientific meetings focusing on particular medicolegal topics—with emphasis on critical, timely issues. **MEMBERSHIP DIRECTORY** is an online membership database that lists all ACLM members by membership category, location, specialty interest, and area of expertise. **REDUCED FEES** for ACLM conferences. **PROFESSIONAL COMMUNITY** the opportunity to communicate and interact with your peers and others who share your interest in and concerns about legal medicine.
The snow has begun to finally melt away. Hopefully, many of you were able to attend the recent ACLM annual meeting in Florida. It was both highly educational and enjoyable. As any of you who have attended an annual meeting can attest, the meetings serve as a forum for some of the best educated minds in this country to converse about and debate topics at the interface of law and medicine. For those of you who were unable to attend the meeting, some of the presenters will adapt their research and presentations into Colleagues’ Corner pieces for this publication over the next few months.

By way of updating an LMP news brief from last year, we discussed an investigation into the butter flavoring used in microwave popcorn and its apparent link to cases of bronchiolitis obliterans (also called “popcorn workers’ lung”). This investigation appears to be ongoing and growing in scope. A recent California newspaper article detailed six more cases reported to the state occupational health and safety board. Although the causative agent is still under investigation, some evidence points to diacetyl vapors. Of some alarm is that several of the initially reported workers have died from this condition, and the progression of the disease after intial exposure appears to be fairly rapid, with symptoms appearing within a few months to years. The risk to end consumers is still theorized to be relatively low secondary to the amount of vapors released by occasional microwaving a single serving as opposed to the vats associated with factory-level production. However, you might think twice before having popcorn with your next home DVD rental, or at least opt for the healthier version of air-popped corn until the final risk numbers are in. See Bowman, Lung damage probe grows, The Sacramento Bee (January 18, 2007).

Moving much faster than the investigation into popcorn factory workers’ safety was the response to the animal research story we reported in the last issue. A Cleveland Clinic neurosurgeon used a dog for a medical device marketing presentation for company sales representatives. After the government’s and institution’s investigation, a report was issued that condemned the demonstration as a violation of research policy. Apparently, the physician obtained the animal pursuant to an approved research study protocol and then used it for the demonstration, in which company representatives got a chance to play with the medical device designed for aneurysm surgeries. Based on the report’s findings, the surgeon in question has been barred from doing animal research for two years, and the institution reportedly took an additional unnamed disciplinary action. According to figures from the United States Department of Agriculture, which is charged with regulating research animal welfare, some 50,000 dogs were used in research last year. See Sarah Treffinger, Doctor in dog demo barred from doing animal research, The Plain Dealer (February 1, 2007).

Finally, the swirl of controversy around the issue of mandatory HPV vaccination—first detailed in the January/February issue of LMP—continues to grow. Since publication of this news brief, the number of states with pending legislation aimed at making the vaccine mandatory for school-aged children has swelled to 20. Moreover, Texas became the first state to require the vaccine when its governor issued an executive order mandating that all girls entering the 6th grade receive the 3-shot series (at an approximate cost of $360 per student). The Texas order allows for parents to opt out for religious or other issues of conscience. However, some of the state bills currently pending do not have such opt-out clauses. The vaccine’s manufacturer, Merck, stands to make billions in revenue if this series of bills becomes law. Although another HPV vaccine is in development, it is unclear when GlaxoSmithKline will be able to bring it to market—leaving Merck with a monopoly at present. Although
FTCA & VA Physicians

Whether sovereign immunity is waived for the tortious acts of Veterans Administration (VA) physicians acting within the scope of their employment was litigated in Bodin v. Vagshenian, 462 F.3d 481 (5th Cir. 2006). Kent Bodin and Gordon Meyers were psychiatric patients of Dr. Gregory Vagshenian at an outpatient facility in Austin, Texas, operated by the Department of Veterans Affairs. Both men alleged that during their regularly scheduled visits, Dr. Vagshenian performed illegal, inappropriate, and unnecessary examinations of their genitalia. Mr. Bodin and Mr. Meyers claimed that the United States was liable for Dr. Vagshenian’s assault and for failing to take steps to prevent his actions. The district court observed that the United States had waived sovereign immunity for the tortious acts or omissions of its employees only when they occur within the scope of employment. Subsequently, the district court found that Dr. Vagshenian was not acting within the scope of his employment when he committed these alleged assaults.

The court reasoned that assaults on third persons fell outside the scope of authority granted to Dr. Vagshenian by the United States. Additionally, the district court found that he was pursuing his own sexual pleasure at the time of the alleged assaults and that he assaulted the men for his own personal gratification and not for the purpose of carrying out the clinic’s treatment of patients. Mr. Bodin’s and Mr. Meyer’s motion for a new trial was denied by the district court. In response, the men sought review of the district court’s judgment.

Except when waived, the United States has sovereign immunity from such suits. However, the Federal Torts Claim Act (FTCA) waives this immunity when the tortfeasor acts within the scope of his employment. The FTCA does not waive immunity for certain intentional torts; including any claim arising out of assault, battery, or various other torts. Mr. Bodin and Mr. Meyers argued that the district court erred in holding that Dr. Vagshenian was not acting within his employment when he committed the assaults. Under Texas law, an employee’s conduct is considered to fall within the scope of his or her employment if it is (1) within the general authority given him or her, (2) in furtherance of the employer’s business, and (3) for the accomplishment of the objective for which the employee was employed.

The district court found that Dr. Vagshenian’s sexual assaults were not in furtherance of the VA’s business. Rather, he acted for his own personal gratification, not for the accomplishment of the objective for which he was hired, and his actions were an expression of his personal animosity. Under Texas law, a finding that an assault was motivated solely by an individual’s personal gratification forecloses the conclusion that he or she was acting within the scope of employment. Mr. Bodin and Mr. Meyers did not cite evidence that Dr. Vagshenian considered his sexual advances to be a legitimate form of treatment. The court affirmed the finding of the district court that Dr. Vagshenian’s tortious conduct was not completed within the scope of his employment.

On appeal, the court also considered whether the district court erred in dismissing Mr. Bodin’s and Mr. Meyer’s negligence claims that the United States failed to protect them from Dr. Vagshenian’s assault. Mr. Bodin and Mr. Meyers presented evidence that VA officials had received prior complaints that Dr. Vagshenian had sexually abused patients. The court stated that there is no question that Dr. Vagshenian’s coworkers were acting within the scope of their employment. The district court held that the claims that the coworkers were negligent fell within the exception to the FTCA’s waiver of sovereign immunity for any claim arising out of assault or battery. Mr. Bodin and Mr. Meyers relied on a decision of the Supreme Court in Sheridan v. United States, 487 U.S. 392 (1988), which held that the intentional tort exception does not bar all negligence claims that are related to an assault or battery committed by a government employee.

The court has since interpreted Sheridan to mean that negligence claims related to a government employee’s intentional tort may proceed where the negligence arises out of an independent, antecedent duty unrelated to the employment relationship between the tortfeasor and the United States. In this case, Mr. Bodin and Mr. Meyers may recover only if the United States breached a duty independent of its employment relationship with Dr. Vagshenian. The men contended that the United States had an antecedent duty to protect patients in VA hospitals from reasonably known dangers. Under Texas law, a hospital has a duty to exercise care to safeguard patients from known and reasonably known dangers. A provider of psychological services has a heightened duty of care to its patients because of their vulnerability and the resulting special relationship. Thus, the district court erred in dismissing Mr. Bodin’s and Mr. Meyer’s claims based on Dr. Vagshenian’s coworkers’ independent acts of negligence in failing to prevent the sexual assaults.

Resident NRMP Lawsuit

The United States Supreme Court recently declined to review a petition filed by the plaintiffs in the lawsuit against the National Resident Matching Program. The original lawsuit was filed in 2002 by three residents at programs across the country. The lawsuit sought to obtain class action status for all residents who had participated in the match since 1998. The primary complaint was alleged antitrust violations (i.e., the match was anticompetitive and suppressed resident salaries), for which the plaintiffs sought both financial compensation and injunctive relief to reform the match process. Since its original file date some 5 years ago, the lawsuit has gone back and forth in federal court. However, the Supreme Court’s action is likely the final nail in the coffin for this lawsuit as it lets stand a circuit court’s 2006 dismissal. The circuit court affirmed the district court’s 2005 dismissal, which was based primarily on language that Congress inserted into the Pension Funding Equity Act of 2004. Congress became involved when several of the lawsuit’s named defendants lobbied for a specific exemption from antitrust scrutiny. Although not related to the title of the bill, Congress did enact specific language that addressed the NRMP and provided retroactive antitrust exemption in the above-mentioned legislation. See Champlin, Supreme Court refuses to hear NRMP suit, AAFP News Now (January 16, 2007).
Physician-Patient Relationship

Seeber v. Ebeling, 141 P.3d 1180 (Kan. App. 2006) raised the question of whether a neurosurgeon on call who refused to come to the ED to evaluate a patient established a physician-patient relationship sufficient for a malpractice action. On June 7, 2001, Christopher Seeber was injured in an automobile accident, suffering a spinal cord injury and fractures to his neck. Mr. Seeber was airlifted to St. Francis Regional Medical Center (St. Francis) and upon arrival could not move his hands or legs. St. Francis emergency room physician Dr. Randall McAllister evaluated Mr. Seeber and determined that he needed neurosurgical care. The notes from the emergency department indicated that more than 2 ½ hours after Mr. Seeber arrived at St. Francis, Dr. McAllister paged Dr. Ebeling, the neurosurgeon on call. During the phone call, Dr. McAllister gave Dr. Ebeling information concerning Mr. Seeber’s patient history, his physician, and pertinent studies. Dr. McAllister explained to Dr. Ebeling that Mr. Seeber had a spinal cord injury and a cervical spine fracture. Dr. Ebeling told Dr. McAllister that he was very fatigued and would not come to the hospital. Dr. McAllister told Dr. Ebeling that if he refused to see Mr. Seeber, he would need to be transferred to another hospital. Dr. Ebeling still refused to see Mr. Seeber and recommended that Dr. McAllister call the University of Kansas Medical Center.

Mr. Seeber was transferred to the University of Kansas Medical Center, where it was determined that he had a C7 fracture with complete paraplegia. He underwent surgery on June 8, 2001, and subsequently filed a suit claiming that the medical and other care rendered by Dr. Ebeling was negligent. Mr. Seeber appealed the district court’s grant of summary judgment in favor of Dr. Ebeling. On appeal, Dr. Ebeling argued that he did not owe Mr. Seeber a duty of care, because he had refused him as a patient. In addition, he argued that even if he owed a duty to Mr. Seeber, Mr. Seeber had failed to present any expert testimony that the standard of care for a neurosurgeon “required immediate surgery and that delaying the surgery until it was performed at KU Medical Center was a breach of such standard of care.”

Mr. Seeber argued in response that Dr. Ebeling owed a duty to him based on public policy and § 324A of the Restatement (Second) of Torts. The court premised its analysis on the fact that Kansas law was clear in stating that duty of care in a medical malpractice action against a physician is based on the existence of a physician-patient relationship. Irvin v. Smith, 31 P.3d 934 (Kan. 2001). The court did not agree with Dr. Ebeling’s public-policy argument of extending a duty of care to an on-call physician where no physician-patient relationship has been established. On the issue of whether a physician-patient relationship was established, the court relied on a factually similar case, Oja v. Kin, 581 N.W.3d 739 (Mich. App. 1998), in which an on-call doctor refused to come to the hospital to treat a patient.

In Oja, the court ruled the doctor never provided any care, treatment, or advice concerning the patient’s condition; thus, the requirement of having a physician-patient relationship was not met. Dr. Ebeling’s only opportunity to treat Mr. Seeber was during the two phone discussions that he had with Dr. McAllister. There was no evidence that Dr. Ebeling provided any advice concerning Mr. Seeber’s treatment and care. Given the factual similarities to Oja, the court ruled that Dr. Ebeling had not established a physician-patient relationship with Mr. Seeber. The court ruled that since Mr. Seeber failed to establish the existence of a physician-patient relationship or a duty on the part of Dr. Ebeling, it was unnecessary to address the standard of care.

Workers’ Compensation

Whether nonmedical home convalescent care is compensable under workers’ compensation law was litigated in Tracy v. Scherwitzky Gutter Co., 901 A.2d 1176 (Conn. 2006). James Tracy was employed by the Scherwitzky Gutter Company (Scherwitzky) as a gutter installer. On October 7, 1999, Mr. Tracy fell from the roof of a two-story home and sustained multiple fractures and traumatic brain injury. He was treated at a local hospital and discharged into the care of his sister in February 2000. Mr. Tracy’s physician, Dr. Alyse Sicklick, recommended that he remain in a supervised setting and be left alone only for short periods of time. Mr. Tracy’s memory diminished considerably, and he became unable to conduct himself in a safe manner. He would forget to take medications, wander off alone, and attempted to climb onto the roof when he believed a gutter needed repair.

Mr. Tracy’s sister was unable to care for him so he moved in with his nephew, Gregory Tracy, in March 2000. Both Gregory and his wife, Susan, who also worked outside of the home as a CNA, cared for Mr. Tracy 24 hours a day, 7 days a week. They provided guardian care rather than medical care, monitoring Mr. Tracy and reminding him to eat, change his clothes, and take his medications. In addition, whenever Mr. Tracy experienced a seizure, the couple would calm him and call an ambulance if necessary.

After Mr. Tracy’s death in November 2001, Gregory and Susan commenced an action against Scherwitzky, claiming they were entitled to benefits for the care provided to Mr. Tracy before his death. The workers’ compensation commissioner found that the care the couple provided “was not rendered by referral or under the supervision of any physician and does not rise to the level qualifying it for compensation.” The compensation review board upheld the decision and the Tracys appealed to the Connecticut Supreme Court. Home convalescent care rendered by a member of a patient’s family must be in accordance with the consent and direction of the treating physician to be compensable. Galway v. Doody Steel Erecting Co., 130 A. 705 (1925).

Under Connecticut statute, as soon as an employer has knowledge of an injury, it shall provide a competent physician or surgeon to attend to the injured employee and shall furnish any medical or surgical aid or hospital and nursing service, including medical rehabilitation services and prescription drugs, as the physician or surgeon deems reasonable or necessary. C.G.S.A. 31-294d(a)(1). In this case, the court held that the care of Mr. Tracy (1) did not fall within the definition of “nursing service,” “medical…aid,” or “medical rehabilitation services” and (2) was not deemed “reasonable or necessary” by an attending physician or surgeon. First, the court looked to the statutory language and determined medically related services to be intrinsic to the practice of nursing. The court concluded that the couple’s care of Mr. Tracy had been nonmedical in nature, and the fact that Susan was a CNA had no bearing on whether the care provided was medical in nature. Further, Mr. Tracy’s postdischarge care was not provided in lieu of hospital treatment and fell outside the scope of compensable care established by Galway.

Second, the court determined Dr. Sicklick did not follow up in any active fashion on the recommendation that Mr. Tracy be maintained in a supervised setting. In fact, Dr. Sicklick made no contact with Mr. Tracy after his follow-up visit in June 2000. The court held that the care the Tracys provided was not in accordance with the consent and direction of the physician in charge, because they did not report to a physician and did not prepare reports of the care provided to Mr. Tracy. As a result, the Connecticut Supreme Court affirmed the review board’s decision to deny compensation benefits to the Tracys.
The Nevada Supreme Court adheres to the “last injurious exposure rule” when deciding which of two employers will be responsible for injured firefighters’ compensation in Empsrs. Ins. Co. of Nevada v. Daniels, 145 P.3d 1024 (Nev. 2006). A Nevada statute provides relief for firefighters disabled from heart disease who are employed for 5 years or more before becoming disabled. The statute specifies that those incidences of heart disease be conclusively presumed to have arisen out of and in the course of the firefighter’s employment, thereby entitling the firefighters to workers’ compensation. Duane Daniels had been employed from 1970 to 1985 as a firefighter for the city of North Las Vegas, and he returned to work as a firefighter at the Nevada Test Site in 1991. In 1994, Mr. Daniels was hospitalized because of tachycardia and palpitations. He was prescribed cardiac medications and advised that being overweight and smoking cigarettes were risk factors for coronary disease.

Mr. Daniels continued taking the medication from 1994 to 1999. In 1999, as part of the requirements to participate on a hazardous materials team, his employer at the Nevada Test Site, Bechtel Nevada Corporation (Bechtel), had him undergo a stress EKG. The results were abnormal, and a follow-up nuclear scan indicated prior ischemia from a possible heart attack. A year later, Mr. Daniels suffered a heart attack, becoming permanently disabled as a firefighter. Subsequently, he filed claims for worker’s compensation with both the City of North Las Vegas and his employer Bechtel.

The District Court imposed liability on the City of North Las Vegas but did not hold Bechtel responsible. The Supreme Court of Nevada reversed and remanded for further proceedings. It determined that, according to the statute at issue, an employee does not become disabled until he is incapacitated for five or more days in a 20-day period. Additionally, the Court indicated that the “conclusive firefighter’s presumption” removed the burden of having to prove that the injury was work-related. However, a firefighter’s failure to correct predisposing conditions that can lead to heart disease can mean he no longer qualifies for benefits, so long as the correction is within the firefighter’s control.

The Court determined that under the “last injurious exposure rule,” Bechtel should be held liable for the injury to Mr. Daniels. However, the Court indicated that Bechtel could present evidence that Mr. Daniels failed to correct risk factors of coronary artery disease that were within his control, including smoking cigarettes and being overweight. The Court noted that the City of North Las Vegas was too proximate to be held liable for Mr. Daniels’ injury, because he was not incapacitated for 5 days within a 20-day time period to qualify as disabled between 1970 and 1985. The concurring opinion indicated that the physician’s order that Mr. Daniels stop smoking was too ambiguous to constitute a correction of predisposing conditions. As such, his history of smoking is relevant, but the burden should be on the employer to demonstrate that the smoking did more than merely accelerate or exacerbate the coronary disease. The burden of overcoming a statutory conclusive presumption should be on the defendant.

MRI Kickback Lawsuit

The Illinois attorney general recently decided to intervene in a whistle-blower lawsuit filed back in 2006. John Donaldson, who owns several MRI imaging centers in Illinois, filed a lawsuit alleging that his competitors were entering into illegal agreements to provide kickbacks to referring physicians. The complaint alleged that the MRI centers involved essentially provided the imaging service to the physicians for a reduced rate and allowed them to pocket the difference. Rather than a direct payment these alleged kickbacks were disguised as complicated lease agreements, whereby the physicians appeared to lease times at the imaging center for their patients; however, because the imaging center employees actually did all the work, the physicians never did more than refer the patients. Despite this, the physicians nevertheless billed insurance providers for part of the service that the complaint alleged represented the kickback amount.

Similar investigations are proceeding in Florida and Louisiana. Medical imaging costs, which have grown some 20% annually since 1999, are one of the fastest-growing Medicare charges. During the 2005 fiscal year, Medicare paid more than $7 billion for imaging-related services, thus providing significant motivation for investigations into allegations of fraudulent billing. Due to a concern about similar lease arrangements and billing by physicians for services that they do not fully provide at their own facilities, the Centers for Medicare and Medicaid Services (CMS) has recently issued guidelines. Even wholly owned facilities raise significant concerns about whether charges are inflated compared with what is obtainable on the open market. The penalties for the Illinois lawsuit could be quite significant, as state antikickback law provides for monetary fines from $5,000 to $10,000 per submitted bill—and with this number easily in the hundreds to thousands, the final total may be impressive. As with other whistle-blower litigation, the initial plaintiff stands to collect 30% of what the government recovers. See Armstrong, Illinois enters lawsuit over MRI kickbacks, The Wall Street Journal (January 18, 2007); Kaiser, Attorney general joins MRI kickback scheme case, Diagnostic Imaging Online (January 22, 2007).

Search Warrants

*United States v. Hurwitz*, 459 F.3d 463 (4th Cir. 2006) involved a physician who was criminally investigated for illegally supplying narcotic pain medications and challenged the search warrant for lacking specificity. Five patients of Dr. Hurwitz collaborated with police officers to obtain tape-recorded evidence that Dr. Hurwitz was supplying patients with methadone, oxycodone, and hydromorphone in a fashion typical of a drug dealer. Dr. Hurwitz was accused of prescribing more than 500,000 pills to one patient in a single year and typically prescribing an average of more than 100 pills per day. Dr. Hurwitz was charged with one count of engaging in a criminal enterprise, two counts of healthcare fraud, and 58 counts of drug trafficking, including two counts each of drug trafficking resulting in serious bodily injury and drug trafficking resulting in death. The jury acquitted Dr. Hurwitz on six counts of drug trafficking and two counts of healthcare fraud, as well as the count related to engaging in a criminal enterprise, but found him guilty of the remaining charges for which he was sentenced to 25 years in prison.

On appeal, the U.S. Court of Appeals had to consider three main issues. First, Dr. Hurwitz contended that in the warrant executed to search his office, the description of items to be seized was too broad and violated the “particularity” requirement for warrants, thereby resulting in a violation of his Fourth Amendment rights against unreasonable search and seizure. Second, Dr. Hurwitz contended that the state had violated the Fourth Amendment because the copy of the warrant
with which he was provided, along with the copy which the executing officers kept for themselves at the time of the search, did not include any description of the items to be seized or locations to be searched. Instead, it read only “See Attachment A” and did not include the attachment. Finally, Dr. Hurwitz argued that his good faith in issuing the challenged prescriptions was relevant to his intent when treating his patients and thus relevant to the jury's determination of whether he acted outside the bounds of accepted medical practice or without a legitimate medical purpose. In vacating the jury verdict and remanding the case back to the lower court for a new trial, this court disagreed with Dr. Hurwitz on the first two issues but determined that some form of good faith intention was required in the jury instruction regarding all of the charges.

The court concluded that the search warrant properly cross-referenced the attachment, which, in turn, supplied the requisite particularity to the search warrant, regardless of whether the attachment accompanied or was appended to the search warrant at the time it was executed. The court also stated that where there is probable cause to believe that a business is “permeated with fraud,” either explicitly stated in the supporting affidavit or implicit from the evidence therein set forth, a warrant may authorize the seizure of all documents relating to the suspected criminal area but may not authorize the seizure of any severable portion of such documents relating to legitimate activities.

Of particular import are the first two claims upon which Dr. Hurwitz requested suppression of the evidence against him. Oddly, this court chose not align itself with the majority of circuits, but joined with only the Sixth Circuit regarding the particularity requirement. In most circuits, for a warrant to be valid, the copy that is used by the police during the search and the copy provided to the individual whose dwelling is being searched or from which items are seized must include a description of the items and locations with particularity, because the officers executing the search are limited to the scope of the warrant. The court concluded that another safeguard was unnecessary and held that the constitutional limitations in question were not erected for the purpose of monitoring searches by the public, but rather were related to the probable-cause determination of an independent magistrate prior to execution of the search alone. The court's decision herein threatens the underpinnings of the Fourth Amendment, because there already exists a constitutional immunity under the statute. The key issue when determining whether physicians are liable for a patient's suicide involves a determination of imminency, as established in Marshall v. Klebanov, 875 A.2d 1035 (N.J. Super. 2005). Ellen Marshall was a 36-year-old married mother of two who suffered from major depression. In December 1999, Ms. Marshall made comments to her mother and her sister that caused them to seek the advice of a psychiatrist, Dr. Klebanov. Ms. Marshall's mother told Dr. Klebanov about her daughter's suicidal tendencies. Ms. Marshall made an appointment with Dr. Klebanov for January 7, 2000. Before the appointment, she completed a questionnaire informing Dr. Klebanov of her past, including her medical history, family history, and two previous suicide attempts.

At the appointment, Dr. Klebanov noted Ms. Marshall's suicidal thoughts and diagnosed her with major depression, depressed mood, blunted affect, poor insight, and poor judgment. He increased her medicine intake, determined it was necessary to see her weekly, and scheduled another appointment for January 14, 2000. When Ms. Marshall returned the following week, the doctor did not see her. The reason she was not seen is in dispute. Mrs. Marshall's husband claims the receptionist would not allow Ms. Marshall to pay with a credit card and therefore, she could not see the doctor. Dr. Klebanov claimed never to have refused to treat a patient because he or she could not pay. Instead, he claimed that upon learning she could not use her credit card, Ms. Marshall cancelled her appointment, because she did not have insurance and could not afford to pay for the session herself. He claimed that Ms. Marshall said she was feeling well and would wait a few weeks until she obtained insurance.

Dr. Klebanov rescheduled Ms. Marshall's appointment for February 4, 2000—almost a month after the initial session. Unfortunately, Ms. Marshall hanged herself on February 2, 2000. Her husband sued Dr. Klebanov on behalf of himself and his wife's estate for malpractice and wrongful death. The trial court granted summary judgment, stating that Dr. Klebanov was statutorily immune from liability for Ms. Marshall's suicide under N.J.S.A. 2A:62A-16. Mr. Marshall appealed and the appellate court reversed the trial court's decision, sending the case back. The court reversed the ruling because Dr. Klebanov's conduct did not warrant immunity under the statute.

The statute creates a duty to warn and protect when the patient informs the doctor of an imminent threat of serious violence against him or herself or another person and a reasonable professional would believe those threats to be real. A doctor who has such a duty can discharge that duty in one of three ways: (1) Arrange for admission or

**Liability for Suicide**

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The statute creates a duty to warn and protect when the patient informs the doctor of an imminent threat of serious violence against him or herself or another person and a reasonable professional would believe those threats to be real. A doctor who has such a duty can discharge that duty in one of three ways: (1) Arrange for admission or
involuntary commitment of the patient to a psychiatric hospital or other appropriate facility, (2) Advise local law enforcement of the threat, or (3) Warn the potential victim (and/or parent or guardian if the patient is a minor). A doctor can also be held liable for failing to discharge the duty. The court claims the legislature did not intend to create immunity from all liability for suicides when the threat was not imminent. Instead, the relevant bill provided immunity from “certain civil suits.”

Dr. Klebanov established that Ms. Marshall’s condition needed to be monitored weekly, yet he failed to treat her weekly. In fact, he scheduled a follow-up appointment almost one month after their first appointment. If Dr. Klebanov had been meeting weekly with Ms. Marshall, he may have seen the immediacy of her suicidal tendencies. Instead, his own negligence may have prevented recognition of an immediate suicide threat. The doctor cannot escape liability simply by “shutting his eyes” for fear of what he might learn and then later claim ignorance. The dissenting judge argued that there is a difference between high risk and imminent risk. The judge claimed that although Ms. Marshall had a high risk for suicide, that high risk did not meet the standard of care necessary for protection. However, under these circumstances, Dr. Klebanov should not be given immunity. The court’s decision clarifies what is covered under N.J.S.A. 28:62A-16. After this case, doctors will not be able to claim immunity from all liability for suicides.

### Genetic Discrimination Legislation

The House Education and Labor Committee recently approved legislation aimed at preventing genetic discrimination. Although similar measures have been debated and pending in Congress for a decade while some Republican leaders worked to prevent bringing the measures to a vote for fear of how they will affect business, this current measure seems to be on the fast track for adoption. The Senate recently passed a version with similar language, and the President has spoken in favor of the bill and indicated his willingness to sign such a measure. The Genetic Information Nondiscrimination Act of 2007 (GINA) has broad bipartisan support. However, the Chamber of Commerce and some from the corporate world have strong objections based on fear that the legislation will lead to an increase in employee discrimination lawsuits. GINA would prevent employers from making hiring or firing decisions based on genetic information. Additionally, the legislation would make it unlawful for insurance providers to base premium rates based on genetic test results. Privacy and consumer-health advocates have testified in strong support for the measure, which would impose uniformity to the patchwork-quilt approach currently in place. There are more than 1,000 commercially available genetic tests that health consumers routinely obtain. GINA would ensure that these test results are afforded a certain amount of privacy and would prevent adverse employment and insurance decisions based on genetic testing. Currently some 41 states have laws that seek to prohibit health discrimination based on genetic test results, and 34 states ban such discrimination in the workplace. See Zhang, Genetic-discrimination ban nears congressional approval, The Wall Street Journal (February 15, 2007); Education & Labor Committee approves legislation to prevent genetic discrimination, Press Release, U.S. House of Representatives (February 14, 2007).

### Medical Device Manufacturer Liability

**Kennedy v. Medtronic, Inc., 851 N.E.2d 778 (Ill. 2006)** involved allegations of negligence against the manufacturer of a medical device whose sales representative watched while a surgeon improperly inserted the device. Medtronic is a medical device manufacturer of prescription medical devices. The company sells its products to licensed physicians. In 1999, Medtronic sold a pacemaker to a physician to be implanted in a patient during an outpatient procedure. A clinical specialist for Medtronic provided technical support during the surgery. Her role was primarily to ensure that once the physician placed the lead into the ventricle of the heart, it was capturing and sensing properly.

Six months after the pacemaker was implanted, the patient was found unresponsive. A second physician determined that the lead needed to be relocated from the left ventricle, where it had been implanted, to the right ventricle. A new pacemaker was implanted in the patient in the hospital. The patient passed away 3 months later from renal and heart failure. He was 75 years old. His daughter filed suit on behalf of his estate, alleging injury and wrongful death.

The physician who implanted the Medtronic pacemaker in the first surgery admitted he deviated from the standard of care by inserting the leads in the left ventricle. Medtronic’s clinical technician testified that it was not her responsibility, nor did she possess the necessary skills, to identify whether the lead was placed in the correct ventricle. The expert witness’s testimony, offered by the decedent’s estate, opined that the insertion of a pacemaker is always an inpatient procedure and Medtronic’s specialist, in his opinion, should not have handed over the pacemaker or proceeded to assist with the surgery once she realized that the facility was an outpatient facility. The safety of the device was not at issue and there was no evidence of a defect in the pacemaker.

The court granted summary judgment in favor of Medtronic. The decedent’s estate appealed, arguing that Medtronic was liable for negligence to the decedent, specifically that Medtronic had a duty to refrain from providing the pacemaker to the physician and from participating in the insertion of the pacemaker because of the conditions surrounding the procedure. Second, the estate argued that Medtronic had a duty to warn the decedent regarding the dangers of proceeding with the surgery under the conditions present. Finally, the estate argued that once Medtronic voluntarily participated in the procedure, it assumed a duty to assist in a reasonable manner. Medtronic responded that there was no legal basis to support any of these claims and that they had no duty to prevent or guarantee against physician malpractice.

The appellate court looked to four factors to determine whether Medtronic had a duty to refrain from providing the pacemaker and assisting in the procedure, and a duty to warn the patient. The factors were 1) the reasonable foreseeability of injury, 2) the likelihood of injury, 3) the burden of guarding against injury, and 4) the consequences of placing that burden on the defendant.

In applying the factors to the facts of the case, the court concluded that a physician could have misplaced the leads in a hospital on an inpatient basis. Therefore, Medtronic had no greater ability to foresee that it was more likely for the leads to be inserted in the left rather than the right ventricle in this particular setting. Furthermore, it would be a significant burden to require Medtronic to monitor the conditions under which a physician performs the surgery, and the consequences of a Medtronic clinical specialist delaying or preventing a procedure would place the manufacturer of medical products in the middle of the doctor-patient relationship. Finally, if manufacturers could deny or delay
the patient’s treatment, there could be harm to the patient and increased liability for manufacturers of medical products.

On the alternative theory that Medtronic owed a duty to assist in a reasonable manner once voluntarily undertaking participation in the procedure, the court held that the duty was limited to the extent of the undertaking. Since Medtronic’s clinical specialist attended surgery to provide technical support and ensure that the leads were functioning properly, Medtronic’s role was limited to this function. This limited role did not entail the placement of the lead in the correct ventricle of the patient’s heart. Since no duty was found, the appellate court affirmed the summary judgment of the circuit court.

Although the court noted the learned intermediary doctrine that requires manufacturers of prescription drugs to warn prescribing physicians of the drugs’ known dangers, the court did not extend this doctrine to the facts presented in this case. The court looked to the question of whether a duty existed and answered it as a question of law properly determined by the court.

However, an alternative view may have looked at the expert testimony and concluded that the experts were not proper standard-of-care experts for the alleged breach of Medtronic. The standard-of-care testimony came from two physicians, not clinical specialists trained or practicing in the role of a medical product manufacturer’s clinical specialist. In Illinois, physicians are not proper standard-of-care experts for nurses. It would seem reasonable to exclude standard-of-care testimony proffered by two physicians regarding the actions of a clinical care specialist because not doing so risks holding the clinical specialist to the elevated standard of a reasonable physician.

Disability Accommodations

A city is required to make exceptions to zoning laws for a mental health facility only if doing so is necessary to avoid discrimination, according to the eventual holding in Wisconsin Community Services, Inc. And Wisconsin Correctional Foundation, Inc. v. City of Milwaukee, 465 F.3d 737 (7th Cir. 2006). Wisconsin Community Services (WCS) is a private, nonprofit provider of mental health services in Milwaukee, Wisconsin. WCS provides patients with psychiatric treatment, medication monitoring, and counseling. Most of these services are administered in the 7,500 square-foot building WCS occupies. Between 1994 and 1998, WCS increased its staff from 20 to 40 full-time employees. Its patient load also increased, growing from 250 to 400 patients. This growth caused a shortage in space for parking, group therapy, and individual treatment. WCS found a building suitable for its expanding operation. The building is located in a “local business district” zone. At the time, it was undergoing a commercial revitalization. The owner agreed to WCS’ offer to buy, which was contingent on obtaining zoning.

WCS submitted its plans to the Department of City Development (the DCD). The DCD determined that the statutory requirements for a special use permit were not met. Specifically, the zoning officials were concerned with protecting neighboring property values, in light of the commercial efforts in the neighborhood. WCS appealed to the Milwaukee Board of Zoning Appeals (BOZA) and had a hearing on March 22, 2001. BOZA prohibited WCS from presenting evidence that the Americans with Disabilities Act (ADA) required BOZA to modify the special-use criteria so that WCS would have the same opportunity to obtain a permit, as would a clinic serving nondisabled individuals. Based on other evidence, BOZA unanimously voted to deny the WCS application on May 9, 2001.

WCS then filed this action in the United States District Court for the Eastern District of Wisconsin. It alleged that BOZA’s failure to modify its method for deciding special use cases violated the ADA and the Rehabilitation Act. The district court found BOZA violated federal disability laws by failing to consider changing its policies for WCS. On September 12, 2002, BOZA heard testimony regarding whether the ADA and the Rehabilitation Act required the city to modify its zoning policies. On December 22, 2003, BOZA denied the special permit because such an accommodation was unreasonable and unnecessary. On January 24, 2003, WCS reinstated its federal court action to challenge BOZA’s second ruling. Again, WCS argued that the permit violated the ADA and the Rehabilitation Act. The district court held that WCS must show that the accommodation was reasonable and necessary to ameliorate the effects of its patients’ disabilities and enhance their quality of life. First, the court held that the benefit to the patients outweighed the purported cost to the city, thereby meeting the reasonableness criteria. Second, the court concluded that necessity may be shown by a good-faith attempt to find an alternative. WCS satisfied the good faith test, and showed that the new facility would ameliorate some of its patients’ disabilities, thereby meeting the necessity criteria.

Upon the district court’s decision, the city appealed to the 7th Circuit Court of Appeals to decide if and to what extent a city must alter its zoning plan to prevent discrimination against the disabled. First, the appellate court relied on the Rehabilitation Act’s “by reason of” test that allows for accommodation only when a person’s disability, and not some quality shared by the general public, is the barrier to benefits. Alexander v. Choate, 469 U.S. 287 (1985). Next, the court invoked the Fair Housing Amendments Act (FHAA) that requires that the housing accommodation be reasonable and necessary, and that the necessity be linked to the goal of equal opportunity. This is enforced by considering whether the particular law in question, hurts “handicapped people by reason of their handicap,” rather than...by virtue of what they have in common with other people, such as a limited amount of money to spend on housing.” Hemisphere Bldg. Co. v. Vill. of Richton Park, 171 F.3d 437, 440 (7th Cir. 1999). Finally, the court relied on Title II of the ADA that forbids discrimination in public services, programs, and activities subject to Title II. Title II provides that a public entity should make reasonable accommodations for the disabled unless it can show that such accommodation would fundamentally alter the nature of the service or program. 28 C.F.R. § 35.130(b)(7). Taking all three regulations into account, the court determined that all three require a disabled party to satisfy the “necessary” element.

WCS argued that if a modification will merely help the disabled it satisfies the “necessary” element. The appellate court finds this view inconsistent with previous applications of the Rehabilitation Act, the FHAA, and Title II of the ADA. Because the patients’ mental illness is not the cause-in-fact of WCS’ inability to move to the new building’s zone, there is no established need to make an exception to the zoning law. To prevail, WCS would have to demonstrate that it cannot find an appropriate building because its patients are disabled. The appellate court remanded the case to the district court to decide if WCS’ inability to relocate was on account of the patients’ disability.
Mental Health Parity

Proponents of mental health parity legislation got a Valentine’s Day present when the Senate Committee on Health, Education, Labor, and Pension passed a measure that now goes to the full Senate. The bipartisan legislation seeks to build upon the 1996 adoption of mental health parity legislation. First, the proposed legislation will define the meaning of parity and expand it to include deductibles, copays, and hospital stays as opposed to the previous legislation, which fell short by addressing lifetime limits. The measure does not mandate coverage for mental health services, but only requires equal treatment with other medical conditions under the patient’s policy. Similar legislation has been stalled for the past decade over industry objections citing significant cost concerns. Significant to the bill’s ultimate passage is that key industry players have signed off on it and compromises have been factored in to ease the possible financial burden. In supporting the measure, industry notes that only employers with more than 50 employees will be affected; the measure exempts plans if costs increase more than 1% year after the first year; and, finally, the measure unifies the definition of parity as opposed to the current piecemeal system of individual state regulations. Bringing about some uniformity is important as many plan providers operate across state lines and compliance with varying regulations has intrinsic costs that can be reduced. Currently about 40 states have adopted definitions of parity. The measure is important because according to National Institutes of Mental Health data about 1 in 4 Americans over the age of 17 suffer from a diagnosable mental illness in any year. See Zhang, Mental health nears ‘parity’, The Wall Street Journal (February 13, 2007). Staff, Mental health bill moves forward in Congress, ScientificAmerican.com (February 15, 2007).

Statute of Limitations

The Supreme Court of Connecticut addressed the applicability of the continuing course of conduct exception to the statute of limitations against healthcare associations and hospitals in Zielinski v. Kotsoris, 901 A.2d 1207 (Conn. 2006). Shelly Zielinski initially sued her neurologist, Dr. Harriet Kotsoris, her radiologist, Dr. Kristan Zimmerman, Stamford Radiological Associates, P.C. (Associates) and Stamford Hospital (Hospital), alleging negligence in the misdiagnosis of her brain tumor. Dr. Zimmerman and Dr. Kotsoris, failed to diagnose her tumor by MRI, and instead diagnosed Ms. Zielinski with Lyme disease. An MRI 3 years later revealed the tumor, which was then determined to be visible on the first MRI. In particular, Ms. Zielinski appeals as to the Associates and the Hospital for their roles in providing ongoing care that should have tolled the statute of limitations and allowed the suit. Ms. Zielinski did not dispute that the statute of limitations had run as to claims against Dr. Kotsoris and Dr. Zimmerman.

At issue was whether the Associates and the Hospital had continued a course of conduct toward Ms. Zielinski by conducting and evaluating both MRIs, thereby tolling the statute of limitations and permitting the case to be heard. The Associates and the Hospital countered that separate consultations by members of the same practice group 3 years apart did not constitute an ongoing provider-patient relationship. The relevant statute of limitations requires allegations of healthcare malprac-
tice to be brought within 2 years of the injury’s discovery, but no longer than 3 years post-negligence. The 3-year limitation, the court noted, existed regardless of whether the patient discovered the injury during that time. The statute of limitations will not toll until treatment of the patient is completed.

Ms. Zielinski filed suit more than 5 years after the alleged negligence of the Associates and the Hospital. The court relied on the modern formulation of the continuing course of conduct doctrine that could toll the statute of limitations. The court determined that the doctrine did not apply in this case, barring the suit against the Associates and the Hospital 5 years after negligent misdiagnosis. The court found that “there must be evidence of the breach of a duty that remained in existence after commission of the original wrong related thereto.” Additionally, that duty must not have terminated before the relevant statutory period. A continuing course of conduct has been found in cases involving a special relationship between the parties and those cases where a subsequent negligence occurred related to the prior act.

Ms. Zielinski had to show (1) an initial wrong, (2) a related continuing duty, and (3) a continual breach of that duty. The court determined that the discrete and isolated contacts with the Associates and the Hospital over the last 3 years did not constitute an ongoing physician-patient relationship, giving rise to a continual duty. Absent a continuing duty or continuing treatment, the statute of limitations is not tolled, and Ms. Zielinski failed to sue before the statute of limitations expired. The court found that treatment had been terminated long before the 3-year limit for the statute of limitations. This case demonstrates the narrow applicability of the continuing course of conduct doctrine as it applies to medical associations and hospitals.

For family physicians, a continuing course of conduct is more easily proven. In particular, there cannot be a large break in treatment of the patient that renders individual consultations separate and distinct. The consults must be of such regularity that they create the presumption of ongoing treatment. When a state sets a firm statute of limitations for medical malpractice, it aims to infuse predictability and certainty into the medical practice. Five years is simply too long for healthcare professionals to face the continuing threat of liability for negligence. Had the Associates and the Hospital been continuing providers of care to Ms. Zielinski, they could be held liable but might have corrected the misdiagnosis sooner. Contributory and/or comparative negligence theories might have applied had the court chosen to evaluate the case on its merits.

The issue of whether actual knowledge is required before a party may invoke the continuing course of conduct exception to the statute of limitations was litigated in Neuhaus v. DeCholnoky, 905 A.2d 1135 (Conn. 2006). Christopher Neuhaus was born prematurely on September 17, 1990, at Stamford Hospital (Hospital). Dr. Corinne DeCholnoky delivered Christopher without performing an amniocentesis prior to inducing labor. Dr. DeCholnoky knew a premature baby could develop respiratory distress syndrome and that an amniocentesis was the only way to determine lung maturity. Subsequently, Christopher developed respiratory distress syndrome, but it was not until Christopher’s parents changed pediatricians and requested his medical records that they discovered brain damage was a common risk of respiratory distress syndrome. Christopher now suffers from brain damage and cerebral palsy.
On July 16, 1996, the Neuhauses filed suit, alleging that the Hospital and Dr. DeCholnoky were negligent in their care of Christopher and his mother. The Hospital and Dr. DeCholnoky argued that because 6 years had passed from the time of the alleged wrongful conduct, the suit was time-barred according to the statute of limitations. The relevant statute requires claims be brought within 2 years of discovery of the injury, but in no event later than 3 years after the act. However, the Neuhauses countered that the continuing course of conduct doctrine applied and therefore the 3-year repose provision of the statute had not run. The Neuhauses claimed the continuing course of conduct doctrine suggested that the Hospital and Dr. DeCholnoky had a continuing duty to inform them of the risk of permanent damage resulting from the respiratory distress syndrome Christopher suffered.

The court determined that the continuing course of conduct doctrine did not apply to the Hospital and rendered summary judgment in their favor. The appeals court reversed the trial court and both parties appealed. The first issue before the Supreme Court was whether the appellate court was correct in applying the continuing course of conduct doctrine to the Hospital. The second issue was whether the Neuhauses’ claims against Dr. DeCholnoky were time-barred because the continuing course of conduct doctrine does not apply to her. The Hospital argued that applying the continuing course of conduct doctrine to them or to Dr. DeCholnoky disregards the statute of repose in medical malpractice cases and imposes a perpetual duty on physicians to warn patients of any risk of future harm.

Furthermore, the Hospital argued that there is no evidence that it believed or had knowledge that Christopher could develop more serious risks of respiratory distress syndrome. The Neuhauses argued that a failure to apply the continuing course of conduct doctrine redefines the scope of duty Dr. DeCholnoky owes according to the statute and fails to recognize the duty to warn of the known risks of failing to conduct necessary tests prior to birth. The Supreme Court of Connecticut recognized that an action commenced more than 3 years after the date of the act is normally time-barred unless the continuing course of conduct doctrine applies. To apply the continuing course of conduct doctrine, a court must find there was a breach of an ongoing duty. This is evidenced by a special relationship between the parties or by later, wrongful conduct, which relates to the original conduct at issue.

The Hospital argued that it had no continuing duty to the Neuhauses. The court agreed; a physician does not have a duty to correct a misdiagnosis unless the physician learns or has actual knowledge that the original diagnosis was in fact incorrect. Blanche v. Barret, 640 A.2d 74 (1994). The court held there was no evidence in this case that any doctor had concerns about potential risks to Christopher or that any doctor later became aware that an initial diagnosis was incorrect. Therefore, the continuing course of conduct doctrine did not apply. The court determined that if it were to apply the continuing course of conduct doctrine to this case, a physician would have a continuing duty to warn a patient of any risks of a procedure regardless of the remoteness of the risks or whether the physician believed the patient was at risk. With respect to Dr. DeCholnoky, the court found she did not owe a continuing duty to warn the Neuhauses that Christopher might develop health problems. The court reiterated that for the continuing course of conduct doctrine to apply, there must be a breach of a duty that continued after the original wrong was committed. Golden v. Johnson Memorial Hospital, Inc., 785 A.2d 234 (2001).

In the case at hand, the court focused on whether Dr. DeCholnoky ever had a legal duty to the Neuhauses. It focused on the public-policy element of whether a legal duty exists and determined that in this case, Dr. DeCholnoky did not have a duty to warn the Neuhauses of the risks associated with respiratory distress syndrome. Dr. DeCholnoky only had a duty prior to and during the delivery of Christopher. After Christopher was delivered, Dr. DeCholnoky no longer had a duty to Christopher because she no longer treated him. To hold otherwise would impose a duty on all physicians to warn of risks after they become aware of a diagnosis of a former patient. Furthermore, to impose a duty to warn, as long as the consequences of the failure to warn were ongoing, would effectively eliminate the statute of limitations applied to medical malpractice suits in the state.

HMO Litigation

Merkle v. Health Options, Inc., 924 So. 2d 808 (Fla. 2006) examines whether Florida statute § 614.513(5) states a private right of action providing for declaratory relief. Merkle is a professional association providing emergency orthopedic services, as a nonparticipating provider, to patients insured by the HMOs as required by Florida statute §614.513(2) (2003) (The statute requires emergency service providers to care for HMO subscribers regardless of whether the provider participates in the HMO’s health plan). Merkle alleges the HMOs violated Florida Statute §614.513(5) (2003), which lists reimbursement for providers without a contract with the HMO shall be the lesser of 1) the provider’s charges, 2) the usual and customary provider charges for similar services in the community, or 3) the mutually agreed upon charge between the provider and the HMO. Merkel claims the HMO’s paid class members amounts equal to 120% of the Medicare reimbursement schedule, rather than the usual and customary provider charges.

The defendant’s motions for dismissal were granted with prejudice by the trial court, which concluded that 1) Florida statute §614.513(2) (2003) did not state a private right of action, thus Merkle must assert the defendant’s claims through an alternative dispute resolution process as provided in §408.7507, thus declaratory and injunctive relief was not available; 2) as there was no benefit received by the HMOs, Merkle’s claim for unjust enrichment failed; 3) a claim for account stated failed as the Explanation of Benefits attached to Merkle’s complaints showed that the HMOs did not agree to pay Merkle’s billed charges. The appellate court reversed the dismissal on all claims except the account stated.

The appellate court stated that Florida statute §614.513(2) (2003) implied a private right of action as the dispute here was not whether civil liability was established heretofore but rather the methodology for use in establishing the extent of that liability and the applicable enforcement remedy. Adventist System/Sunbelt, Inc. v. Blue Cross & Blue Shield, 934 So.2d 602 (Fla. 5th DCA 2006). The court distinguished several cases proposed by appellants as inapplicable that were limited to the provisions of the HMO Act (rather than Florida statute §614.513(2)), which the court held did not establish a private right of action, as it lacked a legislative intent to do so. Additionally, Florida law provided that provisions enacted by the legislature are intended to have some useful purpose. Smith v. Piezo Tech. & Prod’l Adm’rs, 427 So.2d 182, 184 (Fla. 1983). In Smith, the Supreme Court acknowledged that “because the legislature enacted a statute that clearly imposes a duty and because the intent of the section is to preclude retaliatory discharge” (upon review of the legislative history Fla. H.R. Comm. On Health Care, CS for HB 979 [1996]), the statute confers by implication “every particular power necessary to ensure the performance of
that duty” thus clearly imposing a duty on HMOs to reimburse nonparticipating providers according to the statute’s dictates and not based on Medicare reimbursement rates. The court also disagreed with the HMO’s contention that dispute resolution was mandatory, stating that although an option, the intent of the legislature did not confer exclusive jurisdiction, thus the dispute resolution process was voluntary.

The appellate court also dismissed the motion for unjust enrichment where the elements include bestowing a benefit with knowledge of the defendant that is voluntarily accepted and retained, and it would be inequitable for defendant to retain the benefit without paying the value thereof to the plaintiff. Florida law provides that the appellate court should not consider the merits of a claim but only whether the party can plead it when reviewing the dismissal of a claim. As the trial court considered the ultimate merits of the case, the court held it was improper to dismiss, as Merkle had alleged facts sufficient to support its argument that treatment of the subscribers conferred a benefit on the HMOs.

On the claim of account stated, the appellate court agreed with the trial court, stating that there was no agreement between the parties that a certain balance was correct and due as illustrated in the “Explanation of Benefits” attached to Merkle’s claim. As the attachment facially negated the cause of action asserted, the trial court did not err in dismissing the claim for account stated. The court also reversed the claim for declaratory relief, stating that as an actual controversy existed between two parties who had an ongoing dispute concerning the meaning of the statute, unquestionably declaratory relief may be authorized.


Westside filed a complaint against seven HMOs claiming three causes of action. The claim for breach of a third-party beneficiary contract is the claim before this court. The HMOs were unsuccessful in having the case removed to federal court. The trial court dismissed Westside’s complaints with prejudice as they did not allege a cognizable cause of action.

On appeal, the Fourth District Court of Appeal reversed the trial court and remanded the case for further proceedings in *Westside EKG Associates v. Foundation Health et al.*, 932 So.2d 214 (Fla. 4th DCA 2005), concluding that service providers, claiming as third-party beneficiaries under a subscriber’s contract, may bring an action founded on the HMO’s failure to comply with the prompt-pay provisions of the HMO Act.

Westside alleges that subscribers received medical services from its physicians under policies and contracts to which Westside was a third-party beneficiary. Specifically, Westside claims the HMOs breached said contract by violating § 641.3155, 641.17-641.3923, Florida Statutes (2001). § 641.3155, Florida Statutes (2001) (the “prompt pay provisions”) of the HMO Act provides that HMOs shall pay a claim no later than 120 days after receipt, and failure to do so creates an uncontestable obligation for the HMO to pay the claim to the provider.

The Supreme Court agreed with the appellate court, beginning with the fact that although the HMO Act did not expressly authorize a private cause of action to enforce its provisions, it did not preclude the right to bring a common-law claim based upon the same allegations, stating that the HMO Act acknowledges a right to bring a negligence claim. Since the subject of the dispute was statutory interpretation, the parties are presumed to have entered into their agreement with reference to such statute, which becomes a part of the contract. *Id.* Moreover, given the significant statutory regulation surrounding HMO contracts and the integral role of prompt-pay provisions, those provisions may be incorporated into the HMO contract, although not expressly stated.

Florida courts have long recognized that the statutory limitations and requirements surrounding traditional insurance contracts may be incorporated into an insurance contract for purposes of determining the parties’ contractual rights (*Citizens Ins. Co. v. Barnes*, 124 So. 722, 723 [Fla. 1929] [finding an ordinance is “part of the contract of insurance” because there was no reason not to apply the “general doctrine, that, where parties contract upon a subject which is surrounded by statutory limitation and requirements, they are presumed to have entered into their engagements with reference to such statute, and the same enters into and becomes a part of the contract”]). So treated, the principles of statutory incorporation permit the prompt-pay provisions of § 641.3155 to be considered an implicit part of every HMO contract.

Additionally, as medical providers have previously been considered intended beneficiaries of insurance contracts under Florida law, the court held that the provisions of HMO contracts are extended to them. “In essence, we conclude that unless the language of the specific contracts properly provides otherwise, Westside’s status as a nonparticipating provider does not preclude it, as a matter of law, from establishing the intent element in a breach of third-party beneficiary contract claim.” Moreover, the HMO Act does not foreclose a common-law contract action for breach of statutorily imposed prompt-payment provisions; indeed, it contemplates actions to enforce the terms and conditions of an HMO contract and recognizes that these actions may be brought against an HMO. See § 641.28, recognizing that attorney’s fees are available to the prevailing party in a civil action brought to enforce the terms and conditions of an HMO contract and not including HMOs in the list of exempt persons. To establish an action for breach of a third-party beneficiary contract, Westside must allege and prove 1) the existence of a contract, 2) the clear or manifest intent of the contract to benefit the third party, 3) breach of the contract, and 4) damages to the third party as a result of the breach. Thus, the case is remanded for further proceedings.

### Organ Procurement

Although the waiting list for organ transplant continues to lengthen and states have taken an active role in promoting organ donation to its residents, there continue to be issues surrounding the definition of death. LifeBanc, the organ procurement agency for northern Ohio, has been embroiled in a debate with the local prosecutor over proposed guidelines that would allow the harvesting of organs from patients who have had life support removed but who are not yet brain dead. The move to include patients under a cardiac-death definition as opposed to a brain-death definition is aimed at increasing the available pool of donors. However, for the past decade, the prosecutor’s office has objected to this plan and even threatened to bring criminal charges for homicide if organs were harvested in such a manner. According to the prosecutor’s office, the state statutes define death as...
Abortion

South Dakota's recent legislative changes to the disclosure requirement surrounding obtaining informed consent for an elective abortion was challenged in Planned Parenthood Minn. v. Rounds, 467 F.3d 716, (8th Cir. 2006). In 1993, South Dakota enacted a law that stated that no abortion could be performed without the patient's voluntary and informed consent, unless it was impossible to obtain such consent due to a medical emergency. Under the law, a patient's consent was considered informed only if specific information had been given to the patient at least 24 hours before the abortion was performed. Information that had to be given to the patient included the name of the physician who would be performing the procedure, the medical risks associated with the abortion and carrying the child to term, and the probable gestational age of the embryo or fetus. Additionally, the patient had to be told that medical assistance benefits may be available, the father could be found liable for support, and that she had the right to view printed materials with pictures of embryos and fetuses at various developmental stages.

In 2005, the South Dakota legislature enacted a House Bill that sought to expand the disclosure requirements for informed consent with regard to abortions. Under House Bill Section 7, a woman who was considering abortion must receive oral disclosures from the physician that was to perform the procedure (or another individual designated to do such) within 24 hours before the procedure. Additionally, other written disclosures had to be given by the physician to the woman not less than 2 hours before the procedure. All of the informed-consent information required by the 1993 law was still required under this proposed bill. The new disclosures required that the doctor's written statement, given to the woman 2 hours before the abortion was to be performed, must inform the patient that “the abortion will terminate the life of a whole, separate, unique, living human being,” that the patient has an existing relationship with that unborn human that is given protection under the United States Constitution, and that by having the abortion, this relationship will no longer exist. A separate section of the act, Section 8, defines a “human being” as an “individual living member of the species Homo sapiens.” The new Act also requires other disclosures, such as specific information about the psychological risks of abortion and the address, and telephone number of a nearby crisis pregnancy center. The Act requires that the woman sign each page of the statement saying that she understands the information provided. Additionally, the physician must certify that he or she is satisfied that the patient understands the information that was provided.

Planned Parenthood brought an action seeking a preliminary injunction against the Act taking effect, arguing that requiring physicians to state in writing to their patients that abortion “terminates the life of a whole, separate, unique, living human being” and the statements about the patient’s existing relationships violates the First and Fourteenth Amendment rights of both the doctors and the patients involved. State officials argued the statements were medical and scientific in nature and were necessary to give complete and accurate information to women who were considering abortion. The district court granted preliminary injunctive relief analyzing Planned Parenthood’s claims under the four-factor Dataphase test: 1) the probability of success on the merits, 2) the threat of irreparable harm to the movant, 3) the balance between this harm and the injury that will result from granting the injunction, and 4) whether issuance of the injunction was in the public interest. The district court found that the disclosures expressed the state’s beliefs and ideology on the issue of abortion and violated the physician’s First Amendment right against compelled speech. The state officials appealed the finding of the district court.

On review, this court had to determine whether the district court was incorrect in granting the preliminary injunction and, alternatively, whether the district court should only have enjoined specific provisions of the Act that it found unconstitutional. This court first analyzed Planned Parenthood’s likely success on the merits. Under the First Amendment, one has a right to free speech that encompasses both the right to speak or write freely and the right not to do so under some circumstances. The Court in Planned Parenthood v. Casey determined that disclosure requirements are permissible under the First Amendment if they are part of the state’s reasonable licensing and regulation of the practice of medicine. Although state officials argued that the disclosures contained scientific and medical information, this court agreed with the district court that the disclosures expressed a value judgment rather than medical facts. Because of this finding, the court agreed with the district court that requiring doctors to give these disclosures is likely to constitute compelled speech in violation of the First Amendment. This court also found that the proposed requirements violated the patient’s right to due process because they are more burdensome and place a greater obstacle in the woman’s path than permitted. This court found that Planned Parenthood had demonstrated a likelihood of success on the merits.

The court next looked at the threat of irreparable harm. The loss of First Amendment freedom, even for a short period, constitutes irreparable harm. Because this court previously determined that the challenged disclosures expressed an ideological point of view in violation of the First Amendment, this court found a threat of irreparable harm. The court next considered the balance of harms. The court found the State had not shown that the prior informed consent law failed to give adequate protection to the interests of pregnant woman and that after receiving the challenged disclosures, many patients would not view a fetus or embryo as just tissue. This court concluded that because there was no evidence that Planned Parenthood sought to coerce women and no evidence that the current requirements were not satisfactory, the District court did not err in balancing the harms involved. The final factor the court reviewed was that of the public interest. The First Amendment gives individuals the right to control one’s expressive communication, and the public interest is served by this free expression. This court found that the public interest is served and protected by the 1993 law by providing women considering abortion with the state’s desired disclosures. The court finally determined the district court was correct in
enjoining the entire Act, as opposed to enjoining only the challenged disclosures. Section 210 of the Act stated that the prior informed-consent law would remain in effect if any court of law enjoins, suspends, or delays the implantation of the provisions of Section 7 of the Act. Overall, the court affirmed the grant of preliminary injunction finding that the abortion provider demonstrated a likelihood of success on the merits, the provider demonstrated a threat of irreparable harm, and the balance of the harms militated in favor of the requested preliminary injunction.

The dissent in this case thought the provisions of Section 7 of the Act were constitutional and therefore Planned Parenthood would not be able to succeed on the merits, and a preliminary injunction should not have been granted. The dissent thought the court should have analyzed the Act on a provision-by-provision basis, and under this method, most of the Act was Constitutional. The dissent felt the majority erred in enjoining the entire Act when only certain provisions of the Act should have been enjoined if they were found to be unconstitutional. Additionally, the dissent stated that there was no undue burden on the women’s right to receive an abortion, because the Act did not deprive the women of their ultimate decision. Ultimately, the dissent analyzed each section of the new Act and determined it should not be enjoined. The dissent determined that the provisions in question did not violate the physicians’ First Amendment rights and did not impose an undue burden on the patients’ right to receive an abortion. Because of these findings, the dissent believes Planned Parenthood has no chance of prevailing on the merits and the preliminary injunction should be dissolved.

**Abortion Legislation**  
Several states are currently debating legislation aimed at the women who obtain and the physicians who provide abortions. In Colorado, a Senate committee voted down a bill that would have banned all abortions except in cases of rape, incest, or danger to the woman’s life. (SB 145). In addition, a House committee passed a measure that would require all hospitals in the state to inform rape victims about the availability of emergency contraception during the first 72 hours following the assault. (SB 60). In Mississippi, the Senate passed a measure that would ban all abortions except in cases of rape, incest, or potential danger to the pregnant woman. Criminal penalties proposed under the measure include fines and up to 1 year in jail. (SB 2795). The same body also recently passed a bill by a vote of 51-0 that requires physicians to allow the pregnant woman seeking an abortion to listen to the fetal heartbeat and watch a sonogram prior to obtaining the procedure. (SB 2391). South Dakota continues to struggle with the abortion issue. The state last year passed a restrictive measure aimed at becoming a test case for overturning Roe v. Wade. However, after the governor signed the abortion ban into law, it was submitted to the general electorate as a referendum and soundly struck down by the citizens. South Dakota’s legislature has now passed out of committee a new ban on abortions, except that now they have inserted similar exceptions to the bills discussed above. However, to obtain an abortion under this exception, rape victims would have to report the sexual assault within 50 days and blood samples from the aborted fetus would have to be turned over to the police. Additionally, to utilize the incest exception, the woman would have to report the crime along with the alleged identity of the perpetrator and submit blood samples from the fetus. Failure to adhere to these conditions puts the physician at risk for up to 10 years in prison for performing an illegal abortion. Because of an amendment to the bill, if passed by the legislature, the measure will go to the voters again as a referendum, similar to the last prohibition. (HB 1293). Finally, in Utah the House recently enacted an abortion ban measure that is triggered only if the Supreme Court overturns its prior decision in Roe v. Wade. Although abortion opponents had a ban measure floating, estimates from the state’s attorney general’s office indicated that the total cost to defend the measure in court could reach upwards of $4 million. In lieu of these projected costs, the state legislature opted to defer to another state becoming the test case and instead passed the measure, which would ban all abortions—except those performed in cases of rape, incest, or for the protection of the woman—only if the Supreme Court acts. (HB 235). See Kaiser Daily Women’s Health Policy, Legislatures in Colorado, Mississippi, South Dakota, Utah take action on abortion-related legislation, Kaisernetwork.org (February 14, 2007); AP, Lawmakers kill near-ban on abortions, Rocky Mountain News (February 13, 2007); Myers, Abortion ban gains panel’s OK, Sioux Falls Argus Leader (February 13, 2007).

**Antibiotic Label Changes**  
Readers of LMP will recall a previous issue discussed the plight of Sanofi-Aventis’ new antibiotic Ketek (telithromycin), which was under congressional and FDA review for questions of its safety. Reports of liver failure and even a few deaths have been linked to use of this antibiotic, which was widely marketed by the company. It was initially approved in 2004 to treat sinusitis, bronchitis, and community-acquired pneumonia. Since its approval, physicians in this country have prescribed the antibiotic more than 6 million times. The FDA recently agreed with one of its advisory committees and pulled the indications for sinusitis and bronchitis. The committee determined that the risks of using the medication did not outweigh the benefits for these typically time-limited infections. Additionally, the FDA has issued a black box warning on the medication regarding its use for patients with myasthenia gravis. Moreover, the Senate investigation into allegations of fraud in the early clinical trials continues. According to FDA investigators, data integrity problems associated with this pivotal safety study rendered the entire trial unreliable. There continue to be allegations of investigator misconduct, questions about what the FDA knew regarding these safety concerns, and issue with what steps the FDA took to protect the public based on the above. It remains to be seen what further action the FDA or Congress may take against the medication and its manufacturer. Additionally, the changes to the medication’s label will undoubtedly have an impact on the number of prescriptions written by physicians for this antibiotic. See Wilde Mathews, FDA limits use of Sanofi antibiotic, The Wall Street Journal (February 13, 2007); Rubin, FDA: Antibiotic too risky to use for sinusitis, bronchitis, USA Today (February 12, 2007); AP, FDA restricts use of antibiotic, The New York Times (February 12, 2007).
Wrongful Birth

Hall v. Dartmouth Hitchcock Med. Ctr., 899 A.2d 240 (N.H. 2006) examined a claim of wrongful birth based on a child born with a chromosome anomaly to a mother who underwent genetic testing during the pregnancy. In December 2000, Sherry Hall learned she was pregnant. In March 2001, initial screening disclosed that the fetus carried an elevated risk for Trisomy 18. Ms. Hall’s primary prenatal-care provider and a certified nurse midwife referred her to Dartmouth Hitchcock Medical Center (DHMC). A “trisomy” is a chromosomal disorder in which there is an extra copy of one or more chromosomes in a person’s cell structure. On March 7, 2001, Ms. Hall met with a DHMC physician. At that point, Hall was between 16 and 17 weeks of gestation. An ultrasound conducted that day revealed a normal fetal morphology, with the exception of continually clenched hands—a marker for Trisomy 18. As a result, an amniocentesis was recommended to provide further information about the condition of the fetus. Hall informed a DHMC employee that she would terminate her pregnancy if the testing revealed any chromosome abnormalities. Amniotic fluid was withdrawn from Hall for analysis by T.K. Mohandas, a DHMC cytogeneticist and cytotechnician. Mohandas processed the amniotic fluid and created a karyotype of the fetus’ chromosomes. Each chromosome was examined for structural abnormality and then a report was issued indicating “karyotype characteristics of a normal male.”

On March 20, 2001, Ms. Hall was called and told the results were normal. As a result of the normal karyotype report, Ms. Hall was no longer “talking about termination.” Ms. Hall returned to DHMC on March 27, 2001, for a follow-up ultrasound, which again revealed persistently clenched hands and, in addition, a possible “rocker bottom” foot, a congenital deformity in which the foot exhibits a convex, rockerlike shape. Due to elevated concern, the laboratory was ordered to save any remaining amniotic fluid from the first test. No member of the DHMC genetic counseling team contacted Ms. Hall regarding the results of the March 27, 2001, ultrasound. Following an ultrasound on April 24, 2001, Ms. Hall met with a DHMC physician, who told her that in addition to the continually clenched hands and the possible rocker-bottom foot, the fetus exhibited additional problems on the ultrasound, including lower micrognathia, a small umbilical vein varix, possible heart problems, and a “lemon head deformity.” At the time of this meeting, Ms. Hall was between 23 and 24 weeks of gestation. However, in Boston, termination services were available on demand and without proof of medical necessity for up to 24 weeks of gestation. Hall immediately decided to transfer her medical care to providers in Boston.

On April 26, 2001, Ms. Hall had another ultrasound at Massachusetts General Hospital that showed clenched hands, but the test did not detect the other problems reported at DHMC. Hall elected to carry the fetus to term. On July 25, 2001, Brandon Hall was born with multiple severe congenital anomalies. Brandon’s karyotype revealed that he had Partial Trisomy 9q. This was the first reported occurrence of this particular configuration of chromosomal abnormality. Ms. Hall brought a wrongful birth claim against T.K. Mohandas, against Dartmouth College in its capacity as Mohandas’ employer, and against DHMC. The trial court denied the defendant’s motion for directed verdict at the close of Ms. Hall’s case and again at the close of evidence. The jury returned a verdict in favor of T.K. Mohandas and Dartmouth College. It found against DHMC, however, and awarded Ms. Hall damages in the amount of $2.3 million. The trial court denied DHMC’s postverdict motions for

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A wrongful birth claim is a claim brought by the parents of a child born with severe defects against a medical care provider who negligently fails to inform them in a timely fashion of an increased possibility that the mother will give birth to such a child, thereby precluding an informed decision as to whether to have the child. Smith v. Cote, 128 N.H. 231, 513 A.2d 341 (1986). The court concluded that Ms. Hall did not prove through expert testimony that DHMC disclosed insufficient information to meet the requirement under Smith. Ms. Hall agrees that on April 24, 2001, she was informed by DHMC that the fetus had exhibited problems on the ultrasound. During that meeting, a description was given of a broad range of potential outcomes that ranged from “very minor problem that perhaps would require some physical therapy or maybe some surgery,” all the way to “severely affected,” “dying at birth,” or “being severely mentally retarded.” Ms. Hall argued that DHMC was obligated to discover and disclose a specific diagnosis to her since she was not willing to terminate the pregnancy based on “mere possibilities” that her child would suffer serious birth defects. The court disagreed with her construction of Smith and said all that was required was that DHMC disclose to Ms. Hall the increased possibility that Brandon would suffer from birth defects.

Concerning the timeliness of DHMC’s disclosure, Ms. Hall had the burden of producing expert testimony that could lead a reasonable juror to conclude that DHMC could have earlier disclosed the same information concerning the increased possibility of birth defects. The court found that Ms. Hall did not present any expert testimony to establish that DHMC could have provided her the same clinical diagnosis prior to April 24, 2001, or that DHMC breached its standard of care by failing to conduct another ultrasound at an earlier time. In addition, Ms. Hall did not offer any expert testimony to establish that she still could not have terminated her pregnancy after the meeting on April 24th. Therefore, the trial court erred in denying the DHMC’s motions for directed verdict and postverdict motions and reversed the verdict.

Res Ipsa Loquitur

A missing res ipsa loquitur jury instruction convinced a majority of the Pennsylvania Supreme Court to reverse the jury’s verdict in Quinby v. Plumsteadville Family Practice, Inc., 907 A.2d 1061 (Pa. 2006). John Quinby, a quadriplegic, had a small lesion removed from his head in a minor operative procedure. Subsequent to the surgery, he was left unattended on an examination table without side rails or restraints. He fell from the examination table and suffered a broken femur, facial lacerations, and contusions. Mr. Quinby filed a complaint of professional negligence and alleged that the doctor and attending nurse failed to position him properly on the examination table, failed to use side rails or another restraining system, failed to assess the fall risk, and failed to monitor him after the operation. In a deposition, Mr. Quinby stated that he had been left positioned on his right side and was not sure exactly why or how he fell, but that he had felt his body roll to the right and fall to the floor.

The doctor and attending nurse’s testimony at trial was to the contrary. They stated that they had left him on his back in the center of the examination table. After filing the complaint, Mr. Quinby died, and his widow (Ms. Quinby) amended the complaint to include a count of wrongful death, alleging that the fall resulted in complications that caused his death. At the close of the jury trial, Ms. Quinby requested the trial court to instruct the jury on res ipsa loquitur, a doctrine that allows the jury to infer negligence under certain circumstances. The trial court refused to give the jury this instruction.

Ms. Quinby appealed, asserting that the trial court made an error in refusing to give the jury the instruction on res ipsa loquitur because the circumstances of the accident were such that she was entitled to an inference of negligence. The appellate court agreed. Second, Ms. Quinby asserted that the trial court should have set aside the jury’s verdict and rendered a verdict in her favor because the evidence was such that no two reasonable minds could disagree on the issue of negligence. The appellate court agreed, reversed the jury’s verdict, and remanded the case for a new trial on damages. Ms. Quinby also challenged the trial court’s ruling on the admissibility of two videotapes depicting her husband before he died.

The first videotape was made 22 months before Mr. Quinby’s fall for the purpose of explaining his life as a quadriplegic to schoolchildren. The second videotape was taken the day before his death and was his deposition for the case at issue. The trial court ruled that both were inadmissible. The appellate court reversed this ruling and found that the jury was entitled to hear the audio portion of the videotape taken before Mr. Quinby’s fall and to see the videotape of his deposition right before his death to assess the “pace and extent of [Mr. Quinby’s] decline.” The Supreme Court of Pennsylvania upheld the appellate court’s determination that the evidence should be admitted without any discussion that the videotapes, consisting of statements uttered outside the courtroom, constituted hearsay.

The Supreme Court of Pennsylvania reviewed whether the circumstances were such that the jury should have received instructions regarding the doctrine of res ipsa loquitur and whether the appellate court rightfully set aside the jury’s verdict, granting a verdict in favor of Ms. Quinby. The doctrine of res ipsa loquitur allows the jury, in certain circumstances, to infer that the harm suffered was caused by negligence. Hightower-Warren v. Silk, 698 A.2d 52 (Pa. 1997). This inference is permitted if 1) the event does not ordinarily occur without negligence; 2) the evidence sufficiently eliminates other causes, including the conduct of the person harmed; and 3) the negligence is within the scope of the defendant’s duty. Restatement (Second) Torts § 328D. The defendants argued that the court should follow Toogood v. Rogal, a case stating three conditions that must be met before the doctrine of res ipsa loquitur can be applied in a medical malpractice case. It was the defense’s argument that Ms. Quinby failed to satisfy two of the three conditions and therefore was not entitled to a jury instruction on res ipsa loquitur.

The Supreme Court of Pennsylvania distinguished Toogood from the case at issue because Toogood involved a medically complex case beyond lay knowledge. Contrary to Toogood, the issue of negligence regarding Mr. Quinby’s fall from the examination table was unrelated to a medical procedure requiring expert testimony for a jury to understand the issues at stake. Furthermore, an expert witness had in fact...
testified that a quadriplegic would not fall from an examination table without having been negligently placed in a position that increased the chances of such a fall. The court considered the three elements of *res ipsa loquitur* in the Restatements and concluded that (1) there was no question that Mr. Quinby’s fall could have resulted from something other than the defendants’ negligence, (2) there were no other possible causes for his fall, and (3) the defendants should have placed him on the examination table in a manner that ensured that he would not fall. Therefore, the jury should have received an instruction that they could infer negligence according to the doctrine of *res ipsa loquitur*.

Also, the court decided whether the appellate court erred in setting aside the jury’s verdict in favor of Ms. Quinby. A court can enter its own judgment and strike the jury’s judgment when “the evidence is such that no two reasonable minds could disagree.” *Moure v. Raeuchle*, 604 A.2d 1003 (P.A. 1992) (quoting *Cummins v. Nazareth Borough*, 233 A.2d 874 [Pa. 1967]). The court determined that it would have been impossible for a quadriplegic to roll off the table if he had been on his back in the position the defendants claim they had left him. Therefore, the court’s judgment in favor of Ms. Quinby on the issue of negligence was proper. However, the wrongful death claim was reversed and remanded for a new trial because the court determined that whether the injuries from the fall caused Mr. Quinby’s death was a factual issue for the jury to decide.

Two justices dissented with the majority’s opinion. One justice disagreed with the majority’s conclusion that there had been no reasonable dispute at trial concerning whether Mr. Quinby’s fall was due to negligence. The second dissenting justice disagreed that the event could not have occurred in the absence of negligence. Both justices referenced evidence that Mr. Quinby had been a patient of this doctor for 25 years and because of the severe nature of Mr. Quinby’s immobility, the doctor had no reason to foresee that he could fall from a table. While the dissenting justices disagreed on whether the jury should have been instructed that they could infer negligence, they both agreed that the appellate court should not have reversed the verdict. One justice held that there should be a new trial with the instruction to the jury that they could infer negligence, and the second justice held that the jury verdict should not be disturbed, because the jury was in the best position to weigh the credibility of the evidence presented.

**Louisiana Malpractice Damage Caps**

The $500,000 cap on malpractice claims is constitutional—for now—based on the state Supreme Court’s reversal of an appellate court decision that had declared the cap unconstitutional. Louisiana adopted the cap in 1975. Several cases were simultaneously challenging the cap as violating the victims’ due process rights and providing an inadequate remedy, as the caps have not been adjusted for inflationary pressures. The appellate court bought this later argument, declaring that the caps would have to be in the neighborhood of $1.5 million in today’s dollars. Declaring this disparity unconstitutional, the appellate court in 2006 struck down the statutory cap on damages, to the cheers of the plaintiff’s lawyers. Insurance industry representatives were quick to point out that such a ruling will only lead to higher damage awards and more frivolous lawsuits that seek to recover these amounts, with their concomitant increase in expenses for the already-overextended healthcare system. Proponents point out that despite operating under the damage cap for more than a quarter of a century, malpractice insurance costs have continued to increase, suggesting that other causes may be more directly tied to this issue than total amounts of potential damage awards. On procedural grounds, the state Supreme Court declined to affirm the declaration of unconstitutionality and remanded the cases back to the appellate court. See Kaiser Daily Health Policy Report, Louisiana Supreme Court vacates decision on state cap in medical malpractice lawsuits, kaisernetwork.org (February 9, 2007); Griggs, Justices OK malpractice cap, theadvocate.com (February 8, 2007).
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This issue of LMP contains all the usual subjects. Case briefs covering myriad health law topics and excerpts of recent news stories serving as grout for the cracks. Additionally, as ACLM members who attend the annual meetings are aware, the College has strived to reach out to the new generation of health-law scholars. Specifically, the College sponsors several student writing contests, poster sessions, and graduate student presentations during the annual meeting. In this issue, we present a Colleagues’ Corner, which contains two articles prepared by law students. Both of these interesting articles were adapted from poster presentations at the recent annual meeting in Florida. Both presenters agreed to convert their original poster presentation into a brief article, which is included in this issue in order to share with the College membership.

Additionally, Fellow Fred Levy has submitted a brief excerpt of a Colleagues’ Corner article he has prepared on patient safety. This article will be published in an upcoming issue of LMP, but a quick highlight is included immediately following this introduction. It is hoped that these pieces will stimulate the writer in all of us to put pen to paper on a health law topic about which you are passionate. Assuming perusing this publication serves as your muse, consider submitting it to LMP. The editorial staff of LMP is always seeking College members who are interested in submitting a piece of scholarship for consideration of publication in LMP as an upcoming Colleagues’ Corner. When giving a presentation or submitting a poster, please consider sharing your newfound knowledge by also reducing your work into a short piece of prose. Your work product, creative ideas, or comments are welcome by email to whitec@fammed.uc.edu.

### Patient Safety

Since the earliest days of medical practice, patient injury due to iatrogenic error has always been regarded as common. Witness the relatively recent 1999 Institute of Medicine [IOM] report which gave a frightening account of 98,000 fatalities per year in U.S. hospitals attributable to medical mistakes. See Kohn L, Corrigan J, Donaldson M, ed.: Institute of Medicine—To err is human: Building a safer healthcare system, Washington D.C., National Academy Press (1999). The IOM sought to address this national crisis of iatrogenic injury by introducing a model borrowed from the aviation industry. See Perrow, Charles, Normal accidents, New York: Basic Books (1984).

This model is premised upon the concept of error prevention rather than retrospective review and punishment of the person. This new way of thinking viewed individual errors as a symptom of a latent defect in the system. As with many systems, the key to success is the ability to collect and analyze critical data in order to identify error patterns and develop adaptive solutions. In the context of patient safety, these data take the form of provider disclosure of individual mistakes.

Naturally, there has been a tremendous reluctance on the part of providers to disclose their mistakes because of legitimate malpractice concerns. Part of this reluctance stems from the widely held belief that current state laws do not adequately protect error disclosures. In response, the IOM issued a set of recommendations designed to allay provider concerns by suggesting ways in which each state could strengthen their provider protection laws.

To date, virtually all research efforts have been directed towards the “operations” side of patient safety. See Leape LL, Errors in medicine, JAMA, 1994; 272:1851–1857. For example, potentially faulty systems are now analyzed in Root Cause Analysis committees to try to identify and correct defects in the delivery of health care. In addition, methods

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of error analysis borrowed from the aviation model have been successfully applied to certain health care environments such as the ICU (See Pronovost P, Wu A, Dorman T, Morlock L, Building safety into ICU care, J. of Crit. Care, 2002;17(20):78–85) and neonatal delivery rooms (See Thomas EJ, Sexton JB, Teamwork and quality during neonatal care in the delivery room, J. of Perinatology, 2006; 26:163–169).

However, most legal research at present has been limited to a descriptive critique of old methods of dealing with iatrogenic error. These antiquated methods have traditionally been referred to as the "global sanctions" view because they all focus on retrospective review and punishment of the individual provider rather than any system flaw. Without a doubt, the method that has received the most attention has been medical malpractice, but other examples include peer review sanctions, regulatory body penalties, and morbidity and mortality conferences. See Bovbjerg RR, Path to reducing medical injury: Professional liability sanctions and discipline vs. patient safety—the need for a 3rd way, 29 J.L Med & Ethics 369 (2001).

Before the IOM report, virtually no attention had been paid to individual state law variations to try to determine which states had the strongest error-reporting protections. The IOM report highlighted this problem and made a number of recommendations about how to strengthen state laws. However, a recent article in the JAMA provided scant evidence of any effective legal solutions that have been implemented in any setting despite these recommendations. See Leape LL, Berwick DM, Five years after the IOM report—what have we learned? JAMA, 2005;293:2384-2390.

Even after the IOM report’s cautionary tale, little legal research has been done to discover the most effective solutions to encourage provider disclosure. Liang and others were the initial investigators to describe the general contours of the error reporting problem. See Liang BA, The adverse event of unaddressed medical error: Identifying and filling the holes in the healthcare and legal systems, 29 J.L. Med & Ethics 346 (2001). More recently, Palmer and Harrington are among the few who have begun to argue the need for a more comprehensive reporting system with more uniform state law provisions. Palmer LJ, Patient safety, risk reduction and the law, 36 Hous. L. Rev. 1609, 1999. See Harrington MM, Revisiting medical error 5 years after the IOM report: Have reporting systems made a measurable difference?15 Health Matrix 329 (2005).

Unless more emphasis is placed on better protections for error disclosures, it is unlikely that any operational system redesign will have a measurable impact on patient safety. This brief concept piece is intended to give interested readers an overview of the problem. A future issue of LMP will discuss some specific ways in which legal protections for provider disclosure can be enhanced to help improve patient safety.

**Statute of Limitations**

Newman Mem. Hosp. v. Walton Constr. Co., 149 P.3d 525 (Kan. App. 2007), examines whether a hospital’s construction and leasing of a medical office building was a governmental or proprietary function. Newman Memorial Hospital (Hospital) sued Walton Construction Company, Inc. (Walton), alleging breach of contract, breach of express, and implied warranties, negligence, and strict liability with respect to the construction of a medical office building. The case involved the construction and maintenance of an office building for rental to physicians and other tenants. After the District Court concluded that the Hospital was not subject to Walton’s statute of limitations defenses, a jury returned a verdict in favor of the Hospital, which Walton appealed.

The controlling issue was whether the Hospital’s construction and leasing of the medical office building was governmental or a proprietary function for purposes of state law. Kan. Stat. Ann. § 60-521. The Hospital’s Board of Trustees strongly supported establishing the building because of the need to have adequate space available for physicians recruited to the area. The court found the actions of the Hospital in constructing and leasing the building were a proprietary function as the hospital provided services to all Kansas residents. Thus, the Hospital was in competition with both private and corporate hospitals. Conversely, K.S.A. 2005 Supp. 76-3302(a)(1) states that: “Provision of health care is an essential governmental function protecting and promoting the health and welfare of the citizens of the state of Kansas.” This statement was made, however, in the narrow context of a 1998 act establishing and creating the “University of Kansas Hospital Authority.” See K.S.A. 2005 Supp. 76-3301 et seq.

Accordingly, the court found that state law did not support the lower court’s holding that the construction of the building was a governmental function, as the relevant state statute was limited to the creation of a specific state hospital authority, the University of Kansas Hospital Authority. Furthermore, the amendments to Kan. Stat. Ann. § 79-201 (Supp. 2005) did not support the District Court’s holding, as there was no evidence that the amendments were intended to apply to any provisions of the Code of Civil Procedure. Moreover, the statute was not construed in pari materia with Kan. Stat. Ann. § 60-251, as that section’s scope and aim was distinct and unconnected to the tax exemption statute. Specifically, the court held that pursuant to K.S.A. 60-521, the limitations periods prescribed in Article 5 of Chapter 60 of the Kansas Statutes Annotated applied to the actions brought in the name of the Hospital acting in a proprietary function or activity in the same manner as to actions by private parties.

The court also held that equitable estoppel did not exist to prevent Walton, under a written contract with the Hospital, from pleading and relying on a statute of limitations defense. The 3-year period of limitations of K.S.A. 60-512(1) applied to and barred any recovery by the Hospital against Walton for breach of implied warranty of workmanlike performance. Additionally, the 5-year period of limitations of K.S.A. 60-511(1) applied to and barred any recovery by the Hospital against Walton for breach of the terms of a written contract. Therefore, under the facts of the case, the applicable statute of limitations had run on the breach of contract claims. For the reasons set forth in the opinion, the District Court’s judgment was reversed because the Hospital failed to show the requisite equitable estoppel elements as they pertained to Walton’s actions. Consequently, Walton was granted judgment against the Hospital based on the aforementioned statute of limitations defenses.

A patient’s petition for convening a medical malpractice screening panel tolls the statute of limitations with respect to a subsequent malpractice suit only if timely prosecuted. This was the outcome in Smith v. Graham, 147 P. 3d 859 (Kansas 2006). On May 11, 1999, Dr. Becky Graham, a Kansas physician, performed a pelvic laparoscopy with adhesiolysis on Laura Smith. During the procedure, Ms. Smith’s sigmoid colon was lacerated. More specifically, Ms. Smith claimed that the Hospital failed to convert to an open procedure when dense adhesions were noted, causing or contributing to Ms. Smith’s injuries. To initiate her
medical malpractice claim, Mr. Smith filed a "Memorandum Requesting Medical Malpractice Screening Panel" in the district court on April 24, 2001. In her memorandum, she requested a panel review of the procedure Dr. Graham had performed on her.

On April 8, 2002, Ms. Smith requested that the district court dismiss the screening panel so she could file a petition for medical negligence. Ms. Smith then filed a petition in the district court the same day seeking more than $75,000 in damages due to Dr. Graham’s negligent medical treatment. Ms. Smith claimed damages in the form of pain and suffering, loss of income, future medical testing, hospitalizations, and surgical procedures due to Dr. Graham’s negligence. Dr. Graham raised the expiration of the statute of limitations as an affirmative defense and as grounds to dismiss.

Ms. Smith filed a second medical malpractice negligence petition on July 19, 2002. The second petition was filed while the first was pending and was identical to the first, except that it stated that Smith moved to dismiss the screening panel in order to file a petition for medical negligence. On January 16, 2003, the district court dismissed the first petition for lack of prosecution. The second petition was dismissed for lack of prosecution on March 8, 2004.

On September 3, 2004, Ms. Smith filed a third medical malpractice petition. She claimed the third petition was permissible under K.S.A. 60-518 because the second petition was dismissed on grounds other than the merits. Dr. Graham moved to dismiss, claiming the third petition was barred by the statute of limitations. The district court agreed, that an injured patient may not toll the statute of limitations simply by filing a Memorandum Request for a Screening Panel and then failing to take further action. The Court of Appeals agreed, finding that the first clause of the tolling statute, K.S.A. 65-4908, makes the statute applicable only to cases in front of a screening panel.

This case is one of first impression in Kansas, and there are no similar cases in other jurisdictions. Thus, the Kansas Supreme Court incorporated the fundamental rules of statutory interpretation and legislative intent in its ruling. The Court relied on a 1989 case that found the legislature’s intent behind the first clause of 65-4908 was to apply the tolling provision to cases in which screening panel proceedings are the legislature’s intent behind the first clause of 65-4908 was to apply the tolling provision to cases in which screening panel proceedings are the legislature’s intent behind the first clause of 65-4908 was to apply the tolling provision to cases in which screening panel proceedings are the legislature’s intent behind the first clause of 65-4908 was to apply the tolling provision to cases in which screening panel proceedings are the legislature’s intent behind the first clause of 65-4908 was to apply the tolling provision to cases in which screening panel proceedings are the legislature’s intent behind the first clause of 65-4908 was to apply the tolling provision to cases in which screening panel proceedings are

Brain Death Determination: Take 3

Several physicians and the organ procurement agency for California are under the microscope for their roles in a recent patient misadventure. John Foster, a 47-year-old auto mechanic, collapsed and was taken to the hospital, where it was determined that he had suffered a significant brain stem hemorrhage. The hospital per its policy notified the organ procurement agency, which then met with the family, including the patient’s daughter, who was a nurse. After agreeing to organ donation, the daughter reported she was contacted by the agency daily for an update on her father’s condition. Shortly after his admission, a physician declared him brain-dead in preparation for organ harvesting. Per California law, a second physician was called to the bedside to confirm the determination of brain death. Under the rules, neither physician can be affiliated with the procurement of organs. According to the daughter’s report, this second physician, from the hospital’s emergency department, did little more than shine a flashlight on the patient’s pupils. Based on her concern over such a limited exam, she demanded that a third physician assess the patient. Both a neurosurgeon and a nursing supervisor conducted an exam and determined that Mr. Foster exhibited a strong gag reflex and some movement of his head, both of which are inconsistent with a finding of brain death.

This patient died in the hospital 11 days later without being an organ donation candidate. The alleged pressure by the organ procurement agency and roughshod confirmatory exams by the physicians are now being investigated. Obviously, stories such as this affect the public’s willingness to serve as organ donors, a fact that further threatens the already limited supply of available organs. See Charles Orstein & Tracy Weber, Potential organ donor was wrongly declared brain-dead, Los Angeles Times (April 12, 2007).

Expert Affidavits

Whether Arizona's expert witness affidavit statutory requirement contained in A.R.S. § 12-2603 applies to lack of informed consent claims was litigated in Gorney v. Meaney, 150 P. 3d 799 (Ariz. App. 2007). Plaintiff/appellant Dale Gorney brought a medical malpractice action against Dr. John Meaney of Rincon Orthopedic Associates P.C., who performed arthroscopic surgery on Gorney's left knee. The claim alleged a failure to inform him of the material risks of surgery, which caused a worsening of his condition. The trial court granted the surgeon's motion for summary judgment, finding Gorney had not complied with the expert witness requirement of Arizona statute A.R.S. §12-2603. Specifically at issue in the appeal was (1) the factual basis resulting in the alleged breach of duty for each claim as supported by the expert and (2) specific acts of damage causation were not incorporated. The appellate court affirmed grant of summary judgment for the surgeon.

In Gorney v. Meaney, the court of appeals found that the expert incorrectly interpreted the statute as requiring the expert to affirm each of the surgeon's acts of the factual basis for each claim. This court reviewed the Arizona statute and found it required the expert to affirm the factual basis for each claim as supported by the expert and specific acts of damage causation were not incorporated. The appellate court affirmed the trial court's decision.

Ms. Smith's first petition was filed timely, within the statute of limitations. Ms. Smith's second petition was filed while the first was pending and was identical to the first, except that it stated that Smith moved to dismiss the screening panel in order to file a petition for medical negligence. On January 16, 2003, the district court dismissed the first petition for lack of prosecution. The second petition was dismissed for lack of prosecution on March 8, 2004.

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Finally, the Court reached the question of whether the second petition related back to the first, making the second timely. Under K.S.A. 60-203(a)(1), the second petition was barred because it was filed long after the 30-day toll period expired. However, the Court found that the first petition was filed timely within the statute of limitations. Ms. Smith's failure was in three procedural errors: (1) she failed to prosecute the first petition, resulting in a dismiss; (2) her second petition was filed outside the 30 days tolled by K.S.A. 65-4908; and (3) as her second petition was untimely, the third petition cannot be saved by the savings statute. Therefore, the Kansas Supreme Court found the district court was correct in granting Dr. Graham's motion to dismiss.
these more stringent pleading requirements for informed consent claims. Under these exceptions only an affidavit stating an expert has “concluded that a reasonable health professional would have informed the patient of the consequences of the procedure” must be submitted as opposed to an affidavit stating the attorney has consulted with a health care professional who “has determined in the written report... there is a reasonable and meritorious cause for filing of such action.” States adopting such an exception to the more rigorous affidavit requirements noted by the court in its opinion include Illinois, Colorado, Florida, Georgia, Michigan, Minnesota, Missouri, Nevada, New Jersey, New York, and North Dakota. Yet in Arizona, the court held that as the legislature did not create an exception, the absence of such language suggests Arizona’s legislature did not intend to make a special exception requiring less stringent pleadings. Moreover, courts may not read into statutes something the legislature has not put there. See City of Tempe v. Fleming, 168 Ariz. 454, 457, 815 P.2d 1, 4 (App. 1991). Thus, the plain language of the statute is clear on its face and logically capable of only one interpretation. As the witnesses’ affidavits did not state the factual basis for each claim and no exception exists for informed consent claims, the court agreed with the trial court’s grant of summary judgment for the physician-defendant.

Gorney contends that the affidavit could not be submitted because the expert had no personal knowledge of the facts. However, the court held that the expert must simply accept and base his opinion on the facts as alleged by the plaintiff and state that these facts, if true, violate the accepted standard of care. Thus, in this case, the expert’s affidavit should have listed what disclosures the surgeon made to the plaintiff prior to performing the surgery and stated whether, based upon the facts as alleged by the plaintiff, these disclosures were inadequate and fell below the standard of care. The court held that such a conclusion was consistent with the legislature’s express purpose of “curtail[ing] the filing of frivolous lawsuits against health care professionals.”

Second, the plaintiff argued that the “causation” provision of the statute need not be addressed by an expert opinion affidavit in an informed consent claim because “the injury of proceeding with a surgery at all in the absence of informed consent is established without regard to expert testimony.” The court disagreed with this interpretation, stating that failure to disclose a known risk does not, by itself, constitute sufficient grounds for a malpractice action, since occurrence of risk must be harmful to the patient, as negligence unrelated to injury is not actionable. Hales v. Pittman, 118 Ariz. 305, 311, 576 P.2d 493, 499 (1978). However, expert testimony is not required to determine whether adequate disclosure would have caused the plaintiff to decline the treatment. This is clearly a matter to which the plaintiff themselves could testify and is within the knowledge of the average layperson. Considering the function of the expert witness is to provide testimony on subjects beyond common sense, experience, or education of the average person, and expert testimony is inappropriate if a jury can determine issue without such testimony. Expert testimony is required, however, to demonstrate that the treatment proximately caused injury to the plaintiff and was not simply the progression of a pre-existing condition, natural aging, or a subsequent injury. Thus, in the present case, the expert affidavit should have stated that the surgery proximately caused an injury to Gorney and worsened the condition of his knee. As it did not, the trial court properly found the requirements of the expert witness affidavit statute were not met. Although in this case, an attached answering brief contained such language, it was not a part of the affidavit that was in the record on appeal and thus could not be considered.

Lastly, Gorney maintains that summary judgment should have been denied, since the motion did not include the required statement of facts. The court held that although the statement of facts is useful to sort through the myriad factual contentions, it may be less useful when the motion is sought, because the plaintiff failed to comply with a statutory requirement and thus failed to establish a prima facie case, as was true in this case. The expert witness affidavit was required to establish a prima facie case, and because the affidavit was inadequate, a prima facie case was not established and summary judgment by the trial court was proper.

A conflict between the statute of limitations and defective malpractice pleadings because of expert affidavit requirements was the impetus for litigation in Washoe Medical Center v. Second Judicial District Court, 148 P.3d 790 (Nev. 2006). Billie Faye Barker filed a medical malpractice action against her doctor, Bradley Glenn, MD, and Washoe Medical Center (Washoe) on the last day before the statute of limitations expired. However, the action failed to include a medical expert affidavit, which is required in the state of Nevada. Washoe immediately moved to dismiss the complaint, but before the district court could rule on the motion, Ms. Barker amended the complaint. The district court ruled that, under Nevada Rules of Civil Procedure, Ms. Barker could amend her claim once before a response is served. Washoe then filed a writ of mandamus, asking the Supreme Court of Nevada to direct the district court to strike the amended complaint and dismiss the original complaint.

The Court found that, by failing to comply with the expert affidavit requirement, Ms. Barker was not permitted to cure by amending the complaint. The original complaint was dismissed without prejudice because it was void ab initio. The Court noted that a writ of mandamus is an extraordinary remedy— available only at the discretion of the court and only if the petitioner has no other suitable remedy. The issue was whether the defect in Ms. Barker’s claim (failure to comply with statutory filing requirements) could be remedied relying upon rules of civil procedure. The Court examined the statute’s language, legislative history, and policy. It determined that, as soon as a medical malpractice complaint is filed in the state of Nevada without an expert affidavit, it is automatically dismissed for failure to comply with the statute and cannot be amended.

Specifically, the statute indicated that the district court “shall” dismiss an action filed without an affidavit, leaving no room for judicial discretion. The legislative history indicated that the purpose of the statute was “to lower costs, reduce frivolous lawsuits and ensure that medical malpractice actions are filed in good faith based on competent expert medical opinion.” The policy behind the statute was to ensure that claims are meritorious and to discourage filing complaints for the purpose of obtaining a quick settlement. The majority of state courts have interpreted medical expert affidavit requirements similarly. The Court noted that allowing amendment would contradict both the legislative intent and the statute’s purpose.

The dissenting chief justice felt that the majority opinion disregarded the rules of civil procedure, “exal[ing] form over substance.” He noted that the legislature was required to yield to the rules of civil procedure when drafting legislation. For example, New Jersey courts are concerned with inflexible statutory application and the “draconian results” that follow, and Illinois courts liberally construe medical malpractice
Disability Determinations

Forbes v. Workforce Safety & Ins. Fund, 722 N.W.2d 536 (N.D. 2006), examines the topic of disclosure when filing for a determination of disability. On August 13, 2002, Lynette Forbes claimed to have been injured after lifting a heavy piece of equipment while working as a nurse at Mercy Medical Center. Subsequently, she filed a disability claim and began receiving benefits. In making the incident report as required by the hospital, Forbes neglected to indicate whether she had previously sustained an injury in the same area of her body. A year after filing the incident report, she supplemented the original claim with additional injury claims from July and September of 2002.

North Dakota disability applications required Forbes to disclose whether she was employed or had received money from any other sources during the application period. She was also required to update the application frequently after receiving the benefits, including updates regarding any employment or monies received subsequent to the injury. During the period in question, Forbes was still seeing her doctor. During an examination, she told her doctor, Dr. Arazi, that she felt intense pain while doing the most limited activities, such as talking on the phone, driving, and washing dishes. Based on this information, Dr. Arazi took Forbes off of her job and eventually on April 28, 2003, Dr. Moore performed an anterior cervical decompression and fusion at C5-C6. Forbes claimed that the cervical surgery helped with the pain she had been experiencing.

In 2003, the Workforce, Safety and Insurance Fund (WSI), the state’s disability agency, conducted an investigation into whether Forbes made false statements concerning her physical condition, outside sources of income, and employment. The investigation led to an agency determination that Forbes had made materially false claims or false statements in connection with WSI benefits and that notice of the discontinuation of benefits was given on January 20, 2004. The notice stated that Forbes was not entitled to further benefits after February 10, 2004, and that previous medical and disability benefits had been erroneously paid based on the false statements. On March 11, 2004, after a request for reconsideration, WSI found that Forbes willfully made false statements that resulted in requitals of $20,438.55 in disability payments and $31,982.81 in medical payments. WSI ordered Forbes to forfeit all future medical and disability payments after February 10, 2004, and to repay the $52,421.36 paid between September 13, 2002, and September 23, 2003.

At Forbes’ request, an administrative hearing was held in which the judge affirmed the agency’s decision because Forbes made false statements concerning her income and her physical condition between 2002 and 2004. Forbes had been employed with an insurance firm where she conducted a number of tests. Forbes drove to and from work in connection with her employment and earned more than $800 for her services. A doctor who worked with Forbes provided her with $5,000 to sell Mary Kay products, from which she earned approximately $300. Forbes argued that the insurance work was a hobby and that she had not made any profit on the Mary Kay sales, which is why she failed to report either.

As to Forbes’ physical condition, while claiming not to be able to undertake the simplest of tasks without paralyzing pain, she was able to drive to and from her job at the insurance company. She was also able to attend yoga classes and aerobics classes at a wellness center. The instructor of these classes indicated that Forbes was able to complete physically demanding tasks, including weight lifting. Based upon the great weight of the evidence, the district court affirmed the agency decision for forfeiture of future benefits and reimbursement of previously paid benefits.

On appeal, Forbes claimed that the weight of the evidence did not support a determination that she had made materially false statements in connection with either her condition or income. The standard for review for the appellate court is whether a reasonable mind could have reasonably found that the weight of the evidence supported the agency determination.

The Court affirmed in part and reversed in part, holding that all future benefits after February 10, 2004, had been forfeited. The Court also held that all medical and disability benefits paid after the original application for disability, but before Forbes’ extensive back surgery, should be repaid to WSI. However, the court found that both the medical and disability payments made in connection with Forbes’ actual surgery could not be recovered because no evidence established that Forbes was not actually injured or that the doctors would not have

Individual Prescription Practices

The collection and subsequent sale of individual physicians’ prescribing practices has been going on for decades. However, this practice has recently come under increasing scrutiny. A perfect storm of physicians, privacy groups, and state legislators have banded together and started proposing legislative bans on the use of these data. Health mining data companies buy individual prescriber data from the large pharmacy chains. This information has been stripped of patient identifying information. However, individual prescriber patterns can be cross-referenced with information sold by the AMA and others to obtain a fairly accurate assessment of a physician’s current favorite medications. This, when sold to the pharmaceutical companies, it allows for targeted marketing aimed at shoring up physicians who already prescribe the company’s drug and convert those who do not. Such data trading is big business with IMS Health, one of the largest of such companies, recording $2 billion in revenue from the sale of this information to pharmaceutical companies. New Hampshire became the first state to ban the use of these data. States such as Arizona, Illinois, Kansas, Maine, Nevada, New York, Rhode Island, Vermont, and Texas have considered similar bills in their legislatures. A federal bill died in committee during 2006 but likely will be resubmitted. Due to growing criticism of their involvement with the pharmaceutical industry, the AMA recently adopted an opt-out program for physicians who wish to keep their prescription data private. However, as a testament to the financial power of these deals, the AMA has continued to lobby against their prescription data private. However, as a testament to the financial power of these deals, the AMA has continued to lobby against the adoption of state bans on the use of this information. See Joe Mullin, States cracking down on drug marketing, Associated Press (April 12, 2007).
performed the surgery even if Forbes had not exaggerated her physical condition. The dissent argued that it was more likely than not that the misrepresentations had in fact led directly to the decision for surgery, for which the evidence established that but for the misrepresentation there would not have been undertaken.

**Hospital Infection Rates**

The Texas legislature recently enacted a measure that will require hospitals to make available, in a standardized format, data surrounding hospital-acquired infections. The CDC estimates that more than 2 million such infections occur nationally each year at a cost of more than $4 billion. The statistics suggest that about 5% of hospitalized patients will acquire an infection, and an estimated 90,000 will die, partly because of the infection. Although patient rights groups have asked for this data for some time, the Texas legislature is one of the first to compel state hospitals to release it. The federal government already collects several quality-related measures, which are available to the hospitals to use as benchmarks for comparisons. However, collecting the data on a national level does little to help an individual patient select a local hospital based on these measures. The Texas initiative is aimed at promoting competition among the hospitals that will be able to compare directly with their local competitor on the issue of hospital-acquired infections. Advocates state this will then lead to a sharing of best practices in the area of infection control. Although the exact format of the infectious data collection has yet to be determined, the law will mandate disclosure of bloodstream infections and surgical site infections resulting from colon, hip, knee, and hysterectomy procedures. In response to the heightened attention paid to preventing such infections, some hospitals have ramped up screening programs intended for patients—deemed to be at high risk for MRSA or similar resistant bugs—as soon as they are admitted to the hospital. See Kim Breen, Information is new tool in fight against hospital infections, The Dallas Morning News (May 3, 2007).

**Statute of Repose**

Christiansen v. Providence Health System of Oregon Corporation, 150 P.3d 50 (Ore. App. 2006), stands for the idea that under the remedy clause of the Oregon Constitution, there is no absolute right to bring an action in negligence alleging prenatal injuries. Kelly Christiansen, the mother and conservator of the estate of her minor child James Carrier, filed a medical negligence action based on the care received during her labor and delivery of James. After the delivery, James required resuscitation, was unresponsive, and suffered a seizure. At the time of his hospital discharge, a cranial ultrasound and CT scan of the brain showed no sign of abnormality and during a 3-month checkup, Ms. Christiansen was told that James was developing normally. Eventually, however, he was diagnosed with partial epilepsy, developmental disorders, and neurological defects. Ms. Christiansen began to suspect negligence in the medical care provided during the delivery and labor 6 to 8 months after James was born, but no permanent injuries were diagnosed until May 11, 1999.

Ms. Christiansen filed this action more than 5 years after James’ birth, but less than 5 years after she discovered the injuries. St. Vincent Hospital and the doctor involved moved to dismiss the complaint on the basis that it violated Oregon’s statute of limitations or the statute of repose. Ms. Christiansen argued that applying the statute of repose to the case violated the remedy clause of the Oregon Constitution. The trial court found that the statute of repose barred the claim and did not violate the remedy clause of Oregon’s Constitution. Ms. Christiansen appealed and the Court of Appeals of Oregon determined that for purposes of the statute of limitations, she did not discover the injuries to James until May 1999.

Suspicion of an injury does not start the statute of limitations running. Gaston v. Parsons, 318 Ore. 247, 256 (1994). However, under the statute of repose, the action must be brought within 5 years of treatment. As such, under the statute of limitations, Ms. Christiansen had 5 years from May 1999 to bring the action and under the statute of repose; she had 5 years from March 1994 to bring the action. Therefore, Ms. Christiansen’s claim was barred because she filed the claim in January of 2003. Next, to determine whether applying the statute of repose to this case violates the remedy clause of the Oregon Constitution, it must be determined whether an absolute common law right respecting person, property, and reputation, as existed at the time the Constitution was adopted, has been violated.

The issue was whether the cause of action was recognized under the common law of Oregon in 1857. The court held that the characterization of the injury in 1857 was relevant to the disposition of the case. According to the court, while actions for medical negligence existed in 1857, Ms. Christiansen’s cause of action did not exist at that time because courts refused to entertain actions by an infant for prenatal injuries, including injuries incurred during birth. In 1857, a fetus did not fall within the protection of the remedy clause because under tort law a fetus was considered part of its mother until birth. The court noted that even if the action had not been foreclosed from being brought in 1857, the common law cause of action must have been well-established prior to the enactment of the Oregon Constitution to be in violation of the remedy clause. Ms. Christiansen would not have had an absolute common law right to bring the negligence action for the prenatal injuries to James and therefore the remedy clause of the Constitution was not violated.

**Anemia Medications**

The FDA is investigating the ever-increasing use of anemia medications. Mounting evidence suggests that the medications are disproportionately used in this country and may be causing harm to patients. The medications manufactured by Amgen and Johnson & Johnson are marketed for the treatment of severe anemia typically associated with renal disease and chemotherapy. In the United States, physicians are using doses 2–3 times higher than those of their European colleagues. Additionally, many physicians are pushing with the medication to increase hemoglobin levels above 12 mg/dL. A study initiated by Amgen a decade ago was stopped after it revealed that patients treated with its agent experienced increased cardiovascular mortality when dosed in a manner to cause the greatest increases in hemoglobin. Many recommend a target level of 10–12 mg/dL; however, the companies have not conducted studies showing that lower doses aimed at achieving these levels are safer or better tolerated. Additionally, coming under fire is the rebate program utilized by both companies to increase sales of their medications. The companies pay directly to physician groups’ rebates based on both the amount of medication prescribed in a year as well as on
whether the physician group has signed an exclusivity agreement with one of the manufacturers. These payments can be quite significant: One group of 6 oncologists received almost $3 million in payments for using $9 million worth of the medication. Although rebates such as these are illegal for oral tablet medications issued via physicians’ written scripts that are purchased at pharmacies by patients, the anemia medications fall within a loophole. The medications are injectable and typically are purchased by physician groups and then administered to patients during dialysis or chemotherapy. In addition to the rebates from the drug manufacturers, the physicians are also billing the government or private insurance for the medication— often at a premium, compared with what they paid the company. Although many claim such rebate schemes do not improperly increase the use of the medication, evidence of the increasing use and escalating doses suggests otherwise. Like all pharmaceutical marketing, the companies would not give away what amounted to hundreds of millions of dollars if it had not demonstrated an increase in the sale of these anemia medications. The FDA has already strengthened the warning labels based on the evidence of increased cardiac mortality associated with high doses of these medications. What remains to be determined is future FDA action, based on its pending review of this rebate process, as well as evidence that despite the introduction of these medications, survival statistics have not changed appreciably. See Alex Berenson & Andrew Pollack, Doctors reap millions for anaemia drugs, The New York Times (May 9, 2007).

Drug Warnings

Drug manufacturers must disclose the potential risk of both short-term and long-term use of drugs, even if a drug is recommended only for short-term use. This was the holding in McNeil v. Wyeth, 462 F.3d 364, (5th Cir. 2006). In August 2000, Sue McNeil was prescribed Reglan to treat gastroesophageal reflux disease (GERD). Her initial prescription by Dr. Wilkinson was for 6 months. It was extended by Dr. Roy Ragsdale for another 6 months, and extended again by Dr. William Mania for 2 months. The Food and Drug Administration had approved the drug for a maximum use of 12 weeks.

Reglan helps control gastroesophageal reflux disease, a disease that ranges from infrequent heartburn to frequent heartburn with regurgitation, by blocking dopamine receptors in the brain and body. Dopamine is a chemical in the body that sends signals from one nerve to another. The blocking of dopamine enhances the movement or contractions of the esophagus, stomach, and intestines. Reglan’s blocking of dopamine can affect the extrapyramidal system, which controls the fine motor control of coordinated muscle movements. Reglan can cause extrapyramidal symptoms (EPS), including tardive dyskinesia, a severe form of EPS, which can cause involuntary movements of the mouth, tongue, lips, and extremities. It can also cause involuntary chewing movements and a sense of agitation.

After taking Reglan for 14 months, Ms. McNeil was diagnosed with EPS after being admitted to the emergency room with shortness of breath, anxiety, and an involuntary chewing motion. Ms. McNeil sued Wyeth, the drug manufacturer, alleging that Wyeth failed to adequately warn both physicians and consumers about the increased risk of developing tardive dyskinesia after prolonged use of Reglan. Ms. McNeil claimed that the Reglan label was misleading regarding the risk of tardive dyskinesia because it failed to warn about the increased risk of developing tardive dyskinesia after prolonged exposure to Reglan for more than 12 weeks. The court granted summary judgment for Wyeth, thus holding Wyeth not liable for failure to warn. The appellate court reversed this holding and remanded the case to trial.

Under Texas law, the adequacy of a product’s warning is a matter of fact that is to be determined by a jury. Texas follows the Restatement of Torts, which states, “If a product is unreasonably or inherently dangerous, a warning is required.” Furthermore, under the learned intermediary doctrine, a warning is adequate if it specifically mentions the circumstances complained of. Under the learned intermediary doctrine, if a warning to a physician is inadequate or misleading, the manufacturer is liable for any injuries caused by taking the drug. If the risk, as described by the label, is low enough to entice a physician to take the risk, but the physician would not have taken the risk he had been aware of the real risk, then a reasonably jury may conclude the warning was inadequate.

In the case at bar, Wyeth was, or should have been, aware that Reglan was frequently prescribed for long-term use. In fact, Wyeth had data in 1988 that indicated that 84 percent of people were using Reglan for long-term use. Even though Reglan was not labeled to be prescribed for more than 12 weeks, a jury could find the warning to be ineffective and inadequate, because Wyeth had knowledge of long-term use.

The FDA requires a manufacturer to inform physicians of contraindications, i.e., situations in which the drug should not be used because the risks of use outweigh the possible benefits. The label should have indicated that extended use of Reglan was contraindicated.

Furthermore, Wyeth advertised the risk of developing EPS as “comparatively rare” (.2 percent) with short-term use and said simply that the risk is higher with long-term use. This statement of an increased risk is not enough to put a physician on notice of the severity of the risk, especially because studies have shown the prevalence of tardive dyskinesia to be 25 percent with long-term use of the drug. Wyeth is required by the FDA to revise labels to include warnings of serious hazards associated with drug use as soon as reasonable evidence evolves. A causal relationship does not have to be proved before the label should be updated. Manufacturers often change their labels to warn physicians of adverse side effects without actual studies showing causation. In this case, a reasonable jury could find Wyeth did not adequately warn of the adverse effects caused by long-term use of Reglan, and thus the case has been remanded for a new trial.

Hospital CEO Compensation

A recent survey of Boston hospitals revealed a trend tying hospital executive compensation to safety and quality measures. This represents a notable shift from the prior metrics, which were designed to reward aptitude at attracting patients and generating positive cash flow. Although the specific quality markers vary as does the percentage of salary at risk, it is not an insignificant amount. Several of the hospitals contacted link up to one-third of the executive’s bonus directly to these various measures. The percentage of health care workers who wash their hands was a commonly cited criterion. Additional measures included rates of hospital-acquired infections, percentages of health care staff receiving influenza vaccines, and percentages of patients receiving angioplasty within 90 minutes of arriving at the hospital. However, some of the impetus to tie compensation to patient safety grew out of recent lawsuits or inspections. At Massachusetts General, 5 percent of executive compensation was linked to a program aimed at improving performance on these quality measures after the institution received a negative safety review following a Joint Commission inspection. Additionally, Children’s
Duty of Care

Gipson v. Kasey, 150 P.3d 228 (Ariz. 2007), established that individuals who are prescribed medications owe a duty of care when they improperly give these compounds to another individual. Larry Kasey attended an employee holiday party hosted by the restaurant where he worked. Other individuals present included Nathan Followill, his coworker, and Sandy Watters, Mr. Followill’s girlfriend. Although the restaurant provided beer for their guests, Mr. Kasey also brought whiskey, which he gave to other individuals at the party. Mr. Kasey had been prescribed pain pills containing oxycodone for his back pain, which he also brought to the party. On previous occasions, Mr. Kasey had provided these pain pills to other coworkers for their recreational use.

During the party, Ms. Watters asked Mr. Kasey for one of his pain pills for recreational use. Mr. Kasey provided her with eight pills of two different strengths. Although Mr. Kasey had knowledge that taking the pain pills with alcohol or taking more than the prescribed dosage could cause dangerous side effects and even death, he did not inform Ms. Watters of this. Mr. Kasey had knowledge of Ms. Watters’ dating relationship with Mr. Followill and knew that Mr. Followill was interested in taking prescription drugs for recreational use. After Ms. Watters informed her boyfriend that she had the prescription pain pills, Mr. Followill took the pills from her.

The morning after the party, Ms. Watters woke up to find that her boyfriend had died in his sleep. The cause of death was the combined toxicity of the alcohol and oxycodone (from the prescription pain pills). Mr. Followill’s mother, Mrs. Gipson, filed a wrongful death action against Mr. Kasey. The superior court granted Mr. Kasey’s motion for summary judgment, finding that Mr. Kasey owed no duty of care to Mr. Followill and finding that Mr. Kasey’s conduct had not proximately caused Mr. Followill’s death. The court of appeals reversed, holding that Mr. Kasey did owe a duty of care.

This court granted review only on the issue of whether Mr. Kasey owed Mr. Followill a duty of care because he had provided Mr. Followill’s girlfriend with prescription pain pills. Duty is an obligation recognized by law that requires an individual to conform to a particular standard of conduct to protect other individuals against unreasonable risks of harm. If there is no duty of care owed to the individual harmed, then no action for negligence can be maintained. The court of appeals found that Mr. Kasey owed a duty of care to Mr. Followill because he had provided prescription pain pills to Ms. Watters; the presence of statutory law making it unlawful to give one’s prescription drugs to another person not on the prescription; and the foreseeability of harm from giving eight pain pills to Ms. Watters.

Gipson v. Kasey expressed that foreseeability is not a factor to be considered in determining whether a duty of care is owed to an individual. Inquiry into foreseeability requires inquiry into the facts of each individual case, an inquiry that should be left to the jury. Special relationships based on contract, family relations, or conduct undertaken by an individual may cause a duty of care; however, this type of direct or special relationship is not required. Arizona law identifies certain relationships in which a duty of care can arise, and none of those relationships existed between Mr. Followill and Mr. Kasey. Thus, the court declined to recognize a duty of care based on the relationship between Mr. Followill and Mr. Kasey.

Although a duty of care was not established by a relationship between the parties, there may be public policy reasons to recognize a duty of care between individuals. The mere existence of a criminal statute will not create a tort duty unless the statute is designed to protect the class of persons (in which the plaintiff is included) against the risk of the type of harm that has occurred because of its violation. The Arizona statutes were designed to avoid injury to people who were not prescribed the medication and who may be endangered by them and not properly instructed on their usage, potency, and possible dangers. The court found that Mr. Followill was within the class of individuals meant to be protected by the statute and the harm incurred was the risk the statute sought to prevent. Therefore, Mr. Kasey did owe a duty of care based on Arizona’s statutes prohibiting the distribution of prescription medication to persons not covered by the prescription.

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Disclosure of Real Property Used for Methamphetamine Manufacturing

(Ashley A. Nagrodski and Brandon K. Batchelor)

Introduction
After going through the painstaking process of buying a home, most new homeowners will spend several months decorating. However, assume a recent buyer begins to experience trouble breathing after moving into the new home. Initially, the purchaser would likely ignore the symptoms, perhaps attributing the difficulty to mere allergies. As the months pass, however, this buyer becomes increasingly ill.

Perhaps this hypothetical buyer is well read and comes across a recent article discussing a man who purchased a new home and, upon moving into the house, became very ill. The article goes on to say the man’s house had formerly contained a methamphetamine laboratory. Upon completing this article, the buyer investigates the prior owner and discovers an arrest for selling methamphetamine. Moreover, it is also apparent from this initial inquiry that the previous owner had cooked the methamphetamine in the residence, raising a possible link to the aforementioned respiratory symptoms.

Emerging research suggests a correlation between adverse health conditions and homes that formerly contained methamphetamine laboratories. See Michael S. Scott & Kelly Dedel, Clandestine Methamphetamine Labs 2 (2006), available at http://www.cops.usdoj.gov/mime/open.pdf#Item=274. Anyone in this situation would obviously be frustrated that the residential real estate disclosure did not include information that the premises had been a former methamphetamine house. Such conflicts often lead to consultations with attorneys, who then are tasked with determining whether the state in question imposes a duty to disclose former methamphetamine houses to subsequent purchasers. Lacking this obligation, buyers may find themselves with a contaminated home, an increasing amount of medical expenses, and no legal redress.

Real stories like this are occurring more frequently across our nation as the methamphetamine epidemic continues to rise. Felix Dolisora Jr., Family’s World Shaken by Former Meth Lab, Rocky Mountain News, available at http://www.rockymountainnews.com/drmm/government/article/0,2777,DRMN_23906,4481405,00.html. Methamphetamine is the fastest-growing drug problem in America. Many counties across the United States are now reporting methamphetamine to be their number-one drug problem. As further evidence of the scope of the rising problem, 11.7 million people over the age of 12 have reported using methamphetamine, according to the 2004 National Survey on Drug Use and Health. Office of National Drug Control Policy, Section on Methamphetamine, available at http://www.whitehousedrugpolicy.gov/drugfact/methamphetamine (last visited 5/06/2007).

Methamphetamine Background
The increase in the use of methamphetamine can be partially attributed to the simplicity of the manufacturing process. Methamphetamine is typically constructed using a combination of household cleaners and over-the-counter drugs that the aspiring chemist can easily obtain. The over-the-counter cold or asthma medications; such as those containing ephedrine or pseudoephedrine, are the most common ingredients used to make methamphetamine. The extensive diversion of these medications to the manufacture of meth has led the imposition of significant volume restrictions; previously unknown in the sale of over-the-counter medications. These volume restrictions are aimed at limiting the quantities available to methamphetamine operations, which require a quantity vastly larger than that needed by the legitimate user. In addition to the Sudafed-type medications, other common ingredients include: red phosphorus, hydrochloric acid, drain cleaner, battery acid, lye, lantern fuel, and anti-freeze. The Ant-Meth Site, Methamphetamine: Frequently Asked Questions, http://www.kci.org/meth_info/faq_meth.htm (last visited 5/06/2007). Compounding the ease of obtaining the basic ingredients required for methamphetamine manufacturing is the ease of obtaining “recipes,” which are pervasive on the Internet. Dana Hunt, Sara Kuck & Linda Truitt, Methamphetamine Use: Lessons Learned 23 (2006), available at http://www.ncjrs.gov/pdffiles1/nij/grants/209730.pdf.

Methamphetamine is made in a “lab” by a process commonly referred to as “cooking.” Cooking the drug is a very dangerous process that requires mixing the above-named products, which can become unstable and produce both toxic and explosive gases. It is often cooked in small labs set up in homes, trailers, or even in the back of SUVs. As noted above, the process of cooking meth is very volatile and has lead to explosions, chemical burns, fires, and toxic-fume inhalations. See Michael S. Scott & Kelly Dedel, Clandestine Methamphetamine Labs 2 (2006), available at http://www.cops.usdoj.gov/mime/open.pdf#Item=274. Each pound of meth cooked in these labs generates five to six pounds of toxic waste, which can be explosive, dangerous
to breathe, and harmful to the environment. This waste is typically burned, buried, or dumped into the environment by the lab operators in locations where those who come into contact with it are put at risk.

**Health Conditions Associated With Methamphetamine**

Methamphetamine gives users a "high" that can last from 4 to 24 hours. This extended high places extreme pressure on the nervous, circulatory, renal, and respiratory systems. The high makes the user extremely over stimulated; causing rapid thought processes and speech while typically arousing intense feelings of suspicion or paranoia. The high is followed immediately by a "crash," during which the user begins to experience fatigue, hunger, thirst, cravings, and mental confusion. The sensation of crashing is so dysphoric that the user usually feels the need to do another dose to keep from feeling the loss of energy and the inability to feel pleasure, as well as depression, anxiety, and insomnia.

The extended period of alertness associated with repeated intervals of use can lead to several body complications, including hyperthermia, palpitations, chills, hyper motor activity, kidney failure, mental confusion, tremors, and dizziness. Additionally, use of the drug can cause long-term changes in the brain. These neural changes can lead to memory problems, changes in mood, and impairments in motor coordination. Usage can also lead to heart complications such as abnormal heart functioning. Further long-term effects can include kidney failure, brain damage, liver damage, depression, blood clots, and personality disorders.

**Methamphetamine Laboratory Cleanup**

The cleanup of methamphetamine laboratories is a complex process that requires a great deal of time and money. See Signe Levine, Poison in our own backyards: What Minnesota legislators are doing to warn property purchasers of the dangers of former clandestine methamphetamine labs, 31 WMLR 1601, 1614 (2005). Cleanup requires the removal of various items, such as furnishings and carpeting, that cannot be adequately cleaned. All hard surfaces must be scrubbed, rinsed, and often repainted or recoated; ventilation and plumbing systems may have to be completely redone. In severe contamination instances, the entire property may have to be gutted.

**Legal Issues**

Several legal issues arise when former methamphetamine laboratories are sold in the residential real estate market; the issues are based on potential damages suffered by subsequent purchasers. First, is there a duty to disclose when a property formerly hosted a methamphetamine lab? Second, which parties, if any, are liable for such a disclosure? Finally, which parties will bear the cost of cleaning the property?

**Disclosure Requirements under Property Law**

Property law is adamantly about requiring property sellers to disclose information to potential buyers if the information is material to the subsequent owner’s decision to purchase the property. See Duty of Vendor of Real Property to Disclose to Purchaser Condition of Building Thereon which Affects Health or Safety of Persons Using Same, 141 A.L.R. 967 (1947). In fact, the law allows a cause of action against sellers who do not disclose material defects that were known or should have been known to the seller. This duty to disclose is necessary during the sale of property because there is a difference in bargaining power and a difference between the seller’s and the purchaser’s knowledge about the property. The seller is in the best position to know material facts about the house. In fact, if the law would allow, the seller could use this knowledge to his or her advantage by failing to inform the purchaser of vital information that may affect the purchaser’s decision to buy the property. This difference in knowledge and bargaining power has lead to the requirements of disclosing material defects. When a person purchases a home, certain rights are afforded to that person, and there liabilities that fall on the individual selling the home. As a general rule, if material facts regarding the property to be purchased are accessible to both the seller and the purchaser, the seller has no duty to inform the purchaser of such facts as long as the seller does not mislead the purchaser. However, when the seller is the only individual capable of knowing such material facts regarding the property, the seller is under an obligation to disclose the facts to the purchaser; this is referred to as the “duty to disclose.” This obligation arises when only the vendor has knowledge of material facts which, if the purchaser had knowledge of, may affect the purchaser’s decision to buy the property.

One important material fact that should be disclosed is any condition of property that affects the health or safety of the persons purchasing the property. Courts have held that a vendor who has knowledge of a material defect or condition that affects the health or safety of a purchaser, and such condition is not known or easily discoverable by the purchaser, the vendor has a duty to disclose the defect and can be held liable for nondisclosure. See Fennell Realty Co., Inc. v. Martin, 529 So. 2d 1003 (1988).

Several defects are required to be disclosed to potential property purchasers to avoid a cause of action for misrepresentation or nondisclosure. See Diane Allen, Real-estate Broker’s Liability to Purchaser for Misrepresentation or Nondisclosure of Physical Defects in Property Sold, 46 A.L.R. 4th 546 (1986). A broker is expected to disclose information relating to the general condition of the property if the broker knew or apparently knew of physical defects in the property. A broker is also supposed to notify a potential purchaser of defects in the basement or foundation if the broker knew or apparently knew of the defects. A broker is also required to disclose defects in the following: flooding, general construction/materials used, size, filled land, gas lines, drainage, sewer/septic, air/heating conditions, infestations, and water supply.

The underlying reasons for the variety of required disclosures extend from health-related concerns to problems with the physical structure of the property. For example, sellers are required to disclose information regarding infestations, including mold, that have potential harmful health effects. On the other hand, sellers are also required to disclose defects, such as a roof that leaks, that are related to the property itself, when such defects could result in the potential buyer having to spend future earnings to correct the defect. With disclosure requirements for such a wide range of defects, it is not a stretch to consider that prospective buyers would want to know whether their property has formally contained a methamphetamine laboratory and to consider this another material element that must be disclosed by the seller.

**Who Must Disclose Prior Methamphetamine Activity?**

Several individuals may have knowledge regarding the property: property sellers, law enforcement, and city officials. These individuals may have knowledge about the property that may not be easily obtained by
the subsequent purchaser. Those who are selling the property have or should have firsthand knowledge of the condition of their property. It would be a very rare occurrence for a person selling a property to have no idea that the property formerly contained a methamphetamine laboratory. Since these individuals have actual knowledge, it would be sensible to impose a duty to disclose on these individuals.

Law enforcement agencies and their officers may also have knowledge of properties on which meth labs formerly existed. These individuals may have seized the laboratories and arrested the individuals who were operating the labs. Although law enforcement personnel may not personally know the subsequent purchaser of property, it would not be impossible for these individuals to disclose their knowledge about the property to some third party, who can later inform subsequent purchasers. An analogous system may be the sex offender notification websites, maintained by many law enforcement agencies, that provide notice to prospective purchasers of the number and location of registered sex offenders living in the neighborhood being considered.

Finally, city officials are likely to have the same knowledge about property that formally contained methamphetamine laboratories. These officials could also be required to disclose this knowledge to subsequent purchasers of the property.

Who Should Be Responsible for Property Remediation?

The most logical policy would be to require the cost of cleanup to fall on the individual who used the methamphetamine laboratory to “cook” the drug. However, this may not be practical because such individuals likely will either be in jail after they are caught cooking methamphetamine, or are otherwise judgment-proof. Another potential source for cleanup costs would be the city. However, public funds are severely limited, and such a governmental action would accrue benefit to the private parties to the sale and thus constitute an unwise use of general taxpayer money. Most likely, the burden would fall on the owner of the property or the person who is seeking to sell the property to a subsequent purchaser. However, if undisclosed prior to the sale, subsequent purchasers may then be required to carry the financial burden of cleaning up their property.

State Approaches

Most states do not have laws that protect subsequent property owners. However, there is an emerging trend among states to offer some form of protection to the subsequent owners of meth properties. The following states have legislation that offers protection to home buyers: Arkansas, Arizona, California, Colorado, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, Oklahoma, Oregon, South Dakota, and Washington. Cal. Health & Safety § 25400.10 et. seq.; M.S.A. § 152.0275; T.S.A. § 68-212-507. Moreover, some states, such as Alaska, Idaho, Michigan, Montana, Oregon, Tennessee, and Washington, have an online database of methamphetamine properties. Illinois, Montana and Tennessee have lists of meth producers, similar to lists of online sex offenders, that the public can readily access.

Some states make it illegal to live in a methamphetamine property before it has been decontaminated: Arkansas, Arizona, California, Colorado, Idaho, Minnesota, Michigan, Nebraska, North Carolina, Oregon, Tennessee, and Washington. A.R.S. § 12-1000; O.R.S. § 453.855-453.912; Often it is illegal for anyone other than the owner, landowner, or manager to enter the contaminated property. Removal of said persons is enforced by the law enforcement agencies, which are required to give notice of the contamination to the residents of the property. Once the notice is given, some states, like Arizona, make it a class 6 felony to enter the property and a class 2 misdemeanor to remove notice of the contamination. Finally, Alaska, Arizona, Arkansas, California, Colorado, Idaho, Minnesota, Montana, North Carolina, Oregon, Tennessee, Utah, and Washington have adopted specific guidelines for the cleanup of contaminated properties. A.R.S. § 12-1000; O.R.S. § 453.885-§ 453.912. Cleanup of a methamphetamine property can range from scrubbing and painting to complete renovation of the property. Most states require the property owner to cover the cost of cleanup.

Federal Approach

In a typical situation, the laws governing real property disclosure would be governed by state common law or statutory schemes. As noted previously, many state schemes are somewhat lacking and certainly not uniform in the protection of subsequent purchasers of former methamphetamine property. In response to the inadequate protection under state law and the vastness of the problem of methamphetamine, the federal government has begun to acknowledge the problem and discuss solutions.

Currently there are no federal statutes in place to regulate property that has been exposed to methamphetamine toxins or to protect the purchaser of such property. However, the momentum may be shifting in just this direction. Currently, the CLEAN-UP of Methamphetamines Act has been referred to the House Subcommittee on Department Operations, Oversight, Nutrition, and Forestry to respond to the illegal production, distribution, and use of methamphetamines in the United States and for other purposes. CLEAN-UP of Methamphetamines Act, H.R. 955.

This is a step in the right direction, but it does little to directly protect subsequent purchasers of property. Moreover, the guidelines as currently envisioned are purely voluntary. Although the problem is recognized by the federal government, it will most likely be up to the states to deal with, legislate, and enforce the guidelines.

Conclusion

It is clear that meth use is a problem in the United States. The exposure to the toxic aftereffects of meth manufacturing is making subsequent purchasers of former methamphetamine houses seriously ill. These health risks are beginning to be recognized by both state and federal legislatures. The extent of the meth problem, when coupled with the health risks these properties pose to purchasers, provide significant motivation for new legislative approaches in the near term. However, in the absence of a new statute covering meth properties, the former existence of a meth lab on a property should not be treated any differently than other material defects, specifically those that adversely affect the health of subsequent purchasers. However, until the situation is ultimately addressed legislatively, the legal process and the courts must deal with this issue to protect property owners and their health. Furthermore, this is a problem that will only increase with the growing popularity and accessibility of methamphetamine.
The Public Response to West Nile Virus as a Model for Disease Control
(Levi J. Burkett)

Since the summer of 1999, the spread of West Nile virus (WNV) has been a waxing and waning issue on the nightly news. Although it is not the only serious illness to be spread by mosquitoes, many states have singled out the virus by taking actions aimed at preventing its transmission and minimizing the human and animal diseases caused by WNV infection. The governmental response to WNV implicates environmental, municipal, and public health policy concerns. Thus, as an issue, WNV stands as an example of state and local action designed to effectively amuse public concerns when addressing an infectious disease. However, these measures for containing WNV have come with a political price and their true effect in terms of limiting the number of infected individuals or total scope of injury remains uncertain. Some of the concerns over the actions states have taken in response to WNV’s spread focus on relatively short-lived measures. Moreover, some programs adopted have resulted in legal challenges delaying or challenging implementation with continued legal and political attacks waiting in the wings. This article summarizes some essential facts about West Nile virus as a legal-medicine issue, examines the steps various governmental bodies have taken to address WNV as a public health issue, and analyzes the legal actions that have challenged some of these steps.

I. The Virus

Human infections of WNV were first identified in the summer of 1999. Since that time, human WNV infections have been reported in an increasing number of U.S. states. In 2006, the Centers for Disease Control and Prevention recorded 4,256 documented infections involving WNV. Although most of the individuals survived, these 4,000 infections resulted in at least 165 confirmed WNV-related deaths. See Centers for Disease Control and Prevention West Nile Homepage, http://www.cdc.gov/westnile (last visited 4/25/2007). WNV infections generally take one of two courses: a milder form, called West Nile fever, or the more severe form, called encephalitis. West Nile fever, which accounts for the majority of infections, includes general symptoms such as fever, headache, skin rash, and swollen lymph glands. Contrary to the relatively good prognosis associated with the fever version of the infection, some individuals, particularly the elderly and immunocompromised, may develop a life-threatening version of encephalitis from the WNV. WNV-associated encephalitis presents with a high fever, neck stiffness, stupor, muscle weakness, convulsions, and, in extreme cases, coma or death. See National Institute on Allergy and Infectious Diseases, NIAID Research on West Nile Virus, available at www.niaid.nih.gov/factsheets/westnile.htm (last visited on 4/25/2007).

WNV is typically spread to humans through the bite of the common mosquito species. However, the CDC has also identified blood, organ transplant, transplacental transfer, and breastfeeding as potential methods of virus transmission. The mosquito vectors that spread the virus to humans are themselves originally infected following their feeding from an infected bird from one of many known carrier species. See American Mosquito Control Association, http://www.mosquito.org (last visited 4/25/2007).

There is currently no specific anti-viral treatment for human infections with WNV. However, general supportive treatment of the infected individual and their symptoms in healthy adults typically results in recovery. These supportive treatments include administration of fluids, rest, and antibiotics for ancillary infections. For at-risk individuals, primarily adults over age 50, the risk of developing the encephalitic form of WNV infection is higher. Also, immunosuppression from another illness or treatment (e.g., HIV/AIDS or chemotherapy) results in higher infection rates than in healthy individuals. Although a human vaccine aimed at preventing infections is currently in testing protocols, it has yet to be perfected or approved.

However, WNV infection and resulting diseases are not unique to humans. See The Future of West Nile Virus, available at www.cnn.com/SPECIALS/2005/west.nile (last visited 4/25/2007). Indeed, 93 distinct mammal species and more than 150 avian species have been identified as susceptible to WNV infection. Horses represent one group of mammals that are significantly affected by WNV. These animals are particularly prone to a type of WNV encephalitis in addition to their increased exposure to mosquitoes. Treatment for animal infection of WNV is similar to treatment for human infection. However, a vaccine was recently developed for equine use and is successfully being administered.

II. Government Action

The rapid spread of WNV to most of the 48 contiguous states and the resulting dangerous infectious complications present a significant public health risk. Recognizing this risk, Congress, in 2003, passed— and the President signed—the Mosquito Abatement for Safety and Health Act, 42 U.S.C.A. § 201. This budgetary act authorizes the issuance of grants to municipal and state governments through the Centers for Disease Control and Prevention. These modest grants are supposed to fund programs targeted at the prevention of mosquito-borne diseases generally and WNV in particular. The Act does not specify the precise nature of the programs that will be funded, so states have been able to experiment with many different methods of prevention of WNV and other mosquito-borne diseases.

The model for state and local action comes from Louisiana. See Louisiana Mosquito Abatement Plan, available at http://www.lsuagcenter.com/en/environment/insects/Mosquitoes/Louisiana+Mosquito+Abatement+Plan_seriespage-25.htm. The Louisiana Mosquito Abatement Plan is a comprehensive pest control initiative that, while primarily focused on mosquito abatement, includes guidelines for the prevention or reduction of mosquito-borne diseases such as WNV. The Louisiana Mosquito Abatement Plan sets forth detailed surveillance measures to track carrier mosquito species. This surveillance includes testing of captured mosquitoes to determine the infection rates of broods as well as population numbers year by year. Additionally, the plan provides for surveillance of animal infections, especially avian species infection. Since the virus is carried by many different bird species, including migratory birds, the Louisiana plan includes the testing of dead birds as well as live captures to note trends in the movement of the virus.

The Louisiana plan also has guidelines on effective abatement procedures. These include (1) spraying aerosol larvacides and adulticides over areas where mosquitoes are known to breed (also known as “breeding pools”); (2) connecting breeding pools to deep bodies of water; and (3) introducing biological controls on mosquito populations by introducing mosquito-predaceous fish and insects into the habitats. These measures are designed to interrupt the mosquito breeding cycle at the larval stage and kill adult mosquitoes that remain near the breeding pool habitat.
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Included in the spraying programs and biological controls are educational measures to ensure that when chemical agents are used for mosquito abatement, they are done so with an eye toward the potential for mosquitoes to develop resistance to the chemical agents. Pesticide programs must be carefully monitored or else mosquito populations will grow resistant, and more dangerous chemical agents will have to be used to achieve the same desired abatement effect. Finally, the Louisiana plan includes guidelines for sanitation projects to eliminate standing water which, in turn, forms the breeding pools, as well as public education projects about mosquito abatement in general and disease prevention in particular. See also Centers for Disease Control and Prevention, Epidemic/Epipidemic West Nile Virus in the United States: Guidelines for Surveillance, Prevention and Control, US Dept. of Health and Human Services, National Center for Infectious Diseases, 3rd Revision, 2003, available at http://www.cdc.gov/westnile.

While this article is too brief to compare the different ways in which states and municipal districts use aspects of the Louisiana plan, suffice it to say that the foregoing description describes the broad strokes of mosquito abatement and mosquito-borne disease prevention techniques that exist. Generally, such programs are planned and implemented on a local level and are funded either through the Federal Mosquito Abatement for Safety and Health Act of 2003 or through state initiatives. Counties or municipalities are awarded monies and are given the freedom to use the financial resources to develop programs targeted to the particular needs of their districts. While some states have guidelines that officials at the local level must follow, many local level officials are bound only by the limits of federal and state environmental regulations and their own municipal codes.

III. Legal Challenges

So far, there have not been many legal challenges to the way in which states have handled the spread and threat of WNV. However, one case stands as a representative of the types of challenges that are likely to come in the future. No Spray Coalition v. City of New York, 2005 WL 1354041 (S.D.N.Y.), saw a coalition of concerned citizens challenging a municipal mosquito abatement plan. Reacting expressly to the threat of WNV in the state, New York City authorities began massive spraying of chemical agents around and over public water areas. The No Spray Coalition challenged this action under the New York Clean Water Act. When it was decided, the suit garnered national attention because it was the first of its kind to challenge the presumed cost-benefit analysis of mosquito abatement. The argument on one side is the danger pesticides pose to humans; on the other side is the threat posed by mosquito-borne diseases such as WNV. After a lengthy procedural process in which an appellate court had to decide whether such a citizen suit was allowed under the Act (it was), No Spray Coalition lost its case. The coalition lost because the trier of fact did not find that spraying pesticides into public waterways was waste or pollution as defined by the specific language in the Clean Water Act. See generally Wilfredo Lopez, West Nile virus in New York City, Am. J. Pub. Health, vol. 92 no. 8: 1218–1221.

IV. Public Policy

The No Spray Coalition v. City of New York case is both interesting and important because it asks the very difficult question of whether it is appropriate for a federal, state, or local government to exercise its powers to prevent the spread of a disease if it does so in a way that...
endangers the very public it is trying to protect. There are a number of lessons one can take from No Spray, including (1) There is a long history in this country of the government acting in response to public health threats, including wide latitude in a government’s ability to take an action in derivation of some personal rights; (2) Though clearly they pose some threat, the pesticides used to abate mosquitoes, if used in proper levels and with approved safety precautions, have been approved by the EPA and other state environmental agencies; (3) The very fast spread of WNV throughout the United States prompted quick government action in response, which in turn heightened public awareness and insecurity about the effects of the virus; and finally (4) The mechanism of the citizen suit is an efficient way to ensure that the power of state agencies is checked against overreaching and at the same time given full effect through public action.

V. Conclusion

The governmental response to the danger and the spread of WNV may serve as a good model for public disease control. With the passing of the Federal Mosquito Abatement for Safety and Health Act, WNV response has begun to resemble a funnel approach to government. At the wide part of the funnel are the federal grants submitted to many different municipalities seeking to counteract WNV. These are broad and not uniquely targeted to local issues. At the narrow end are local government officials who receive the grants and are able to apply specifically tailored solutions to their jurisdictions’ unique situations. Although time will obviously tell the ultimate success or failure of this approach to controlling the spread and impact of WNV; it is important to recognize that fast action and wide public support (as well as federal dollars) can make for an effective solution to a public health problem in a manner none of the local municipalities acting alone could likely have achieved.

Physician Discipline

Chalifoux v. Texas State Board of Medical Examiners, 2006 Tex. App. LEXIS 9598 (Tex. App. 2006), raised the issue of whether substantial evidence existed to support the Board’s revocation of a physician’s medical license. In 2002, the Texas State Board of Medical Examiners filed a formal disciplinary complaint against neurosurgeon Dr. Roland Chalifoux. The Board alleged Dr. Chalifoux’s treatment of thirteen patients fell below the accepted standards of care and constituted unprofessional or dishonorable conduct under the Medical Practices Act. After a full evidentiary hearing, an administrative law judge (ALJ) concluded that Dr. Chalifoux failed to practice medicine in an acceptable professional manner in treating three patients.

Patient E.F. was diagnosed in 1996 with a giant aneurysm involving the right carotid artery and referred to Dr. Chalifoux for a neurological consultation. During an exploratory craniotomy, Dr. Chalifoux clipped the internal carotid artery to reduce blood flow to the aneurysm. Relying on an intra-operative angiogram as well as an intra-operative doppler, Dr. Chalifoux made the occlusion permanent. The next day E.F. did not regain consciousness and a CT scan showed a severe infarct of the brain’s right hemisphere. E.F. remained in a coma until his death 3 days later. The Board argued that no life-threatening emergency existed that necessitated immediate surgery and Dr. Chalifoux had never performed this procedure as a primary surgeon. Furthermore, the Board argued that Dr. Chalifoux failed to perform a balloon temporary occlusion test to determine potential adverse neurological deficits. The ALJ found that Dr. Chalifoux’s treatment of E.F. fell below the accepted standard of care and resulted in the patient’s death.

Patient C.Y. was diagnosed in 1996 with an arteriovenous malformation in her brain. She was prescribed Dilantin to control her occasional seizures and was referred to Dr. Chalifoux for a neurosurgical consultation. Dr. Chalifoux excised the malformation and C.Y. was discharged from the hospital, even though doctors failed to stabilize the Dilantin level in her system. As a result, C.Y. suffered a grand mal seizure, attributable to a sub-therapeutic Dilantin level. The ALJ found that Dr. Chalifoux’s post-surgery management of C.Y.’s seizures fell below the accepted standard of care and caused her post-discharge seizure.

Patient A.J. injured her back at work and in an automobile accident. In 1997, Dr. Chalifoux performed a posterior lumbar inter-body fusion. A second operation was performed to remove the spinal implants from the first operation. After the second surgery, A.J. complained of headaches when walking but not when sitting. Dr. Chalifoux instructed A.J. to lie on her side for 2 hours to monitor any drainage from the wound. A.J. was discharged from the hospital after no drainage was discovered. However, A.J. was readmitted the next day after complaining of leg pain, headaches, and wound drainage. After three additional surgeries, Dr. Chalifoux successfully repaired a dural tear and the wound drainage subsided. The ALJ found that Dr. Chalifoux should have recognized that A.J. had a cerebrospinal fluid leak and should not have discharged her from the hospital since dural leaks cause headaches and drainage when a patient is upright due to the increase in hydrostatic pressure. As a result, the ALJ found that the discharge of patient A.J. was substandard.

In the proposal for decision, the ALJ concluded that Dr. Chalifoux violated an accepted medical standard of care in his treatment of the three patients, failed to practice medicine in an acceptable professional manner, and committed unprofessional conduct that was likely to injure the public. Although the ALJ recommended a suspension of Dr. Chalifoux’s medical license for a period of 5 years, the Board decided to permanently revoke his license. Dr. Chalifoux appealed this decision and the district court affirmed the Board’s final order. As a result, Dr. Chalifoux filed a rehearing motion in the Court of Appeals, claiming the Board violated his due process rights, that the final order was arbitrary and capricious, and that the final order was not supported by substantial evidence. Dr. Chalifoux argued that his due process rights were violated because the Board relied on peer-review materials for the final order. The Board notified Dr. Chalifoux of its intent to offer into evidence peer-review records pertaining to prior disciplinary actions at four different hospitals. Although the ALJ refused to admit the evidence, the final order mentioned that the evidence would have demonstrated the egregious nature of Dr. Chalifoux’s conduct and would have supported a severe sanction. The appeals court held that no violation of Dr. Chalifoux’s due process rights occurred because there was no evidence that the board relied on the peer-review materials, and there was no evidence that it would have harmed him.

Dr. Chalifoux further argued that his due process rights were violated because two Board members had previously served on a disciplinary panel that suspended his license in 2002. Due process requires that the parties be accorded a full and fair hearing on disputed fact issues. Hammack v. Public Util. Comm’n, 131 S.W.3d 713, 731 (Tex.App.-Austin 2004 pet. Denied). To overcome a presumption that decision makers are unbiased, Dr. Chalifoux must show that the doctors’ participation on the previous panel caused them to be incapable of judging
the current case. In this case, the appeals court held that no due process violation occurred because the doctors did not violate any rule by serving on both panels, and Dr. Chalifoux should have requested that the doctors recuse themselves prior to participating in the panel. Dr. Chalifoux insisted that the Board's final order was also based on arbitrary and capricious actions because the Board considered mitigating evidence that would have supported a lesser sanction.

A court must reverse or remand a case if substantial rights of a party have been prejudiced because administrative findings, conclusions, or decisions are arbitrary or capricious or characterized by an abuse of discretion. Tex. Gov't Code Ann. § 2001.174(2)(F). An agency's decision is arbitrary if the agency failed to consider a necessary factor, considers an irrelevant factor, or weighs only relevant factors but still reaches a completely unreasonable result. City of El Paso v. Public Util. Comm'n, 883 S.W.2d 179, 186 (Tex. 1994). The appeals court agreed with Dr. Chalifoux that the Board's findings included mitigating evidence that could support a lesser sanction. However, the mere presence of mitigating evidence does not by itself preclude the Board from concluding that Dr. Chalifoux failed to practice medicine in an acceptable manner consistent with public health and welfare, or that he committed unprofessional or dishonorable conduct that was likely to deceive or defraud the public. See Tex. Occ.Code Ann., § 164.051(a)(6) and § 164.052(a)(5). The court held the Board's order was neither arbitrary nor capricious.

For the final issue, Dr. Chalifoux argued that the Board's order was not supported by substantial evidence. In a substantial evidence review, a court reviews the agency's legal conclusions for errors of law and its findings of fact for support by substantial evidence. Buddy Gregg Motor Homes, Inc. v. Motor Vehicle Bd., 156 S.W.3d 91, 99 (Tex.App.-Austin 2004, pet. denied). A substantial evidence review is satisfied if "some reasonable basis exists in the record for the agency's action." Graff Chevrolet Co., Inc. v. Texas Motor Vehicle Bd., 60 S.W.3d 154, 159 (Tex.App.-Austin 2001, pet. denied). In this case, the Board is permitted to discipline a physician who commits a prohibited act, such as unprofessional or dishonorable conduct that is likely to deceive, defraud, or injure the public. See Tex. Occ.Code Ann. § 164.051(a)(1) and § 164.052(a)(5). The appeals court held that the use of the word "likely" indicated a finding of actual harm to be unnecessary and as a result, the court held that all disputed findings of fact were supported by substantial evidence.

Furthermore, the court held that construing the Medical Practices Act to require only egregious or grossly negligent conduct before permitting the Board to discipline a physician would unnecessarily limit the scope of the statutes. The appeals court affirmed the district court judgment upholding the Board's final order. Dr. Chalifoux failed to prove that the Board's findings were not based on substantial evidence or arbitrary and capricious actions. Furthermore, Dr. Chalifoux failed to demonstrate a violation of his due process rights. As a result, the appeals court affirmed the revocation of Dr. Chalifoux's medical license.

### Informed Consent

**Matley v. Minkoff**, 68 Mass. App. Ct. 48 (2006), affirmed that the failure to raise informed-consent-related issues and defenses at trial waives the right of physicians to do so on appeal. Dr. Kenneth Minkoff treated Nancy Matley for mental illness over a period of 4 years. Ms. Matley suffered mental retardation and her parents made all treatment decisions for her. However, Ms. Matley's parents were not her legal guardians until 1 year after treatment by Dr. Minkoff ended.

During the course of Ms. Matley's treatment, Dr. Minkoff prescribed Thorazine, a neuroleptic medication. Nancy Matley developed tardive dyskinesia, a serious side effect of Thorazine. Ms. Matley's symptoms included twitching movements, smacking of the mouth, and a severe gait disturbance requiring the need for a wheelchair.

The Matley's brought a claim on behalf of their daughter that alleged that Dr. Minkoff had negligently prescribed the medication and negligently failed to obtain Ms. Matley's informed consent for the use of the medication. Throughout the trial, Dr. Minkoff and the Matley's assumed that the Matley's were Nancy Matley's legal guardians. The Matley's argued that Kenneth Minkoff had to obtain their informed consent before using Thorazine. The jury returned a verdict in favor of Ms. Matley on the claim of failure to obtain informed consent and awarded her $200,000.

After the verdict, Dr. Minkoff moved for a judgment notwithstanding the verdict or, in the alternative, a new trial. The judgment notwithstanding the verdict was granted because of the Supreme Judicial Court's ruling that before a patient can be treated with neuroleptic medication, a judge must first determine the patient's competency. Guardianship of Roe, 383 Mass. 415, 434-435 (1981). If the patient is deemed incompetent, the judge must determine what the patient would do if competent. Id. This is known as the substituted judgment rule. The Matleys appealed and sought to have the verdict reinstated.

On appeal, the court concluded that the judgment notwithstanding the verdict should not have been granted because a party cannot raise an issue on appeal that was not raised in the original trial. Dr. Minkoff argued that he had no duty to obtain the consent of the Matleys because no determination was made as to Ms. Matley's competence. However, in the original trial, Dr. Minkoff failed to make this argument in his motion for a directed verdict. A motion for a judgment notwithstanding the verdict cannot raise an issue that was not raised in the party's motion for a directed verdict. Shafir v. Steele, 727 N.E.3d 1140 (2000).

The court determined that the jury's verdict should be reinstated. Dr. Minkoff waived any rights to argue that he had no duty to obtain the Matleys informed consent before prescribing the medication to Ms. Matley, because he failed to object to the Matleys contention that he had such a duty during the original trial. The verdict award of $200,000 was reinstated.
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