

# HEALTH LAW WEEK

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## In The News

### Jury awards \$130 million in wrongful birth case

A Michigan jury has awarded \$130 million to a 15-year-old girl who requires round-the-clock medical care as a result of injuries she suffered during birth.

The lawsuit, filed in 2006, alleged that Markell VanSlembrouck was unusually large at birth because of her mother's gestational diabetes. The lawsuit claims that Dr. Andrew Halperin and William Beaumont Hospital in Royal Oak, Mich., failed to assess VanSlembrouck's size and perform a caesarian section. VanSlembrouck was born with brain damage and a broken clavicle.

VanSlembrouck was born with cerebral palsy, which the lawsuit claimed was caused by her negligent prenatal care and birth. She is now a quadriplegic and requires around-the-clock care.

**VanSlembrouck v. Halperin**, No. 2006-074585-NH (Mich. Cir. Ct., Oakland County *verdict entered* Oct. 18, 2011)

### Lawsuit against Merck alleges sexual side effects from Propecia use

A lawsuit alleges that Merck & Co. downplayed the sexual side effects of the hair loss supplement Propecia.

Merck allegedly indicated that Propecia—a prescription drug used to treat male pattern hair loss—had a small chance of causing sexual side effects. The lawsuit alleges that, in fact, the supplement has come under criticism from experts worldwide who believe it can cause permanent sexual dysfunction.

The lawsuit was filed on behalf of an unnamed John Doe plaintiff and includes claims for negligence, strict products liability and breach of warranty.

**Doe v. Merck & Co. Inc.**, No. 11-2680 (D. Colo. *complaint filed* Oct. 14, 2011)

### Doctor sued for disclosing patient's HIV status

A Wisconsin man has filed a lawsuit alleging his doctor wrongfully disclosed the man's HIV-positive status.

The patient—who is not identified by name—underwent surgery after which his doctor, Dr. Christopher Doro, called the man's mother to tell her that the surgery was successful. The lawsuit alleges that during the call, Doro mentioned that the man was HIV positive.

The plaintiff claims that his mother was only listed as his emergency contact and Doro was not authorized to share confidential medical information with her. The lawsuit alleges the plaintiff has experienced panic attacks and insomnia as the result of the mistake. The lawsuit seeks compensatory and punitive damages.

**Doe v. Univ. of Wis. Bd. of Regents**, No. 2011CV004491 (Wis. Cir. Ct., Dane County *complaint filed* Oct. 7, 2011)

### Antitrust class action filed against Wyeth over antidepressant

Wyeth Inc. is the defendant in a class action lawsuit that claims the company sought fraudulent patents to keep generic versions of a popular drug from the marketplace.

According to the lawsuit, Wyeth claimed that its Effexor XR antidepressant had other uses in order to obtain additional patents. The lawsuit alleges Wyeth's actions resulted in an inability of other competing companies to get generic versions of the drug on the market. The lawsuit alleges that Wyeth's claims were fraudulent and used solely to thwart competition.

**Painters Dist. Council No. 30 Health & Welfare Fund v. Wyeth Inc.**, No. 11-5590 (D.N.J. *complaint filed* Sept. 26, 2011)

**Strafford**

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# In The Courts

## Antitrust

### Employment

### Physicians

#### Judgment in favor of practice group in action brought by former member affirmed

**Marsh v. Anesthesia Servs. Med. Group Inc.,**  
No. D057858 (Cal. Ct. App. Oct. 6, 2011) *unpublished*

The California Court of Appeal affirmed a trial court's judgment sustaining demurrers by an anesthesiology practice group to numerous statutory and tort claims brought against the group by a former member.

Anesthesiologist Dr. Lou Marsh sued her former practice group, Anesthesia Services Medical Group Inc. (ASMG), alleging unlawful and unfair business practices which caused her unfair exclusion from practice, as well as interference with prospective business advantage and intentional infliction of severe emotional distress.

A trial court sustained demurrers to portions of Marsh's complaint, and Marsh, after voluntarily dismissing an additional cause of action, appealed.

The court of appeal concluded that Marsh failed to allege her statutory causes of action under the Cartwright Act or the Unfair Competition Law (UCL). As to the Cartwright Act, which related to state antitrust claims, the court found that the staffing decisions challenged by Marsh could not of themselves constitute an antitrust injury. Under applicable precedent, unless the effect of the conduct of a single healthcare provider is to deny patients reasonable access to any healthcare, the marketplace is not significantly affected by such individualized conduct.

As to the UCL claim, the court concluded that absent more extensive allegations of how the challenged administrative decisions amounted to anti-competitive business practices that injured consumers, Marsh as well could not state a claim for necessary preservation of fair business competition.

The court of appeal separately held that Marsh failed to adequately allege her tort claims of negligent interference with prospective economic advantage or intentional infliction of emotion distress against ASMG and, therefore, affirmed the trial court's judgment on those claims. However, the court of appeal ordered the trial court to allow further proceedings to enable Marsh to file an amended complaint, if desired, to plead a theory of intentional interference with prospective economic advantage.

## Arbitration

### Contracts

### Physicians

#### Healthcare providers cannot compel arbitration under equitable estoppel principles

**Sweidan v. Fountain Valley Reg'l Hosp.,**  
No. B228392 (Cal. Ct. App. Oct. 7, 2011) *unpublished*

The California Court of Appeal ruled that healthcare providers are not entitled to compel arbitration of claims stemming from a coverage agreement under equitable estoppel principles.

Dr. Jacob Sweidan and Pediatrics & Neonatology Medical Group of Orange County Inc. brought an action against Fountain Valley Regional Hospital, Deborah Keel, Tenet Healthcare Corp., Cotkin & Collins (a law firm), Kevin Duffis, Dr. Veeraiah Chundu, and OC Neonatal Group Inc. The complaint alleged the hospital entered into negotiations with the plaintiffs to have Pediatrics & Neonatology Medical Group replace Pediatrix Medical Group of California (Pediatrix Group) as the exclusive provider of physician ser-

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vices at the hospital's neonatal intensive care unit. Keel, the hospital's CEO, wanted Chundu, the Pediatrix Group medical director, to remain working at the hospital's neonatal intensive care unit.

The hospital and Sweidan, on behalf of Pediatrics & Neonatology Medical Group, signed an agreement (the coverage agreement) that granted Pediatrics & Neonatology Medical Group the exclusive right to provide physician services in the hospital's neonatal intensive care unit. The coverage agreement also required Pediatrics & Neonatology Medical Group to appoint a medical director to administer the neonatal intensive care unit subject to the hospital's prior approval.

Initially, Chundu agreed to work for the plaintiffs and agreed to the terms of an employment agreement. But, the plaintiffs alleged, Chundu later materially changed the terms of the employment agreement by demanding a greater salary and a higher profit sharing percentage. Allegedly, Keel supported Chundu's efforts to "wrest the [c]overage [a]greement" from the plaintiffs in return for patient referrals from him. Law firm attorney Duffis allegedly aided Chundu by advising the plaintiffs to assign the coverage agreement to Chundu and his corporation, OC Neonatal Group, because Keel and the hospital had decided not to "work" with the plaintiffs.

After Keel cancelled the coverage agreement and the plaintiffs sued, the hospital, Keel and Tenet petitioned to compel arbitration under the coverage agreement. The trial court denied the petition. It ruled the hospital, Keel and Tenet could enforce the arbitration provision in the coverage agreement and Duffis under the fee agreement, but Chundu's actions were so intertwined with those of the other defendants that arbitration would likely result in conflicting rulings. After the trial court denied the defendants' renewed petition to compel arbitration, the defendants appealed.

The court of appeal affirmed the trial court's judgment. In so ruling, the court of appeal rejected the defendants' argument that even though Chundu and OC Neonatal Group were not signatories to a written arbitration agreement, equitable estoppel principles required arbitration of the plaintiffs' claims because all of the plaintiffs' claims relied on the coverage agreement. The equitable estoppel doctrine applies when a party has signed an agreement to arbitrate but attempts to avoid arbitration by suing nonsignatory defendants for claims that are based on the same facts and are inherently inseparable from arbitrable claims against signatory parties.

The court of appeal found that not all of the plaintiffs' claims against the nonsignatory defendants were dependent upon, or inextricably bound up with, the coverage agreement. Thus, equitable estoppel principles were not controlling.

## Certificate of Need

### Administrative Law

### Physicians

#### **MRI facility owned solely by physicians does not require CON**

**Commw. v. Fleming Reg'l Med. Imaging P.L.L.C.**,  
No. 2009-CA-001318 (Ky. Ct. App. Sept. 30, 2011)  
*unpublished*

Affirming the trial court's judgment, the Kentucky Court of Appeals concluded that a medical facility is exempt from statutory certificate of need (CON) requirements because the facility was wholly physician-owned.

A primary care physician and two radiologists formed Fleming Regional Medical Imaging P.L.L.C. to operate an MRI facility. Before opening the facility, Medical Imaging sought an advisory opinion from the Kentucky Cabinet for Health and Family Services as to whether it was exempt from certificate of need requirements. The Cabinet determined that Medical Imaging was exempt as a private physician office.

Fleming County Hospital District and the Kentucky Hospital Association requested a hearing. A hearing officer found that Medical Imaging did not meet the criteria for the exemption. Medical Imaging petitioned for judicial review. The trial court reversed the hearing officer. The hospital and the association appealed.

The trial court correctly concluded that 900 KAR 6:050 § 18 did not apply to Medical Imaging. That provision permits the Cabinet to conduct a show cause hearing in order to determine if a person has established or is operating a health facility in violation of KRS Chapter 216B.

The court of appeals observed that Medical Imaging had not been established and was not operating at the time of the advisory opinion; instead, the facility was merely in the planning stages. The evidence supported the trial court's conclusion that Medical Imaging was physician-owned and thus exempt from the certificate of need requirements. The three physicians were the sole owners of Medical Imaging. Most, if not all, of the patient referrals to Medical Imaging would come from the primary care physician's practice and the facility was located in office space adjacent to his office.

## Contracts

### Medical Devices

### Patents

#### Stent inventor seeks portion of \$1.75 billion patent infringement settlement

**Jang v. Boston Scientific Scimed Inc.**, No. 10-0681 (D. Del. Sept. 30, 2011)

The U.S. District Court for the District of Delaware, granting a motion for judgment on the pleadings, concluded that a doctor who assigned the patent for stent technology he developed is not entitled to additional payments under the assignment agreement since the assignee of the patent recovered no monies from a third-party infringer.

Dr. David Jang invented the intravascular stent covered by U.S. Patent No. 5,922,021 (the '021 patent). Boston Scientific Scimed Inc. (Scimed) and Jang entered into an assignment agreement in which Jang agreed to assign the '021 patent and other patents (collectively, the stent patents). Jang and Boston Scientific Corp. (BSC) entered into a separate agreement to facilitate commercialization of the stent technology.

Scimed paid Jang \$50 million for the stent patents and agreed to pay up to an additional \$110 million if various contingencies occurred. One contingency obligated Scimed to pay Jang 10% of any recovery that Scimed obtained in litigation against a third-party infringer of the stent patents.

Cordis Corp. subsequently sued BCS and Scimed for patent infringement. BCS and Scimed filed a counterclaim alleging that Cordis infringed the '021 patent. The three companies ultimately reached a settlement whereby BCS and Scimed would recover licenses to two Cordis patents and would pay \$1.75 billion to Cordis after offsetting its own liability for infringement.

Jang sued BCS and Scimed alleging that he was entitled to his share of the settlement monies pursuant to the assignment agreement. BCS and Scimed filed a motion for judgment on the pleadings. The district court granted the motion.

Jang's breach of contract claim failed because the assignment agreement clearly did not provide that he could recover damages in the event of a non-monetary settlement. The assignment agreement spoke of apportionment of monetary balances between the parties but there was no balance to be processed because BCS and Scimed received no money.

The complaint alleged that BCS and Scimed violated the covenant of good faith and fair dealing by depriving Jang of the benefits to which he was entitled under the assignment agreement. The district court found that because there was no breach of contract, there could be no breach of the covenant of good faith and fair dealing.

Jang claimed that BCS and Scimed breached their fiduciary duties in structuring the settlement with Cordis. However, the assignment agreement did not contemplate any fiduciary duties—the parties instead agreed to act on their own behalf.

### Physicians

### Notice

#### Surgery center operator properly terminated membership interest of ousted member

**Pittman v. Fairway Med. Ctr. L.L.C.**, No. 2011 CA 0278 (La. Ct. App. Oct. 6, 2011) *unpublished*

The Louisiana Court of Appeal ruled that a trial court erred in ordering a limited liability company operating an outpatient surgery center to reinstate the membership interest of an ousted member based upon the finding that the company failed to timely exercise an option to purchase the member's interest.

Fairway Medical Center L.L.C. owned and operated an outpatient medical center and specialty hospital in St. Tammany Parish. Dr. Michael Pittman was a practicing urologist and one of Fairway's members. Pittman and his wife had established a revocable inter vivos trust, the Four M Family Trust, purporting to transfer to the trust all of their membership interest in Fairway. Pittman was designated as trustee and the couple's four children were designated as beneficiaries.

Subsequently, Fairway terminated Pittman's membership interest and exercised its option to purchase Pittman's interest under its operating agreement. Pittman and Four M filed a petition against Fairway, alleging that the termination of his membership interest was without cause and in violation of Fairway's operating agreement and articles of organization. The trial court ordered the reinstatement of Pittman's membership interest, finding Fairway failed to timely exercise its option to purchase the member's interest. Fairway appealed.

The court of appeal reversed the trial court's order. Fairway's notice of the exercise of its option was unquestionably valid, and a contract to sell Pittman's membership interest was created. The trial court confused the deadline for Fairway's exercise of its purchase option with the deadline for closing of the sale of the membership interest.

## Employment

### Discrimination

### Handicapped Persons

#### Hospital's termination of employee with ADHD was lawful

**Zangara v. Somerset Med. Ctr.**, No. A-1041-10T2 (N.J. Super. Ct. App. Div. Oct. 5, 2011) *unpublished*

The New Jersey Superior Court, Appellate Division, ruled that a hospital did not terminate an employee with attention deficit hyperactivity disorder (ADHD) because of his disability in violation of the New Jersey Law Against Discrimination (LAD).

Jason Zangara worked at Somerset Medical Center (SMC) from June 2003 until March 2008, when he was terminated. According to Zangara, he was terminated because of a disability, specifically ADHD. However, according to SMC,

Zangara was terminated because of complaints from SMC staff that his behavior was inappropriate and unprofessional.

Zangara brought an action against SMC alleging it discriminated against him in violation of the LAD. The trial court denied Zangara's motion for summary judgment and granted SMC's cross-motion for summary judgment. Zangara appealed.

The appellate division affirmed the trial court's judgment. While Zangara established a prima facie case of disability discrimination, SMC articulated a legitimate, non-discriminatory reason for its decision to terminate him. Moreover, Zangara failed to show a jury question on whether the reasons articulated by SMC were merely pretextual where, although there may be factual disputes about details and the merits of the decision to terminate, there was a well-documented history of problems between Zangara and the staff members of the units in which he worked prior to his termination.

## Expert Testimony

### Malpractice

### Physicians

#### Expert witness' failure to explain changed causation testimony supports dismissal

**Pettiford v. Aggarwal**, No. 24557 (Ohio Ct. App. Oct. 7, 2011)

The Ohio Court of Appeals affirmed a trial court's dismissal of a malpractice action brought by former patient against a physician.

In 1999, Barbara Pettiford underwent a chest X-ray and MRI that Pettiford later alleged was misinterpreted as normal by Dr. Rajendra Aggarwal. In 2002, a tumor was discovered in Pettiford's lung. Pettiford sued Aggarwal alleging that he was negligent in failing to detect the tumor in 1999.

During a deposition, Pettiford's medical expert, Dr. Trent Sickles, opined that Aggarwal deviated from the acceptable standard of care by not detecting a lung mass in Pettiford's 1999 X-ray. Sickles offered no opinion about causation or the effect of a three-year delay in diagnosis on Pettiford's treatment or the course of her illness.

The trial court entered summary judgment in Aggarwal's favor. Following a lengthy procedural history, the trial court on a later remand again granted summary judgment in Aggarwal's favor, and Pettiford appealed.

The court of appeal noted that, in his deposition Sickles stated he could not testify or give any opinion about causation, but in a later affidavit did offer an opinion on causation. The court of appeal concluded that, because Sickles gave no explanation for his newly found ability to provide causation testimony, the trial court correctly held that the affidavit failed to raise a fact issue requiring trial. Pettiford's related assignment of error was accordingly overruled.

The court of appeal further noted that, under an Ohio Supreme Court ruling previously issued in this case, Sickles

bore the burden to explain why his deposition testimony conflicted with his affidavit regarding his ability to testify on causation. Because Sickles failed to provide such an explanation, the court of appeal affirmed the trial court's dismissal of the action.

## Insurance

### Discrimination

### Contracts

#### Podiatrists challenge health insurer's reimbursement rates

**Conn. Podiatric Med. Ass'n v. Health Net of Conn. Inc.**, No. 18267 (Conn. Oct. 18, 2011)

The Connecticut Supreme Court affirmed a trial court's judgment in favor of a health insurer in an action brought by certain podiatrists challenging the insurer's practice of reimbursing podiatrists at a lower rate than medical doctors for the same procedures.

Podiatrists Drs. Jeffrey Yale, Anthony Iorio and Daniel Davis, and the Connecticut Podiatric Medical Association sued Health Net of Connecticut Inc., a health insurer, alleging that Health Net's practice of reimbursing the podiatrists at a lower rate than other medical doctors for the same procedures constituted unfair discrimination under the Connecticut Unfair Insurance Practices Act (CUIPA), and the Connecticut Unfair Trade Practices Act (CUTPA).

After dismissing the association for lack of standing, a trial court found that the applicable statutes did not require insurance providers to reimburse podiatrists at the same rate at which they reimburse medical doctors for the same services. The court entered judgment in favor of Health Net. The podiatrists appealed.

The supreme court concluded that the two statutes did not directly address the issue of whether insurers were prohibited from reimbursing practitioners holding different licenses at different rates for the same procedures. The supreme court found, however, that the legislative history of both the CUIPA and the CUTPA supported the conclusion that these statutes were intended to prevent discriminatory denials of reimbursement and that the legislature did not intend to prohibit insurers from reimbursing practitioners at different rates based on license.

The supreme court concluded that if the legislature had intended to include such a prohibition, it seemed likely that insurance industry representatives would have expressed an opinion on the matter in committee hearings. The transcripts of these hearings however contained no opposition on the subject of pay parity. Accordingly, the trial court's judgment in favor of Health Net was affirmed.

**ERISA Coverage**

**Insurer must adequately explain decision to deny benefits to hospital**

**OSF Healthcare Sys. v. Concert Health Plan Ins. Co.**, No. 08-1328 (C.D. Ill. Oct. 4, 2011)

The U.S. District Court for the Central District of Illinois ruled that an ERISA plan administrator’s denial of benefits to a hospital was arbitrary and capricious because the administrator did not adequately explain the basis for its decision.

St. Francis Medical Center brought a claim pursuant to ERISA against Concert Health Plan Insurance Co. for denying the bulk of Ronald Miller’s benefits claim arising from his hospitalization and surgery at St. Francis. Concert processed the claim at the out-of-network rate. St. Francis contended the claim should have been processed at in-network rates.

According to St. Francis, in-network rates applied because a preferred provider referred Miller to St. Francis and that no in-network provider was “reasonably available.” Concert disputed this assertion, arguing preferred providers were reasonably available. Both St. Francis and Concert moved for summary judgment.

The district court denied Concert’s motion and allowed St. Francis’ motion. Concert must conduct a more thorough inquiry into whether the services provided by St. Francis to Miller were reasonably available at Methodist Medical Center, an in-network hospital, in light of all the facts and circumstances. If Concert concluded they were, it was required to adequately explain its decision, setting forth the facts upon which it relied and the applicable policy provisions, and addressing the arguments and evidence presented by St. Francis.

The district court found Concert did not do this. Thus, the court remanded the action to Concert’s plan administrator to explain the basis of its decision.

**Class Action Fraud**

**Class certification denied in fraud action brought by physician against HMO**

**Windisch v. Hometown Health Plan Inc.**, No. 08-0664 (D. Nev. Oct. 7, 2011)

The U.S. District Court for the District of Nevada denied a motion to certify a class in a putative class action brought by a physician against an HMO and related entities alleging an illicit scheme to pay improperly reduced reimbursement on covered patient claims.

Dr. Kevin Windisch sued Hometown Health Plan Inc., an HMO, and related entities for breach of contract alleging that the defendants carried out “a scheme to deny and reduce lawful reimbursement” to Windisch and to a putative class of healthcare providers that rendered services to the defendants’ enrollees.

Windisch alleged that the defendants, through utilization of the “ClaimsCheck” billing system, refused to pay for more than one service per visit or incident (bundling), changed submitted claims to billing codes with lower reimbursement rates (downcoding), and refused to reimburse at the proper rate in complex cases. In a prior order the court denied the defendants’ motion to dismiss based on ERISA preemption because coverage under non-party enrollees’ ERISA plans was not in dispute, but only reimbursements under the non-ERISA-dependent agreement. The court further found that the complaint adequately alleged consumer fraud. The case came before the court on Windisch’s motion for class certification.

The court concluded that although the complaint alleged the numerosity of persons who may have been harmed, it failed to allege, as required, the numerosity of persons who actually have been harmed. The plaintiff failed to meet the requirement of alleging that the same act or acts by the defendants caused the same harm to a sufficient numerous class of persons. In this case, this would require alleging that a certain number of doctors with substantially similar agreements were subjected to certain particular improper downcodings and/or bundlings.

The court separately concluded the complaint failed to show commonality because it was not clear how many doctors were alleged to have suffered which allegedly wrongful downcodings or bundling via the billing system operated or utilized by the defendants.

The district court found that, as in a similar Eleventh U.S. Circuit Court of Appeals case, the plaintiff in order to satisfy the requirements of class certification would have to identify subclasses of doctors who were allegedly cheated under specific ClaimsCheck algorithms in order for common issues to predominate over individualized issues for any particular subset of doctors. Accordingly, the plaintiffs’ motion for class certification was denied.

**HIPAA Jurisdiction**

**Class action alleges insurers lost confidential medical information**

**Baum v. Keystone Mercy Health Plan**, No. 11-1261 (E.D. Pa. Oct. 4, 2011)

The U.S. District Court for the Eastern District of Pennsylvania ruled that it lacked jurisdiction over parents’ action alleging insurers lost a flash drive containing confidential medical information about children.

Avrum Baum, as the parent of C.B., brought an action in state court on behalf of himself and all other similarly situated individuals against Keystone Mercy Health Plan and its affiliate, Amerihealth Mercy Health Plan (collectively, Keystone). According to the complaint, a portable USB flash drive containing the personal health information of C.B. and more than 280,000 other children insured by Keystone “went missing” from Keystone’s corporate offices. Although the specific nature of the health information on the

drive was not identified, Baum believed it included names, addresses, phone numbers, policy identification numbers, full and partial social security numbers, customer financial information, and health histories.

Following a report by the *Philadelphia Inquirer*, Keystone informed Baum that the flash drive was lost within its office. Baum alleged Keystone was negligent by permitting its employees to routinely transport the flash drive to community health fairs, not encrypting or otherwise protecting the health information on the flash drive, failing to restrict access to the data on the flash drive by person or scope, and generally failing to secure the contents of the flash drive. Keystone removed the case to federal court, and Baum moved to remand to state court.

The district court granted Baum's motion. Keystone alleged federal question existed and, therefore, this action could have originally been filed in district court because Baum's claims necessarily involved interpretation of the Health Insurance Portability and Accountability Act (HIPAA). The court disagreed. In spite of the fact that the personal data at the heart of this case was protected by HIPAA, the court concluded the case was a fairly straightforward one asserting state law tort claims for negligence and violation of the state's consumer protection law.

## Malpractice

### Physicians

### Civil Procedure

#### Sanctions against patient for filing second medical malpractice action reversed

**Compere v. St. Dominic Jackson Mem'l Hosp.**, No. 2010-CA-00490-SCT (Miss. Sept. 29, 2011)

The Mississippi Supreme Court determined that a trial court erred in dismissing a patient's medical malpractice action and imposing sanctions because the patient had previously filed the same action.

Richard Compere underwent a fluoroscopically guided lumbar puncture performed by Dr. Bryan Lantrip at St. Dominic-Jackson Memorial Hospital to treat his headaches. Lantrip dictated a report concerning the procedure, which Compere alleged contained an error causing him to undergo additional, unnecessary treatment.

Compere brought a medical malpractice action against Lantrip and St. Dominic. The trial court dismissed the action with prejudice and imposed monetary sanctions because Compere had previously filed the same action and it was pending at the time Compere filed his second complaint. Compere appealed.

The supreme court reversed the trial court's judgment and remanded the case. Compere admitted he failed to wait 60 days before filing his first complaint as statutorily required, and he did not appeal the trial court's dismissal without prejudice of that complaint. However, Compere waited the re-

quired 60 days before refiling the second medical malpractice action and the trial court should have retained the second complaint instead of dismissing it with prejudice and imposing monetary sanctions.

### Negligence

### Expert Testimony

#### Verdict finding hospital negligence was not cause of plaintiff's injuries upheld

**Schreiber v. Univ. of Rochester Med. Ctr.**, No. 07093 (N.Y. App. Oct. 7, 2011)

The New York Supreme Court, Appellate Division, Fourth Department, affirmed a trial court's denial of a motion to set aside a jury verdict finding a medical center's negligence was not the cause of a plaintiff's skin ulceration and related injuries.

Dean Schreiber sued the University of Rochester Medical Center and its agents or employees for medical malpractice, seeking damages for a skin ulceration and resulting leg injuries that he sustained after undergoing right ankle fusion surgery at the medical center. The case was tried, and a jury found the defendants negligent, but it concluded that the negligence was not a cause of Schreiber's injuries.

The trial court denied Schreiber's motion to set aside the verdict as against the weight of the evidence, and Schreiber appealed.

The appellate division concluded that the evidence was sufficient to support a finding that even in the event that the medical center's agents were negligent in placing a cast on Schreiber's ankle, such negligence was not a substantial factor in causing his skin ulceration.

Expert testimony was presented indicating that skin ulcerations can occur even with proper cast placement, and that Schreiber's ulceration resulted from the surgical realignment of his ankle and not from the cast. Accordingly, the trial court's judgment was affirmed.

### Evidence

### Juries

#### Patient is not entitled to new medical malpractice trial based on juror affidavits

**Cummings v. Ortega**, No. 417PA10 (N.C. Oct. 7, 2011)

The North Carolina Supreme Court ruled that evidence contained in juror affidavits was inadmissible to support a patient's motion for a new trial in her medical malpractice case.

Penny Cummings brought a medical malpractice action against Dr. Agnes Ortega and Women's Health Care Specialists P.A. alleging she suffered personal injuries during a diagnostic laparoscopy performed by Ortega. At the time of the surgery, Ortega was the owner of Women's Health Care Specialists.

The trial court entered judgment for the defendants after a jury found they were not liable for Cummings' injuries. Based on affidavits submitted by jurors after the trial alleging juror misconduct, Cummings moved to set aside the verdict and grant a new trial. The trial court granted Cummings' motion. The appeals court affirmed (see 19 HLawWk 552, Sept. 3, 2010), and the defendants appealed.

The supreme court reversed the trial court's judgment and remanded the case. The trial court erred by considering the evidence of alleged juror misconduct in the form of the affidavits because the affidavits were inadmissible pursuant to North Carolina Rules of Evidence 606(b). This rule reflects the common law rule that affidavits of jurors are inadmissible for the purposes of impeaching the verdict except as they pertain to extraneous influences that may have affected the jury's decision. In this case, the affidavits only alleged that a juror announced during the trial and prior to deliberations that he had already made up his mind about the case.

## Medicaid

Administrative Law

Notice

### Disallowance for federal matching funds paid for outpatient hospital services upheld

**Ark. Dep't of Human Servs. v. Sebelius**, No. 10-1251 (D.D.C. Oct. 12, 2011)

The U.S. District Court for the District of Columbia upheld the Centers for Medicare and Medicaid Services' (CMS) disallowance of federal matching funds it had paid to the Arkansas Department of Human Services for outpatient hospital services.

CMS issued a notice of disallowance for \$4,449,682 in federal matching funds it had paid to Arkansas for outpatient hospital services. The Department Appeals Board (DAB) of the U.S. Department of Health and Human Services upheld the disallowance, finding it was consistent with CMS's reasonable interpretation of the regulation governing Medicaid payment limits for those services.

Arkansas brought an action against the Health and Human Services Secretary and the CMS administrator seeking to overturn the DAB's decision on the grounds that it was arbitrary and capricious and not in accordance with law, in violation of the Administrative Procedure Act. Arkansas argued CMS's interpretation of the regulation was inconsistent with the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). Arkansas also maintained that even if CMS's interpretation was permissible, CMS was precluded from applying it to Arkansas' detriment because Arkansas lacked fair notice of this interpretation. Both parties moved for summary judgment.

The district court granted the defendants' motion and denied Arkansas' motion. CMS's interpretation of the regulation was consistent with its reasonable construction of BIPA. Moreover, the disallowance did not rise to the level of the sanctions contemplated by the "fair notice" doctrine.

## Medicare

Ambulance Services

Fraud

### Ambulance service's petition for injunction against continued Medicare audit denied

**Nationwide Ambulance Servs. Inc. v. SafeGuard Servs. L.L.C.**, No. 11-5213 (D.N.J. Oct. 7, 2011)  
*unpublished*

Denying an ambulance service provider's petition for a preliminary injunction to enjoin the continuation of an audit of Medicare claims, the U.S. District Court for the District of New Jersey held that it was without authority to interpret the Medicare statute's requirements for coverage because the ambulance service provider did not exhaust administrative remedies.

Nationwide Ambulance Services Inc. provided non-emergency, scheduled transportation of dialysis patients from their homes to the nearest dialysis center for treatment. Highmark Medicare Services made payments on Medicare claims that Nationwide submitted.

The Centers for Medicare and Medicaid Services (CMS) notified Highmark that a program safeguard contractor (PSC) would be conducting an audit to ensure that all payments made by the Medicare program were appropriate. SafeGuard Services L.L.C. was the PSC for New Jersey. Upon SafeGuard's recommendation, Highmark denied some of Nationwide's claims for want of evidence beyond a physician's certificate of medical necessity (CMN).

Nationwide sued SafeGuard and sought a preliminary injunction restraining SafeGuard from continuing its audit of Nationwide's Medicare claims that were based on the provision of non-emergency ambulance services. The complaint alleged that SafeGuard's interference with the timely processing of Nationwide's Medicare claims unreasonably delayed receipt of payments due.

Nationwide requested a determination that a physician's CMN was sufficient to prove coverage. The district court found that making such a determination would require interpretation of the Medicare statute's requirement for proving "medical necessity." The court, however, lacked the power of judicial review because Nationwide did not exhaust its administrative remedies.

Nationwide contended that the audit was resulting in a loss of business and placing the corporation in a perilous financial situation. The district court ruled that the harm resulting from SafeGuard's alleged interference was not irreparable. A loss of business is compensable with money damages rather than injunctive relief. The public interest factor weighed in favor of SafeGuard. SafeGuard was a government contractor charged with investigating Medicare claims to prevent fraud.

## Mental Health

Involuntary Commitment	Evidence
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### Involuntary commitment of mental patient supported by substantial evidence

**In re Pima County Mental Health No. MH-20110196**, No. 2 CA-MH 2011-0006 (Ariz. Ct. App. Oct. 6, 2011)

The Arizona Court of Appeals affirmed a trial court's order of involuntary commitment in an action brought by a mental patient challenging the order.

After investigating a threatening phone call to the receptionist at the Pima County Board of Supervisors, Pima County sheriff's detective Aaron Cross determined that an individual (the plaintiff) had made the call. Cross filed an application for involuntary mental health examination of the plaintiff. A clinical social worker conducted a mental health screening and subsequently filed a petition for a court-ordered evaluation. The court granted the petition.

Two psychiatrists evaluated the plaintiff and filed a petition for court-ordered treatment. Following a hearing, a trial court found the plaintiff to be a danger to others as a result of a mental condition, and issued an order of involuntary commitment. The plaintiff appealed.

The court of appeal rejected the plaintiff's contention that the evidence that he was a danger to others was not clear and convincing. The record indicated that in addition to his threats toward the receptionist, the plaintiff had called the office of a United States senator to inform the senator and his staff that Korean assassins were attempting to mutilate African-American men.

Moreover, the psychiatrists who evaluated the plaintiff testified that he rambled incoherently, and that his speech was "hypervocal, pressured and very tangential." The plaintiff gave nonsensical answers to questions and described delusional thoughts. Police officers who had investigated the plaintiff testified that on three occasions he told the receptionist that he was going to shoot her with his M-16 rifle.

The court of appeal concluded that, based on this record, the trial court had sufficient basis for finding by clear and convincing evidence that the plaintiff was a danger to others as a result of a mental condition and, as a result, met the standard for involuntary commitment. Accordingly, the trial court's judgment was affirmed.

Involuntary Commitment	Evidence
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### Court orders involuntary commitment of patient suffering from bipolar disorder

**In re A.M.**, No. 82A01-1101-MH-29 (Ind. Ct. App. Oct. 12, 2011)

The Indiana Court of Appeals affirmed a trial court's order of involuntary commitment of a mental patient diagnosed with bipolar disorder.

On Sept. 23, 2010, A.M. was involved in an incident at a restaurant where she was talking to several staff members and patrons, causing a disturbance, and exhibiting behaviors consistent with mania. Police were called, and A.M. was detained on an emergency basis at Deaconess Hospital. After evaluating A.M., psychologist Dr. James Given concluded she suffered from bipolar disorder and was gravely disabled.

On Oct. 1, 2010, a trial court held a hearing on the emergency detention and approved Given's petition for a temporary commitment of A.M. On Dec. 6, 2010, Given filed a report requesting a regular commitment of A.M.; following a hearing, the trial court found that A.M. remained gravely disabled and ordered regular involuntary commitment. A.M. appealed.

The court of appeal concluded that the evidence presented was more than sufficient to support the trial court's commitment order. A.M. has had a history of non-compliance with her medication regimen and had demonstrated no insight into her condition. The evidence also indicated that without her medication, A.M.'s prognosis was very poor and would lead to continued problems and delayed recovery.

Furthermore, A.M. exhibited behaviors which involved interfering in the affairs of others and recommending that they not follow the directions of medical staff. Her treating physician testified that her mood and affect were labile, that her judgment was "poor" and that her insight was "nil."

Treating physicians further testified that unless A.M.'s compliance was monitored, her condition was likely to worsen over time. Accordingly, the court of appeal affirmed the trial court's order of involuntary commitment.

## Negligence

### Pharmacies

### Contracts

#### Denial of pharmacy's motion to dismiss negligence action by former patient reversed

**McKesson Medication Mgmt. L.L.C. v. Slavin**, No. 3D09-2077 (Fla. Dist. Ct. App. Oct. 12, 2011)

The Florida District Court of Appeal reversed a trial court's denial of a pharmacy services provider's motion for summary judgment in an action brought by a former patient who was severely injured by the improper administration of a medication during surgery.

On Oct. 24, 2003, Amanda Slavin underwent exploratory surgery at Mt. Sinai Medical Center to repair a spinal fluid leak that developed following a prior spinal surgery. During the operation, Dr. Mario Nanes instructed a nurse to obtain two ampoules of methylene blue, a drug frequently used as a medical dye but which was contraindicated for intraspinal injections. Nanes injected it into Slavin's spine.

Following the surgery Slavin exhibited the classic signs of neurotoxic poisoning, and ultimately developed a rare form of arachnoiditis, a painful condition which causes widespread damage to the nervous system.

Slavin sued Nanes, Mt. Sinai and McKesson Medical Management L.L.C., the provider of pharmacy services to Mt. Sinai. Slavin's claim against McKesson alleged that it breached a duty of care to her by failing to establish appropriate procedures for the management, stocking and dispensation of the drugs stored in the surgical suite medicine cabinet, by failing to provide written or oral warnings of the contraindications of methylene blue, and by failing to comply with its pharmaceutical services agreement with Mt. Sinai, under which McKesson was required to adequately train hospital staff as to medications retrieved from the surgical medicine cabinet.

A trial court denied McKesson's motion for summary judgment, and McKesson later appealed from a final judgment in Slavin's favor on her negligence claim.

The court of appeal concluded that the applicable contract provision did not obligate McKesson to train Nanes' surgical nurse in the contraindications of methylene blue. The contract in fact expressly stated that the procedures it enumerated were to ensure controls when no on-site pharmacy was available.

The court of appeal concluded that the duty claimed to be owed by McKesson was based on the trial court's misinterpretation of an inapplicable contract provision and, accordingly, the trial court's denial of McKesson motion for summary judgment was reversed, and the case remanded for entry of judgment in McKesson's favor. (For an earlier decision in this case see 18 **HLawWk** 194, Mar. 27, 2009.)

## Patents

### Medical Equipment

### Fraud

#### Suit alleges baby thermometer maker marked packaging with expired patent

**Mikityanskiy v. DMS Holdings Inc.**, No. 11-1243 (S.D.N.Y. Oct. 3, 2011)

The U.S. District Court for the Southern District of New York, granting a motion to dismiss, ruled that the complaint did not adequately allege that a manufacturer marketed a product with an expired patent number with the intent to deceive the public. Allegations of a single instance of updating product packaging following expiration of the patent were insufficient to satisfy the heightened pleading standard applicable to false marking claims.

DMS Holdings Inc., d/b/a Mabis Healthcare, and Duro-Med Industries Inc. (collectively DMS) manufactured and sold the "Tender Tykes Digital Pacifier Thermometer." The patent for the thermometer expired on May 7, 2003, due to non-payment of maintenance fees.

Leonid Mikityanskiy purchased a Tender Tykes Digital Pacifier Thermometer on Feb. 19, 2011. He sued DMS asserting a false patent marking claim under 35 U.S.C. § 292. The complaint alleged that DMS distributed and sold the thermometer in packaging with the expired patent. DMS moved to dismiss for failure to state a claim.

A complaint alleging violation of § 292 must provide some objective indication from which to reasonably infer that the defendant was aware that its patent had expired. Mikityanskiy alleged that DMS was aware that its patent had expired at the time they revised the thermometer packaging in 2008.

The district court found that the single allegation of package revision with an expired marking did not support an inference of deceptive intent on the part of DMS. In oral argument opposing the motion to dismiss, Mikityanskiy contended that the thermometer packaging underwent multiple revisions because new packaging was designed in 2004 as well.

The district court concluded that even if it considered the alleged 2004 revision, there was still no showing of an intent to deceive. Generally, additional evidence in combination with multiple revisions is required to avoid dismissal. The complaint contained no allegations about whether DMS had been involved in lawsuits over the patent, for example, or which company employees knew that the thermometer's patent had expired.

## Physician Licensing

### Suspension

#### Medical board erred in failing to identify standard of care in disciplinary proceeding

**Rich v. Tenn. Bd. of Med. Exam'rs**, No. M2009-00813 (Tenn. Oct. 10, 2011)

The Tennessee Supreme Court remanded to a state medical board an order suspending the license of a physician based on disciplinary charges with instructions to conduct renewed deliberations based on the applicable standard of care.

In June 2005, the Tennessee Department of Health, Division of Health Related Boards filed charges against Dr. Joseph Rich alleging that Rich instructed his 18-year-old receptionist to fill out pre-signed prescriptions of Phentermine and Fenfluramine for patients while he was on vacation.

The Division also alleged that Rich provided grossly inadequate treatment to a patient by failing to document prescription of anti-hyperglycemic or anti-hypertensive medications and by failing to document the performance of an EKG on the patient, who was receiving chelation therapy from Rich, and that Rich without a license to provide detoxification treatment using methadone treated numerous patients in his clinic's "detoxification program with multiple prescriptions for methadone.

The Board suspended Rich's license for one year and imposed additional sanctions. Rich sought judicial review, and a trial court affirmed the Board's determination. Rich appealed, and the court of appeals reversed after concluding that the Board was required but failed to articulate the applicable standard of care. (see 19 **HLawWk** 618, Oct. 10, 2010) The supreme court granted certiorari.

The supreme court concluded that the Board erred in failing to articulate the applicable standard of care. An applicable statute unambiguously required the Board to "articulate what the standard of care is in its deliberations."

The supreme court held, however, that the Board's error did not warrant reversal of its ruling. The case did not involve an error or deficiency in the administrative hearing or the facts, but rather an error of law and a deficiency in the record. Under applicable precedent, a reviewing court may remand a case to an administrative agency where the agency committed an error of law or the record presented to the court is inadequate, for the purpose of allowing the agency to correct noted deficiencies based on the existing administrative record.

Accordingly, the case was remanded to the Board with instructions to conduct deliberations based on the existing record and articulate the applicable standard of care in its deliberations.

### Administrative Law

## Products Liability

### Drugs

#### Patient is not entitled to file second amended complaint against drug manufacturers

**Mills v. Bristol-Myers Squibb Co.**, No. 11-0968 (D. Ariz. Oct. 7, 2011)

The U.S. District Court for the District of Arizona ruled that a patient is not entitled to leave to amend her complaint against drug manufacturers since amendment would be futile.

Beatrice Mills was prescribed Clopidogrel (branded as Plavix) for the treatment of peripheral vascular disease. Each day, Mills ingested one tablet of Plavix along with aspirin pursuant to her physician's instructions.

Subsequently, Mills began bleeding extensively from her rectum. She was taken by ambulance to Mercy Gilbert Medical Center. Her bleeding continued, and she underwent surgery to stop the bleeding. Afterwards, she was discharged, but five days later she returned to the hospital due to respiratory distress. Mills was treated for bilateral pulmonary embolism and thrombocytopenia, and was released.

Mills brought an action against Bristol-Myers Squibb Co., Sanofi-Aventis U.S. L.L.C., Sanofi-Aventis U.S. Inc. and Sanofi-Synthelabo Inc. and filed a first amended complaint. The district court granted the defendants' motion to dismiss the action without prejudice.

Mills then moved to file a second amended complaint (the SAC). The SAC asserted: strict products liability, negligence, negligent misrepresentation, breach of express warranty and breach of implied warranty.

Mills alleged that the chemical structure of Plavix is defective because it carries a higher risk of adverse events for patients who carry the genetic variant CYP, who are poor metabolizers of the drug. However, Mills failed to show Plavix was unreasonably dangerous because she failed to show that reasonable healthcare providers would not prescribe it for any class of patient.

The district court denied Mills' motion to for leave to amend. Mills' allegations in the SAC would not withstand a Rule 12(b)(6) motion to dismiss. Thus, amendment would be futile.

### Negligence

## Statute of Limitations

### Negligence

### Birth-Related Injuries

#### Mother's suit seeking damages resulting from child's premature birth dismissed

**Ramos v. Bronx-Lebanon Hosp. Ctr.**, No. 11-2265 (S.D.N.Y. Oct. 4, 2011)

The U.S. District Court for the Southern District of New York dismissed an action as time-barred, finding in part that the claim accrued when the claimant knew the critical facts about her child's injuries and their cause, not when a lawyer confirmed that the claimant had a legal claim.

Aida Diaz received prenatal care at Bronx Lebanon Hospital, a federal entity. During a visit on June 3, 2005, Diaz told a nurse that she was experiencing abdominal pain and pressure. The nurse informed Diaz that her symptoms were normal.

The next day Diaz gave birth to her son, Ralph Ramos, more than two months early. Ramos suffered from several health problems, including cerebral palsy. In December 2006 or January 2007, Diaz spoke to a friend about retaining a lawyer to pursue claims related to Ramos' condition. On May 4, 2009, Diaz sued the United States.

The United States moved to dismiss arguing that a two-year statute of limitations barred the action. The district court granted the motion. Diaz's claim accrued, at the latest, in December 2006 or January 2007 when she considered suing Bronx-Lebanon. By that time, Diaz was aware of the cause of Ramos' injuries and the entity responsible for them.

Even if equitable tolling were permitted under the Federal Tort Claims Act, Diaz did not identify any extraordinary circumstance that supported tolling of the limitations period. She failed to show a causal connection between her misunderstanding about Bronx-Lebanon's federal status and the late filing of her complaint.

## Wrongful Death

### Statute of Limitations

### Malpractice

#### Wrongful death claim added to malpractice action following death of plaintiff

**Sisson v. Lowe**, No. 10809 (Mass. App. Ct. Oct. 6, 2011)

The Massachusetts Appeals Court vacated a trial court's dismissal of a wrongful death claim added to a malpractice action following the death of the former patient on whose behalf the action was filed.

Dawn Sisson and her husband Richard Sisson Jr. sued Dr. David Lowe, alleging that Lowe provided substandard medical care to Dawn Sisson in 1999, resulting in in-

juries including expected premature death from metastatic osteosarcoma.

On Mar. 29, 2007, while the malpractice action was still pending, Dawn died. Richard then amended the complaint to add a claim for wrongful death. The trial court dismissed the wrongful death claim as barred under the applicable statute of limitations, and Richard appealed.

The court of appeal noted that it had not previously addressed the question of whether a plaintiff may, after the period of time set forth in the statute of repose had expired, amend a complaint alleging malpractice to add a claim for wrongful death where the underlying complaint alleged an injury including expected premature death.

The court concluded that, considering the state legislature's goal in enacting the applicable statute of repose of eliminating costly and stale claims, the legislature could not have intended to treat a claim of expected premature death as separate from a claim of wrongful death where both were based on the same set of facts alleging medical malpractice.

As a result, the court of appeal concluded that a wrongful death claim may be substituted for a personal injury claim only where trial has not commenced, the original complaint alleging malpractice was filed within the statutes of limitation and repose, and the allegations of liability supporting the personal injury claim were the same as those supporting the wrongful death claim.

Accordingly, the trial court's judgment was vacated and the case was remanded for further consistent proceedings.

## In The Law Journals

### Examining consent and contracts in embryo disposition after divorce

Deborah L. Forman, *Embryo Disposition and Divorce: Why Clinic Consent Forms Are Not the Answer*, 24 J. Am. Acad. Matrim. Law 57 (2011)

Families and children play a huge role in American society, but the high rates of divorce have influenced how families have developed in the United States in the last few decades. While many couples are able to have children, some couples have to use advanced medical techniques to conceive a child. In some cases, divorce complicates the conception practices of couples, especially with regard to embryos that have been frozen for future development. According to Deborah L. Forman, clinic consent forms do not provide sufficient consideration regarding potential changes in relationships in order to be enforced as contracts.

A number of cases have considered the disposition of embryos in light of divorce. In one case, the Tennessee Supreme Court decided in favor of the ex-husband's right not to procreate over the ex-wife's right to procreate with respect to embryos that had been cryopreserved prior to the

couple's divorce. However, in that case, there was no prior agreement between the parties with respect to the disposition of the embryos. The court stated that, had there been an agreement in place, there would be no need to weigh the factors related to one party's right to procreate and another party's right not to procreate.

Cases that have followed the Tennessee Supreme Court's decision have focused on whether there was a consent form signed by the couple at the fertilization clinic. In a case in New York, the court found that a provision which stated the embryos should be donated for research if the couple disagreed on the use of the embryos. In Oregon, a court held that a provision that gave the wife the discretion if the couple disagreed was controlling. In Texas, the court enforced a provision that called for discarding the embryos if the couple disagreed.

While the prevailing approach is for the court to honor the intentions expressed in the consent form, other courts have allowed the couple to change their minds, even when there is a consent form in place. This line of cases involves disputes between the couple and the fertilization clinic and not between the husband and wife. This approach has been described as the "contemporaneous consent" approach. However, the consent between the husband and wife must be mutual.

Consent forms couples sign at fertilization clinics may be a good starting point for the courts, but the courts must consider a wider range of facts and circumstances. Most courts have adopted the contract approach, where the provisions of the consent form at the fertilization clinic are controlling.

However, this approach has a fair number of downsides, too. For instance, the consent form process is slightly flawed because the parties might not have given the disposition of the embryos much thought before being confronted with the lengthy and dense consent forms. In addition, the number of variables that could occur and change the parties' wishes between the time when the eggs are fertilized and the time when the embryos are needed is almost infinite. The couple might not have the necessary time to review the forms, and the parties almost never get legal advice to review the documents, which may have been ineffectively and confusingly drafted without legal advice.

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