

Massachusetts

Medical Law Report

Legal news for the medical community

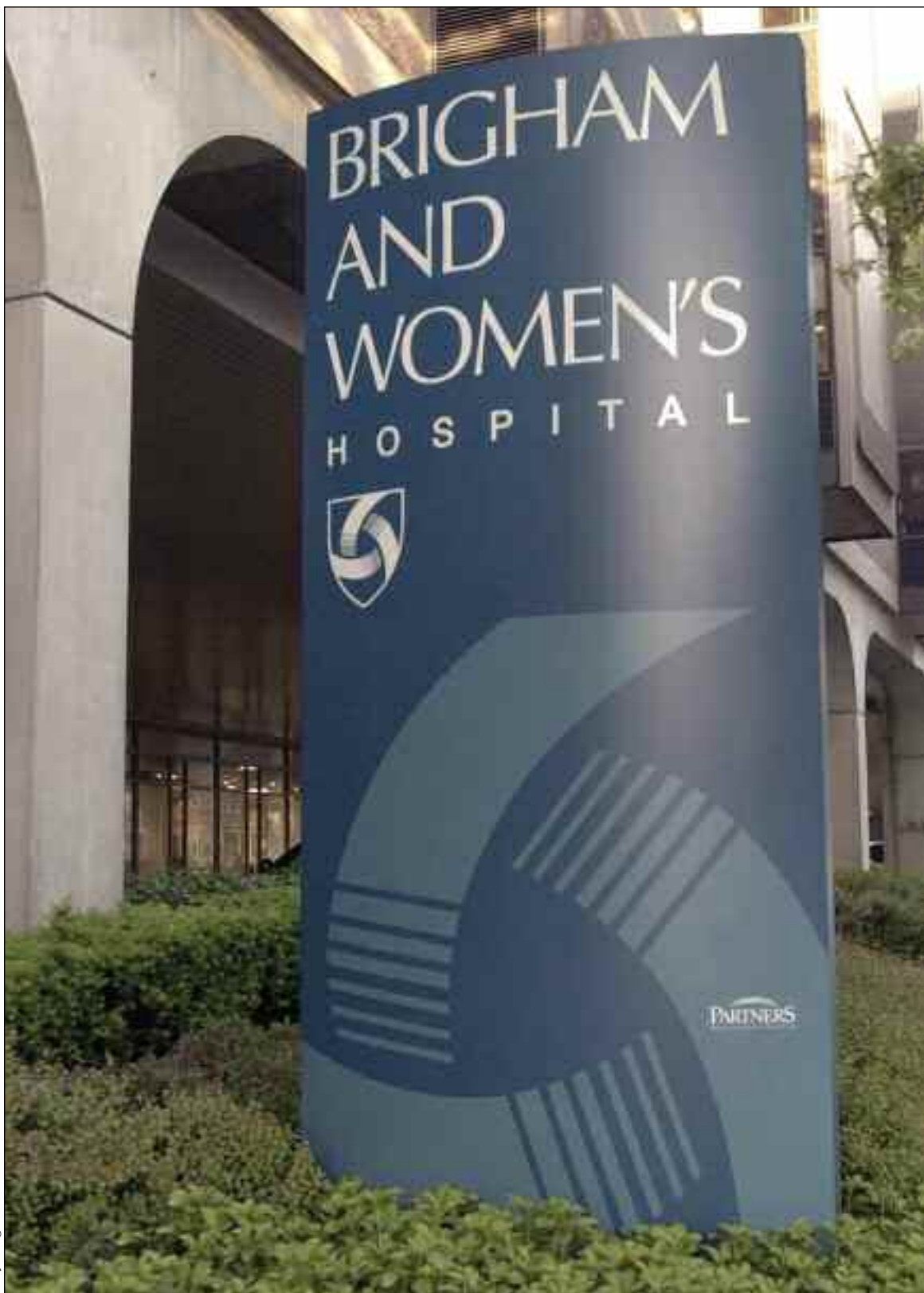
A Quarterly Publication of **JM DOLAN MEDIA COMPANY**

Pre-Sorted Standard
U.S. Postage Paid
Boston, MA
Permit No. 55916

Address service requested
Lawyers Weekly
10 Milk Street, 10th Floor
Boston, MA 02108

Vol. 4, No. 3 Spring 2009
\$10.00 per copy
www.mamedicalaw.com

CME
Home Study
see page 13



Getty Images/Darren McCollister

Surgeon wins \$1.6 million sex bias verdict

By Nora Lockwood Toohar

A federal jury has found that a prominent neurosurgeon and Brigham and Women's Hospital subjected a female surgeon to a hostile work environment and then retaliated against her when she complained.

On Feb. 24 jurors awarded \$1.6 million in damages to Dr. Sagun Tuli, 39, who had complained for several years about discriminatory treatment by Dr. Arthur Day, 61, chairman of Brigham and Women's Hospital's neurosurgery department.

Margaret M. Pinkham, a partner at Brown Rudnick in Boston who represented Tuli, credited her client with pursuing the case through a six-week trial.

"It would have been a lot easier for Dr. Tuli to let this go," she said. "It takes a special person to stand up and take it all the way through a long, grueling trial."

Both surgeons are still working at Brigham and Women's; their testimony presented starkly differing views of the inner workings of the hospital's male-dominated neurosurgery department.

"Medicine is still generally an old boys' network, and particularly surgeons and neurosurgeons," Pinkham said. "Every witness agreed it's a male-dominated field."

The trial also offered a rare glimpse into the hospital's confi-

dential peer review process. Tuli claimed that during the process she was slandered by Day and then retaliated against by the hospital.

Pinkham said she was able to unearth many of the notes relating to the peer review process because the case was filed in federal court. Under state law, such material is confidential.

Tuli and other witnesses said that Day trivialized female doctors, frequently referring to them as "girls."

He also allegedly questioned Tuli's surgical judgment, asking, "What's the matter, are you afraid you can't handle it because you're a girl?"

At a hospital dinner, Tuli claimed, Day asked: "Sagun, can you get up on the table and dance for us to show the female residents how to behave?"

And in his October 2007 evaluation – laden with gender stereotypes and negative generalizations – Day skewered Tuli, claiming she suffered from "mood swings," "volatile" behavior and an inability to work with staff, according to Tuli and Janet Barnes, the hospital's risk manager.

Although a human resources investigation corroborated many of Tuli's allegations about Day, the hospital failed to take any action. Instead, Tuli was ordered to un-

Continued on page 10

Health employers grapple with new disability law

By Sylvia Hsieh

Health care providers need to get up to speed on big new changes that significantly broaden the definition of disability and the number of employees who will be covered under the Americans with Disabilities Act, employment lawyers say.

The new law, known as the Americans with Disabilities Act Amendments Act (ADAAA), took effect on Jan. 1. It applies to employers with 15 or more workers.

The original law generally prohibits disability-based discrimination in the workplace and in public accommodations, and requires a reasonable accommodation for dis-

Continued on page 15

Doctors must pay attention to drug company gift ban

By Eric Berkman

Now that the state Public Health Council has approved of the most extensive and restrictive ban in the country on pharmaceutical companies giving gifts to doctors, physicians cannot rest easy.

While the regulations govern only the activity of drug and device companies, not doctors themselves, any prescriber who receives an improper benefit from a drug or device company still risks serious reputational damage – and possibly professional discipline or even prosecution under state anti-kick-back laws, health law experts say.

"Though [the regulations] won't cre-

ate liability for doctors, they can still suffer a collateral adverse impact," says William M. Mandell, an attorney at Pierce & Mandell in Boston and co-author of the 2008 book, *Managing Relationships with Industry: A Physician's Compliance Manual*. "Not to mention that being party to a relationship with a company called into question could cause harm to their reputation, which is the most important thing doctors have."

Under the regs – which go into effect on July 1 – doctors in Massachusetts will no longer be able to enjoy Red Sox tickets, dinners at Locke-Ober or even

Continued on page 15



Social media hits health care

There's no denying it: Social networking is here to stay.

Professionals across many industries are blogging, connecting on LinkedIn, gathering information on Facebook and Twittering as a marketing tool.

So what about physicians?

There are, of course, several highly trafficked blogs written by physicians. And Sermo, the online community for physicians to discuss insights about caring for their patients, is gaining popularity. In this paper, we have also covered the legal implications of

physicians using e-mail with their patients.

Social media is undoubtedly impacting health care.

San Francisco business writer Carleen Hawn makes this point persuasively in the March 2009 issue of *Health Affairs*, with a piece entitled,

"Take Two Aspirin And Tweet Me In The Morning: How Twitter, Facebook, And Other Social Media Are Reshaping Health Care."

Writes Hawn: "Facebook-like physician profiles and secure e-mail messaging are increasingly the norm." Patients are blogging about their care, and physicians are giving treatment advice by online video and instant-messaging.

Ted Eytan, a family physician in Washington, D.C. who's quoted in the article, commented on his blog about how quickly social media is transforming health care: "Who would have thought four years ago that an article about social networking/media would be front cover material for the Health Affairs issue on Health Information Technology?"

But this change in health care isn't without legal risk.

For one thing, there are HIPAA privacy and security issues that arise as patients' medical information is discussed online. And

when physicians start to advise patients through social media, is that enough to replace an old-fashioned, in-person visit?

Also, as the article points out, there are no regulatory standards yet for this type of care, and no universal protocols for reimbursement.

In Hawn's article, Eytan contends that social media is a clear route to improve patient care, largely by empowering patients and centering care around their personal needs.

So have you embraced social media? Are you using these tools to connect with colleagues or to interact with your patients?

And when patients interact with their physicians in this way, what's the impact?

I would love to hear about your experiences. If you have interesting stories you'd like to share with me – and perhaps other readers too – please e-mail me at reni.gertner@mamedicallaw.com.

Reni Gertner, MPH

Editor's Note



Table of contents

3 Third party liability: Supreme Judicial Court preview
State's highest court weighs doctors' liability for third-party injuries

4 Listening In
The news beat of the medical profession

5 Patient safety
U.S. creates new program for reporting, analyzing adverse medical outcomes

6 Verdicts & Settlements

8 Good Medicine
Q&A: Improving the reporting systems for suspected domestic violence

9 Doctor's Rx
The public health problem of domestic violence

12 Bills, Rules & Regs

13 CME Home Study

Topic: 'Minute Clinics' raise round-the-clock risks

Letters to the Editor

Dear Editor,

Regarding the recent report, "All eyes on BI," Massachusetts Medical Law Report, Winter 2009, the most pertinent question is not "What Hospitals Can Do" to prevent their workers from having a voice, but instead, how hospitals can work cooperatively with their employees on the front lines to improve the quality of care.

EyeOnBI.org was created by people who believe in Beth Israel Deaconess Medical Center's mission of service to community, treating patients compassionately and fostering a work environment based on mutual respect and collaboration.

Unfortunately, there is mounting evidence that BIDMC's current administration is running the institution as a business above all else – losing sight of its original ideals and raising questions as to whether the hospital is failing to put first the needs of patients, workers and Greater Boston communities.

EyeOnBI.org is a compendium of dozens of independent media investigations, lawsuits and governmental reports, giving visitors the full picture of the growing problems at BIDMC.

From the drastic overbilling of Medicare to the failure to provide many BIDMC employees and their dependents with affordable health care coverage, Beth Israel Deaconess finds itself with an administration operating outside the principles the medical center was founded upon.

It is productive and necessary to address Beth Israel's ongoing problems so that we can work together towards enduring solutions.

One of these solutions must be to ensure that hospital workers have a free and fair election process to form unions if they so choose, and to ensure that resources are not wasted on fear and intimidation campaigns coordinated by hospital executives that violate workers' rights and take the focus away from patient care.

When hospital workers join together as a union, they have the ability to advocate for improved jobs and patient care, to blow the whistle when necessary, to defend fair hospital funding, to pass legislation that protects patients and workers, to stand up for their families and to ensure that the health care needs of our Greater Boston communities are being met.

Both the former Beth Israel and Deaconess hospitals have proud histories – of

fering generations of families both employment and quality care – and it is our hope that by revealing ongoing systemic problems at BIDMC we will return this institution to its founding principles.

Mike Fadel
Vice President

1199SEIU United Healthcare Workers East

Dear Editor:

I was interested to read "Stopping disruptive physician behavior" in the Autumn 2008 issue of Massachusetts Medical Law Report.

I realize you are reporting the information and not making the rules, but a few points came to mind.

While "punishment" is often inappropriate, there are times when punishment is a necessary consequence. As a case in point, when a high-profit physician is maliciously abusive toward a patient, and "appropriate leadership staff" looks the other way, that doctor's malicious behavior is reinforced. Such lax regard for the basic tenet "do no harm" does little to protect future patients or help patients who have already been wronged.

Often those most familiar with disruptive physician behavior are least able to effectively voice objections. Support staff who report reckless care by physicians do so at their own professional peril. Likewise, patients who report problematic physicians to hospital "patient relations" departments may be dismissed as cantankerous litigants-in-the-making. (I am guessing such departments are accustomed to deflecting complaints about repeat offenders.)

Some doctors' egos are so inflated and their interpersonal skills so inadequate that one must question whether they should be working with patients; they are loose cannons. An ordinary person who intentionally harms someone due to stress is held accountable for his or her actions. I do not see why malicious physicians should be held to a different standard because they may generate high gross revenue.

I do not favor punishing a physician who has acted professionally and in good faith. The most diligent efforts cannot totally eliminate bad outcomes and human error, and I

Massachusetts Medical Law Report

Publisher
David L. Yas, Esq.

Editor
Reni Gertner, MPH

Contributing Writer
Matt Yas

Art Director
Amanda Adams

Advertising Director
Charlene J. Smith

Circulation Marketing Director
JoAnn Griffin

Senior Account Executives
Esther Berkowitz
Mark Schultz
Edie Stringfellow
Catherine Howe

Classified Account Executives
Joan McGonagle
Megan Hamner
Sophie Besl
Michelle Cerulli

Ad Traffic Manager/Reprints
Lon Varangkounh

Advertising Intern
Caitlin Ball

Dolan Media Company

Chairman, President/CEO
James P. Dolan

Executive Vice President/CFO
Scott J. Pollei

Vice President/Newspapers
Mark W.C. Stodder

Massachusetts Medical Law Report
www.mamedicallaw.com

For editorial inquiries, e-mail reni.gertner@mamedicallaw.com or call 800-444-5297, Ext. 12142.

For advertising, e-mail charlene.smith@lawyersweekly.com or call 800-444-5297, Ext. 12211.

Massachusetts Medical Law Report is published quarterly by Massachusetts Lawyers Weekly, a subsidiary of Dolan Media Company. Publication Price is \$10.00 per copy, plus shipping and handling, or \$39.95 per year. **POSTMASTER:** Send address changes to **Massachusetts Medical Law Report**, 10 Milk Street, 10th Floor, Boston, MA 02108. Copyright 2009 Dolan Media Company. Material published in Massachusetts Medical Law Report is compiled at substantial expense and is for the sole and exclusive use of purchasers and subscribers. The material may not be republished, resold, recorded, or used in any manner, in whole or in part, without the publisher's explicit consent. Any infringement will be subject to legal redress.

strongly support "Sorry Works!" Unfortunately, those physicians most in need of appreciating the healing properties of apology seem most likely disdain them in favor of childish "duck and cover" defenses. Contrary to any ill-conceived stereotype of the obnoxious-but-brilliant physician, being a jerk does not make one a medical genius; in the real world, it squanders resources and lives, in addition to eroding public trust.

As a provider and a patient, I am outraged. Why do the powers that be pussyfoot around the issue of punitive measures? The literature shows that the same small group of Teflon-coated physicians is responsible for the majority of disruptive behavior. What are the actual costs and benefits of maintaining supportive (i.e., preferential) environments for disruptive physicians, and who really wins?

Punishment and "rehabilitation" (the current buzzword) need not be mutually exclusive.

Nevertheless, bully physicians should not be sustainable because they are profitable to hospitals. Some of those offending physicians are just plain offensive.

Sarah B. Dougherty
Lexington, MA

State's highest court weighs doctors' liability for third-party injuries

By David E. Frank

The Massachusetts Supreme Judicial Court has heard arguments in a medical-malpractice case that could significantly expand the duty health care providers owe to third parties.

In *Leavitt v. Brockton Hospital Inc.* (SJC No. 10296), the court will decide if a hospital and two nurses owed a duty of care to a Whitman police officer injured while responding to an accident involving a discharged patient. The patient allegedly was allowed to walk home unaccompanied after undergoing a medical procedure.

"The question [is] whether the defendants should be held to have reasonably foreseen that a police officer, responding to a scene involving a patient who had left the hospital, would be injured in an accident between his cruiser and a second vehicle that had no affiliation whatsoever with the defendant or with the patient," wrote the hospital's lawyer, Daniel J. Buoniconti of Foster & Eldridge in Cambridge.

Jeffrey S. Beeler, a lawyer at Heinlein & Beeler in Natick who represented the police officer, countered in his brief that the hospital's negligent decision to allow the patient to leave without a guardian caused his client's injuries.

'Unprecedented' expansion

The case came to the SJC after Superior Court Judge Frank M. Gaziano dismissed it.

Several lawyers say this case marks the first time an appellate court has been asked to weigh in on the SJC's controversial 2007 *Coombes v. Florio* decision.

In *Coombes*, a divided court held that a physician could owe a duty to a non-patient who was foreseeably harmed by the failure to warn a patient about the risks of driving while taking medication.

"Of the jurisdictions that have looked at third-party liability, none has ever determined that an event as remote [as the one in the officer's case] should be covered," said John J. Barter of Boston. "If a court were to take the step of finding liability under these circumstances, it would not only be unprecedented, but it would likely cause drastic increases in the cost of medical care, medical-malpractice insurance and general liability insurance for health-care institutions."

Barter, who submitted a friend-of-the-court brief on behalf of the Professional Liability Foundation in the *Leavitt* case, said a ruling against the hospital would also change the way plaintiffs assess possible causes of actions.

"It would be fair to assume that every time someone was injured, no matter what the context, whether an industrial accident or car accident or any other sort of situation where there was an injury, the first thing they would do is go back through the medical history of every person who had any contact with the accident and try to find a doctor or hospital to try to hold them accountable," he said.

Fatal colonoscopy

On Nov. 1, 2004, an elderly patient, Augusto DaSilva, was allegedly discharged from Brockton Hospital and allowed to walk home alone after undergoing a colonoscopy.

During the procedure, the patient had received several sedatives and anesthetics, which are known to cause fatigue, weakness, problems with coordination and the inability to think clearly.

Shortly after his release, the patient was struck and killed by a passing car. In response, a police officer, Dean Leavitt, was dispatched to the scene.

En route, a car driven by an individual with no connection to the accident failed to yield and hit the officer, causing him to suffer permanent injuries.

The officer claimed in a 2007 suit filed against the hospital and two nurses that, by releasing the patient without an escort, they violated hospital policy and accepted practices.

In May, the judge dismissed the case, say-

ing that that the officer "is unable to point to any case law supporting the imposition of a duty of care against a medical professional for injuries suffered by a third party in an accident which did not directly involve a patient."

Unacceptable risk?

Rejecting defense claims that a ruling in his client's favor would unfairly prejudice health care providers, Beeler said in a statement that it is not unusual for litigants to make such arguments before the court.

"The defendants are suggesting there are many occasions where medical professionals deviate from good and accepted practices in their industry, hospital policies and physician's orders," he wrote. "We all know that this is not the case and that the courts are well equipped to cull the meritorious cases from those that are lacking. In any event,

such baseless assertions of vague systematic harm should not be viewed as sufficient grounds for denying an injured person access to justice."

By releasing the patient without an escort while still under the influence of medication,

"Of the jurisdictions that have looked at third-party liability, none has ever determined that an event as remote [as the one in this case] should be covered."


— John J. Barter

Beeler argued in his brief, the defendants knew they were creating an unacceptable risk of harm.

"[T]his case is somewhat similar to a licensed commercial establishment that knowingly overserves an intoxicated customer and then discharges them onto the roadway where they cause plainly foreseeable carnage," he wrote. "Indeed, this case presents a stronger liability profile than the typical commercial vendor of alcohol case in that the substances intentionally administered to [the patient] were known and intended to have a debilitating effect."

Beeler said the lower court judge also made an error by refusing to recognize the existence of a special relationship between doctor and patient. With the effects of the patient's drugs well known, Beeler said the hospital had an obligation to use due care to

Continued on page 11



Pierce & Mandell, P.C.

Legal Services for Physicians, Hospitals, and Health Care Organizations

*We are committed to providing
large firm quality service and expertise
in a cost effective manner.*

- Stark/Anti-Kickback Compliance
- Joint Ventures
- Practice Buy-Ins/Buy-Outs
- Physician Employment and Partnership Agreements
- Physician Recruitment
- Facility and Practice Sales and Acquisitions
- Medical Staff Bylaws & Policies
- Licensure/DoN
- Health Information/HIPAA Compliance
- Peer Review and Reporting Requirements
- Patient Consent Issues and Court Intervention
- Alternative Dispute Resolution/Litigation
- Non-Profit Organization/Governance
- Managed Care & Reimbursement

For further information please contact:

OUR HEALTH CARE ATTORNEYS


William M. Mandell
Email: bill@piercemandell.com

Dean P. Nicastro
Email: dean@piercemandell.com

Emily B. Kretchmer
Email: emily@piercemandell.com

Pierce & Mandell, P.C.
11 Beacon Street, Suite 800
Boston, MA 02108
T. (617) 720-2444 • F. (617) 720-3693
Offices in Boston, Chatham and Sudbury

www.piercemandell.com





Listening In

The news beat
of the medical profession

First-ever insurance penalty data released

Most Massachusetts residents penalized in 2007 for not having health insurance paid the \$219 they owed and many of the appeals protesting the penalty were approved, according to the State House News Service.

State Connector Authority officials said that 1,780 appeals were

approved and 450 were denied, with 200 appeals being dismissed for failure to provide documents or failing to show up for hearings, which were mostly conducted via telephone. Thirty appeals remain underway.

The state collected \$16 million last year from 60,000 individuals

who paid the health insurance penalties, which were deposited into a trust fund to offset the cost of providing coverage across the state, according to the state Department of Revenue.

The penalty is expected to rise to \$1,068 in 2009, the State House News Service reported.

Drug giant will face Mass. suit

A U.S. District Court judge has ruled that the country's biggest maker of generic drugs must face a lawsuit brought by Massachusetts over prices the company charged the state's Medicaid program for anxiety medications, according to Bloomberg.

Judge Patti Saris ruled that the state's suit, which claims Pennsylvania-based Mylan Inc. fraudulently inflated prices for generic prescription drugs, isn't barred by the company's 2002 antitrust settlement with Massachusetts and other states.

Mylan and three other

drugmakers agreed to pay \$100 million to settle a suit by the Federal Trade Commission and 33 states over allegations they conspired to deny competitors key ingredients for lorazepam, the generic version of Ativan, and clonazepam, the generic for Tranxene. That agreement won final approval in 2002, Bloomberg reported.

Lawyers for Mylan claimed the settlement barred Massachusetts from bringing suit over the prices the company charged the state for those drugs, as well as phenytoin sodium, used to treat seizures.



istockphoto.com

Vaccine rulings may drive plaintiffs to sue manufacturers

Now that special masters in a federal vaccine court have rejected three test cases alleging that childhood vaccinations cause autism, plaintiffs are weighing whether to appeal or to sue the vaccine manufacturers in civil court.

"Although disappointing, we know this is just one step in a long, uphill battle," said Kevin Conway of Conway, Homer & Chin-Caplan in Boston, who represented one of the plaintiffs.

The three cases addressed whether a combination of mercury and the MMR vaccine – or the MMR vaccine alone – contribute to autism by weakening the immune system.

"The science on the issue is close, even though they made it sound like it

was not close at all. This was like losing by one point at the end of double overtime," said Curtis Webb of Webb, Webb & Guerry, another of the plaintiffs' attorneys.

The rulings – issued by the U.S. Court of Federal Claims, which has exclusive jurisdiction to hear vaccine claims – are not binding on any of the other nearly 5,000 autistic children seeking compensation under the National Vaccine Compensation Program, Conway noted.

An appeal of the special masters' rulings would be heard by a single judge of the same court.

Another option is to go outside of the program and sue the vaccine makers in civil court.

– Sylvia Hsieh



istockphoto.com

Gift ban compels group to cancel Hub convention

A major medical group has canceled a multimillion-dollar convention in Boston, citing a recently implemented state law that cracks down on free gifts, meals and other items given to doctors by the pharmaceutical industry.

Meanwhile, other life-sciences groups are sending strong signals that they also won't hold conventions in Boston, claiming that the law is unclear and out of sync with

industry gift-giving standards.

In a letter to the Massachusetts Convention Center Authority, the executive director of the American Academy of Allergy, Asthma & Immunology said it was pulling out of its 2015 con-

vention contract in Boston because it's "very difficult" to find sponsorships and to provide continuing medical education courses under the new Massachusetts regulations.

The group's move will likely cost Boston businesses millions of dollars, as the group moves its 8,000-attendee convention and cancels thousands of local hotel bookings.

For more information on what physicians need to know about the gift ban regulations, see page 1.



istockphoto.com

PIAM, Cardinal launch purchasing program for supplies

PIAM, a subsidiary of the Massachusetts Medical Society, has partnered with Cardinal Health to offer physician members direct-purchasing access to medical/surgical supplies; resources to analyze and improve practice profitability; and guidance on setup, design and cost-savings for new of-

fices. Members will be able to order supplies from manufacturers such as Quidel, Midmark, Welch Allyn, Siemens, Inverness, Roche and others.

Available merchandise includes capital equipment, diagnostic tests, bandages and sutures, pharmaceuticals and lab products.

In addition, PIAM has arranged for Cardinal Health to provide members with promotions and discounts on a monthly basis.

The program is available through PIAM at (800) 522-7426 or through Leo Proppe Jr. at Cardinal Health at (800) 456-1894, ext. 7716.





GREENWAY

What is Your Experience?®

Greenway Medical Technologies is a fully integrated electronic health record (EHR), practice management and interoperability solution provider.

martinomalley@greenwaymedical.com
www.greenwaymedical.com

Tufts Medical Center makes deal with Blue Cross

Blue Cross Blue Shield has reached an agreement on a new contract with Tufts Medical Center, where physicians had threatened to stop accepting members of the state's largest insurer.

Doctors at the Boston hospital previously had said they would no longer accept some Blue Cross members after Jan. 31 because the insurer refused to pay them at "a reasonable rate."

The two sides said Tufts and its affiliated physicians had agreed to join Blue Cross's "Alternative Quality Contract," which is designed to improve care and moderate costs.

They said the new deal means there will be no disruption of service at Tufts for Blue Cross members.

The agreement was reached after nearly a year of negotiations.

Visit our website
www.mamedicallaw.com

U.S. creates new program for reporting, analyzing adverse medical outcomes

By Dean P. Nicastro, Esq.

The U.S. has created a new system whereby physicians and health care provider entities can confidentially report adverse medical events, and organizations can collect this data and use it to make safety recommendations.

The new program encourages health care providers to voluntarily report patient safety events to entities called "Patient Safety Organizations," or PSOs.

PSOs must be listed with the federal Secretary of Health and Human Services and must have the improvement of patient safety as their mission and primary activity. They can receive reports and aggregate and analyze the information in order to provide patient safety guidance and recommendations back to the providers.

PSOs may be public or private, and they may be component organizations of a sponsoring entity, such as a hospital system or a professional society.

Health insurers, though, can't be PSOs and can't have a PSO as a component entity.

The government's goal is to "develop a national system for analyzing and learning from patient safety events," and the long-term plan calls for a network of patient safety databases.

Confidentiality

The program creates federal confidentiality protections for information that is reported to a PSO, and for the data that is developed by a PSO for various patient safety initiatives, including any root cause analyses.

This information may not be requested by a party in litigation and may not be used at trial, nor can it be admitted in professional disciplinary proceedings before a state licensing board, with certain exceptions.

There are civil monetary penalties for anyone who improperly discloses the information.

Health care providers are not allowed to retaliate against an employee who makes a good faith report, and an accrediting body is not allowed to punish a provider for its good faith participation in the program.

The program is outlined in regulations, effective this past January, that implement the Patient Safety and Quality Improvement Act, which was enacted by Congress in 2005.

The regulations say that the new program "will enable all health care providers, including multi-facility health care systems, to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers."

Not a peer review privilege

The program is not the same as a federal peer review privilege.

Since 1986, medical peer review activities in Massachusetts have had robust protection under state laws that, with a few exceptions, make the proceedings, reports and records of peer review committees confidential and protect them against discovery and admissibility in court and administrative proceedings.

In the federal system, however, no such peer review committee privilege exists. As a result, federal judges must weigh various policy considerations when deciding whether

to allow peer review material into evidence.

While the new program makes confidential information provided to or by a PSO, it doesn't create a privilege for peer review materials.

The program also doesn't relieve Massachusetts health care providers of their obligation to report disciplinary actions, major incidents and legal violations to the Massachusetts Board of Registration in Medicine and the National Practitioner Data Bank. (This includes hospital and professional society discipline, major incident reporting under the Patient Care Assessment program, and individual "snitch" law reporting.)

However, any such reports may not include the work product reported to or de-

veloped by a PSO. This could create challenges for institutional providers with regard to mandatory state reporting of adverse events, depending on how patient safety information is collected and utilized.

The government's goal is to "develop a national system for analyzing and learning from patient safety events."

The regulations specify that any state laws that impose greater confidentiality restrictions on patient safety materials still apply.

Benefit to physicians

The program is expected to create new venues for the analysis and enhancement of quality health care in a dedicated and confidential setting, which ultimately should benefit physicians.

In addition, the federal immunity and confidentiality protections may possibly cover some materials that are not currently covered by the Massachusetts peer review protections, although all this will likely have to be worked out on a case-by-case basis in the future.

MMLR



MARCH 5, 10:40 AM

You respond to a request from The Center for Medicare Services for 100 of your patients' charts.

MAY 23, 12:00 PM

Investigators from the Inspector General's office arrive, unannounced, at your office to interview you and your staff.

MAY 23, 12:05 PM

You call Dwyer & Collora. Immediately, they advise you on how to proceed.

WHAT HAPPENS NEXT?

To find out, go to dwyercollora.com/healthcare

Dwyer & Collora, LLP
SHAPE FATE.®

Business Litigation • White Collar Defense • Securities Litigation • Health Care Law • Employment Law • Appeals

617.371.1000 • 600 Atlantic Avenue, Boston, MA 02210 • dwyercollora.com

Dean P. Nicastro is an attorney at Pierce & Mandell, P.C., in Boston. He advises physicians, and physician and other health care organizations on peer review, medical staff matters, regulatory compliance and business transactions, and also non-profit organizations on corporate and programmatic issues.



Verdicts & Settlements

Texas amputee wins \$17.5 million in hospital-acquired MRSA infection case

By Nora Lockwood Toohar

A Dallas jury awarded \$17.5 million in damages to a man who lost all his limbs because of a hospital-acquired MRSA infection.

But a \$250,000 cap on non-economic damages in Texas will reduce the award – one of the largest medical malpractice verdicts ever in Dallas County – to less than \$7 million.

David Fitzgerald had both arms and legs amputated after contracting a severe staph infection – known as MRSA, or methicillin-resistant *Staphylococcus aureus* – after surgery for ulcers at RHD Memorial Medical Center in Farmers Branch, Texas, in 2003.

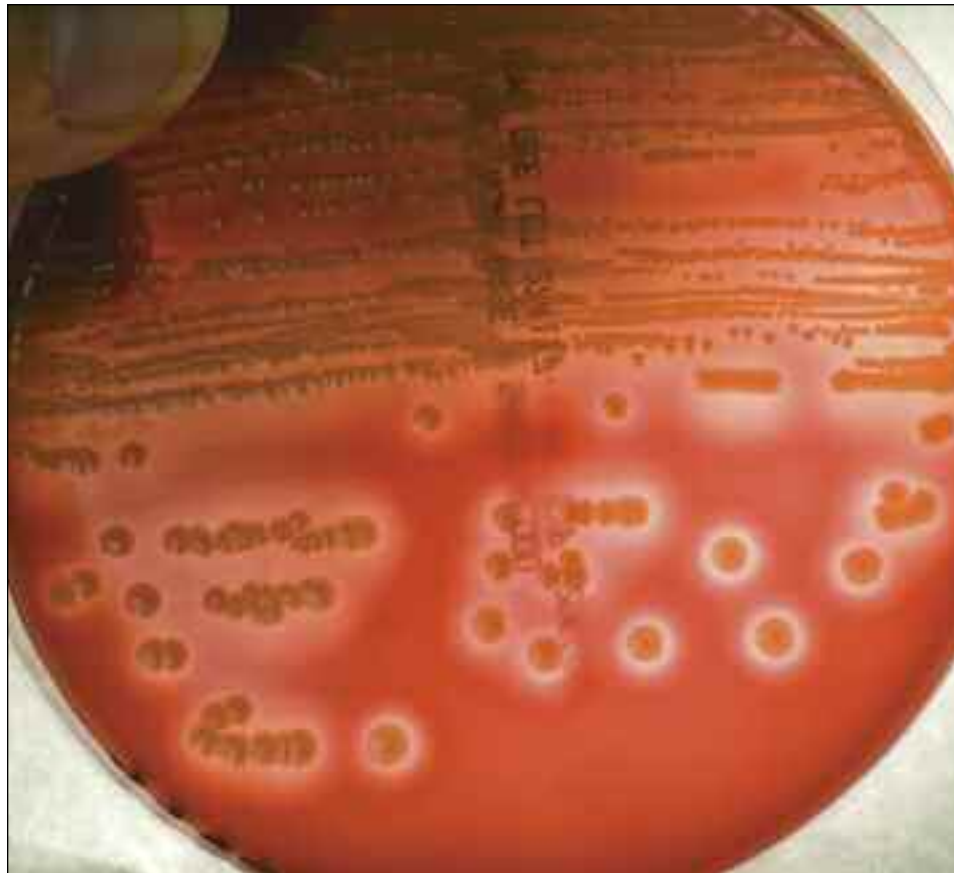
Linda Turley, his attorney, said several doctors treated him, but failed to prescribe Vancomycin, an antibiotic used to treat MRSA.

The infection was followed by septic shock; Fitzgerald developed gangrene in all four limbs. He was transferred to another hospital for the amputations and is now a quadruple amputee.

“He will require 24-hour assistance the rest of his life,” Turley said. “The basic things we take for granted – cleaning ourselves after we go to the bathroom, bathing, shaving and brushing our teeth – he can’t do any of that.”

Fitzgerald sued the hospital and doctors who treated him for misdiagnosis and negligence. The hospital and two of the doctors settled, but infectious disease specialist Dr. Meenakshi Prabhakar refused to do so.

On Feb. 13, the jury found Prabhakar neg-



AP Photo/The Seattle Times/Mike Siegel

MRSA bacteria, or Methicillin-resistant *Staphylococcus aureus* – pictured here growing in a Petri dish – caused a hospital patient to lose all of his limbs. He was awarded \$17.5 million by a Texas jury.

ligent and liable for misdiagnosis.

In non-economic damages, jurors awarded \$5 million for past and future pain and suffering; \$3 million for past and future disfigurement; and \$3 million for past and future physical impairment, for a total of \$11 million.

The jury awarded economic damages in the amount of \$444,650 for past and future lost earnings and \$6.28 million for past and future medical care, for a total of \$6.72 million.

With the reduction of non-economic damages to \$250,000, the total damages will be \$6.97 million.

Signs ignored

Fitzgerald, 53, a former apartment maintenance worker, was admitted to the hospital on Aug. 29, 2003 for ulcer surgery.

Turley said Fitzgerald began showing signs of infection on the third day following his surgery. He had a fever, a high white blood cell count that then dropped dramatically and signs of a chest infection.

By the end of the third day, he went into septic shock. Prabhakar, who was called in as an infectious disease specialist, ruled out an infection of the lung, and “provided no antibiotic coverage for the suspected pathogens” of hospital-acquired MRSA infection, according to Turley.

Fitzgerald “didn’t get the right antibiotics,” she said.

By the time he was discharged on Sept. 30,

Continued on page 11



MASSACHUSETTS
MEDICAL SOCIETY

SPECIALTY PROGRAMS FOR THE HEALTH CARE INDUSTRY

Medical Malpractice – choice of carriers
Business Office, Workers Comp Coverage
Health & Dental Insurance
Disability & Life Insurance
Specialized Banking Services
Medical Supplies
Healthcare Linen Service
Copiers, Printers, Faxes

800.522.7426
www.piam.com

PIAM
a subsidiary of the
Massachusetts Medical Society



The Fireplace at your service.

Catered Events & Functions

The Fireplace delivers to medical office lunches and department dinners.
Or have your private presentations here at *The Fireplace!*

★★★★★

Recent Awards:

Best Neighborhood Brunch
Boston Magazine

Award of Excellence
Wine Spectator

Most Authentic New England
Boston Globe

Most Romantic
WBZ TV #4 & City Search All Stars

★★★★

Lunch · Brunch · Dinner · Catering
Convenient Beacon Street location with free parking lot.

The Fireplace
New England Grill

1634 Beacon Street, Brookline, MA 02446 tel: (617) 975-1900 www.fireplacere.com

Verdicts & Settlements

MIT professor settles case for \$500,000

A 71-year-old renowned, semi-retired MIT professor in cellular biology was forced to stop working due to spinal stenosis.

He underwent a laminectomy and was then admitted to an inpatient infirmary at MIT. After three days, he was discharged.

During his stay at MIT, the patient developed signs of a surgical infection, including greatly increasing drainage from the wound and a skin rash extending from the wound site.

His treating physician diagnosed him with contact dermatitis and confirmed that diagnosis with a dermatologist. After three days, visiting nurses contacted the patient's surgeon due to concern over continuing drainage. He returned to the hospital, where cultures came back positive for Serratia bacteria.

As a result of the infection, the patient suffered nerve damage and was left with diminished left leg and ankle function, occasional urinary incontinence and impotence. He required extensive follow-up surgery to remove infected and damaged tissue.

The defense argued that the infection was superficial and could not have caused neurological damage.

As its last witness, the defendant presented a physician with expertise in infectious disease. However, during cross-examination, he asserted an explanation for wound site drainage and neurological symptoms that had not been mentioned by any of the defense's three prior experts, defense

Patient rendered quadriplegic settles suit for \$2.9M

The patient, 62, was admitted to the emergency department after the vehicle she was driving was rear-ended by another car.

Upon admission, she complained of neck and bilateral shoulder pain. An examination revealed diffused neck tenderness. She was given Percocet for pain, which was not effective.

The ER physician described X-rays of the patient's cervical spine as normal except for "degenerative joint disease." She was discharged with a diagnosis of acute cervical muscle strain.

Six days later, the patient returned to the hospital. Triage records note that the patient continued to complain of head and neck pain, that she could not feel her arms,

that she was suffering from visual and auditory hallucinations and that she had spasms in her arms, legs and elsewhere.

The ER physician noted in his record a "generalized paresis." He ordered a CT scan of the patient's neck but subsequently canceled it, claiming that he was told by the radiologist that it was an inappropriate study. The radiologist testified that he also told the doctor to repeat the plain film studies of the cervical spine, a claim that the ER physician denied.

Two days later, the patient was noted to have no use of her arms and legs and was med-flighted to a different hospital. Despite treatment to stabilize her spine and surgery, the patient remains quadriplegic.

The patient's experts were prepared to testify that the ER physician and the radiologist who reviewed the patient's films failed to recognize abnormalities suggestive of ligament damage. They also planned to state that the physicians failed to perform the corresponding diagnostic imaging studies of the patient's cervical spine when she returned with new and lingering symptoms that suggested a neurological injury.

Type of action: Medical malpractice

Injuries alleged: Quadriplegia

Date: Jan. 14, 2009

Submitted by: Robert A. Shuman and Christina Shepherd, Law Offices of Robert A. Shuman, Sharon (for the patient)

counsel or the witness himself during direct examination.

The patient's attorney used medical records to argue that the expert's theory had been made up while he was on the stand.

Type of action: Medical malpractice

Injuries alleged: Complications from post-surgical infection

Date: Oct. 23, 2008

Submitted by: Keith Halpern, Boston (for the plaintiff)

Verdict & Settlement Reports

Massachusetts Medical Law Report compiles the summaries of verdicts and settlements on this page from reports sent by attorneys to us or to Massachusetts Lawyers Weekly. The report information is generally provided by one of the lawyers in the case, although occasional reports may be based on court records and news reports. We edit the material for style, grammar, length and, where appropriate, content. We are interested in printing verdicts won by both health care providers and plaintiffs, in addition to settlements.

If you have an item you would like to submit, please contact Matt Yas at matt.yas@lawyersweekly.com or 617-218-8152.



ProMutualGroup®

FINANCIAL INTEGRITY, PHYSICIAN LOYALTY

TOUGH TIMES CALL FOR A STRONG PARTNER

Will your medical liability provider be there if you have a claim years, months or even weeks from now?

The state of the economy is uncertain and now, more than ever, is not the time to leave you or your practice unprotected. With so much at stake, it is more important than ever that you are protected by a company that will be there when you need it.

Financial strength when it is needed most.

In this challenging economy, ProMutual Group continues to maintain the financial strength necessary to defend, protect and provide our policyholders with the medical liability coverage they require and the peace of mind they deserve. This is evidenced by the reaffirmation of our Best's rating of A- (Excellent), a rating which we have held for 13 consecutive years.

ProMutual Group has been protecting healthcare providers for more than three decades and has weathered tough economic cycles. Our conservative investment strategy is based upon only taking modest risk in our investments, which has made our portfolio less vulnerable to difficult markets and helped us steer a steady course during these stressful times. To learn more about ProMutual Group, visit www.promutualgroup.com or call us at (800) 225-6168.



ProMutualGroup® | 101 Arch Street, Boston, Massachusetts 02110 | 1.800.225.6168 | www.promutualgroup.com

Connecticut Maine Massachusetts New Hampshire New Jersey Pennsylvania Rhode Island Vermont

The public health problem of domestic violence

By Barbara Herbert, M.D.

It was another first for the state. Last June, Governor Patrick signed a violence intervention bill making Massachusetts the first state to require health care providers to refer victims of violence to a variety of social services.

The impetus behind the action was clear: the soaring number of deaths from domestic violence. Murders of domestic partners in the Commonwealth were nearly three times higher in 2007 than in 2005, reaching 42 in 2007, with an additional 13 suicides. In 2008, 25 homicides occurred, with 10 suicides.

At the same time the bill was signed, the Department of Public Health (DPH) released a landmark public health advisory on domestic violence, the first time such an advisory has ever been issued for a non-disease-related cause. The bill requires DPH to draft voluntary guidelines suggesting ways that hospitals and community health centers can link domestic violence victims to services.

The bill and advisory were welcomed by victim advocates, as they recognized domestic violence as a public health problem.

Domestic violence has never been just a personal matter; it affects an entire community's sense of safety. Intervention in domestic violence cases offers models to address other forms of violence, such as dating violence, shaken baby syndrome and elder abuse.

Physicians have been involved, often with the legal community, in public-private prevention and intervention partnerships to decrease domestic violence, just as we have with shaken baby syndrome and elder violence. With the state's new commitment, we might combine our legal and medical experience to develop more effective interventions, even in an era of diminished public resources.

It is, of course, valuable to remind physicians and attorneys that restraining orders work most of the time to protect victims and their dependents from potentially lethal violence from perpetrators.

Early screening and support from physicians increases the reach and efficacy of these legal interventions in periods of acute crisis. Further, careful physician documentation augments the possibility of meaningful court action to protect survivors whenever they turn to the courts.

State law for some time has required physicians and other providers to report suspected cases of abuse to appropriate protective service agencies.

Physicians must report abuse or neglect of children and disabled persons and abuse, neglect or financial exploitation of elderly persons, defined as those over 60 years old. They must also file written reports within 48 hours of suspecting such treatment with reasonable cause, or face fines up to \$1,000.

As an emergency physician who has seen too many victims, I know the responsibility to report and protect patients is well accepted and taken with the utmost seriousness among the medical community.

However, the state's action also raises physician concerns about the reporting re-

quirements and what action is taken when reports are filed.

Physicians and citizens need to know that the state will take action as a result of reporting. This gives citizens incentive to participate, instills credibility and faith in the system, and tells citizens the system is working as it should. Thus, some mechanism to measure response and reaction by the state should be put forward.

We also need clarification on reporting. How, for example, do we determine the hidden violence of emotional abuse or financial abuse? How aggressively should physicians press patients for information to reach the point that they have "reasonable cause" to believe that violence has occurred?

Some cases are obvious; others, not so. The line between suspicion and reasonable cause can be wide or narrow.

The violence intervention bill is a great step forward. Yet, the voluntary guidelines for providers required by the bill, nearly a year after its enactment, have not been released. That isn't surprising, given the tremendous burden of new regulations the legislature has imposed on DPH in the past year and given that the complexities of tailoring effective responses to domestic violence are daunting.

It does point out, however, the difficulty of the task of attacking domestic violence. More information and more direction can only help patients, attorneys and physicians.

Barbara Herbert, M.D., an emergency physician, is the Medical Director of St. Elizabeth's Medical Center's Comprehensive Addiction Program and Chair of the Massachusetts Medical Society's Committee on Violence Intervention and Prevention.

Doctor's Rx



Finally.

A fresh insurance alternative for Massachusetts' doctors.

CMIC
REAL DOCTORS. REAL SOLUTIONS.

Choose a partner you can depend on.

Choose doctor owned.

We were built by doctors, for doctors. Our products and services reflect our members input and the leadership of practicing doctors.

Choose disciplined growth.

Our financial strength and corporate growth are based on meticulous planning and knowledge garnered from 25 years of regional experience.

Choose tailored programs.

Online loss prevention programs provide convenient access to required CME credits. Online specialty specific informed consent protocols and patient education are at your fingertips.

Choose personalized service.

Interaction with CMIC is a personal experience with the industry's most competent and personable staff at your service.

Choose superior defense counsel.

We provide our members with the largest choice of defense counsel in Connecticut and Massachusetts.

Choose CMIC.

80 Glastonbury Boulevard
Glastonbury, CT 06033
800.228.0287
www.cmic.biz



Surgeon wins \$1.6 million sex bias verdict

Continued from page 1

dergo an evaluation to determine her fitness to retain privileges at the hospital.

Hostile work environment

After deliberating for two and a half days, the jury of seven men and two women found that Tuli was subjected to harassment, ridicule, intimidation and other abusive conduct by Day because of her gender or national origin.

The hospital was ordered to pay \$1 million for subjecting Tuli to a hostile work environment. The jury also found the hospital liable for retaliating against Tuli by requiring her to be evaluated by outside physicians after she complained about Day, and assessed an additional \$600,000 in damages.

Day was found liable for slandering Tuli and intentionally interfering with her relationship with the hospital. He was assessed \$20,001 in damages for interference (\$20,000

for economic damages and \$1 for non-economic damages), but only nominal damages of \$1 for slander.

Jurors found in favor of the hospital on Tuli's claims of disparate treatment and unequal pay.

The hospital said it is considering whether to file an appeal.

In a statement, Robert Hamel Jr., the hospital's lead counsel, said he was disappointed in the findings against the hospital, but "pleased that the jury recognized that Dr. Tuli had been paid fairly by the hospital in comparison to male doctors in rejecting both her state and federal pay claims."

John Ryan, Day's attorney, said he is pursuing post-trial motions to have the findings vacated, and that he believes there are "flaws in certain of the jury's findings regarding Dr. Day."

"Dr. Day is an outstanding neurosurgeon whose character is best exemplified in the

In 2005, an investigation by the hospital's human resources department corroborated some of Tuli's allegations, but no action was taken.

Over the next two years, Tuli raised her concerns about Day with several hospital officials, including Andy Whittemore, the hospital's chief medical officer.

Although in a 2006 e-mail Whittemore acknowledged the seriousness of Tuli's complaints and pledged that the hospital would protect her rights, he also suggested that she leave Brigham and Women's, because she "really might benefit from moving to another setting with a clean slate."

Tuli was a key witness during the trial. Day also testified, but downplayed his comments about women surgeons, according to Pinkham.

"He admitted he would make comments relating to gender, but testified that it was in the spirit of joking," she said.

Tips for avoiding communication problems in the hospital

As hospital staffs become more diverse, cross-cultural and cross-gender communication snafus are common, according to Janet H. Moore, a trainer and executive coach based in Houston.

"Even if the surgeon understood these comments as jokes from his perspective, maybe they didn't come across to anyone else, particularly the plaintiff, as a joke," she said.

"Hospitals can help themselves by doing advanced and consistent communications training, which will help them avoid problems among their staff, but also problems between their staff and their patients," she said.

If a senior physician is offending staff members by insensitive remarks, Moore suggests that the hospital provide a combination of communications training and one-on-one coaching.

"Their communication style has been engrained over time," Moore said. "First, you've got to bring awareness to them of how they're coming across, and then you can begin to change their communication style."

— Nora Lockwood Tooher



"Even if the surgeon understood these comments as jokes from his perspective, maybe they didn't come across to anyone else, particularly the plaintiff, as a joke."

— Janet H. Moore

thousands of patients whom he has cared for during his career," Ryan added. He "looks forward to continuing his work now that this trial is over."

Complaints ignored

An assistant professor at Harvard Medical School, Tuli, who specializes in spinal surgery, is the first and only female neurosurgeon of Indian descent at a Harvard Medical teaching hospital.

She and Day both joined the department around 2002. Their relationship deteriorated around 2004, and Tuli began complaining that Day did not take her seriously as a peer.

His comments went beyond trivializing female doctors, however, with his suggestion of table-top dancing at a year-end party for residents in 2004. (Day denied the allegation; there were no other witnesses who overheard the alleged remark.)

The hospital contended that Tuli had "interpersonal problems," specifically in dealing with other physicians and staff, including Day.

But Barnes, the risk manager, testified that she was concerned Tuli's behavior was evaluated in a way that male surgeons' wasn't.

And several staffers and physicians backed up Tuli's allegations.

Dana Thomas, a surgical technician, and Robin Beal, a patient service representative, testified about Day's biased treatment of female doctors.

In addition, Dr. Peter Black, the former chair of the Brigham and Women's neurosurgery department, testified at trial he had heard Day call female doctors "girls," according to Pinkham.

MMLR

Questions or comments can be directed to the writer at: nora.tooher@lawyersusaonline.com

Legal ER
Your medical legal questions answered here...

Q. A 17-year-old patient who is married and on active duty in the military needs surgery. Can he provide consent for treatment, even though he's a minor?

A. Yes. Although he is one year shy of majority age in Massachusetts, he fits within the "mature minor" exception to the consent requirement. ...

Q. How long am I required to keep a patient's records once he leaves my practice?

A. You are required to retain patient records for seven years after the last patient contact.



Answers provided by
Elizabeth Brody Gluck, Esq.
of Verrill Dana LLP in Boston.

Want more details? Go to mamedicallaw.com.

Submit your own question to: reni.gertner@mamedicallaw.com

State's highest court weighs doctors' liability for third-party injuries

Continued from page 3

ensure that patients and others who might be foreseeably affected were not unreasonably put at risk.

Broadened scope of liability

Adler, Pollock & Sheehan attorney Michael D. Riseberg said that, like *Coombes*, the *Leavitt* case could require doctors to take additional factors into account when making treatment decisions.

"If the court reverses, you'd be broadening the scope of tort liability to extend to additional third-party non-patient plaintiffs arising from decisions regarding the treatment of a patient," said Riseberg, who submitted a friend-of-the-court brief for the Massachusetts Defense Lawyers Association.

"Physicians, when they make treatment decisions about whether to discharge someone or what prescription medication they're going to prescribe, would have to consider consequences that could give rise

to liability to third parties," the Boston lawyer added.

Even assuming all the facts in the plaintiff's complaint are true, Buoniconti said in his brief, there was no direct relationship between the officer and Buoniconti's clients.

There is also no evidence, he said, to suggest the defendants in any way voluntarily assumed a duty to the officer that would otherwise not exist.

"No case law exists that allows for recovery by a plaintiff against a medical provider,

for injuries resulting from a patient's impaired condition, where the plaintiff had no contact with the patient," he wrote. "The plaintiffs simply remain too far removed from the defendants or the patient for any duty to have been created."

Due to the pending nature of the case, Buoniconti declined to comment. **MMLR**

Questions or comments should be directed to the writer at: david.frank@lawyersweekly.com

Verdicts & Settlements

Texas amputee wins \$17.5 million in hospital-acquired MRSA infection case

Continued from page 6

2003, Fitzgerald suffered from acute renal and respiratory failure, internal bleeding, malnutrition, pneumonia secondary to the MRSA, MRSA septicemia and gangrene of his arms and legs.

Due to his deteriorated condition, he underwent quadruple amputations at another hospital.

'Time is of the essence'

Turley said that Prabhakar failed to swiftly treat Fitzgerald's MRSA infection with Vancomycin. Instead, Fitzgerald was treated with eight different antibiotics, all of which are known to be ineffective in treating MRSA.

Turley, who has represented plaintiffs in several hospital-acquired MRSA lawsuits, said that "time is of the essence" in treating the infection, which can be deadly if it enters the bloodstream.

U.S. health officials said this month that hospitals in general are making progress in curbing at least one source of MRSA. Rates of MRSA caused by tubes used to give drugs and fluids to intensive-care patients fell nearly 50 percent between 1997 and 2007, according to the U.S. Centers for Disease Control and Prevention.

Medical experts testified at the trial that about a third of all hospital-acquired infections are in the lungs, and that a third of

those lung infections are MRSA cases.

A critical care physician, pulmonologist and infectious disease specialist testified that "hospital-acquired infections need to be treated broadly for all the suspected pathogens," Turley said.

The experts also agreed that a "broad-spectrum antibiotic," such as Vancomycin, should be used to treat hospital-acquired infections.

On the stand, Prabhakar defended his decision to reject that theory of practice.

"I asked him about it twice – in the afternoon when crossing, and then I asked him again the next morning," Turley recalled. "He said, 'I don't believe in that, Miss Turley.'"

Prabhakar said he didn't believe Fitzgerald had MRSA at the time, but instead had multiple infections.

Jurors deliberated for three days before reaching a verdict. Turley said there was no pre-trial settlement offer, and that the defense offered only \$200,000 as a settlement after the first day and a half of juror deliberations.

Defense attorney William Chamblee did not return a phone call seeking comment. **MMLR**

Questions or comments should be directed to the writer at: nora.tooher@lawyersusaonline.com

Compliance Headaches? We Can Help.

Contact us for a free consultation.

Compliance Audits

Compliance Programs

Independent Monitoring

Assessments

Hot Line Services

AFFILIATED MONITORS, INC.
INTEGRITY THROUGH COMPLIANCE

www.affiliatedmonitors.com/contact.htm

ARCHITECTURALLY STUNNING ENVIRONMENTALLY RESPONSIBLE ECONOMICALLY BRILLIANT



SAGE BUILDERS LLP

Design-Build
Renovations
Additions



Modern. Traditional. Or somewhere in between. Whatever your style, together we can make your next renovation a little easier on the earth without breaking your budget or compromising form or function. For more than a decade, Sage has been helping clients make smart design and construction decisions. Put our vast knowledge and experience to work for you.

617.965.5272
SAGEBUILDERS.COM

Bills, Rules & Regs



From Beacon Hill

Bill would ban tobacco sales in pharmacies

Massachusetts would be the first state in the nation to ban tobacco sales in pharmacies, under a bill that will be considered by the state legislature this year, according to the Worcester Telegram & Gazette.

Sen. Susan C. Fargo, D-Lincoln, and Rep. Sean Garballey, D-Arlington, have filed a bill that would ban the sale of tobacco products in any health care institution, which would include "hospitals, clinics, health centers [and] pharmacies, [as well as] doctors' and dentists' offices."

Of those, only pharmacies would likely be affected because most health care institutions stopped selling tobacco products years ago.

The city of San Francisco, followed this month by Boston, has passed a local ordinance that prohibits tobacco product sales in pharmacies. Boston's ordinance also banned the sale of tobacco products on all educational campuses, including colleges, the Telegram reported.

New insurance plan stirs up controversy

State regulators have voted to accept a controversial bid by a Massachusetts Catholic hospital chain and a secular health organization to provide health insurance to low-income residents.

The Connector Authority board, which oversees the Commonwealth Care program, voted unanimously in favor of the joint venture proposed by Caritas Christi Health Care Network and the Centene Corporation, a St. Louis-based health organization.

Earlier statements by a spokeswoman for the joint venture said that the entity would "contract with providers, both in and out of the Caritas network, to ensure access to all services required by the Authority, including confidential family planning services," The Boston Globe reported.

Those statements infuriated anti-abortion activists, who claimed that such an arrangement would betray Catholic teachings. Abortion rights advocates voiced concerns for low-income women, saying the entity was not clear about how the services would be provided, especially in Caritas' six-hospital chain, which adheres to Catholic teachings.

Starting July 1, the new insurance will be available to the roughly 164,000 consumers in the state's Commonwealth Care program, according to The Globe.

Rep. pushes for dental exam bill

A state legislator from Western Massachusetts joined with dentists to support a bill requiring every child in the state to have a dental exam before entering public or private kindergarten, according to The Springfield Republican.

The legislation, co-sponsored by Rep. John W. Scibak, D-South Hadley, is being backed by the Massachusetts Dental Society in Southborough.

Dental disease is the most common chronic childhood disease, five times more common than asthma, according to the dental society.

Patrick cuts senior assistance program

More than 44,000 Massachusetts seniors must pay larger prescription drug copayments as a result of an \$11 million cut to the state Prescription Advantage program, which provides co-pay assistance for seniors who meet an income-eligibility requirement, according to The Boston Globe.

The cut, which was part of Gov. Deval L. Patrick's \$1 billion state budget reduction in October 2008, could leave many seniors paying double or triple their previous co-pays, state officials said.

As of Jan. 1, 2009, state assistance for covered drugs is no longer available until Medicare and the beneficiary have spent a combined \$2,700.

"The pain will go away once they reach the \$2,700, but it will be a heck of a lot of pain until then," Deborah Banda, state director of AARP Massachusetts, said. "The vast majority of these people are on fixed incomes." Banda added that with more budget cuts likely, "if people are cutting back because they can't afford these costs, they may stop taking their prescriptions, and they may end up at emergency rooms all over the state," the Globe reported.

Gov. proposes shift in elder service oversight

Gov. Deval L. Patrick is proposing a shift in the oversight of elderly care services, such as adult day care and home health care, from the Executive Office of Elder Affairs to the agency that oversees Medicaid, The Boston Globe reports.

According to the proposal, the shift is "primarily about administrative simplification" and is intended to improve care and cost management.

The proposal states that "consumers and providers will not experience any change in their access to services, payment, or direct program administration."

AARP and other advocates for the elderly oppose the shift, according to The Globe. Some observers claim that the reorganization would not save the state money. The state legislature must reject the gubernatorial proposal within 60 days or it will become law. Lawmakers cannot make changes to the proposal.



From Capitol Hill

Legislators allocate \$157B for health care

The Obama administration's economic stimulus package includes more than \$157.5 billion for health care programs.

A key element of the package that impacts the medical community is \$20 billion for health care information technology – with all medical records becoming electronic by 2014. It also includes \$1.1 billion for comparative effectiveness research – aimed at finding the best treatments that are cost-effective – conducted by the Agency for Healthcare Research and Quality.

The package includes \$87 billion to temporarily increase federal funds for state Medicaid programs, as well as funds to allow low-income workers who lose jobs that didn't include health insurance to apply for Medicaid through 2010.

Another provision will provide \$39 billion in federal subsidies for COBRA, which allows recently laid-off workers to retain their group health insurance, provided that they pay 102 percent of the premiums.

Under the new provision, workers who lose or have lost their jobs and their health insurance between Sept. 1, 2008 and Dec. 31, 2009 can receive subsidies to cover 65 percent of their premiums. The package also extends the time laid-off workers age 55 or older can retain their health insurance under COBRA.

'Wyeth' case gives life to medical device bill

A day after the U.S. Supreme Court decided that Food and Drug Administration rules did not protect drug makers from state lawsuits, Democrats in Congress moved to overturn a decision that has shielded medical device companies from similar legal action.

The court turned away drug maker Wyeth's contention that it was not subject to lawsuits in state court for its anti-nausea drug Phenergan, because the drug had already been approved by the FDA. The ruling upheld a \$6.7 million jury award to a Vermont woman who lost her arm after she was improperly injected with the drug.

In response to the decision, Democrats reintroduced the Medical Device Safety Act, a bill that would allow similar lawsuits against companies that make heart devices, catheters, replacement hips and other medical devices.

The device industry's chief lobbying group quickly criticized the effort, saying it would "produce a chilling effect on medical innovation, create more lawsuits and ultimately result in higher health care costs for all Americans."

Despite opposition from the industry, a broad range of interest groups support the bill, including consumer advocates, trial lawyers and AARP. Companion legislation was introduced in the Senate by Sen. Edward M. Kennedy, D-Mass.

Obama removes barrier to stem cell research

President Barack Obama lifted restrictions on federal funding of human embryonic stem cell research, angering abortion opponents but cheering those who believe the studies could produce treatments for many diseases.

The decision was a clear repudiation of the approach taken by Obama's predecessor, George W. Bush. Federal law limits the use of federal money to make human stem cells, but Bush tightened the restrictions even further to include most studies using such cells.

Religious conservatives who supported Bush generally opposed embryonic stem cell research because it involves destruction of embryos, which they view as human life.

Obama rejected that view. "When it comes to stem cell research, rather than furthering discovery, our government has forced what I believe is a false choice between sound science and moral values," he said. "As a person of faith, I believe we are called to care for each other and work to ease human suffering. I believe we have been given the capacity and will to pursue this research – and the humanity and conscience to do so responsibly."

Aides said Obama would not dictate details about how stem cell research should be overseen but would give the National Institutes of Health 120 days to establish guidelines.

Most fertility clinics violate guidelines

Fewer than 20 percent of fertility clinics across the country follow professional guidelines on how many embryos should be used for younger women undergoing in vitro fertilization, according to reports filed with the Centers for Disease Control and Prevention.

The recent furor over Nadya Suleman and her octuplets has brought scrutiny to U.S. fertility clinics and how well they observe the guidelines, which are voluntary. The controversy has led to talk of passing laws to regulate clinics, something that has already been done in Western Europe.

The only penalty for violating the guidelines is expulsion from some of the industry's professional organizations, though that can affect whether insurance companies will cover a clinic's treatments.

When the guidelines were issued by the American Society for Reproductive Medicine in 1996, the intent was to cut down the number of multiple births, particularly triplets and higher, that can result when many embryos are implanted and more than one takes.

But for women under 35, government records indicate that just 83 out of 426 clinics followed the guideline calling for no more than two embryos. The average number of fresh embryos (as opposed to frozen) implanted in women in that age group ranged from 1.4 to 4.8. The vast majority of the clinics averaged between two and three embryos.

Get into doctors' offices - without an appointment.

Advertising in Massachusetts Medical Law Report is a great way to reach thousands doctors, health care administrators and in-house counsel in the health industry.

Call 617-218-8180 now to reserve space in the next issue or e-mail catherine.howe@lawyersweekly.com.

Earn CME Credits

| | |
|------------------------------------|-------------------|
| Original Publish Date: | 3/16/09 |
| Review Date: | NA |
| Estimated Time to Complete: | 1 Hour |
| Term of Approval End Date: | 3/16/10 |
| Risk Management: | Yes |
| Course Format: | Text and Graphics |

Instructions for Completing this Course and Exam

Please submit your exam along with a check (see course fees below) made payable to the Massachusetts Medical Society, P.O. Box 9155, Waltham, MA 02354-9155, (phone: (781) 434-7306, fax: (781) 642-1246, email: continuingeducation@mms.org).

Course Fees

Massachusetts Medical Society (MMS) Member: \$10 (\$10 per credit)
Non-MMS member: \$20 (\$20 per credit)

Course Information

Intended Audience

This course is intended for physicians and allied health professionals.

Course Objectives

- Provide physicians and other health care professionals with information on Minute Clinics.
- Explain which regulatory agency oversees these clinics.
- Discuss the practice parameters under which nurse practitioners may operate in these clinics.
- Identify areas that may cause legal issues to arise related to Minute Clinics

Course Credit

The Massachusetts Medical Society designates "Minute Clinics" Raise Round the Clock Risks for a maximum of 1 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This program meets the criteria of the Massachusetts Board of Registration in Medicine for risk management study.

Participants will receive a confidential report of their examination score. You must receive a score of 70% or better to receive AMA PRA Category 1 Credit™. A confirmation of credit will be issued at the end of the course to those who successfully complete the examination.

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the Joint Sponsorship of the Massachusetts Medical Society and Lawyers Weekly, Inc.

The Massachusetts Medical Society is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Course Fees

Massachusetts Medical Society (MMS) Member: \$10 (\$10 per credit)
Non-MMS member: \$20 (\$20 per credit)

Disclosure/Commercial Support

The following writers and course developers have no financial interests or relationships to disclose.

Henry Tulgan, MD, FACP
Eric Berkman, Freelancer for Lawyers Weekly
Reni Gertner, MPH, Editor Lawyers Weekly
Kathleen Bellisle, Manager of MMS Distance Learning

Off-label Disclosure:

This course does not include any discussion of an off-label use of a commercial product or an investigational use not yet approved for any purpose by the FDA.

Commercial Support

No commercial support was received for this online program.

Content Disclaimer

The Massachusetts Medical Society does not take responsibility for the accuracy of the information in this CME program, which was provided by Lawyers Weekly, Inc. and summarized by Henry Tulgan, MD, FACP. The views expressed are not necessarily those of the Massachusetts Medical Society.

Course Developers

Henry Tulgan, MD, FACP
Reni Gertner, MPH, Editor Lawyers Weekly
Kathleen Bellisle, Manager of MMS Distance Learning

Bibliography – see page 14

'Minute clinics' raise round-the-clock risks

By Eric Berkman

"Minute clinics" will soon be opening in CVS stores across Massachusetts, with nurses dispensing medical advice and prescriptions in what the pharmacy chain claims to be a quick and inexpensive way for patients to get care for minor medical problems.

But in approving these clinics, has the state Public Health Council made a risky move?

Doctors, lawyers and consultants warn that the clinics open a host of liability risks and other concerns for the nurse practitioners who will staff them, the physicians who will supervise them and the primary care physicians whose patients may visit them.

Lawyers tell Massachusetts Medical Law Report that the operational model for the typical clinic – a nurse practitioner treating patients on site with the supervision of an offsite physician – creates legal concerns for doctors and nurses alike.

"If I were a physician, I'd be very concerned about trying to supervise someone else at a distance whom I don't really know, dealing with a patient whom I'll never see," said Leonard Simon, a lawyer in Waltham who represents plaintiffs in medical-malpractice cases.

In addition, doctors and lawyers are concerned about the fragmentation of care that could result when patients visit clinics without the knowledge of their primary care physician.

"From what we've seen, these clinics are not integrated into the health care systems that have been developed by physicians, provider groups and hospital networks over the last number of

years," says Bruce S. Auerbach, president-elect of the Massachusetts Medical Society and vice president and chief of ambulatory services at Sturdy Memorial Hospital in Attleboro.

With the arrival of limited-service clinics – at more than two dozen CVS stores in Massachusetts this year and probably other retailers in the not-too-distant future – there will be new job opportunities for nurse practitioners and primary care doctors.

But before jumping in, doctors and lawyers suggest that providers:

- Ensure that the retailer will cover any malpractice claims that arise;
- Verify that the retailer has acceptable written guidelines for when to refer a patient to their own physician or the emergency room; and
- Affirm that systems are in place to receive a patient's medical history and to report details of the visit back to the primary care physician.

Risky rewards?

David Harlow, a health care consultant and lawyer in Newton, says the shortage of primary care physicians, coupled with patients' desire for quick, convenient and cheap care, is the big driver behind the clinics.

Despite myriad concerns, professionals acknowledge that the clinics could help relieve an over-taxed primary care system.

"I think limited-service clinics are a bad answer to a primary-care supply problem, but they're better than the current answer, which is the emergency room," says Robert M.

Hartley, medical director of the Brookside Community Health Center in Jamaica Plain.

Barbara H. Buell, a med-mal defense lawyer in Boston who practices with Bloom & Buell, agrees.

"If a place like CVS can properly take care of a person's medical problem for \$59 where an emergency department would have had to bill \$1,000 or more, it's all to the good," she says. "But it all depends on the triaging of the problem and the judgment of the first medical person the patient encounters."

That's a huge caveat, says Boston plaintiffs' lawyer Paul Sugarman, a partner with Sugarman & Sugarman, who says that supervising physicians must be aware that they could be liable for any negligence that arises from care in the clinic.

One major concern is the clinic's "reliance on nurse practitioners some distance away making their own decisions and diagnoses, unlike in a doctor's office or hospital where the physician is available on site," he says.

Supervising doctors should also know that if they recommend proper treatment, but a nurse practitioner improperly executes it, they might still get sued, says Heather Beattie, a malpractice defense lawyer in Springfield who also has 25 years' experience as a registered nurse.

"I could see someone ... suing the nurse and then trying their damndest to show the doctor knew something and should have done something," says Beattie, who practices with Morrison Mahoney.

But Sara Ratner, senior counsel for MinuteClinic, says these bad scenarios are highly unlikely and this

Continued on page 14

Minute clinics: what providers can do to protect themselves from liability

Given the risks of working with the new limited-service clinics in pharmacies, health care professionals associated with them should do the following to protect themselves:

• Verify coverage for medical malpractice claims

"Any [supervising physician] would want to make sure the retailer is taking responsibility either directly or through an indemnity agreement for any negligence that may arise on their part," says Leonard Simon, a medical-malpractice plaintiffs' attorney in Waltham. "I'd also avoid holding myself out as an independent contractor or signing an agreement with a retailer that would allow me to be thought of as an independent contractor."

At CVS's MinuteClinic, while all collaborating physicians are independent contractors who maintain their own practices, the company purchases professional liability insurance for them, Ratner says.

• Ensure that protocols are in place for nurse-physician relations

It is critical for nurse practitioners to make sure there are guidelines for the relationship between them and any supervising physicians, says Heather Beattie, a med-mal defense lawyer in Springfield, who practices with Morrison Mahoney.

Under state guidelines issued by the Board of Registration in Nursing, the nurse practitioner is supposed to have written guidelines as to what kinds of findings dictate that he or she call the physician, send a patient to the emergency room or call an ambulance.

These guidelines – if well-crafted and followed – should help avoid many of the potential liability scenarios that can arise from supervision issues. Because the board has the power to discipline a nurse based on insufficient guidelines, says Beattie, he or she should have the board sign off on them before starting at the clinic.

Even if MinuteClinic or another retailer has guidelines in place, Beattie recommends that the nurse still clear them with the board. She also suggests that doctors run the guidelines by the Board of Registration in Medicine.

"This may put a stumbling block in the contractual agreement between the nurse or doctor and the company," she says. "But I'd rather do that than put my license at risk. This is a new area that will eventually be tested and I'd want to make sure I was on sure footing before I jumped in."

• Share information with patients' regular providers

Limited-service clinics will want to cause as little disruption to their

patients' regular physicians as possible.

As a result, MinuteClinic, and presumably potential competitors, will be passing along records of visits to primary care providers.

But primary care doctors must also do their part to minimize disruption. This means implementing procedures to ensure that they actually see reports from the clinics and act on them.

"Keeping in good contact with other health care providers who see their patients is a problem that a lot of primary care doctors have," says Beattie. "A report from a clinic could be important information that leads to further workup."

Simon also urges primary care-givers to establish systems for fielding calls from clinics that may seek advice on how to proceed with one of their patients.

For one thing, the doctor should avoid giving actual treatment advice. By doing so, the doctor would be assuming joint liability with someone he does not know at a time when he has no physical access to the patient.

Karen R. McAlmon, president of the Massachusetts Chapter of the American Academy of Pediatrics, agrees.

"That's why most [physicians] will most likely just say, 'I need to see my patient myself.'" MMLR

-Eric Berkman

'Minute clinics' raise round-the-clock risks

Continued from page 13

type of arrangement is nothing new.

"There are other types of clinics that operate primarily with nurse practitioners and MinuteClinic is really no different from the way they practice in other settings," she says.

Errors treating kids?

Karen R. McAlmon, president of the Massachusetts Chapter of the American Academy of Pediatrics, believes that the lack of an on-site physician creates a risk of medical errors—a risk that is amplified when treating children with no pediatric specialist on site.

"If you have people who aren't used to dealing with children and aren't up to date on what's new in the field, then an older treatment that's no longer being used has the risk of being continued," she says.

To avoid this problem, the guidelines for the new clinics say they cannot treat children age 24 months or younger.

"But even with older children, there's more risk than with adults being seen in these clinics," McAlmon adds.

MinuteClinic's Ratner disagrees, explaining that all of the company's practitioners are board-certified family nurses.

Plus, they have built-in safeguards to prevent medical errors stemming from special pediatric needs. For example, MinuteClinic has a prohibition on certain vaccines for children under 4. And if a child presents for the same condition at MinuteClinic three times in a year, the clinic has a system built in to reject the patient and refer him or her to a pediatrician or specialist.

Profit motives

Even with safeguards in place, the reality of the corporate world could compromise practices on the ground, says Simon.

For example, while a supervising physician is required to be available by phone, clinic nurses could avoid calling too often for fear of being tagged as a cost center.

"Realistically, a nurse is going to be reluctant to call the supervising physician every time a kid walks in with a sore throat or the croup to

make sure it's not epiglottitis," he says.

"If they find her making too many calls to the physician, the retailer could say, 'We have someone here with not enough confidence in her abilities.' The clinics run on volume and quickness."

But Ratner says if collaborating physicians find they're fielding too many calls, MinuteClinic will bring in more to pick up the slack, or look into adding a new clinic somewhere nearby.

"We have the ability to respond to demand in a unique way," she says, noting that MinuteClinic is accredited by the Joint Commission. "We will not compromise quality in order to generate greater profit."

Critics complain that the profit motive could push clinic staff to over-recommend prescriptions and over-the-counter medications to boost the pharmacy's bottom line.

Ratner points to safeguards for this as well.

MinuteClinic puts a statement on every prescription saying the patient can fill it at any pharmacy. Any e-prescriptions are linked to all

pharmacies in the area. And MinuteClinic trains nurse practitioners not to direct the prescription to the CVS pharmacy.

However, Simon remains unconvinced.

"You want a slice of the health care dollars pie and if you're a pharmacy, it is going to boost sales of over-the-counter and prescription medication," says Simon, who is a former pharmacist himself. "It then becomes at least in part a product-sale-driven kind of practice with inherent conflicts and risks."

Fragmented care

Primary care providers are apprehensive about the potential fragmentation of care that could occur when their patients visit limited-service clinics.

For instance, patients might not provide a full picture of their medical history, which could create problems with the treatment they receive, says Auerbach. Or the treatment may never make it into the patient's medical record.

Ratner states that MinuteClinic addresses these issues by asking

patients what medication they are taking and then saving the information in the system for the next time the patient comes.

If clinic staffers are concerned that they may not be getting the full picture, they will send the patient to his or her primary caregiver. Additionally, their systems are capable of pulling a patient's medical history—as long as the primary caregiver maintains an electronic medical record and is willing to share the information.

But Simon notes that obtaining a comprehensive history will take time, and in an establishment designed for quick processing of patients, time is money.

"If there's a line out the door, you can't call in another nurse or technician" as you can in a fully-staffed facility, he says. **MMLR**

These articles were first published in the Spring 2008 issue of Massachusetts Medical Law Report.

Questions or comments should be directed to the editor at: reni.gertner@mamedicalaw.com

The Physician's Corner

MinuteClinics open in Massachusetts

By Henry Tulgan, M.D., FACP

Massachusetts has now joined 25 other states in allowing MinuteClinics to be established in a number of CVS pharmacies across the Commonwealth.

Several years ago, MinuteClinics began as an independent organization providing walk-in care. It was then purchased by CVS Caremark in 2006. In other states, similar clinics are operated by a number of other retailers, including Walgreen's, Wal-Mart, Target and Kroger's.

These clinics have arisen as a response to the serious shortage of primary care physicians (PCPs). They are also a response to the overutilization of hospital emergency departments and the often prolonged delays and staggering costs involved in their use.

The average cost for a visit to a MinuteClinic for a "common family illness" is \$59 and wellness and screening visits are \$29.

Other minor services such as flu shots and other vaccinations are

also available. Patients can pay with cash or a credit card, or submit the bill to insurance.

In-store limited service clinics are regulated by the state Department of Public Health, which has defined appropriate conditions that may be treated.

They are staffed by nurse practitioners who are supervised by off-site physicians. The relationships between them are delineated by The Board of Registration in Nursing. These nurses may also attempt to contact a patient's primary physician.

Does this arrangement have the potential to raise medicolegal issues?

It most certainly seems that the answer is yes.

Patients who are seen at these clinics are at a distance from the supervising physician and their PCPs, and both the treating nurses and the physicians may be vulnerable to lawsuits.

In addition, if a patient visits one

of the clinics and fails to disclose an ongoing treatment plan from his or her primary physician, it opens the door to possible liability for all parties involved.

Any practitioner who wants to become a supervising physician should employ several safeguards. First and foremost, the physician must be certain that CVS or other operators of such facilities will assume coverage for any malpractice actions.

In addition, policies should be in place for the clinic to refer patients back to their primary care physician as needed or, when necessary, to an emergency department.

Clinics and PCPs must also have mechanisms for the PCP to receive prompt reports of patient visits to the clinic. This places an additional responsibility on the PCP to follow through with recommendations made at the clinic visit.

Hopefully, as electronic medical records become more readily available and easier to share among health care institutions, communi-

cation about patients will also become smoother.

Another concern is that many clinics are not open 24 hours and therefore they cannot obviate the usage of emergency departments at times that are usually busy.

It is still early in the era of in-store limited service clinics. Time will likely clarify their usefulness and sort out some of the potential legal issues. But the clinics are now a presence in the health care delivery system and expected to grow rapidly, so we will have to continue to observe them carefully.

Risk management strategies

For supervising physicians

- Verify that coverage is provided by the retailer for medical malpractice claims.
- Establish protocols and guidelines for nurse-physician relations.
- Share information with the patients' regular provider.

For primary care physicians

- Establish a system in your practice for fielding calls from clinics about a patient.
- Avoid giving any treatment advice over the phone.

Bibliography

Massachusetts Department of Public Health
105 CMR 140.000: LICENSURE OF CLINICS
<http://www.mass.gov/Eoehhs2/docs/dph/regs/105cmr140.pdf>

National Academy for State Health Policy
NASHP Report: Analysis of State Regulations and Policies Governing the Operation and Licensure of Retail Clinics
<http://www.nashp.org/files/RetailClinics.pdf>

Henry Tulgan, M.D., FACP is a clinical professor of medicine at the University of Massachusetts Medical School, a consultant to the MMS Committee on Sponsored Programs, which he formerly chaired, and Director of Medical Education at Wing Memorial Hospital in Palmer, Mass.

CME Exam and Evaluation

"Minute Clinics" Raise Round-the-Clock Risks

NAME _____

DESIGNATION _____

EMAIL _____

TELEPHONE _____

STREET _____

CITY _____ STATE _____ ZIP _____

DATE _____

Instructions for Requesting CME Credit

Please submit your test along with a check (see course fees below) made payable to the Massachusetts Medical Society, P.O. Box 9155, Waltham, MA 02354-9155, (phone: (781) 434-7306, fax: (781) 642-1246, email: continuingeducation@mms.org). Participants seeking *AMA PRA Category 1 Credit™* will receive a confidential report of their examination score and the correct answers. A score of at least 70% is required to receive 1 *AMA PRA Category 1 Credit™*.

Course Fees

Massachusetts Medical Society (MMS) Member: \$10 (\$10 per credit)
Non-MMS member: \$20 (\$20 per credit)

Please answer the following questions. A score of at least 70% is required to receive 1 *AMA PRA Category 1 Credit™*.
Deadline for completing the exam is March 16, 2010. Please make a copy for your records.

- Massachusetts is unique in offering MinuteClinics.
 - a. True
 - b. False
- MinuteClinics operate under guidelines developed by the Massachusetts Department of Public Health. (DPH)
 - a. True
 - b. False
- Physicians should be certain that clinic providers will assume coverage for potential malpractice actions.
 - a. True
 - b. False
- Patients who utilize MinuteClinics must fill prescriptions in the pharmacy where the clinic is located.
 - a. True
 - b. False

Please complete the evaluation portion of this activity. Your feedback is important in developing future educational programs. Please send additional comments to continuingeducation@mms.org.

Did this activity meet the stated objectives?

- Yes No

How do you rank the effectiveness of this activity as it pertains to your practice?

- High Average Low

Will you make any changes in your practice as a result of participating in this CME activity?

- Yes No

If yes, please explain.

How do you rank the quality of this education program?

- High Average Low

Did you perceive any evidence of bias for or against any commercial products?

- Yes No

What are your topics of interest for future CME activities?

Doctors must pay attention to drug company gift ban

Continued from page 1

notepads provided gratis by pharmaceutical and medical device companies.

Plus, as of July 2010, even legitimate benefits that drug-and-device companies bestow upon doctors, such as bona fide consulting fees, will be catalogued on a publicly searchable database on the DPH website.

The regulations emerged from a sweeping package of legislation enacted last summer intending to contain health care costs while promoting quality and transparency in delivery. Part of the Legislature's goal in passing the law was to address potential conflicts of interest arising in relationships between the drug industry and health care providers.

Accordingly, the Legislature included a provision directing DPH to regulate such relationships by developing a "Massachusetts Marketing Code of Conduct" for the industry to follow and by creating a public disclosure system.

DPH issued its proposed regulations in December 2008 and the state Public Health Council unanimously approved them on March 11.

Under the new code, drug and device companies are barred from giving practitioners:

- Free meals unless consumed in a hospital or office setting, accompanied by an informational presentation;

- Entertainment or recreational items like concert tickets, sports equipment or vacations or complimentary items like pens and coffee mugs;
- Coverage of travel, lodging and meal expenses at medical conferences, professional meetings or CME events;
- Grants, scholarships, subsidies and consulting contracts in exchange for prescription of drugs or devices; and
- Monetary compensation for anything other than bona fide professional services.

However, the code will still permit prescription drug samples and compensation for legitimate professional or consulting services.

Meanwhile, the disclosure requirement mandates that companies report to DPH the nature, value and recipient of any fee, payment or other benefit worth \$50 or more. All such disclosures would be made publicly available and easily searchable on the DPH website, though payment for consulting in connection with genuine research or clinical trials would be exempt from the reporting requirement.

According to Steven C. Schachter, a neurologist at Beth Israel-Deaconess Medical Center in Boston and Mandell's co-author, the proposed regulations are reasonable.

"I'm reassured to see provisions in place that enable relationships between physi-

cians and industry that pertain to advancing medical research and knowledge," he says.

Schachter also predicts that physicians on staff at hospitals with strict rules already in place won't notice anything new.

"But for those in private practice or who belong to institutions without significant rules in place, it will represent a change," he says.

At the same time, lawyers emphasize that while only industry is accountable under the regulations, doctors should still be aware of what's permissible and what isn't.

For one thing, the reporting system creates the potential for reputational fallout for doctors who tend to receive significant benefits from drug companies, even where the benefits are technically permissible, says Carl Rosenfield, a Newton attorney and former DPH deputy general counsel.

"It depends who goes to the trouble of looking through the database, who does the analysis and what's reported in the paper," he says. If the benefits a doctor is receiving are "substantial enough, there could be questions."

Pat Cerundolo of Foley Hoag in Boston, who advises pharmaceutical companies, adds that any investigations or proceedings against drug companies suspected of violating the regulations would most likely embroil physicians.

"To the extent that any physician could be implicated in [improper] transactions, it could raise questions under federal anti-kickback laws," he said. "It might also raise questions about the doctor's conduct as a licensed physician in Massachusetts and whether the conduct violates any disciplinary rules."

That's because, according to Mandell, a doctor can violate anti-kickback laws by entering a contract with a pharmaceutical company where the fee he's receiving noticeably exceeds a fair market value for the time and services he's been asked to provide. Because the new regs require companies to disclose any benefits they confer upon doctors, it could become easier for authorities to detect these kinds of arrangements.

"This code of conduct and disclosure law that only imposes prohibitions on drug companies still creates a basis on which there will be a higher profile for all physician interactions with industry," he says. "You're going to be on their radar screen. So if you weren't careful before and weren't aware of the rules of the road, you need to get cracking and understand the rules at both the state and federal level." **MMLR**

Questions or comments should be directed to the editor at: reni.gertner@mamedicalaw.com

Health employers grapple with new disability law

Continued from page 1

abled workers.

In the past, courts have interpreted the definition of disability narrowly, but the new Act explicitly rejects those interpretations and is expected to lead to an uptick in employees arguing they are disabled under the law.

Some attorneys say that under the new law, health care providers may be held to a higher standard than other employers when it comes to finding a reasonable accommodation for a disabled employee because of their expertise in evaluating medical conditions and solving medical problems.

Even though Massachusetts state disability law was already broader than the older federal law, the new law clarifies some areas, said Dahlia Rudavsky, a partner with Messing, Rudavsky & Weliky in Boston.

Here are some key aspects of the new federal law:

- The law clarifies that the definition of "disability" is to be broadly construed;
- The law states that medications or corrective measures (other than ordinary eyeglasses) should not be taken into account when determining whether an individual has a "substantial impairment."
- It lowers the burden for an individual claiming he or she was "regarded as" disabled for purposes of being covered under the new law;
- Impairments that are episodic or in remission are covered if they limit a major life activity;
- Major life activities include bodily functions, such as immune disorders, cancer, organ functions or reproductive problems; and
- An individual need not show that an impairment restricts multiple activities.

The EEOC has not released guidelines on implementing the law yet, but their regulations are expected to shed more light on how various definitions will be interpreted.

Higher standard for providers?

As a result of the new law, the focus will shift from whether an individual is disabled to whether the employer provided a reasonable accommodation.

"My hunch is that courts are going to look at hospitals as possibly having a higher burden in terms of providing a reasonable accommodation," said Daniel Bretz, an attorney at Clark Hill in Detroit who represents employers.

Eve Horwitz, an attorney with the Archstone Law Group in Waltham, Mass., which focuses on health care and high-tech, agreed.

"My hunch is that courts are going to look at hospitals as possibly having a higher burden in terms of providing a reasonable accommodation."

— Daniel Bretz

does not require someone to come in and sit in a cubicle. An individual can do it online and e-mail it in. In hospitals, there are a variety of jobs that may not require an employee to show up," said Bretz.

What health care employers should do now

Health care employers should be providing training to first-level managers and supervisors to avoid comments about an employee's condition or knee-jerk decisions that an employee is not disabled.

"Managers need to understand the [new disability law] and what is demanded. Derogatory remarks or assumptions about

somebody's position can be the proverbial smoking gun," said Bretz, who noted that some courts have said the mere failure to train can justify an award of punitive damages.

Robert Silverstein, a principal at Powers, Pyles, Sutter & Verville in Washington, D.C., who practices in the areas of disability and health care law, also recommends that employers have a "go-to" person for disability issues so that there is centralized expertise.

"It's just a good idea so that if somebody wants to file a complaint, they know who to go to and if there's a question you're not just flying by the seat of your pants," he said.

Employers should also review employees' job descriptions, which will be important in determining whether an individual can perform the essential functions of the job.

And Silverstein suggests that employers stay up to date on the different technologies or tools that exist for providing low cost accommodations for various disabilities. **MMLR**

Questions or comments should be directed to the writer at: sylvia.hsieh@lawyersusaonline.com



istockphoto.com

Recommend a Life Saving Choice for Your Patient and Her Baby.



Experienced
Simple
Affordable
Local

*\$800 Grants
Now Available*

Your Patient Can Enroll
Today And Receive
An \$800 Grant

Enroll online at
www.cordbloodbank.com
or over the phone at
888.700.2673



Diseases That Can Currently Be Treated By Cord Blood

Stem Cell Disorders

- Aplastic Anemia (Severe)
- Fanconi Anemia
- Paroxysmal Nocturnal Hemoglobinuria (PNH)

Acute Leukemias

- Acute Lymphoblastic Leukemia (ALL)
- Acute Myelogenous Leukemia (AML)
- Acute Biphentotypic Leukemia
- Acute Undifferentiated Leukemia

Chronic Leukemias

- Chronic Myelogenous Leukemia (CML)
- Chronic Lymphocytic Leukemia (CLL)
- Juvenile Chronic Myelogenous Leukemia (JCML)
- Juvenile Myelomonocytic Leukemia (JMML)

Myeloproliferative Disorders

- Acute Myelofibrosis
- Agnogenic Myeloid Metaplasia (myelofibrosis)
- Polycythemia Vera
- Essential Thrombocythemia

Myelodysplastic Syndromes

- Refractory Anemia (RA)
- Refractory Anemia with Ringed Sideroblasts (RARS)
- Refractory Anemia with Excess Blasts (RAEB)
- Refractory Anemia with Excess Blasts in Transformation (RAEB-T)
- Chronic Myelomonocytic Leukemia (CMML)

Lymphoproliferative Disorders

- Non-Hodgkin's Lymphoma
- Hodgkin's Disease
- Prolymphocytic Leukemia

Liposomal Storage Diseases

- Mucopolysaccharidoses (MPS)
- Hurler Syndrome (MPS-IH)
- Scheie Syndrome (MPS-IS)
- Hunter's Syndrome (MPS-II)
- Sanfilippo Syndrome (MPS-III)
- Morquio Syndrome (MPS-IV)
- Maroteaux-Lamy Syndrome (MPS-VI)
- Sly Syndrome, Beta-Glucuronidase Deficiency (MPS-VII)
- Adrenoleukodystrophy
- Mucopolipidosis II (I-cell Disease)
- Krabbe Disease
- Gaucher's Disease
- Niemann-Pick Disease
- Wolman Disease

Histiocytic Disorders

- Familial Erythrophagocytic Lymphohistiocytosis
- Histiocytosis-X
- Hemophagocytosis

Phagocyte Disorders

- Chediak-Higashi Syndrome
- Chronic Granulomatous Disease
- Neutrophil Actin Deficiency
- Reticular Dysgenesis

Congenital Immune System Disorders

- Ataxia-Telangiectasia
- Kostmann Syndrome
- Leukocyte Adhesion Deficiency
- DiGeorge Syndrome
- Bare Lymphocyte Syndrome
- Omenn's Syndrome
- Severe Combined Immunodeficiency (SCID)
- SCID with Adenosine Deaminase Deficiency
- Absence of T & B Cells SCID
- Absence of T Cells, Normal B Cell SCID
- Common Variable Immunodeficiency
- Wiskott-Aldrich Syndrome
- X-Linked Lymphoproliferative Disorder

Inherited Platelet Abnormalities

- Amegakaryocytosis / Congenital Thrombocytopenia

Plasma Cell Disorders

- Multiple Myeloma
- Plasma Cell Leukemia
- Waldenstrom's Macroglobulinemia

Inherited Erythrocyte Abnormalities

- Beta Thalassemia Major
- Pure Red Cell Aplasia
- Sickle Cell Disease

Other Inherited Disorders

- Lesch-Nyhan Syndrome
- Cartilage-Hair Hypoplasia
- Glanzmann Thrombasthenia
- Osteopetrosis

Other Malignancies

- Breast Cancer
- Ewing Sarcoma
- Neuroblastoma
- Renal Cell Carcinoma

World Headquarters
153 Needham Street, Newton, MA 02464
617.244.3933 or 888.700.2673
www.cordbloodbank.com

NE♂CBB
NEW ENGLAND CORD BLOOD BANK, INC.

Saving Cord Blood.
Saving Lives.