physician about off-label uses, the rep can do no more than to refer the doctor to someone at the company with additional training, often called a medical science liaison, and usually someone with a clinical background, such as a nurse, a pharmacist, or even a physician.

In the recent Caronia case, the drug rep broke these rules. He promoted the drug for off-label uses to a physician who was a government informant. The Caronia court noted that, if information on off-label uses is withheld from physicians, the public could be harmed. FDA elected not to appeal the case.

"In the wake of Caronia, companies will probably proceed cautiously. FDA law remains substantially intact," says McMenamin. "Caronia is good law only in the Second Circuit: New York, Connecticut, and Vermont."

FDA rules stand

Even there, untruthful or misleading information is not protected, and FDA's rules on labeling, misbranding, and adulteration still stand. Nevertheless, the decision eventually could help physicians who prescribe medications off-label because, at least in the Second Circuit, drug companies might believe they face a lower risk of prosecution for making information on off-label uses more readily available.

"That information that could help physicians make better judgments about therapy," says McMenamin.

While the decision involves communication between regulated industry and the medical profession, it also has some potential implications for malpractice litigation, says McMenamin.

"I can imagine some confusion in the minds of jurors, if they hear about the seemingly inconsistent rule that although the doctor is at liberty to write for the product for whatever reason he thinks appropriate, the company is not allowed to promote it except for government-approved indications," he says.

The ruling could make it easier for physician defendants to convince jurors that that off-label use isn't necessarily a breach of the standard of care, says McMenamin. "Doctors write off label all the time, and in fact, in certain situations doing so may be required by the standard of care," he says.

If a drug's off-label use is admissible, the plaintiff's attorney likely would emphasize the demonstration of safety and efficacy that the FDA insists on before it allows a drug to be marketed in the United States, says McMenamin. "The expert would say, 'The indication is not on the label for a reason. No one has ever satisfied FDA that it is any good for Condition X, yet this maverick doctor over there wrote this script, and my client came to harm,'" he says.

The defense then would need to explain that many times, off-label use is not only appropriate but required, and that the FDA approval process is slow and cumbersome, says McMenamin. The defense also could point out to jurors that Medicare pays for off-label uses of medications, he says.

"So it's not only accepted by the profession as the standard of care, it's accepted by a third party payer — even though another branch of the U.S. government is telling pharmaceutical houses that they are not allowed to advertise this information," says McMenamin.

Executive Summary

Physicians might find it easier to prove that off-label use of medications wasn't a breach of the standard of care, due to a recent court ruling. Defense lawyers can point out the following:

- ✦ In some cases, off-label use is required by the standard of care.
- ✦ The approval process is slow and cumbersome.
- ✦ Medicare pays for off-label uses of medications.

Reference

1. United States v. Caronia, 703 F.3d 149 (2d Cir. December 3, 2012

SOURCE

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Parent removing child AMA? Know legal risks! MD protecting child is easier to defend

(Editor's Note: This is a part one of a two-part series on legal risks involving parents refusing medical care for a child. This month, we cover how to document. Next month, we cover reporting obligations.)

Was a physician attempting to protect a child from harm due to a parent's refusal of care? This scenario is much more defensible, from the point of view of malpractice insurers and defense attorneys, than defending a medical negligence case against the physician when a child suffers as a result of the naïve decision of the parent, says **John W. Miller II**, a malpractice insurance broker and principal at Sterling Risk Advisors in Marietta, GA.

"The struggle between parental autonomy and child welfare occasionally falls in the lap of physicians," says Miller. "Physicians should not be fearful of the legal repercussions of advocacy for their pediatric patients."

Executive Summary

Physicians should not fear legal repercussions of advocacy for their pediatric patients when protecting a child from harm by a parent's refusal of care. Physicians should consider:

✦ documenting the parent's responses;
✦ documenting a parent's awareness of risks and ability to communicate;
✦ writing `against medical advice' discharges at a sixth-grade literacy level.

Many times, parents project guilt over a bad outcome that occurred due to their leaving against medical advice (AMA) onto physicians and decide to file a malpractice suit, says Miller. "The defense 'I tried to warn them and they ignored my advice' often works to sway juries in adult AMA cases," says Miller. "The same juries may hold the physician responsible in a pediatric case, because he or she should have been an ardent advocate for the pediatric patient that cannot protect him or herself."

Miller says that generally, physicians dealing with parents who wish to sign their children out AMA should go through this list of questions and document the parent's responses just as they would if faced with a patient refusing treatment:

• Does the parent understand and appreciate the diagnosis, prognosis, and the likelihood of risks and benefits of leaving the hospital?

• Is the parent aware of the alternatives to treatment in the hospital and the risks and benefits associated with these?

• Can the parent make and communicate a choice?

• Can the parent articulate a reason for the refusal that is consistent with his or her values?[1]

"Positive responses to these questions make the claim more defensible," says Miller. "Any negative answers to these questions raises the stakes for defending a physician's inaction." He adds that physicians should be mindful of the literacy level of parents signing their children out AMA. "Many of the malpractice insurers now encourage physicians to write their AMA discharges at the sixth-grade level," says Miller.

Medical Mutual Insurance Company of North Carolina partnered with Health Literacy Innovations after a 2007 North Carolina Institute of Medicine report challenged malpractice carriers to incorporate health literacy education and effective communication skills into their risk management training.

"They've found that tailoring AMA documents to the appropriate reading level has assisted their physicians in providing effective communication to a population of patients who need the education of the risks and benefits posed by an AMA discharge the most," says Miller. ✦

Reference

1. Lo B. Resolving Ethical Dilemmas: A Guide for Clinicians, Second ed. New York, NY: Lippincott; 2005. ✦

COMING IN FUTURE MONTHS

✦ Why handoffs are coming up in malpractice claims

✦ Factors make it likely MD will be dismissed from suit

✦ Little-known legal risks of hearing-impaired patients

✦ Pros and cons of using captive malpractice insurers

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After reading *Physician Risk Management*, the participant will be able to:

- describe the legal, clinical, financial, and managerial issues pertinent to physician risk management;
- explain the impact of risk management issues on patients, physicians, legal counsel, and management;
- identify solutions to risk management problems for physicians, administrators, risk managers, and insurers to use in overcoming the challenges they face in daily practice.

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.

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2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.

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