The following closed claim study is based on an actual malpractice claim from TMLT. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician’s defensibility. The ultimate goal in presenting this case is to help physicians practice safe medicine. An attempt has been made to make the material less easy to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.

Presentation
A 25-year-old woman came to the emergency department (ED) complaining of epigastric pain for approximately one hour before arrival. Her history was remarkable for a vaginal delivery five days before. She denied fever, nausea, vomiting, or diarrhea. She also denied chest pain. Lab results indicated her WBC was 10,700 and hemoglobin was 12. A chest x-ray was done and reported as normal. Abdominal x-rays were read as non-specific, but the ED physician was concerned about free air.

Physician action
The ED physician consulted with the radiologist responsible for coverage to interpret imaging studies via teleradiology. A CT scan to identify or rule out free air in the abdomen was recommended. The radiologist reviewed the CT and ruled out free air. A family physician admitted the patient with differential diagnoses of acute pancreatitis, gallstones, peptic ulcer disease, and perforation of a peptic ulcer.

The following morning, another radiologist on duty at the hospital performed a complete review of the abdominal CT. She reported the findings as normal in the final report. She also reviewed the chest x-ray and reported cardiac size and pulmonary vascularity as normal.

Ultrasound was ordered and found to be positive for gallstones. The attending physician consulted with a general surgeon. The patient complained of excruciating pain and IV pain medication was ordered. Later in the day, the patient became unresponsive and was resuscitated. Labs drawn during this time revealed hemoglobin of 8.4. Her blood pressure was 87/50 mm/Hg and respirations 30. She felt moist and complained of being cold. It was thought that the patient coded because she had received too much pain medication.

Repeat lab work revealed hemoglobin of 7.4 and hematocrit 21.5. The attending physician ordered the transfusion of three units of blood. The patient continued to complain of persistent mid-epigastric pain. A repeat ultrasound revealed no evidence of free fluid in the pelvis.

On the afternoon of her second day in the hospital, 40 hours after admission, the patient suffered a cardiopulmonary arrest and died. The autopsy revealed a dissecting thoracic aorta beginning just above the aortic valve with a “blow out” in the distal thoracic aorta. Cause of death was listed as an exsanguinating hemorrhage.

Allegations
The plaintiffs in this case filed claims against the radiologist who reviewed the preliminary CT for the ED physician, the attending physician, and the radiologist who completed the final review and report of the CT scan. The plaintiffs alleged that the first radiologist failed to properly interpret the CT scan. They alleged that the second radiologist failed to properly interpret the abdominal CT scan and failed to recommend additional studies to confirm or rule out aneurysm. The plaintiffs alleged that the attending physician failed to order repeat studies, and when the patient arrested the first time, failed to recognize that it was due to hemorrhagic shock.

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rather than a drug reaction. They also asserted that he failed to recognize the signs and symptoms of internal bleeding.

Legal implications

Adding to the complexity of this case was the divergent opinions of physicians who reviewed the claim as consultants. A surgeon consultant acknowledged that the second radiologist failed to recognize the distal aortic dissection, but noted several points in her defense. He stated that the standard of care does not require a physician, including a radiologist, to delineate any and all pathologies that could potentially occur, or are occurring, in a patient. A physician is charged with putting together the pieces of a puzzle and making a reasonable diagnosis.

A radiologist consultant stated that after reviewing the films, it was clear the patient had an aortic dissection that was missed by the reporting radiologist. However, this reviewer acknowledged that it would be easy to miss such an important diagnosis because the index of suspicion for aortic dissection in a 25-year-old would be low or to the point of not being considered. According to this consultant’s report, “the aorta is normal in diameter but shows a subtle intimal flap extending at least from the lower thoracic aorta to the infrarenal abdominal aorta. The contrast density is too high on the windows provided, thus making the detection of the flap difficult. Impression: Aortic dissection of the abdominal and lower thoracic aorta. It probably extends into the upper thoracic aorta which could be confirmed by a chest CT.”

The defendant radiologist failed to note or comment on the presence of the intimal flap in the upper slices of the descending aorta. In deposition she acknowledged that the intimal flap was apparent and is diagnostic of an aortic dissection. She further stated that the treating physicians had cause to rely on her interpretation of the CT scan and this affected their treatment decisions and search for an accurate diagnosis.

Disposition

The claims against the first radiologist and the attending family physician were closed without indemnity payment. It was felt that the second radiologist had a less than 50% chance at a successful defense based on her deposition testimony. Added to this was the sympathy this case would generate pursuant to the death of a 25-year-old mother with a one-week-old infant. After settlement discussions and mediations, this claim was settled on behalf of the defendant radiologist.

Risk management considerations

When one considers the myriad of physician specialties in health care today, those who practice radiology experience the impact of hindsight almost without exception when claims are filed against them. The outcome is known and when a colleague reviews the study in which it is alleged something was missed, generally what was not seen at the point of care can now be identified. One radiologist described this as the “where’s Waldo?” syndrome. Waldo is there somewhere and must be found. With hindsight and a known outcome, the opinions of the physician reviewers and expert witnesses are difficult to refute and lay the foundation to create bias.

The Physician Insurers Association of America collects closed claim data from more than 40 physician-owned insurance companies. PIAA radiology claims data reported by severity between 1985 and 2003 revealed patient death in almost 24% of the claims. For this group of claims, a payment resulted in 28.74% of the closed claims. More than 28% of the total indemnity paid on behalf of radiologists was for claims where the patient died. Errors in diagnosis was the most prevalent allegation reported (50.9%) against radiologists when the patient died.

Failure to diagnose is an error of perception. This physician took responsibility for missing the abnormality on the CT scan, and did not try to deflect blame on others. Perhaps those who practice radiology will ask — was she tired or in a hurry when she reviewed the scans? Did she rely on the preliminary read by a colleague? Was her reading environment noisy with frequent interruptions? Was the quality of the images satisfactory? These factors can affect the practice of any radiologist and need to be addressed when relevant.

Sources


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The FDA in 2007: criticism, caution, and confusion

by Barbara Rose and Anna Tauzin

It seems safe to say that many physicians and a well-informed segment of the population have experienced confusion and sometimes distrust regarding the actions of the Food and Drug Administration (FDA) in recent years. Drugs and devices have been approved as safe and subsequently withdrawn, sometimes in quick succession to the dismay of physicians and patients. In the case of silicone gel breast implants, the implants were approved, pulled off the market, and then approved again.

This article will address the mission, responsibility, and decisions of the FDA in recent years; its impact on the delivery of health care, physician confidence, and patient safety; and ways to stay informed and react in a timely manner when the care of your patient(s) requires a change.

History

Following the exposure of hazards in the meat-packing industry, Congress passed the Federal Food and Drugs Act in 1906. The law required adequate labeling of food and drugs, specifically that the label could not be incorrect or misleading. However, deceptively packaged products continued to materialize.

A more stringent act was introduced in June 1938, bringing cosmetics and medical devices under the FDA’s control. It required drug labels to provide directions for safe use. The act also required that new drugs meet pre-market approvals, forcing the manufacturers to prove to the FDA that their product was safe before being approved for public use.

In the last quarter-century, regulation of food on planes, radiation-emitting products, and pre-market licensing for therapeutic agents have been added to the list of FDA responsibilities. The administration is also accountable for post-market monitoring and recall authority of medical devices. Through decades of change, the FDA strives to adhere to its mission statement, found at www.fda.gov.

“The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.”

Recent issues

Disrepute has tainted the FDA in recent years. Critics have asked if the FDA is losing sight of its responsibility to the public. Is the FDA too anxious to push certain drugs or products through the approval process without sufficient research?

The most recent and media-saturated issue involves Merck and their anti-inflammatory drug Vioxx (rofecoxib). A company-sponsored trial from 2004 showed that patients who took the medication for more than 18 months were at an increased risk for a heart attack or stroke. Following this trial, Merck voluntarily recalled the drug. However, later evidence suggested that the FDA knew about the increased risk long before Merck’s recall.

According to Dr. Richard Horton, editor of The Lancet, “In the case of Vioxx, the FDA was urged to mandate further clinical safety testing after a 2001 analysis suggested a ‘clear-cut excess number of myocardial infarctions.’ It did not do so. This refusal to engage with an issue of grave clinical concern illustrates the agency’s in-built paralysis, a predicament that has to be addressed through fundamental organizational reform.”

In June 2006, longtime FDA critic Senator Charles Grassley of Iowa said, “I’m fed up with resistance from the bureaucracy. It’s been one excuse after another. Practices and policies have changed from one day to the next. Files available one day become ‘confidential’ overnight. A line agent isn’t allowed to tell his story, even though line agents have been made available in other cases.” (Line agents are domestic representatives to foreign pharmaceutical companies. The FDA requires that all foreign pharmaceutical companies who import drugs into the U.S. appoint a domestic representative through whom all communication with the FDA takes place.)

Senator Grassley, in a follow-up letter from September 2006, expressed concern about the FDA’s handling of pre-market review and post-market surveillance of drugs, biologics, and devices. Grassley is not the only one who has noticed a problem within the FDA. Scientific journals, the Government Accountability Office (GAO), the Institute of Medicine, and current and former FDA employees have all expressed their dissatisfaction with the FDA’s leadership.

Said Senator Grassley, “The FDA needs to distance itself from the industry and return to its role as regulator, not a facilitator. Despite findings from a Merck study that heart attacks were five times higher for Vioxx patients than for patients on another drug, nearly two years passed before label changes were made. The overriding concern of the FDA should have been the health and safety of the American people. However, while the FDA was negotiating label changes with the company, patients and doctors remained largely unaware of the cardiovascular risks.”

Risk management considerations

How do physicians manage the almost daily reports regarding FDA actions, notices to pharmaceutical companies, alerts, recalls, etc.? Ultimately, the responsibility for understanding and keeping up with this information falls squarely on the shoulders of physicians, who may not be given enough information to help patients make informed decisions. With this in mind, the following risk management practices may help avoid patient harm and possible litigation related to the prescription and use of FDA-approved products.

• Physicians need to be proactive and stay informed on a daily basis. If you have not done so, sign up to receive the FDA’s MedWatch notices via email or RSS feed. (Visit http://www.fda.gov/medwatch/continued on page 4
for complete instructions.) Open all of your mail. GE Healthcare mailed a letter to physicians in December 2006 informing them of the reports on nephrogenic fibrosing dermopathy after imaging studies with Gadolinium.

- Require a comprehensive medical history from your patients including their use of illegal drugs, prescription pain medications, and OTC products (analgesics, vitamins, herbs, weight loss products). Patients may be poor historians or may consider their use of herbal medications unimportant. (For example, use of St. John’s Wort is contraindicated in patients who will be undergoing general anesthesia.)

- Review all current information about drugs, medical products, and devices that are part of your practice. It is unwise to base treatment recommendations on the abbreviated information provided by a marketing representative.

- When discussing treatment decisions and options with patients, remember to include the most current information available along with the known risks. Document this exchange and the patient’s informed choice in the medical record.

**Sources**


**Sample alerts from MedWatch**

The FDA communicates their safety and recall information to physicians through several channels, including emails to those who subscribe to the MedWatch E-list. The following is a sample of notices sent out in 2006 and early 2007:

- failure of implanted cardiac defibrillator (ICD) devices;
- gadolinium used in imaging studies and reports of nephrogenic fibrosing dermopathy;
- recall of the Davol/Bard Composix Kugel large sized patch;
- an alert about the antibiotic Ketek and links to severe liver damage;
- potential side effects of antidepressant drug use in children and adolescents generating a Black Box warning;
- an alert about drug-eluting stents; and
- the dangers of several over-the-counter drugs (analgesics, antipyretics, cough and cold medications for infants and children).