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PROFESSION



An injectable steroid from the New England Compounding Center was implicated in a deadly fungal meningitis outbreak that killed 45 patients and sickened hundreds across the country. Some physicians now are facing lawsuits from patients over the outbreak. [Photo by AP Wide World Photos]

Physicians entangled in tainted drugs lawsuits

Doctors often are sued after medical product disasters, such as a recent meningitis outbreak linked to a compounding pharmacy. How can they reduce their risks?

By ALICIA GALLEGOS, amednews staff. **Posted Feb. 11, 2013.**

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A deadly meningitis outbreak involving tainted steroid shots that has killed at least 45 people and sickened nearly 700 more has led to an explosion of lawsuits against the compounding pharmacy linked to the infections. But with the New England Compounding Center now in bankruptcy, patients and their families are searching for alternative legal relief — such as from the physicians who prescribed the injections.

So far, several New Jersey doctors face lawsuits because of the outbreak, and legal experts expect hundreds more suits against doctors, clinics and hospitals connected to the outbreak. Patients have sued doctors successfully in the past after being injured by medical products under claims such as failure to warn, medical negligence and product liability. The suits can mean faster and larger payouts for plaintiffs than those against drug or device makers.

“The only remedy really in these injury cases is money,” said David A. Oliver, a Texas-based civil defense attorney with a biochemistry background. “You’ve got an entity that has caused a lot of harm that does not have anywhere near the resources to compensate all who are harmed. The plaintiff lawyers [are going to say], ‘Let’s look and see if we can cast blame on whoever facilitated this bacteria going from one step to the next.’ ”

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The New England Compounding Center, based in Framingham, Mass., recalled three batches of preservative-free steroid injections in September 2012 after widespread reports of fungal meningitis. More than 70 health care clinics and hospitals in 23 states received the shots, according to Centers for Disease Control and Prevention data. An estimated 14,000 patients were exposed to the contaminated steroid. Amid hundreds of lawsuits, the compounding center in December 2012 filed for Chapter 11 bankruptcy. The company said it wants to establish, subject to court approval, a fund to pay claims made by parties affected by “this great tragedy.”

Success suing physicians

In the aftermath of large-scale medical product injuries, it's not uncommon for doctors to be drawn into the ensuing litigation, said George F. Indest III, president and managing partner of The Health Law Firm, based in Orlando, Fla.

“When you think back to the big medical products liability cases of the recent past — breast implant litigation, fentanyl patch litigation, defective drug and pharmaceutical cases — once the defects become known, physicians are generally held to be liable for using the product if there is an adverse outcome,” he said.

A 1999 study in *Clinics in Plastic Surgery* detailed lawsuits filed against physicians in the early 1990s after widespread claims of defective breast implants. While implant manufacturers also faced suits, plaintiffs used individual claims to push doctor-defendants into quick and lower settlements that could help finance the more serious legal effort against the manufacturers, said the article, written by Charles O'Brien, a founder of The Doctors Company, a physician-owned medical liability insurer.

In recent years, plaintiffs have won lawsuits against physicians over medication and device mishaps:

- In July 2012, a California jury ordered a physician and manufacturer to pay \$5.5 million to a woman injured by a vaginal-mesh implant. Jurors found the manufacturer 60% at fault for the woman's injuries and the doctor who surgically implanted the device 40% responsible. The case is among hundreds of lawsuits asserting organ damage from the mesh implants.
- Also in July 2012, a San Diego court granted a \$7.5 million award to a patient against her doctor and a manufacturer after she allegedly acquired frostbite from using a cold-therapy medical device.
- In a 2011 case, physicians with the Rehabilitation Institute of Chicago, without admitting wrongdoing, agreed to pay a \$3.7 million settlement to the family of a patient who allegedly died after being administered a fentanyl patch. The woman's husband sued the institute and its doctors for negligence for prescribing the patch. Overdoses linked to defective fentanyl patches have led to dozens of lawsuits, primarily against Johnson & Johnson and its subsidiaries.

Holding a doctor liable in such cases hinges on whether the physician could have prevented the patient's injury in some way, said Andrew C. Meyer Jr., a plaintiff's attorney based in Boston.

“If a doctor receives what they believe in good faith is an appropriately tested drug, they may not have responsibility,” said Meyer, whose firm represents several plaintiffs suing the New England Compounding Center. “Each case stands on its own facts.”

How doctors are vulnerable

Negligence is the most common claim used against doctors in cases of defective medications, Indest said. The assertion is that the physician breached the standard of care because he or she knew or should have known that the pharmacy was not meeting applicable standards in compounding the medications. Another legal theory is that the physician should have known that certain medications should not have been compounded, but rather obtained directly from a manufacturer.

“The mere fact of ordering and using the medications in large quantities from

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a compounding pharmacy [could] constitute substandard care,” Indest said.

Failure to warn is another frequently used claim in such cases, Oliver said. Plaintiff attorneys claim that the drug was foreseeably dangerous, and that a doctor should have alerted a patient to the risks. Related claims are failure to test, failure to sterilize and failure to enact quality control.

“What you have to do is show some independent fault,” Oliver said. “Not just that you gave a drug that was bad, but that you failed to do something you should have done.”

A lesser-known legal risk for physicians is that of product liability. The claim generally refers to the liability of any or all parties along the chain of product manufacture for damage caused by the product.

Physicians can be held under product liability scrutiny if they are deemed “sellers” of a product, said Alfred F. Belcuore, a Washington-based medical liability defense attorney. For example, if the steroid was itemized separately on a medical bill, an attorney could argue that a doctor was selling the product as opposed to providing a medical service, Belcuore said.

States vary in how they impose product liability claims, said Charles E. Joern Jr., a Chicago-based product liability defense attorney. For instance, California courts have repeatedly held that strict liability may not be imposed against health care professionals for drug or device injuries. Courts in Missouri, New Hampshire, New York and Pennsylvania have issued similar decisions.

Taking precautions to prevent liability

Doctors seriously should consider the costs and benefits of using a compounding facility and be sure the risks are worth it, said Michael E. Clark, vice chair of the American Bar Assn.’s Health Law Section. The fact that compounding centers are not regulated by the Food and Drug Administration makes them less legally secure than alternatives, he said. If such a facility must be used, doctors should warn patients of the dangers and record these conversations.

“You have to basically warn the patient this is not your normal drug that you get from a manufacturer in accordance with FDA approval,” he said.

Being sure of the credentials of all vendors and suppliers is also key, Indest said.

Complaints about a certain drug or the use of a facility should be taken very seriously, Oliver said.

“If somebody raises a valid concern, you need to address it and keep a record of how it was addressed,” he said. “If you don’t, somebody else, the plaintiff’s lawyers, they’re going to create the narrative. They’re going to create the story of why you didn’t do anything.”

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Quotable

What was said: "Whenever we get these reports from the CDC, we're reminded that although we do have the safest food supply in the world, it's not completely safe."

Who said it: William Schaffner, MD, chair of the Dept. of Preventive Medicine at Vanderbilt University School of Medicine in Nashville, Tenn., on the prevalence of foodborne illness in the U.S.

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