

1 of 1 DOCUMENT

Copyright 2009 Dolan Media Newswires
Missouri Lawyers Weekly

February 2, 2009

SECTION: NEWS

LENGTH: 1605 words

HEADLINE: Gadolinium law suits picks up pace

BYLINE: Correy E. Stephenson

BODY:

With almost 400 lawsuits already filed across the country, gadolinium litigation is heating up.

Gadolinium is used in contrast solutions to enhance the images when a patient undergoes magnetic imaging, such as an MRI or MRA (magnetic resonance angiography, in which the contrast agent is injected to look at blood vessels in various parts of the body).

The plaintiffs claim that the gadolinium-based contrast agents used when they underwent magnetic imaging procedures caused nephrogenic systemic fibrosis, a debilitating disease with no cure.

Nephrogenic systemic fibrosis is a rare disorder that causes scarring or fibrosis of the skin and internal organs. Symptoms include red or dark patches of skin or thick, coarse and hard patches of skin; generalized muscle weakness; stiff joints; and burning, itching or swelling skin.

Symptoms may appear as early as two days after receiving an injection or up to 18 months after exposure.

The vast majority of these cases involve people whose kidney function was already compromised when they received gadolinium injections.

Most cases have been consolidated into a multidistrict litigation before U.S. District Court Judge Dan Polster in the Northern District of Ohio, but some remain in state court in California, New Jersey and here in Missouri, according to Peter W. Burg, co-chairman of the plaintiffs' steering committee and a partner at **Burg Simpson** in Englewood, Co.

Peter Brodhead, a partner at Spangenberg, Shibley & Liber in Cleveland and the plaintiffs' liaison counsel for the multidistrict litigation, predicted that 500 to 1,000 cases will ultimately be filed.

Brodhead, who has about 25 cases, said the plaintiffs are alleging that the defendants' products were not adequately designed, and they failed to warn about the dangers of using them.

Four manufacturers of gadolinium agents are named as defendants in the suits: GE Healthcare, Bayer HealthCare Pharmaceuticals, Tyco/Mallinckrodt and Bracco Diagnostics.

Heidi Levine, a partner at DLA Piper in New York and the lead counsel for GE Healthcare, was the only defense lawyer to respond to a request for comment.

In a statement, she expressed concern about the health of patients diagnosed with nephrogenic systemic fibrosis but said plaintiffs' attorneys "face a significant challenge in proving their legal case" because "both the causes of NSF and the mechanism of injury remain unknown. "

Missouri cases on hold

Gadolinium cases filed or pending filing in Missouri are relatively few at the moment, but their numbers are expected to grow, according to Dave Peterson, managing partner with Peterson & Associates in Kansas City.

"We have around 25 cases waiting to file," Peterson said of his firm's work on the issue. "We'll file in either state or federal court, but I want to wait and see how other litigation will play out first. "

An important decision he is awaiting is in the *Levine v. Wyeth Pharmaceuticals* case going before the U.S. Supreme Court, expected to be handed down early this year. Wyeth's defense in that case depends on pre-emption, the idea that FDA approval of a pharmaceutical overrides state law claims challenging safety, efficacy or labeling of the product.

"We could get adverse pre-emption rulings in some courts and not others," he said. "But we are hoping that pre-emption doesn't bar any of these cases, and we can proceed to trial. "

Peterson said he doubts there will be a very large number of other Missouri gadolinium cases, but he does think there will be more.

"This isn't like a fen-phen or Vioxx situation, where 50,000 or 100,000 patients are impacted," he said. "It'll be a more limited volume. "

Kristine Kraft, counsel with downtown St. Louis -based Schlichter Bogard & Denton, said her firm has entered one gadolinium case in St. Louis.

The case, filed at the end of October, was on behalf of a 70-year-old man diagnosed with nephrogenic systemic fibrosis. There are two primary defendants: Bayer HealthCare Pharmaceuticals, which makes Magnevist, and St. Louis-based Mallinckrodt, maker of Optimark.

Kraft's firm was able to show that the client received both in MRA procedures, which is an off-label use of the products. According to Kraft, when a gadolinium-based agent is used in an MRA, the dose is typically three times higher than that used in an MRI. So there's potential for a much larger amount of the toxin to enter the patient's system.

Kraft said her firm's gadolinium case has not yet reached the deposition phase.

"We are reviewing documents Mallinckrodt has produced in conjunction with the multidistrict litigation," she said. She said she has searched for other gadolinium cases pending in St. Louis but has not found any.

FDA warnings

The product usually adversely affects people who already have chronic kidney failure at the time gadolinium-based agents are administered.

"Gadolinium is a metal ion that's very toxic if it's allowed to be released into the bloodstream," Kraft said. "The binding agent that's used in these products is insufficient, causing that release to happen and poisoning the body. "

When a patient is in renal failure, his kidneys can take 30 to 120 hours to flush the toxin from the body, as opposed to the 90 to 120 minutes it takes a person with normal kidneys, according to Kraft.

In June 2006, the FDA issued its first warning about the effects of gadolinium contrast agents on people with renal failure. The agency urged physicians to screen patients for kidney problems before using gadolinium in MRIs.

"The interesting thing is, in Europe, food and drug officials have put in place warning labels contraindicating these agents in all patients with chronic renal failure, so doctors cannot use them in those cases," Kraft said. "Here in the U.S., it's not that blatant a product warning. Labeling here basically says that doctors can only use it in renal failure patients if it's essential to the case. "

According to a December 2006 public health advisory, the FDA had received 90 reports of patients with moderate to end-stage kidney disease who had developed nephrogenic systemic fibrosis after being exposed to gadolinium.

In May 2007, the FDA requested that the manufacturers of gadolinium contrast agents include a warning on their product labels highlighting the risk posed to patients with kidney problems.

The agency also set up a program for health care providers to report instances of nephrogenic systemic fibrosis. (For more information on gadolinium, go to www.fda.gov/cder/drug/infopage/gcca/default.htm.)

Potential issues for trial

The parties are still in the discovery stage of litigation but have set an aggressive calendar with the goal of a first trial around May.

Judge Polster has asked each side to select 10 cases by mid-November to be "eligible trial pool cases" that will undergo case-specific discovery.

By next May, the parties will strike five of the other side's 10 cases; the remaining 10 will be potential trial cases.

Both sides are reviewing documents and beginning the deposition process, especially in cases in which the plaintiffs are close to death.

"One of the problems about this disease is that while there are some manifestations in the skin, that doesn't tell us what is going on with the internal organs. We have had a number of clients who appeared to be stable and then dramatically deteriorated," Burg said.

To date, the parties have not engaged in any meaningful settlement talks, said Burg, whose firm has about 100 cases.

Writer Julia Johnson contributed to this story.

Key issues will include:

Identifying the correct defendant

Heidi Levine, lead counsel for GE Healthcare, said plaintiffs' attorneys must confirm a diagnosis of nephrogenic systemic fibrosis for each client and "face a difficult problem in identifying whether a specific contrast agent, if any, was used in any given diagnostic procedure. "

"It is not always readily apparent from a patient's medical records which gadolinium contrast agent was used, so we sometimes have to do further investigation to find out," said Peter Brodhead, plaintiffs' liaison counsel with Spangenberg, Shibley & Liber.

Typically, the radiology department can determine which contrast agents it was using at the time a patient received an MRI.

"In many cases we are directing discovery to the defendants, who are responding as to whether or not they supplied their contrast agents to the particular facilities," Brodhead said.

Pre-emption.

The defendants have raised a pre-emption defense, but **Peter W. Burg**, partner at **Burg Simpson** in Englewood, Colo., said plaintiffs' **lawyers** aren't concerned.

"Pre-emption is in the background of any pharmaceutical litigation these days," he said, adding that both sides are keeping their eyes on Wyeth v. Levine, pending before the U.S. Supreme Court.

Gadolinium is approved for MRI use, but the FDA has not approved its use for MRAs.

Causation

As in any personal injury litigation, Brodhead expects issues to arise regarding causation.

Burg argues, however, the medical literature is "abundantly clear on the specific causation" between gadolinium-based agents and nephrogenic systemic fibrosis.

Because the overwhelming majority of those afflicted with nephrogenic systemic fibrosis already suffered from some form of kidney problem, this could affect potential damages.

Burg expects legal wrangling over life expectancy as well.

"I have a significant number of clients who already had kidney transplants who would be leading relatively normal, productive lives but for this disease," he said.

For links to court orders and more information on the litigation, visit the Web site for the plaintiffs' steering committee: www.gadoliniumpsc.org/.

LOAD-DATE: February 1, 2009