

## Local Attorney Reviews Digitek Recall Cases

The first call the attorney received was from a family whose loved one had died.

The family said doctors told them they weren't sure why the person had died. Then the family started to hear about a recall of the heart drug Digitek (digoxin), a drug the person had been taking.

That attorney, David Hill of the Memphis office of Nahon, Saharovich & Trotz PLC, declined to reveal any of the people involved because of confidentiality issues.

The firm hasn't yet filed a lawsuit related to the Digitek recall, but is considering several situations with clients.

"We have several clients whose cases we are reviewing," Hill said. "Once a suit has been filed on their behalf, we would be able to disclose those persons' names and the substance of their claims."

The law firm has sent the pills to a laboratory to be analyzed. They also have experts analyzing medical records for the people "who died or who were rendered ill because of this."

### Double dose woes

A nationwide recall was issued in April for the drug Digitek that is manufactured by Actavis Totowa LLC in its Little Falls, N.J., facility.

Digitek is a drug used to treat heart failure and abnormal heart rhythms.

The drug was recalled because it contained double the dose of the active ingredient, a mistake that could have various side effects for the patients taking them ranging from nausea and vomiting to death.

The double-strength pills pose a risk of digitalis toxicity, which can result in nausea, vomiting, low blood pressure, arrhythmia (abnormal heart rhythms), ventricular fibrillation (heart's electrical activity becomes disordered), atrial tachycardia (rhythm disturbance that arises in atria), bradycardia (resting heart rate of less than 60 beats per minute), heart attack, strokes and death.

The company has yet to say how long the manufacturing glitch went on, which would give patients and doctors some idea of time periods for which they should be concerned.

Numerous attempts to reach someone with Actavis Totowa were unsuccessful by press time.

A receptionist, who declined to identify herself, said the only person who could answer questions about Digitek was Ajordis Arnadottir, the company's media representative. But repeated attempts to reach Arnadottir were unsuccessful as well.

"As far as any types of dates of manufacture when these drugs might have been tainted, we haven't seen anything like that yet," Hill said. "So, we think it's something from fairly recent; here within the last two years, I would say for sure."

Digitek was approved by the U.S. Food and Drug Administration in 1999. But it's unclear if that's when the drug went on the market.

"I would assume this manufacturing defect is probably a fairly recent thing," Hill said. "But I'm certainly not going to assume that unless I can see some proof."

## **Pharmacist as messenger**

Despite the fact that the manufacturing glitch could lead to such dire consequences, there appears not to have been a rush to get information out to the public, Hill said.

Many people found out about it when they went to have their prescriptions refilled. The pharmacists, who had been informed of the recall, would then tell the patients, sending many of them into a panic because no one had told them before that point.

"One of the first people that contacted us brought in to our office a letter from their pharmacy," Hill said. "Their pharmacy had received a letter from the FDA saying there's been this voluntary recall of Digitek."

Some of the pharmacists would then send letters out to their customers telling them to contact their doctors as soon as possible.

Having such a malfunction could be a disaster for any type of patient, but it's especially dire for heart patients who already are on tenuous tracks, Hill said.

"Doctors take a long time, many times, in adjusting their drugs and adjusting their dosages and then balancing ... sometimes people with multiple health problems, balancing what all drugs they can take," he said. "And then all of sudden to have something like this come along and totally throw the balance off. You're taking someone who already has some heart problems and now you're giving them too much of the active ingredient, it's almost like pushing them right over the edge."

An Associated Press story reported earlier this month that Actavis was asking pharmacists and hospitals to return all prescription drug products made at one of its facilities because it did not pass health authorities' standards.

An inspection of the New Jersey facility by FDA officials "revealed operations which did not meet the FDA's or Actavis' standards for good manufacturing practices," read a statement issued by the company and printed in the story.

Numerous messages left at the FDA were not returned by press time.

The recall, only on the pharmacy and retail level, included about 65 prescription drugs.

Hill said there's no definitive timeline for when a lawsuit could be filed regarding the drug recall since they have to wait and see what all the reports will say.

***The Associated Press contributed to this story.***