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Minn. Ruling Saps Power Of Genetic Links In Food Suits

By Greg Ryan

Law360, New York (March 07, 2013, 8:09 PM ET) -- In nixing an infant formula contamination suit against Mead Johnson & Co. LLC last week, a Minnesota federal judge said a genetic test was insufficient to link the product to the illness — an unprecedented finding that could offer companies a new way out of foodborne-illness litigation.

U.S. District Judge Joan Ericksen granted summary judgment to Mead on Feb. 27 in a suit brought on behalf of an infant who allegedly suffered severe brain damage as a result of ingesting the company's Enfamil formula. Plaintiff Scott Johnson was the infant's legal guardian in the suit.

One of Johnson's experts, a former U.S. Centers for Disease Control and Prevention scientist, did not rebut Mead's assertion that a genetic test was unreliable, Judge Ericksen said. The test matched the strain of pathogen found in the infant to the strain found in two other infants who ingested Mead formula, but used only one enzyme to do so, rather than the CDC standard of two or three, according to the judge.

The test, known as a pulsed-field gel electrophoresis, or PFGE, analysis, is used widely in foodborne illness litigation. The decision may be the first time a PFGE analysis has been excluded as evidence because a judge deemed it unreliable, attorneys said. It opens the door for other companies to attack the reliability of PFGE analyses that use only one enzyme, which is still the standard for many state health departments, according to Faegre Baker Daniels partner Sarah Brew.

"Now defendants will be in a much better position to say, 'You may have a one-enzyme match, but that's not good enough,'" Brew said.

The extent to which PFGE analyses become vulnerable to challenge will depend on whether other courts follow Judge Ericksen, attorneys said. In the meantime, companies can try to use the decision as another way to discredit plaintiffs' experts.

"Not only do you have to look at their method for deciding the source [of contamination], but [you also have to consider] their method for testing," Oppenheimer Wolff & Donnelly LLP partner David Graham said.

In addition to convincing Judge Ericksen that the test was questionable, Mead successfully argued that Johnson's experts couldn't rule out the possibility that the pathogen that caused the injury, known as Cronobacter sakazakii, came from the water mixed with the formula or from the infant's home.

The decision contradicted a January ruling made by another Minnesota judge, U.S. District Judge John Tunheim, in a separate suit against Mead over an infant who allegedly contracted C. sakazakii from formula. Judge Tunheim refused to exclude testimony from the same CDC scientist who drew skepticism from Judge Ericksen, saying Mead's critiques should be raised on cross-examination of the scientist, not as the basis for his exclusion.

A lawyer for Johnson, Stephen Rathke of Lommen Abdo Cole King & Stageberg PA, said Thursday that his client would appeal the ruling to the Eighth Circuit. Judge Ericksen "interjected herself into matters which should go to the jury," he said.

A Mead spokesman declined to comment Thursday.

Attorneys emphasized that Judge Ericksen hadn't granted summary judgment on the basis of the perceived weakness of the PFGE analysis alone, but in tandem with her finding that Johnson couldn't rule out other sources for the C. sakazakii.

In addition, the Enfamil package that contained the formula fed to the infant had been used up and could not be tested. If a sample from the infant matched a sample from the package, it may not matter the PFGE analysis was performed with only one enzyme, attorneys said.

On the other hand, it may not be enough for an analysis performed with multiple enzymes to show a genetic match between the infant's sample and samples from other infants who had consumed Enfamil, according to attorneys. A plaintiff in that situation may still need evidence the Enfamil was consumed in the same time frame or originated from the same production lot to win in court.

In many outbreaks, health officials use PFGE analyses with multiple enzymes, or an even more reliable test known as a multiple-locus variable-number tandem repeat analysis, or MLVA, attorneys said. But the ruling should still serve as a reminder to plaintiffs that genetic tests are just a tool in foodborne illness suits, and one that needs to be supplemented with other evidence, they said.

"When you've got weak epidemiological evidence coupled with, relatively speaking, weak microbiological evidence, then you're going to have a problem," Fred Pritzker of Pritzker Olsen PA said.

Johnson is represented by Robert King, Stephen Rathke and Nick Dolejsi of Lommen Abdo Cole King & Stageberg PA.

Mead is represented by Anthony Anscombe, Margaret Daday, David Grycz and Karen Woodward of Sedgwick LLP.

The case is Johnson v. Mead Johnson & Co., case number 0:11-cv-00225, in the U.S. District Court for the District of Minnesota.

--Editing by Elizabeth Bowen and Katherine Rautenberg.