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Meningitis Suits Stand To Benefit From FDA Criminal Probe

By **Greg Ryan**

Law360, New York (October 18, 2012, 8:41 PM ET) -- If the U.S. Food and Drug Administration's recent raid of the pharmacy at the center of the ongoing meningitis outbreak leads to criminal charges, attorneys say they could bog down civil litigation brought by recipients of the outfit's steroids but ultimately help those plaintiffs prevail on their claims.

The FDA's Office of Criminal Investigations and members of the U.S. attorney's office in Massachusetts searched the New England Compounding Center's Framingham, Mass., facility Tuesday. Authorities have been tight-lipped about the nature of the investigation, and the warrant used to conduct the search remains under seal.

As the outbreak's death toll has climbed — the total increased to 20 on Thursday, and the number of illnesses to 257 — the number of personal injury lawsuits filed against the pharmacy has also risen. The suits are based in federal and state courts in Minnesota, Tennessee and elsewhere, and plaintiffs attorneys are soliciting clients from the 14,000 thought to have been potentially exposed to the tainted steroids.

A criminal case could frustrate plaintiffs' ability to gain access to key documents and witnesses, attorneys said. The FDA or other authorities might take the documents for their own use, and prosecutors might even seek to stay the civil proceedings, they said.

"If they did prosecute them, you'd probably see a situation where prosecutors would want to go first, in a sense, and get what they can from the defendant," said Marler Clark LLP managing partner Bill Marler.

Despite the potential delays, however, criminal charges would be a boon to plaintiffs, according to attorneys. In addition to the benefits a conviction or plea bargain would bring to civil suits, the mere existence of charges could deliver other advantages, they said. For instance, NECC owner Barry Cadden or other employees might plead the Fifth Amendment to avoid incriminating themselves.

"We can say, 'Look, he had a chance here to tell the truth, and he pled the Fifth. What's he hiding?'" said Ron Simon of the Houston-based firm Simon & Luke LLP, which is considering filing claims against the compounding center on behalf of clients.

The center shut down production at its facility and surrendered its manufacturing license after the outbreak began. If prosecutors decide to pursue charges, the NECC's precarious financial position would make its higher-ups an especially tempting mark, attorneys said.

"In a small, closely held company, a prosecutor would want to consider charging any

executives found to be involved in making deliberate misrepresentations about the sterility or efficacy of the product," said Paul Pelletier, a Mintz Levin Cohn Ferris Glovsky & Popeo PC attorney who investigated health care fraud as a member of the U.S. attorney's office in Florida.

Prosecutors could be looking to determine whether NECC higher-ups misrepresented the sterility or efficacy of the steroids in pamphlets and marketing materials they sent to customers, Pelletier said. Charges against the center could include mail fraud and wire fraud, he said.

It is unclear at this point whether authorities will pursue charges against the NECC and Cadden, but federal authorities' recent track record in bringing charges against the sources of outbreaks suggests there is no guarantee.

Marler told Law360 in August, for example, that the U.S. attorney's office in Colorado had opened a criminal investigation into Jensen Farms, whose cantaloupes were connected to a 2011 Listeria outbreak that killed at least 30 people. But no charges have been brought.

Peanut Corp. of America and its executives have not been charged criminally for a 2008-09 salmonella outbreak that led to more than 700 illnesses in 46 states, including at least nine deaths, though the U.S. attorney's office opened an investigation into the executives.

That outbreak prompted a congressional investigation that uncovered internal company emails that family members of the victims believe show former PCA chief executive Stewart Parnell knew the company was shipping peanuts tainted with salmonella.

The last major outbreak to result in criminal penalties, Marler said, was the 1996 E. coli outbreak linked to juice maker Odwalla Inc. The company pled guilty to 16 criminal charges and agreed to a \$1.5 million fine in 1998.

In that instance, federal authorities did not prosecute Odwalla for the death and illnesses resulting from the outbreak, but for its representations about the product, Marler said.

"It's not necessarily the act that causes a criminal fine or a conviction — it's either the cover-up or something else within the plant," he said. "Prosecutors are looking for a smoking gun ... as opposed to mold or E. coli in a product, which can be spun off as a mistake."

The evidence netted by the FDA and other authorities in their raid Tuesday will go a long way toward determining whether charges are brought against the compounding center, according to attorneys.

"Sometimes you have gross stupidity and actually write it down, and that's when you're dead in the water," Simon said.

--Additional reporting by Erin Coe. Editing by Kat Laskowski and Lindsay Naylor.

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