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Drug Companies Settle Mad Cow Contamination Claim

By **John Pacenti**

Nordion attorney Raymond L. Robin

Dania Beach-based BioAxone BioSciences Inc. has settled a lawsuit against a Canadian company it accused of derailing the development of a spinal cord injury drug with contaminated products that could cause mad cow disease.

BioAxone alleged in its federal negligence complaint that the Food and Drug Administration ruled its drug Cethrin could result in the deadly brain disease because of the tainted material provided by a subsidiary of Ottawa-based Nordion Inc.

The complaint sought $90 million in damages. Terms of the settlement were not disclosed, but Nordion said the settlement was "for a nominal amount." A company release said, "The settlement is expected to have a nonmaterial impact on Nordion's financial position."

BioAxone said it ordered a bacterial master cell bank in 2003 to be used in the testing of Cethrin, which was designated an orphan drug by the FDA. However, the company said what was supposed to be a sterile cell stock was tainted with beef extract and chicken feathers. As a result, testing failed, and Cethrin failed to get FDA approval.

The complaint said the master cell bank produced in a lab owned by Nordion and purchased by BioAxone was "contaminated with beef broth and avian products that cause human disease, including bovine spongiform encephalopathy," commonly known as mad cow disease. The fatal neurodegenerative disease easily passes to humans through the ingestion of nerve tissue from infected cattle. The lawsuit said the Nordion product would have posed a danger to patients in human trials.

BioAxone attorney Andrew Bryan Zelmanowitz of the Aronovitz Law Firm in Miami did not return a call for comment by deadline. A spokewoman for BioAxone refused to comment.

The company's website said Cethrin is a protein that promotes regeneration of damaged circuits in the spinal cord. The company states Cethrin has been tested on 48 patients in early-phase clinical trials designed to test safety and tolerability. Increased motor function was seen in some patients receiving the drug over control subjects after a year.

The settlement came after Nordion filed a motion for summary judgment in July. The two sides told U.S. District Judge Robert Scola in Miami on Sept. 24 that they had reached a settlement.

Nordion attorney Raymond L. Robin, a partner at Keller Landsberg in Fort Lauderdale, said the company was pleased with the settlement because the company had been reporting the $90 million damages claim on its quarterly financial reports.

Robin argued the negligence claim was barred by the statue of limitations and evidence showed there was no breach in the standard of care.

The basis for BioAxone's negligence lawsuit was its claim that it specifically requested no animal products be used in the preparation of the sterile stock of cells.

Nordion's motion for summary judgment said BioAxone's drug manufacturing subsidiary advised that the cell bank should be purchased from China.

The lawsuit filed in April 2012 said documents showed Nordion and its drug lab in Nebraska created the master cell bank using material purchased from China that was not animal free.

Nordion "followed explicit instructions and approval of (BioAxone) in the creation of the master cell bank," the motion read.