Conn. Joins Wave Of Suits Over Anti-Stroke Drug
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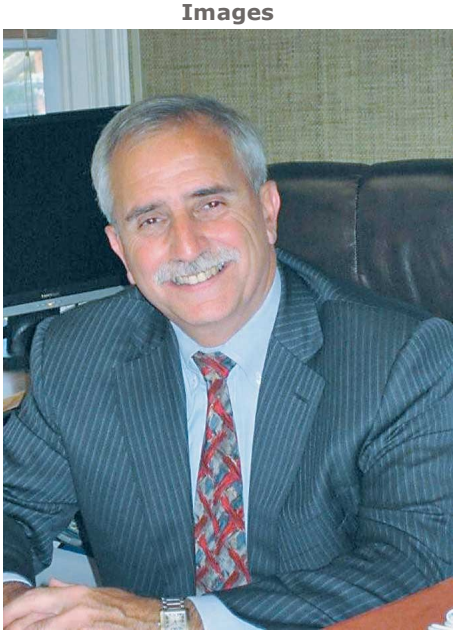

Law Tribune file photo

New Haven Attorney Steven J. Errante claims the drug Praxada has been linked to 650 deaths nationwide, though his client survived.

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Ron M. Meneo of the Meneo Law Group in New Haven.

pharmaceutical firm targeted in hundreds of actions nationwide

By JAY STAPLETON

When the anticoagulant drug Pradaxa hit the U.S. market in late 2010, part of the marketing appeal was that the medication did not require blood monitoring, dose adjustments or dietary restrictions.

But dozens of plaintiffs in Louisianna, Illinois, Tennessee and now Connecticut claim they were injured — in one case fatally — because the manufacturer did not provide an antidote to stop dangerous bleeding and did not adequately warn doctors about bleeding risks.

"We filed the first case in Connecticut," said Steven J. Errante, of the New Haven law firm of Lynch, Traub, Keefe & Errante. "There have been over 650 deaths involving this drug and thousands of people have suffered gastrointestinal bleeds and had serious repercussions. "

Errante and attorney Ron Meneo, also based in New Haven, filed their lawsuit on behalf of Frank Sardinha against Boehringer Ingelheim Corp. The 2,000-employee company, based in Ridgefield, Conn., is the manufacturer of Pradaxa.

Errante said he anticipates he and Mineo will be handling more Pradaxa cases in Superior Court in coming months, although he hesitated to speculate on what that number might be. "More cases are going to be filed in Connecticut," Errante said.

In a 13-page complaint, Sardinha seeks an unspecified amount in compensatory damages, punitive damages and other relief from Boehringer Ingelheim.

Sardinha is 86, a Lowell, Mass., native, a World War II vet and retired administrator in the California univerisity system who has been living out his retirement years in Las Vegas. On Jan. 18, 2011, he was prescribed Pradaxa by his doctor. Less than two weeks later, he was rushed to the emergency room, suffering from "severe blood loss due to gastrointestinal bleeding," the lawsuit says.

Sardinha spent eight days in the hospital, being treated for a blood loss the lawsuit claims was caused by the "anticoagulation effects of Pradaxa."

"Because there is no antidote to reverse the anticoagulation effects of Pradaxa, the Plaintiff suffered uncontrollable and prolonged bleeding and other injuries as a result of taking Pradaxa," the lawsuit states.

Sardinha's lawyers claim the pharmaceutical company violated the Connecticut Products Liability Act by negligently designing the drug and by failing to provide adequate safety warnings. "The company failed to provide adequate warnings with regard to the irreversibility of bleeding and because there are no agents to reverse the bleeding," Meneo said. "The defendants misrepresented the true nature of the risks."

Emily E. Baier, a spokeswoman for Boehringer Ingelheim, said the company is aware of the lawsuits, but does not comment on pending litigation.

She pointed out that Pradaxa is intended to prevent strokes, which are caused by blood clots, and that blood thinners increase risks for bleeding. "That's important for people to understand when they are taking this product," said Baier, who added that warnings of bleeding risks were "included on the label from the very beginning."

The medication remains on the market today.

Clear Provisions

Nationally, Pradaxa lawsuits began to be filed late last year. One lawsuit, part of a proposed class action, claims a woman died in Tennessee after being treated with the medication for her atrial fibrillation. The rest, including cases filed in Illinois, Louisiana and Kentucky, all claim serious injuries resulted from gastrointestinal, kidney and brain bleeding incidents after patients took Pradaxa.

So far, most of the other cases have been filed in federal court. Asked why Sardinha's case was filed in Superior Court, rather than in U.S. District Court, Meneo pointed out that the legal team had that option other plaintiffs didn't have "because Boehringer Ingelheim's primary place of business" is in Connecticut.

Besides, "Connecticut's Product Liability Act is pretty clear in its provisions," Meneo added, "as far as what the plaintiff needs to show in order to prevail."

Pradaxa, otherwise known as dabigatran etexilate mesylate, was approved for sale in the U.S. in 2010. Considered a newer version of the blood-thinning drug Coumadin, or warfarin, the drug is considered an important tool in the fight

against strokes.

The drug is designed to inhibit the body from forming clots. In the United States, Pradaxa was approved only for use in patients who have been diagnosed with atrial fibrillation. Known in medical circles as "A-Fib," the atrial fibrillation diagnosis means that the heart's atria beats erratically and out of normal rhythm with the ventricles, which are lower, larger cardiac chambers in the heart.

The disorder A-Fib is known to cause clots, which can migrate to the brain and cause strokes. The clots can also end up in the lungs, causing pulmonary embolisms.

According to plaintiffs, there is a major difference between Pradaxa and older versions of blood-thinning drugs. Warfarin, marketed as Coumadin for use in preventing strokes, had a built-in reversal agent, in the form of vitamin K. But Pradaxa had no reversal agent for the anticoagulation effects, Sardinha's lawsuit claims.

The lawsuit points to extensive advertising campaigns, in which the company spent a reported $464 million in 2011 to promote Pradaxa.

Those ads, plaintiffs' lawyers say, overstated the efficacy of Pradaxa in the prevention of strokes, while failing to adequately disclose the risks.

From October 2010 to March 2011, 272,119 prescriptions for Pradaxa were issued in the U.S., records show. During that time frame, there were 932 "serious adverse events" reported to the Food and Drug Administration, with more than 500 reports of severe, life-threatening bleeding and 120 deaths.

As of December 2011, the FDA had received more than 500 reports of deaths in the U.S. linked to Pradaxa, according to court records. In 14 months on the market, Pradaxa was linked to 900 reports of gastrointestinal hemorrhages, over 300 reports of rectal hemorrhages and over 200 reports of cerebrovascular accidents associated with Pradaxa.

The company did not modify their labeling and prescription information to provide warnings of bleeding risks, in bold, until January, Meneo said.

"It was only after extensive information had been written about the irreversibility of the anticoagulation effects had been written," Meneo said. "And then they put a sentence in the warnings section."•