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Whistleblower's lawsuit could shake up the drug industry

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BOSTON -- When Dr. Edgar L. Ross wants information about anti-pain drugs, he does not need to look far: He can attend dinner meetings funded by drug companies, fly to industry-sponsored conferences and seek out company representatives eager to answer questions.

But none of that, he said, influences his decisions about prescriptions. Only one source does: "peer-reviewed journals I read and trust."

Ross, medical director of the Pain Management Center at Boston's Brigham and Women's Hospital, said he began prescribing the anti-seizure medication Neurontin after he read about it in a medical journal in the mid-1990s, convincing him the drug worked for pain. What Ross couldn't have known at the time was that an author of that paper was eventually paid thousands of dollars by Neurontin's manufacturer in what a federal whistleblower now alleges was part of an elaborate scheme to skirt federal rules for promoting drugs.

The lawsuit in U.S. District Court in Boston charges that Neurontin's manufacturer, Parke-Davis, and its parent company, Warner Lambert, which merged with Pfizer Inc. two years ago, flouted federal law in the 1990s with an illegal marketing plan intended to drive up Neurontin's sales.

David Franklin's lawsuit is being closely watched by the drug industry, regulators and critics who say pharmaceutical companies have become well-versed in using subtle tactics for increasing sales of drugs for "off-label" uses that the Food and Drug Administration has not yet approved.

The federal government, 11 states and the District of Columbia have joined Franklin's complaint, which has provided a rare look at the tactics drug makers use to provide information about different uses of new drugs to doctors.

Franklin, who worked as a Parke-Davis drug liaison for less than five months in 1996, claims the company adopted a strategy to increase publicity about Neurontin's effectiveness for unapproved uses such as relieving pain, headaches and psychiatric illnesses -- defrauding the government in the process by encouraging doctors to write prescriptions and seek Medicaid reimbursement.

The strategy allegedly included paying doctors to put their names on ghostwritten articles -- and, in one case, publish a book on Neurontin for $300,000 -- and fly them to lavish "educational" junkets. The company wanted "Neurontin champions" at prestigious teaching hospitals to spread the word about the drug and take part in phony studies, the suit said.

Franklin alleges that he and other liaisons were instructed to lie about Neurontin's effectiveness, and that a Parke-Davis medical director told him that what the company was doing was "brazenly criminal."

Franklin, who now works for the medical device maker Boston Scientific, stands to claim a portion of any settlement if the lawsuit is successful. His attorney, Thomas M. Green, refused repeated requests for interviews with Franklin.

The suit alleges that the strategy raised the drug's sales enormously, from $97.5 million in sales in 1995 to nearly $1.2 billion in 2000. Today, about 80 percent of Neurontin prescriptions are for off-label uses. The FDA has since approved the drug's use for a type of neuropathic pain.

Pfizer has strongly disputed Franklin's claims in court documents, saying "no evidence supports the allegations that false statements were made."

"As a result, the allegations provided by (Franklin) that the statements are false are unsupported, conclusory assertions made by (Franklin), with no evidentiary support," Pfizer attorney David B. Chaffin wrote.

A spokeswoman for U.S. Attorney Michael Sullivan, whose office has joined Franklin in the lawsuit, declined to comment on the Neurontin case.

Ahaviah Glaser, director of the Prescription Access Litigation Project in Boston, which has brought a similar lawsuit against Pfizer and Parke-Davis in California, said doctors often rely on biased drug marketing information disguised as education.

"I think everyone's feet need to be held to the fire," she said. "I do think that a few strong court opinions critiquing these practices will be very helpful in discouraging these practices from being as widely used as they are."

Once the FDA has approved a drug, the agency allows doctors to prescribe it for other uses. But with few exceptions, it forbids companies and their representatives from promoting such off-label uses.

The FDA has purposefully left its definition of "promotion" vague, according to former FDA associate commissioner Marc J. Scheineson, now an attorney with Reed Smith in Washington.

"The courts have consistently said in the United States that they want consumers and they want physicians to get as much information as they can, as long as that information isn't false or misleading," he said. "Keeping it ambiguous enough to create a penumbra around most marketing pieces, you're never sure whether this will trigger FDA enforcement action."

In the lawsuit, Franklin cites Ross as an example of how the scheme increased Neurontin sales, saying the doctor began writing prescriptions and asking for reimbursement from Medicaid right after he attended a conference in Atlanta on pain medications in 1997. Ross said the reason Medicaid has no records of his Neurontin prescriptions in Massachusetts before that conference was because he only recently moved to the state.

But when asked what has influenced his prescription writing, Ross cited the 1995 article by Dr. Gary Mellick and his brother, Dr. Larry Mellick, saying it first drew his attention to Neurontin's efficacy for pain.

Franklin's lawsuit cites Gary Mellick's writing as part of the scheme, saying he was paid at least $21,000 by Parke-Davis and didn't divulge the income in his published articles. Mellick, a pain specialist with a practice in Grafton, Ohio, told The Associated Press that he received more than $20,000 from Parke-

Davis for consulting and speaking about Neurontin, but said that all of his pay was after the article cited in the lawsuit was published. When that article and others were written, he had nothing to divulge, he said.

Mellick denied any wrongdoing, saying that Franklin has made factual errors in the lawsuit, but also said that Parke-Davis may have overstepped ethical boundaries in promoting Neurontin.

"It was after the second or third article that I began lecturing for them. The lecturing has nothing to do with the article. None of my articles were sponsored by Parke-Davis, not a bit," he said. "Parke-Davis did not give us a dime in writing that."

"Ethically, it is extremely important that the lawsuit continue, but at the same time I think I would like to see Parke-Davis come out of this with only a slap on the hand," Mellick said. "They need to learn a lesson on the proper ethics of marketing, but I don't think a lot of damage was done, and I think a lot of this was hype."

Ross said he cannot remember whether he knew that Parke-Davis paid Mellick, but he said he wants to know whether doctors are being paid to write about drugs. "I definitely rely on accurate information, and I look at the bottom of the article for who's funding it," he said.

Other doctors allegedly received more money from Parke-Davis. A neurologist at Beth Israel Deaconess Medical Center, received more than $71,000 to speak about off-label uses; the highest-paid speaker took almost $308,000 for speaking at conferences, according to the lawsuit.

Dr. Robert Levine, who teaches medical ethics at the Yale University School of Medicine, said there are good reasons for the FDA's rules on off-label uses.

Without flexible rules to allow free-flowing information, medicine wouldn't evolve as quickly and some common medical practices might be out of bounds, he said. And long-standing practices that are common today -- such as sponsoring meetings about drugs over dinner -- may look unethical on their face, but actually improve medicine.

"If you just say, look, they're getting a lot of expenses or perks, that can superficially look really bad, but you've got to look underneath to find out," he said.

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