



BY Courtney L. Davenport

Courtney L. Davenport is an associate editor with AAJ's Law Reporters and a contributing writer for *Trial*.

spotlight]

Justice after a 14-year Battle

In re: Neurontin Mktg., Sales Pracs. & Prods. Liab. Litig., No. 1:04-cv-10981 (D. Mass. Mar. 25, 2010).

Cases against pharmaceutical giants are always complex and time consuming. But Boston attorney Thomas Greene had no idea when he agreed to take on Pfizer, Inc., for off-label promotion of its seizure drug Neurontin that the case would consume 14 years of his life. It would eventually set precedent, both as a whistleblower action against a pharmaceutical company and as a RICO case based on fraudulent off-label promotion.

In July 1996, former Pfizer employee David Franklin came to Greene with evidence showing that Parke-Davis, a division of Warner Lambert, had been promoting Neurontin for pain relief and treatment of bipolar disorder in violation of the federal Food, Drug, and Cosmetic Act (FDCA).

Greene, on Franklin's behalf, filed a qui tam action under the False Claims Act, alleging that Warner Lambert, through its Parke-Davis subsidiary, and Pfizer defrauded Medicaid by causing it to pay for Neurontin for unapproved indications. (*U.S. ex rel Franklin v. Pfizer, Inc.*, No. 1:96-cv-11651 (D. Mass. filed Aug. 13, 1996).)

After a three-year investigation, the federal government decided not to intervene in the suit, leaving Greene to prosecute it alone. In May 2004, the parties reached a global settlement of \$430 million, including \$152 million in Franklin's False Claims Act case, \$240

million in criminal fines, and \$38 million to several state attorneys general.

"It was groundbreaking," said Greene. "It was the first time the False Claims Act had been used in one of these off-label promotion cases, and it set a precedent that's been followed."

But during the eight years of discovery in the *Franklin* case, Greene learned that Pfizer's misconduct extended beyond off-label promotion: Since the mid-1990s, the company had partnered with advertising firms in developing marketing strategies that included publishing false statements about Neurontin's efficacy by misrepresenting negative outcomes as positive and concealing other negative clinical trials.

"This was fraud because the drug wasn't effective [for off-label uses], and they were misrepresenting it as effective," said Greene. "Consumers and health care plans paid billions of dollars for drug uses that didn't work. It was no more effective than a sugar pill."

Greene and his cocounsel decided to sue the drug companies using a novel claim for drug cases: They alleged that the defendants and their advertising agencies were a RICO enterprise created to defraud health care plans into paying much more for their insureds' Neurontin prescriptions than they would

have paid for other pain medications.

Although several actions by health care plans and consumers had been filed, the court selected nonprofit Kaiser Foundation Health Plan, Inc., for the first third-party-payer trial. Greene said the greatest obstacle was that some doctors still prescribe Neurontin for pain and bipolar disorder, and jurors might wonder why they do that if the drug is ineffective. Greene argued that the answer is threefold.

"One, the physicians were duped and hoodwinked. None of them knew of the negative studies," he said. "Second, the conditions they were promoting it for, to treat subjective complaints, such as pain and depression, are subjective, and there's no objective test to establish whether the drug is working. Additionally, there is a very high placebo effect that could explain why doctors and patients may think the drug is effective."

Kaiser presented several medical witnesses to demonstrate that the drug was not effective and that Pfizer's clinical trials were not randomized or double-blind—as required by clinical trial protocol—and were ghostwritten by paid physicians. Greene also argued that medical decisions should be evidence-based rather than market-based, and

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physicians should make prescription decisions based purely on scientific studies, not drug makers' promotions.

Ironically, Pfizer's defense may have been the plaintiff's best weapon. The company presented experts to counter Kaiser's experts, but not one company executive or employee testified at trial. In a jury trial in which the judge permitted jurors to question witnesses, the absence was noticeable.

"I was trying to develop the theme that, Where are they? What do they have to hide? What are they lying about? Why haven't they come to answer your questions?" said Greene. "They didn't want to because they didn't want to get cross-examined about their incriminating documents."

After a month-long trial, the jury awarded Kaiser about \$47.36 million, which will be trebled under RICO. It also issued an advisory verdict finding violations of California's unfair competition law. The court's ruling on that issue, which could result in an additional award of damages, was pending at press time.

Greene's involvement in the suits against Pfizer is ongoing, as he is chairman of the plaintiffs' steering committee in the Neurontin Sales and Marketing MDL. He did not foresee such a commitment when he first took Franklin's case, but he's glad he did.

"It's why you become a lawyer. What they did was wrong. These defendants were engaged in an end-run around the FDA approval process and were breaking the law," said Greene. "Somebody had to take them on." 

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