

Schering-Plough Sued in NJ for Marketing Drugs for Off-Label Uses

Page printed from: <http://www.law.com>

Mary Pat Gallagher
04-24-2007

A raft of lawsuits centered in New Jersey allege that Schering-Plough Corp. offered bribes, kickbacks and other incentives to doctors to get them to prescribe its hepatitis and cancer drugs for uses not approved by the Food and Drug Administration.

Of six lawsuits filed, five are pending with U.S. District Judge Stanley Chesler in Newark, N.J., and the Kenilworth, N.J., drug company wants the cases tried in that state.

But plaintiffs in the sixth suit, filed on March 27 in Arizona, are asking the Judicial Panel on Multidistrict Litigation that the matter be centralized in Arizona or Massachusetts, where a federal investigation into off-label marketing by Schering ended last year in a plea bargain and a \$180 million criminal fine.

On Thursday, Schering-Plough and two wholly owned subsidiaries, Schering Sales Corp. and Schering Corp., which have also been sued, filed a motion in Arizona asking that the case be transferred to New Jersey for the convenience of parties and witnesses and in the interest of justice, including New Jersey's interest in regulating conduct within its borders.

Schering-Plough has already prevailed on three similar motions in the Eastern District of Pennsylvania, where three of the cases pending in New Jersey were originally filed. Plaintiffs in those cases had asked the multidistrict-litigation panel to centralize the cases there, but the panel denied the motions as moot because of the transfer to New Jersey.

The five consolidated cases, captioned *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 06-Civ.-5774, are filed by health insurers, unions and consumers.

The drugs at the center of the litigation are Intron A and Temador. Intron A, approved to treat hepatitis, has been prescribed for such off-label uses as superficial bladder cancer. Temador, approved for certain brain tumors, has been widely used for other illnesses like metastatic melanomas.

The plaintiffs claim Intron A and Temador are more expensive than the approved drugs, leading them to pay hundreds of millions of dollars more than they would have. For example, an Internet search yielded prices for Temador ranging from \$7.50 for a 5-milligram capsule to \$353.28 for a 250-milligram capsule.

The plaintiffs are hoping to get a leg up as a result of the federal investigation into Schering's marketing practices that began in 2001 and culminated in the plea deal in Massachusetts on Aug. 29, 2006.

The deal called for Schering Sales to pay a criminal fine of \$180 million and to plead guilty to one count of conspiracy to make false statements to the government in response to a July 2001 inquiry by the FDA about Schering's off-label marketing activities. Schering Sales is also excluded permanently from participating in federal health care programs, and it admitted it was guilty of the broader criminal conduct charged in a related criminal information.

Prosecutors contended that between 1999 and 2003, the Schering companies got doctors to prescribe certain drugs for off-label uses by buying them off with money -- as much as hundreds of dollars per patient -- preceptorships, advisory boards and entertainment. Other alleged means included placing "Schering-funded physician assistants in busy physician practices."

A prosecutor's statement accompanying the plea agreement says the false statements admitted by Schering Sales "were designed to reassure the FDA that the promotional activities were isolated and not directed by the home office, when in fact, the activities were widespread and part of the national marketing plan."

"In addition, the Company sought to falsely lull the FDA into believing that it has taken appropriate steps to reinforce the message with its sales representatives that such promotional activities were prohibited, when in fact the Company knew and expected that those activities would continue."

Last year's settlement tightened the leash placed on the company by a 2004 agreement with federal authorities. Among other provisions, Schering must prohibit off-label marketing by sales personnel, require that inquiries about unapproved uses be directed to headquarters and set up an independent monitor.

The union plaintiffs have asked the Schering defendants to produce the materials that were provided to the government in the criminal investigation in Boston and an earlier one by the U.S. Attorney in Philadelphia that led to the 2004 agreement.

The only entity to plead guilty was Schering Sales and the only crime pleaded to, "the false statement to the FDA, does not establish anything with respect to the allegations being brought," says McPhee, of Boston's Ropes & Gray. "The allegations about kickbacks have not been tested to, admitted or proved." She calls the Philadelphia investigation unrelated.

Schering disagrees with the government view that off-label sales are illegal, says McPhee. Statements made about off-label uses were truthful and not misleading and had strong scientific support, she says. She terms it a First Amendment issue, noting that off-label usage is common, appropriate and sometimes life-saving.

Federal law requires reimbursement for off-label uses if they are listed in so-called compendia that identify medically accepted uses.