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Women Unleash Complaints Over Side Effects of Birth Control Pill

Legal Challenges Pile Up Against Yaz

By **Rebecca Beyer**

Daily Journal Staff Writer

Susan Galinis was picking up a cheesecake for a party last January when the store clerk asked about her hair, which had been shaved for brain surgery. Galinis told the young woman the surgery was to repair damage from a stroke she suffered after taking a birth control pill called Yaz.

"She said she was just about to go to the doctor to get the pill because she'd seen the commercials," said Galinis, whose hair has since grown back, in a recent interview. "So I warned her."

To help warn others, Galinis and her husband filed a lawsuit in San Francisco federal court this week claiming the pill caused her stroke and that the pill's maker, Pennsylvania-based Bayer Corp., had fraudulently marketed the drug, playing up its benefits and downplaying its risks. *Galinis v. Bayer*, 09-4980.

'I'm hoping to get the word out to other women about how dangerous that drug is. It devastated my whole life.'

SUSAN GALINIS
PLAINTIFF

"I'm hoping to get the word out to other women about how dangerous that drug is," she said. "It devastated my whole life."

Rose Talarico, a Bayer spokeswoman, declined to comment on specific lawsuits. She said "patient safety is Bayer's top priority."

"Bayer's oral contraceptives have been and continue to be extensively studied worldwide and are safe and effective when used according to the product labeling," Talarico said.



S. TODD ROGERS/ Daily Journal

Lawyer Michael S. Danko, left, and his clients Susan and Rick Galinis have sued Bayer Corp., alleging devastating side effects from its birth control pill Yaz.

The Galinis' attorney, Michael S. Danko, of the Danko Law Firm in San Mateo, has another Yaz lawsuit in the Eastern District of California and plans to file more. He and other California attorneys are entering the litigation in its nascent stages.

Earlier this month, federal lawsuits involving Yaz and its predecessor Yasmin were coordinated in multi-district litigation in the Southern District of Illinois. About 60 cases have been filed in the proceeding so far, but the proposed plaintiffs' liaison counsel for the federal suits says 35 plaintiffs' firms are lined up with at least 1,500 more.

"We expect that number to grow," said Roger C. Denton, of St. Louis' Schlichter, Bogard & Denton, who has the support of several California attorneys in his efforts to become liaison counsel. "A lot of firms are not filing cases yet because they're waiting for it to go forward. I expect there will be easily 5,000 or more claims ultimately pending."

Cases in California state court are piling up too, against Bayer and San Francisco-based McKesson Corp., which distributes the drugs. Mark P. Robinson Jr., of Robinson, Calcagnie & Robinson in Newport Beach, said in the last month

Legal Challenges Stack Up Over Pill's Alleged Side Effects

he had filed what he believes are the first state lawsuits. He said he filed a motion to coordinate the state cases in Los Angeles County Superior Court's Central Civil West, which handles complex litigation.

"I'd say we're really just at the very beginning," Robinson said, adding that his firm had so far received between 300 and 400 calls from women who say they have injuries from the drugs.

Robinson has signed on to support Denton's role as plaintiffs' liaison counsel in the federal cases, a decision that will ultimately be made by the judge overseeing the proceedings. He said he and Thomas V. Girardi, of Girardi & Keese in Los Angeles, are also seeking a leadership position in the federal cases and to be co-lead plaintiffs' counsel in the state cases if those are coordinated.

San Francisco attorney Steven J. Skikos, of Skikos, Crawford, Skikos, Joseph & Millican, who has 100 clients so far, is seeking to serve as liaison counsel between the California cases and the federal litigation.

"Nothing's finalized yet and it's really up to the courts," he said. "But we're trying to build consent on a cooperative effort

between California and the [multi-district litigation]."

One reason for the sudden surge in suits is that in August two studies came out in the British Medical Journal linking the drugs' main hormone, drospirenone, with a higher risk of injuries, including blood clots, which can lead to strokes, with no added benefit.

"What happened is, anecdotally we were learning that these drugs appeared to be riskier but in order to file the lawsuit you really need to have some research behind you," said Danko, Galinis's attorney. "A number of attorneys who had clients were basically waiting for the research."

Bayer's sales of Yaz and Yasmin last year were approximately \$1.8 billion, up 17 percent from 2007. The drug was marketed heavily in commercials geared toward young women, with emphasis on its benefits in reducing menstrual pain and acne. One showed women pushing words like "irritability," "moodiness," "bloating," and "feeling anxious" off the screen with the song "We're Not Gonna Take It" playing in the background. The Food and Drug Administration sent several warning letters to the company saying the ads overstated benefits and understated risks. Earlier this

year, Bayer agreed to pay \$20 million to run national advertisements correcting the misleading information in a settlement with 27 states, including California. Bayer's spokeswoman said that settlement was reached "without any admission of liability, fault or wrongdoing."

Regardless, for Galinis, it's not enough. The 39-year-old mother of twins wants the drug off the market. Since her stroke, the former veterinarian's technician can no longer work. She suffers from short-term memory loss and chronic headaches and cannot drive because her left side is weak. Her husband, Richard Galinis, is also a plaintiff in the suit. He has not been able to return to his work as a police officer because of the care his wife and children need.

Galinis's attorney said every woman knows that birth control comes with risks. But he said women expect that drugs on the market will have the lowest risk possible. He said the warnings on Yaz and Yasmin are not sufficient.

"If the warning said this: This birth control contains a greater risk of stroke and death than other birth control pills on the market but is no more effective - that's the warning I want to hear," he said.