Pfizer Disputes Suit Claiming Zoloft Doesn't Work

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TRENTON, N.J. (AP) — The maker of Zoloft is being sued in an unusual case alleging the popular antidepressant has no more benefit than a dummy pill and that patients who took it should be reimbursed for their costs.

Zoloft's maker, Pfizer Inc., the world's biggest drugmaker by revenue, disputes the claim, telling The Associated Press Thursday that clinical studies and the experience of millions of patients and their doctors over two decades prove Zoloft is effective.

The lawsuit was described as frivolous by Pfizer and four psychiatry experts interviewed by The AP.

Not so, according to plaintiff Laura A. Plumlee, who says Zoloft didn't help her during three years of treatment. Her attorney, R. Brent Wisner of the Los Angeles firm Baum Hedlund Aristei Goldman, argues the Food and Drug Administration shouldn't have approved Zoloft because Pfizer didn't publish some clinical studies that found the drug about as effective as a placebo.

"It's about Pfizer deliberately withholding this information from consumers and then advertising this drug as very effective," Wisner said.

The suit accuses Pfizer of consumer fraud and other offenses, including quietly paying prominent doctors to tout Zoloft to colleagues or to be listed as authors of positive medical journal articles the company prepared for publication. New York-based Pfizer did not specifically respond to those allegations.

"Pfizer believes the lawsuit filed in California is groundless and is based largely on information ... that has been widely criticized by many experts in the mental health field," the company said in a statement provided to The AP. It said the FDA approved Zoloft in 1991 after reviewing "efficacy and safety data from more than 20 clinical studies involving more than 5,000 patients."

The president-elect of the American Psychiatric Association, Dr. Jeffrey Lieberman, said the lawsuit's claims are "ridiculous" and without merit.

"As a class, antidepressant medications are highly effective. They alleviate substantial amounts, if not complete symptoms, in 50 to as high as 80 percent of patients treated who suffer from major depression," Lieberman said.

He stressed the medicines must be given at the proper dose, usually for several weeks to months, to get the full benefit. Also, patients should not stop taking any antidepressant without consulting their doctor.

Dr. Norman Sussman, a New York University psychiatry professor, said for any given

patient, there's only about a 35 percent chance a particular antidepressant will help.

Patients may have to try a few to find one that works for them, due to differences in patients' brains and the structure of the drug molecules.

Also, antidepressants tend to help severely depressed patients far more than people with mild depression or those who are temporarily blue from troubles such as a relative dying, rather than chemical imbalances in the brain.

The lawsuit, filed Wednesday in federal court in San Jose, Calif., asks a judge to approve two class-action cases, one for California residents who took Zoloft and one for all U.S. users.

It asks the judge to order Pfizer to correct "misleading" information in Zoloft's package insert and refund everything California patients paid for Zoloft. Consumer fraud laws differ from state to state, so if Wisner wins the case, he said he'll likely sue in other states.

Two law school professors, Benjamin Zipursky at Fordham University and Carl Tobias of the University of Richmond, said Plumlee's suit might end up being dismissed based on a decade-old Supreme Court ruling that plaintiffs can't recover alleged damages by claiming a company defrauded the FDA to get a drug approved. Zipursky said the lawsuit stresses that consumers were harmed financially, so it could get approved as a class action.

"Federal courts have taken different views as to ... whether you can use a federal lawsuit to second-guess the FDA," he added.

Drugmakers frequently are sued by patients claiming a medicine harmed them and lawyers alleging companies hid medicine risks from the public. Federal and state prosecutors regularly sue drugmakers for overcharging government health programs, marketing drugs for unapproved uses and other criminal or civil offenses.

But a lawsuit claiming a drug doesn't work, so patients should get their money back, might be a first, experts said.

The case also is unusual because Zoloft has had cheap generic competition since 2006, so it's no longer advertised, and little brand-name Zoloft is sold.

The lawsuit opens a window into the ongoing debate about just how effective and safe the many newer-generation antidepressants are — drugs including the huge blockbusters Zoloft, Prozac, Paxil and Effexor.

These medicines, approved starting in the late 1980s, were thought to have less-dangerous side effects than early antidepressants. Over time, the newer antidepressants were increasingly prescribed by primary care doctors, not just psychiatrists.

Pharmaceutical companies marketed the drugs heavily, with very-positive ads targeting consumers. Millions, many with just mild or temporary depression, asked their family doctor for a prescription. Sales grew steadily, declined for several years when the drugs were linked to suicidal thoughts, then rose again the last few years.

Today, antidepressants are the ninth-most popular type of prescription medicine, with annual sales topping $20 billion worldwide, according to health data firm IMS Health.

Plumlee, 49, said in an exclusive interview that she took Zoloft from 2005 through 2008, while her doctor repeatedly increased the dose. He "swore it was working," but she felt it didn't help. Frustrated, and having gained 50 pounds as a side effect, the Watsonville, Calif., homemaker and mother of two teenagers quit Zoloft cold turkey and was hospitalized for six days with flu-like withdrawal symptoms.

"I kind of had a breakdown," she said. "I just felt like I couldn't hope."

Four years later, Plumlee saw a "60 Minutes" news program in which the key expert witness since hired for her case, Irving Kirsch, said his research on antidepressants indicated most improvement in depressed patients was from the placebo effect. That's the benefit most patients get from believing a medicine works and from having doctors and nurses caring for them.

Kirsch, associate director of Harvard Medical School's Program in Placebo Studies, has published a book and several medical journal articles on the effect. With colleagues, he reviewed numerous studies of popular antidepressants, including unpublished studies obtained using the Freedom of Information Act.

"The difference between drug and placebo is very small," below the level that benefits patients, Kirsch concluded.

He said Pfizer produced two studies showing Zoloft worked better than placebo — the FDA's requirement for approval — but most Zoloft studies showed its effect was the same as a placebo.

Dr. Michael Thase, who heads the mood and anxiety disorders program at the University of Pennsylvania's medical school, said research by others using the same unpublished studies concluded antidepressants have "a modest effect over placebo," on average about 15 percentage points.

That's partly because the rate of study participants improving when they're taking a placebo has been rising, said New York University's Sussman.

Why? Back in the 1970s and '80s, patients in clinical trials were generally hospitalized with severe depression. More recent trials mainly include outpatients — many with milder depression and so more likely to feel the placebo effect.

Plumlee, who watched the "60 Minutes" program, saw it as proof she'd been right about Zoloft.

"It made me angry that ... I had to be depressed for three extra years," said Plumlee, who's now doing much better with a new psychiatrist and different medication.

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