

## FDA to Review Safety Issues Surrounding Leading Birth Control Pill Yaz

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Yaz was pitched as the blockbuster birth control pill with benefits, the choice for women desperate for relief from severe PMS and acne. But now, several new independent studies have found that Yaz carries higher blood clotting risks than other leading birth control pills, leading to new scrutiny from safety regulators.

Former FDA Commissioner Dr. David A. Kessler, who is now working for lawyers suing Bayer, which makes Yaz, accusing the drugmaker of concealing the contraceptive's health risks.

"Bayer violated its duties under FDA regulations and state law by selectively presenting data as to [blood clotting] events," Kessler said in court documents, citing studies that Bayer itself conducted but allegedly misreported to regulators.

He indicated that if he had been head of the FDA in 2000 and knew what he knows now, he may not have approved the drug.

"In my opinion, had I, or a medical review officer, known these facts prior to approval, further investigation would be warranted," he wrote.

Citing conflicting safety studies, the FDA is holding hearings Thursday to determine whether new safety measures, like package label changes, are warranted.

Bayer maintains that Yaz is safe.

"Based on a thorough assessment of the available scientific data, Bayer believes that its drospirenone-containing products are safe and effective and have a favorable benefit-risk profile when used in accordance with U.S. product labeling," Bayer spokeswoman Rose Talarico told ABC News.

Yaz was the best-selling birth control pill in the United States for 2008 and 2009. Tens of millions of women switched to Yaz since it was launched a decade ago.

ABC News investigated whether these women switched to a more potentially risky pill that, as it turns out, was never proven to treat common PMS.

In 2007, Carissa Ubersox, 24, was fresh out of college and starting her dream job as a pediatric nurse in Madison, Wis. On Christmas day, while working the holiday shift, her boyfriend surprised her at the hospital with a marriage proposal.

Wanting to look and feel her best for her wedding day, Ubersox said she switched to Yaz after watching one of its commercials that suggested this pill could help with bloating and acne.

"Yaz is the only birth control proven to treat the physical and emotional premenstrual symptoms that are severe enough to impact your life," claimed the ad.

It "sounds like a miracle drug," Ubersox said she remembers thinking.

But just three months later, in February 2008, Ubersox's legs started to ache. She didn't pay much attention to it, assuming, she said, that it was just soreness from being on her feet for a 12-hour shift.

By the next evening, she was gasping for air. Blood clots in her legs had traveled through her veins to her lungs, causing a massive double pulmonary embolism.

Her fiance called 911, but on the way to the hospital Ubersox's heart stopped. Doctors revived her, but she slipped into a coma for almost two weeks.

Ubersox's only memory of that time is something she refers to as an extraordinary dreamlike experience. She said she remembers a big ornate gate and seeing a recently deceased cousin.

That cousin, Ubersox said, told her, "You can stay here with me or you can go back."

But, she recounted, he told her if she goes back she'll end up blind.

"I just remember waking up in the hospital and I was like, 'Oh, I guess I chose to stay,'" Ubersox told ABC News.

Like her cousin in her dreamlike experience foretold, she actually did wake up blind, and remains blind to this day.

No one can say for sure whether Yaz caused Ubersox's blindness, but Yaz contains a unique hormone called drospirenone that some experts say may trigger more blood clots than other birth control pills. Clots can cause serious breathing problems, a stroke or even death.

All birth control pills come with some risk. Two to four women per 10,000 on the pill will suffer blood clots, and some will die as a result. But with Yaz, several new independent studies have put that risk two to three times higher.

"It's a disappointing finding," said Dr. Susan Jick, author of one of those independent studies involving almost a million women. "As a public safety concern that's not what one wants to find."

Made by Bayer HealthCare Pharmaceuticals, Yaz sales rocketed to nearly \$2 billion a year after its release in 2006, making it at one time the leading birth control pill on the market and Bayer's top-selling drug.

And there was a lot of buzz surrounding Yaz, from popular women's magazines touting it as "the pill for PMS" and "super pill" to TV news segments, like one in Dallas that called Yaz, "a miracle pill that gets rid of most of the uncomfortable symptoms of PMS."

Some company executives apparently encouraged these exaggerated claims, ABC News has learned. Internal documents obtained by ABC News show their reactions: "[T]his is outstanding!!! can we get good morning america to do the same segment!!!????!! (tee hee)," one executive wrote about the Dallas segment that called Yaz a miracle pill for PMS.

But the Food and Drug Administration wasn't amused. In 2008, the FDA said Yaz was not shown to be effective for common PMS, just a rare and serious form of menstrual symptoms, and that Yaz's success with acne was "misleadingly overstate(d)."

State authorities also accused Bayer of deceptive advertising.

Bayer denied any wrongdoing, but in an unusual legal settlement agreed to spend \$20 million on corrective TV ads, which said, "Yaz is for the treatment of premenstrual dysphonic disorder, or PMDD, and moderate acne, not for the treatment of PMS or mild acne."

But by then, millions of women had already opted for Yaz.

Some experts say there is cause for concern about recent medical findings. Jick found it noteworthy that the studies funded by Bayer found no difference in risk, while all four of the most recent independent studies found increased risk.

Jick added that when she sent her study to Bayer, she was surprised that they never responded or asked to work with her.

"The studies that have found increased risks are not in the best interest of the company," Jick said.

Columbia University medical ethicist David Rothman added that, in general, "We have got to look at drug studies published by the company producing the products with a lot of suspicion. They have too much skin in the game."

Internal Bayer documents obtained by ABC News raise questions about some of the company's research. According to one report, Bayer apparently kept the name of one of two employees off a company-sponsored study because, according to an internal email, "there is a negative value to having a corporate author on the paper."

"It's really nefarious, a basic violation of scientific integrity, when the person who did the research doesn't even appear on the paper," Rothman said.

Thousands of women are now suing Bayer, including Carissa Ubersox, but the company continues to deny any wrongdoing. Citing those lawsuits, Bayer refused to be interviewed for this story and instead sent ABC News a statement saying Yaz is as safe as any other birth control pill when used correctly.

There are no answers yet for Ubersox, whose life has changed forever. She is no longer a pediatric nurse, no longer engaged and, she said, "everything that I thought I worked so hard for has disappeared."

Yaz, she said, is to blame.