

FDA panel wants more risk information on Yaz pills

December 9 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- Federal health experts said Thursday that drug labeling for Yaz and other widely-used birth control pills should be updated to emphasize recent data suggesting a higher risk of blood clots with the drugs than older contraceptive pills.

The Food and Drug Administration's panel of experts voted 21-5 Thursday that labeling on the popular drugs made by Bayer is inadequate and needs more information about the potential risk of blood clots in the legs and lungs.

Yaz, its predecessor Yasmin and related prescriptions use a manmade hormone called [drospirenone](#), which mimics the naturally occurring [female hormone](#) progesterone. Approved in 2006, Yaz grew into the best-selling birth control pill in the U.S. by 2008, backed by hundreds of millions of dollars in TV and magazine advertising that emphasized its ability to clear up acne and other hormonal side effects. But prescriptions have fallen more than 80 percent in the last two years amid safety concerns.

Panelists spent more than nine hours discussing often conflicting data on the blood clot risk of drospirenone-containing drugs compared with older medications. While the group disagreed on the quality of the evidence, the overwhelming majority said it should be clearly stated in the label, including the potentially fatal nature of blood clots.

"Clearly the wording is inadequate and incomplete," said Dr. Richard

Bockman of New York's Hospital for Special Surgery. "[Adverse events](#) have to be made graphic so physicians and patients are aware of the consequences."

In an earlier vote, panelists voted 15-11 that the pills remain a beneficial option for preventing pregnancy. The majority ruling amounts to a vote of confidence for keeping the drugs on the market, though well over a third of panelists voted against the drug's overall benefit, citing numerous alternatives available.

"I can see no real group of patients that this drug benefited over existing alternatives," said Mark Woods of New York University School of Medicine. "Without any clear benefit, and given the potentially catastrophic risk, I voted no."

Two large studies conducted by German drugmaker Bayer have shown no difference in blood clots between patients taking the company's drugs and patients taking older medications.

But since 2009, five large studies have suggested drospirenone-containing pills carry a slightly higher risk of blood clots than older birth control pills, though events in both groups are very rare. Even a slightly higher risk can be critical because blood clots can trigger heart attacks, strokes and blockages in lungs or blood vessels.

The most recent study by the FDA found women taking Yasmin had a 75 percent higher chance of suffering a blood clot than patients taking a combination of older drugs. The absolute risk of a blood clot is still far less than a fraction of a percent.

FDA scientists noted shortcomings with all the recent studies of Yaz and Yasmin, including missing information about patient weight and smoking status, which can increase the risk of blood clots. While not

definitive, panelists said the information should be explained clearly in the labeling for physicians and patients.

"I think we can do a much better job than labels I have seen," said Dr. Valerie Montgomery Rice, of the Morehouse School of Medicine.

Panelists said future studies must take into account patients' lifestyle, race and family history to accurately capture blood clot risk.

With the slogan, "beyond birth control," Bayer's advertisements pitched Yaz to women in their 20s as a drug with "lifestyle" benefits over older contraceptives. One advertisement featured young women singing the Twisted Sister anthem, "We're Not Gonna Take It," while popping balloons labeled "moodiness," "bloating" and "acne."

Within two years of its marketing approval, Yaz had grown into the best-selling birth control pill in the U.S. with peak sales of \$781 million in 2009, according to data from IMS Health. But sales plummeted from one million per month to about 200,000 per month after the company added information about studies that found a heightened risk of blood clots. Additionally, Bayer was forced to run corrective advertisements after the FDA said the company's marketing campaign overstated Yaz's effectiveness in treating premenstrual mood disorders, and used distracting music and visuals to downplay the drug's side effects.

Earlier in the day, panelists heard more than a half-dozen patients or their family members who blame Yaz or Yasmin for sometimes deadly blood clots.

Cindy Rippee spoke about her last conversation with her 20-year-old daughter Elizabeth Rippee, who died Christmas Eve 2008 when a blood clot traveled to her lung. Rippee said her daughter had been taking Yasmin for about two months, after taking another birth control pill, Tri-

Sprintec, for a year previously.

"My daughter was a very smart young woman. If Elizabeth had been clearly told that Yasmin had more risk, maybe twice as much risk, as other pills she never would have switched to Yasmin and would be here today," said Rippee, of Escondido, Calif.

Rippee is among 4,000 to 6,000 plaintiffs suing Bayer in personal injury lawsuits pending throughout the U.S. court system.

Yaz and other drospirenone-containing pills accounted for 16 percent of the hormonal contraceptives used in the U.S. last year, behind Warner Chilcott's Loestren, Johnson & Johnson's Ortho Tri-Cyclen and several other oral contraceptives.

The FDA has not set a timetable for any changes in Yaz's labeling. For now, many doctors say they don't expect to stop prescribing the drugs anytime soon. They point out that the risk of [blood clots](#) with any [birth control pill](#) is still far lower than that associated with pregnancy and birth, when surging hormone levels and reduced blood flow dramatically increase the chances of clotting.

Studies suggest that 10 in 10,000 women taking the newer [birth control](#) pills will experience a blood clot, compared with 20 in 10,000 women who are pregnant or have just given birth.

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