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Heart surgery drug carries serious risks

BY MICHELLE L. START
Florida Weekly Correspondent

The U.S. Food and Drug Administration has recommended that additional clinical trials be conducted on a drug used locally in heart surgeries after finding patients who took it had a higher risks of serious side effects including kidney problems, heart attacks and strokes.

Although the agency stopped short of pulling Bayer's Trasylol from the market, officials did require it carry additional guidelines for physicians, informing them of potential risks. Recently Bayer conducted some safety studies that the FDA is taking into consideration before making a final decision.

The action came 19 months after the FDA announced that it was investigating the risk of Trasylol, which is used in open-heart surgeries. During an initial

review, investigators found that Bayer withheld thousands of hospital records that showed the drug was linked to higher mortality and renal failure rates.

Peter Duggan, director of pharmacy at Southwest Florida Regional Medical Center, said surgeons there began to reduce the frequency in which Trasylol was used following the initial studies that showed a higher risk for side effects.

"We still use it on select patients," he said. "There has not been a formal recall. We use a lot less of it then we did in January 2006. There has been a precipitous drop. The physicians use it less often. But, we do a lot of open heart surgeries and it is still used by some physicians."

The benefit of using Trasylol is that it reduces internal bleeding, which means less patients need to undergo blood transfusions. Additionally, less bleeding means surgeons have a better picture of what is happening internally.

Duggan said the hospital uses several drugs that have a "black box" warning.

"A lot of drugs have it," he said. "It's like an extra type of warning for the physician. It's a highlighted area that you can't miss. It generally refers to a specific patient population."

The FDA recommended that Trasylol carry the "black box" warning last December.

The warning serves to alert physicians that the drug may have adverse effects on certain patient populations.

"You just have to be select when choosing patients," Duggan said. ■



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