

November 5, 2007

Bayer Halts U.S. Sale of Trasylol

By ANNA WILDE MATHEWS

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Bayer AG will pull its antibleeding drug Trasylol from the U.S. market amid growing evidence it may be linked to a higher risk of death than that of competing drugs, according to people with knowledge of the matter.

It wasn't clear late yesterday if Bayer, based in Germany, would halt sales of the drug in other countries, although such a move would be likely in light of a suspension of U.S. sales.

Trasylol, which is supposed to reduce blood loss and allow patients undergoing heart-bypass surgery to avoid transfusions, would be the third drug this year whose sale in the U.S. was halted under scrutiny from the Food and Drug Administration, a signal of how the agency is weighing safety issues heavily in drug decisions. Still, the history of Trasylol, which was approved in the U.S. in 1993 and has been tied to high-profile safety concerns at least since early 2006, is likely to draw questions from Congress and plaintiff attorneys.


The drug had world-wide sales of £230 million (\$338 million) in 2005. Sales dropped by about a third last year.

Last month, after a Canadian clinical trial stopped enrolling patients to take the drug because it appeared linked to a higher risk of death, the FDA said it was reviewing Trasylol.

The drug's safety became a high-profile issue with the publication of a study in the *New England Journal of Medicine* in January 2006, which found the drug might be linked to a doubled risk of kidney failure, as well as increased risk of heart attacks, heart failure and strokes. The authors concluded "continued use is not prudent" and said two generic medications were safe alternatives. However, the study didn't involve patients being randomly assigned to take the drug.

The FDA put out a notice about Trasylol in February 2006, urging doctors to closely monitor patients taking the drug. In September 2006, an agency advisory committee voted unanimously that the drug should remain on the market. After the meeting, the FDA said a safety study commissioned by Bayer hadn't been submitted to the agency in time to be reviewed by the committee.

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The FDA made changes to Trasylol's label in December 2006, including a warning about potential kidney damage and a narrowing of the recommended population of patients.

In September, another advisory committee examined the drug, this time including the Bayer study, which suggested Trasylol might be tied to a higher risk of death and kidney damage. A follow-up to the earlier New England Journal study, this one published in the Journal of the American Medical Association in February, also tied Trasylol to mortality risk, and it advised that its use "does not appear prudent." Still, none of the safety studies were randomized.

The committee still voted, 16-1, that Trasylol remain on the market. Some doctors argued that the drug filled an important niche for patients who couldn't handle blood transfusions.

Finally, late last month, the FDA announced the new review in the wake of the early findings from the randomized Canadian trial, which suggested Trasylol "increases the risk of death" compared to the risk from other drugs, the agency said.

Write to Anna Wilde Mathews at anna.mathews@wsj.com¹

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