

news

Bayer's Trasylol Boosts Death, Kidney Risks After Heart Surgery

By Michelle Fay Cortez

Feb. 21 (Bloomberg) -- Bayer AG's Trasylol, a drug whose sales were halted last year, raises the risk of death and kidney damage when used to control bleeding in heart surgery, two studies in the New England Journal of Medicine found.

Trasylol patients were 27 percent more likely to die than those getting a rival drug a decade after open-heart surgery, according to a review of 10,275 consecutive patients at Duke University Medical Center. Another study of 78,199 patients, presented to regulators last year after Bayer initially withheld it, found a 78 percent higher death risk a week after surgery.

Trasylol was approved in the U.S. in 1993 to reduce transfusions and bleeding during open-heart surgery. It became a mainstay of care, generating about \$333 million in 2005, until an international study the next year tied it to higher rates of heart attack, stroke, kidney failure and death. Leverkusen, Germany-based Bayer suspended sales in November after a pivotal Canadian trial linked it to higher death rates.

"It's become part of the fabric of cardiac surgery for the past decade," said Andrew Shaw, lead author of one study and associate professor of anesthesiology at Duke, in a telephone interview. "Our study doesn't provide a definitive answer, but it intensifies the debate over the drug safety."

Bayer challenged the findings from both studies, raising questions about how the researchers analyzed the data and accounted for differences between the patients getting Trasylol and those on the alternate, generic drug aminocaproic acid.

Sicker Patients

Trasylol patients were sicker, which could have altered the results even after researchers tried to adjust for differences, everyone involved agreed.

Two U.S. Food and Drug Administration advisory panels, including one that had information on the research, recommended keeping the drug on the market. The studies, which looked back at how patients fared without first putting them in treatment groups, aren't considered conclusive.

Bayer, Germany's largest drug company, is waiting for a detailed analysis of the more definitive Canadian trial that was halted last year to determine the most appropriate course of action, said Staci Gouveia, a company spokeswoman. Officials will work with the FDA after the information is available to see what impact it, and other recent research, should have on Trasylol, she said in a statement.

"At that time, the temporary marketing suspension will be re-evaluated," she said, adding that the company has no idea when the details will be available. "Bayer believes that the totality of the available data continue to support a favorable risk-benefit profile for Trasylol."

200,000 Patients

More than 200,000 bypass patients a year worldwide were getting Trasylol before sales were halted. The company has said 4.3 million people have been treated with the injectable drug. It costs 10 times more than its closest rival.

Sebastian Schneeweiss, the lead researcher of the second study and an associate professor of medicine at Harvard Medical School in Boston, defended his team's work. The study was done using data from one sixth of all hospitalizations in the U.S. by Schneeweiss and other researchers at i3 Drug Safety, a unit of Minnetonka, Minnesota-based UnitedHealth Group Inc.

"It is the largest cohort study ever on the issue, representing routine care," he

Jane Bryant Quinn
Find out how to make the most of it.
Click here



More News

- Munich Re Fourth-Quarter Profit Falls 12 Percent After Year-Ago Tax Gain
- LGT Says Stolen Records Handed to Tax Authorities Had Data on 1,400 People
- DAX Index Rises, Led by Commerzbank, Hypo Real Estate; MAN AG Advances

- Exclusive
- Worldwide
- Regions
- Africa
- Asia
- Australia & New Zealand
- Canada
- China
- Eastern Europe
- Europe
- France
- Germany
- India & Pakistan
- Italy
- Japan
- Latin America
- Middle East
- U.K. & Ireland
- U.S.
- Markets
- Economy
- Politics
- Industries
- Opinion
- Invest
- Sports
- Muse Arts
- Spend
- Audio/Video
- Reports
- Bloomberg
- Markets
- Magazine
- Special Report

RESOURCES

- Bloomberg TV
- Bloomberg Radio
- Bloomberg Podcasts
- Bloomberg Press

said. "It's another data point in the accumulating number of studies that show this increased risk of death," Schneeweiss said in a telephone interview.

He declined to say if he thought Trasyolol should be permanently removed from the market. Currently, doctors can get it through a restricted access program in the U.S.

'Informed Decision'




"The data have to be reviewed and seen in the light of all the evidence," he said. "The bottom line is there are still more people dying using this drug. FDA is the agency that has all the evidence together at this point, and they need to make an informed decision."

The predicament with Trasyolol underscores the need for more definitive studies on the safety of new products before they are widely used, Wayne A. Ray, director of drug epidemiology and professor of preventive medicine at Vanderbilt University School of Medicine, wrote in an editorial accompanying the studies. Such drugs should be compared directly to their rivals, he said.

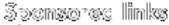
"The manufacturer cannot be relied on to perform these studies voluntarily, because they frequently serve no commercial purpose," Ray wrote. As a result, the studies "supervised by the FDA, should be mandatory. To limit the risk for patients, distribution of new drugs should be restricted while these trials are being conducted, with selective extension of patents to reduce the economic burden on manufacturers."

To contact the reporter on this story: Michelle Fay Cortez in Minneapolis at mcortez@bloomberg.net

Last Updated: February 21, 2008 00:13 EST

 [News tools](#)  [Email this article](#)  [Printer friendly format](#)

[Advertisement: dbFX: Online FX Trading](#)



[Trasyolol Heart Surgery](#)

Have You Been Injured as a Result of the use of Trasyolol? Learn More.

www.JimSokolove.com/Trasyolol

[Coronary Angioplasty](#)

Learn About a Stent Used to Treat Blocked Arteries.

CypherUSA.com

[Robotic heart surgery](#)

Minimally invasive robotic surgery Saint Joseph's Hospital in Atlanta.

www.StJosephsAtlanta.org/

Ads by Google

Bloomberg.com [NEWS](#) | [MARKET DATA](#) | [INVESTMENT TOOLS](#) | [TV AND RADIO](#) | [ABOUT BLOOMBERG](#) | [CAREERS](#) | [CONTACT US](#) | [LOG IN/REGISTER](#)

©2008 BLOOMBERG L.P. ALL RIGHTS RESERVED. [Terms of Service](#) | [Privacy Policy](#) | [Trademarks](#) | [Site Map](#) | [Help](#) | [Feedback](#) | [Advertising](#) | [日本語サイト](#)