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Trasylol Sales In U.S. And Canada Suspended Temporarily By Bayer In Early November 2007 powered by BlogBurst

POSTED: Monday, November 05, 2007

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Market Withdrawal Or Recall Of Trasylol Seems Possible As Bayer Waits For Final Data From Halted BART Study

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On November 5, 2007 [the FDA announced](#) and [Health Canada announced](#) that sales of Bayer AG's anti-bleeding drug Trasylol (aprotinin) would be suspended temporarily in the U.S. and Canada while investigations continued about whether Trayslol is linked to a higher risk of death than competing heart surgery drugs.

As we had reported previously, [the FDA has been reviewing the safety of Trasylol since early 2006](#):

In mid-February 2006 the FDA issued a Public Health Advisory informing doctors and patients that the agency was evaluating the safety of Bayer AG's heart surgery drug Trasylol (aprotinin injection) after new studies had linked it to higher risks of kidney problems, heart attacks, and strokes. At the end of February 2006, a "Dear Doctor" letter from Bayer regarding Trasylol was posted on Health Canada's MedEffect web site.

Later, in September 2006, an FDA advisory panel reviewed data from medical journals that suggested that Trasylol might increase the chance of kidney damage, heart attacks, and strokes.

A second Trayslol advisory panel meeting was scheduled for September 2007. Two days before, FDA staff released [235 pages of briefing documents they had prepared for that Trasylol advisory panel meeting](#) which seemingly foreshadowed this most recent development in the Trasylol saga.

From a September 10, 2007 *Reuters* article, "[Bayer's Trasylol may boost death risk: FDA staff](#)", by reporter Kim Dixon:

FDA staff, in briefing documents ahead of Wednesday's advisory panel,

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said the totality of three recent studies support the risk of renal failure and dysfunction, and noted a "mortality disadvantage detected" in the Bayer study.

A Bayer spokeswoman said the company looks forward to discussing the drug's merits at the advisory panel meeting....

"There is still no new clinical data, so the question is whether (Bayer's) observational study is enough of an alarm," said Ira Loss, an analyst at the investor research firm Washington Analysis.

"My assumption is this drug is being put into the dead-end of drug land," he added.

While the September 2007 Trasyolol advisory panel decided this heart surgery drug should remain on the market despite its increased renal and cardiovascular risks, it urged Bayer to conduct a randomly controlled clinical trial on Trasyolol.

Bad news for Bayer, however, soon followed when a Canadian study -- the BART study, an independent randomized, controlled trial that was being conducted in high-risk cardiac surgery patients -- was suddenly stopped in mid-October 2007 due to emerging serious safety concerns regarding Trasyolol.

On October 25, 2007 the FDA posted on its web site an "[Early Communication about an Ongoing Safety Review Aprotinin Injection \(marketed as Trasyolol\)](#)" which said, in part, stated that the 30-day mortality risk in the Trasyolol group of the BART trial was nearing statistical significance, compared with other treatments Trasyolol was being tested against.

A [November 5, 2007 Reuters article about the suspension of Trasyolol sales](#) brings us up-to-date with this information:

- On [November 5, 2007] Bayer said it had been informed that BART trial data were now being collected from centers throughout Canada and final data analysis would emerge in around eight weeks.
- "Once the complete BART dataset is available, Bayer will work with health authorities to evaluate whether these data have any impact on the positive benefit-risk assessment for Trasyolol," Bayer said [November 5, 2007].
- "Bayer believes that the totality of the available data continue to support a favorable risk-benefit profile for Trasyolol when used according to labeling," the company said.

We will wait to see whether or not the final analysis of this BART study data and any other relevant information leads to Bayer withdrawing Trasyolol from the market altogether in the months to come. Of course, it is possible that based on their findings the FDA or Health Canada may make that choice for the drug company.

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