

Trasylo^l

RECALLED FROM MARKET

TRASYL^{OL} - 60 MINUTES EXPOSÉ - AT LEAST 22,000 UNNECESSARY DEATHS

Trasylo^l, also known as aprotinin, is a blood-clotting drug used during heart surgery to prevent bleeding, and was pulled from the market in November 2007 because of serious adverse side effects including renal failure and death. **On February 17, 2008 CBS News' 60 Minutes reported how manufacturer Bayer conducted a Trasylo^l study led by a prominent Harvard physician and deceptively kept the negative research findings from the FDA and the unsuspecting public, delaying the recall in an effort to boost sales and dominate the cardiac surgery market. Bayer knew of Trasylo^l's serious adverse health effects long before the recall, and reported nothing for more than two years, during which time it's estimated that the drug contributed to the loss of one thousand lives a month.**

In 2005, Dr. Dennis Mangano, an eminent medical researcher, completed a study that followed more than 5000 patients, the largest Trasylo^l study ever conducted. **The study showed an important association between the drug and kidney failure requiring dialysis.** In early 2006, Mangano presented his study to the FDA's advisory committee, but it was not embraced wholeheartedly because the study looked at hospital records of real-world patients, and was not a clinically controlled experiment testing Trasylo^l against a placebo.

At the same time, Bayer was holding the results of its own study, led by Alexander Walker of Harvard, with much of it concurring what Dr. Mangano's study had already shown. **Bayer representatives stood before the advisory committee and did not reveal that their study and negative findings even existed.** A member of the FDA advisory committee, Dr. William Hiatt told 60 Minutes that had he known about Bayer's study at that first meeting, he would have voted to take Trasylo^l off the market.

In 2007, the Canadian government conducted its own large clinical trial of Trasylo^l, but the study had to be stopped because patients in the study group were dying as a result of taking Trasylo^l. When the study was halted, Germany banned Trasylo^l, and both Canada and the FDA persuaded Bayer on November 5th, 2007 to pull worldwide sales of Trasylo^l.

There were concerns about Trasylo^l even before it got FDA approval in 1993. In the early 1980's, Dr. Juergen Fischer, director of the Institute of Experimental Medicine at the University of Cologne, the hometown of Bayer no less, found severe kidney damage in animals given Trasylo^l. He reported his findings to Bayer, but felt the manufacturer wasn't interested in examining these side effects. Soon after, the same side effects were being seen in patients in America.

In 1992, a small study was conducted, not funded by Bayer, in which Trasylo^l was given to 20 patients. Thirteen of these patients had problems with kidney failure after the procedure, a definite red flag. Safety concerns are often hard to assess until thousands of patients have been given the drug. But since Bayer never paid for any studies to determine whether there was a kidney failure problem, and their research did show that Trasylo^l controlled bleeding, the FDA approved it in 1993.

Bayer has marketed the drug aggressively, getting the FDA in 1998 to expand its approval to cover all heart bypass patients. It is estimated that by 2005, nearly 1/3 of all cardiac surgery patients were being given Trasylo^l, totaling nearly \$300 million in sales annually.

If you, your family or someone you know has been injured as a result of Trasylo^l, contact us now for a free, private consultation. Knowledge is power - we'd like to help you!

Side Effects associated with Trasylo^l®:

- Congestive Heart Failure
- Renal Failure
- Kidney Failure / Damage
- Stroke
- Dialysis
- Death

If you've suffered KIDNEY FAILURE WITHIN THREE MONTHS of an OPEN HEART or BYPASS PROCEDURE where TRASYL^{OL} was used, you may be entitled to COMPENSATION.

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1-800-555-8123

Your time to file is SHORT • You may lose your right to a claim FOREVER • CALL US NOW • Deadlines are FAST APPROACHING