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Bayer Vows to Fix Problems Causing Shortage of Hemophilia Treatment

By Vanessa Fuhrmans Staff Reporter of The Wall Street Journal
Dec. 21, 2001 12:01 am ET

For the companies that make life-saving blood-clotting drugs, the National Hemophilia Foundation's annual conference is a marketing must -- a one-stop chance to pitch products and goodwill to one of America's most organized patient communities.

But at the meeting in Nashville, Tenn., last month, one of the biggest companies -- Bayer AG -- was banned as a sponsor, and organizers forbade it to set up a booth for much of the meeting. It was allowed to attend one session: to explain a series of manufacturing problems that have triggered one of the worst shortages of hemophilia drugs in a decade.

For Bayer, which recently took a public-relations blow over the price and supply of its anthrax-fighting Cipro, the rebuke marks a potent lesson in how easy it is to alienate even the most captive of markets. Once hailed as the maker of the most cutting-edge hemophilia drug on the market, Kogenate FS, the German company can barely produce it this year as it corrects manufacturing problems found by regulators.

As a result, Bayer is taking steps to introduce some glasnost in its traditionally tight-lipped relations with consumers. At the Nashville meeting, company representatives openly told the crowd not to count on Bayer as a primary supplier now, then explained how it was fixing the problems. "They were very honest, very apologetic, and they did all right, considering," says Glenn Pierce, president-elect of the National Hemophilia Foundation. Organizers also softened their stance on Bayer's marketing after it made more provisions to channel what Kogenate it produces to health-care providers and doctors with emergency requests.

But the lesson has been costly. Bayer estimates it will lose about $300 million in operating profit this year from the troubles. The reorganization includes $30 million in plant improvements, more than 150 new employees in quality control and a revamped system to track a batch of Kogenate from start to finish. The problems also point to distant, and

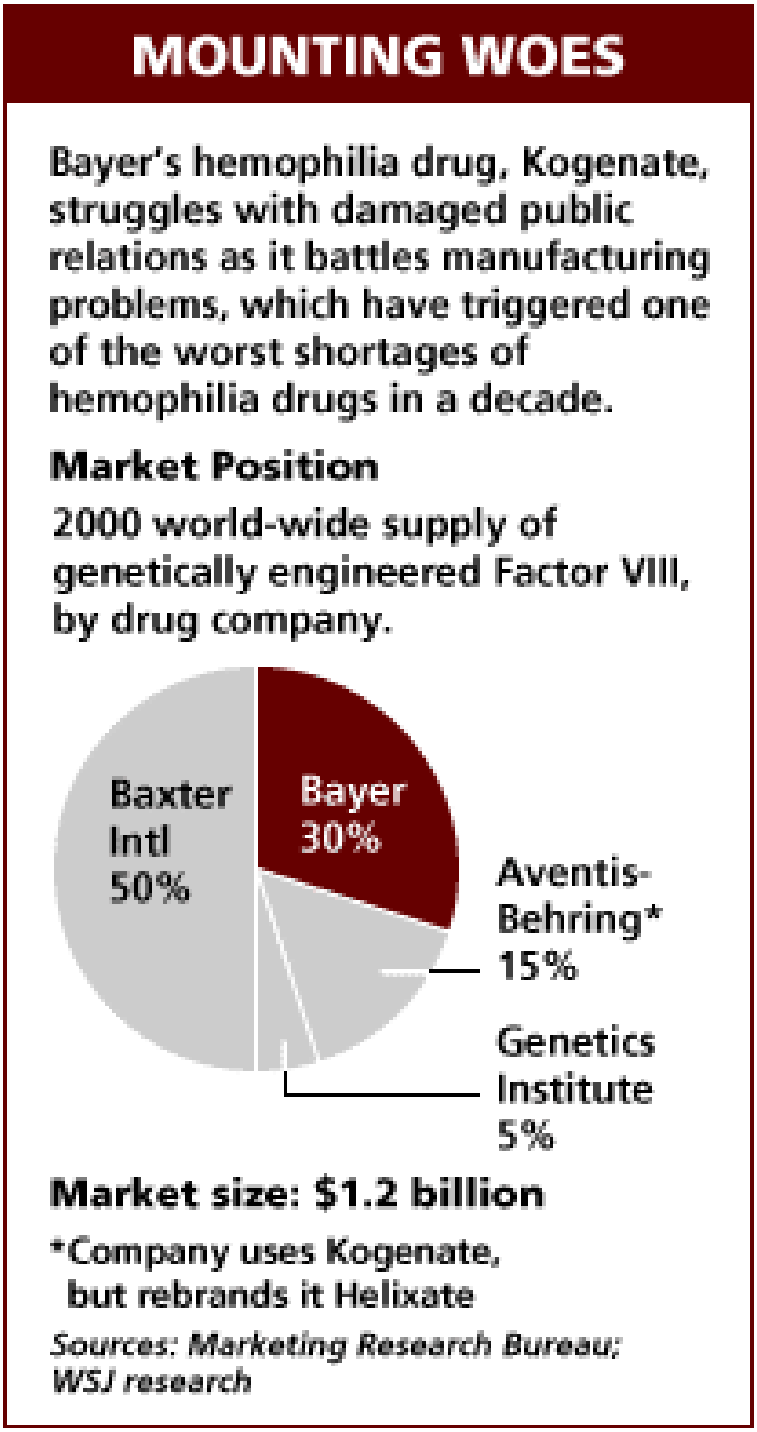
sometimes tense, relations between Bayer's German headquarters and U.S. managers running the Kogenate business, which critics say hobbled its ability to keep atop ever-tightening regulatory standards.

"Our management -- the middle management in America in charge of the business -- did not handle the situation as we would have wanted," says Bayer's chief executive officer, Manfred Schneider.

Beyond the financial impact is the crisis that the Kogenate shortfall has triggered among many patients, some of whom are postponing operations, or switching to older versions of Factor VIII that are made from human blood. Parents say they have sharply cut back the prophylactic treatment that allows their children to play sports and engage in other physical activity without the constant risk of injury.

"We've got just enough for day-to-day life. That's barring anything else," says Patricia DeRatto of Chesterfield, Va., who has banned her 10-year-old son Daniel from sleeping over at friends' houses for fear that even some playful roughhousing might lead to a bruise -- and dangerous bleeding.

Introduced a year ago, Kogenate FS entered a market already clamoring for it. An earlier version of the drug already had won 30% of the global market for genetically engineered Factor VIII, a blood-clotting protein that an estimated 350,000 hemophiliac males world-wide lack.



Because it is genetically engineered, not derived from human plasma, Kogenate greatly reduces the risk of viral infection, a critical issue for the hemophilia community devastated by products contaminated by HIV and Hepatitis C in the 1980s. Kogenate sales, which rose 30% to $440 million last year, had been soaring every year since the first version was launched in 1993. The latest generation reduced the level of human albumin, making it safer and more desirable.

No sooner had Bayer launched the new version last autumn than it started to stumble. Bayer angered customers by creating an Internet distribution channel, called Bayer Direct, that forced all patients to buy Kogenate exclusively through the site.

The company claimed direct distribution would alleviate shortages and price fluctuations. But patients pilloried the company for cutting out home-health-care providers and hemophilia centers through which many buy their treatment, and the hemophilia foundation slapped the company with the marketing boycott. Within a few months, the company retreated, pledging to dismantle the constraints.

Before it had a chance to make good, its supply problems began. FDA inspectors visited its Kogenate plant in Berkeley, Calif., in November 2000 just as the company was shifting to the second generation of the drug. In a 30-page report four weeks later, they outlined systemwide problems ranging from employee training to erratic monitoring for bacteria and poor safety documentation.

At first, Bayer tried to fix the problems as it continued to ramp up output of the new version of Kogenate. But the effort quickly crippled production.

With customer relations badly frayed, Bayer officials called a summit of hemophilia group leaders from around the world in Chicago in June to explain how the problems had occurred and what it would take to fix them. Since then, the company has conducted monthly teleconferences to update patients on the reorganization.

Once the overhaul is complete next year, says Paul Heiden, Bayer's new head of technical quality assurance at the Berkeley plant, "we think we will come out ahead of the game."

TIMELINE OF KOGENATE PROBLEMS

- **September 2000:** Kogenate FS is launched; company initiates Bayer Direct sales program.
- **November 2000:** Bayer retracts exclusive constraints on Bayer Direct.
- **December 2000:** FDA finishes Kogenate plant inspection and issues 30-page report of manufacturing problems.
- **January 2001:** Bayer announces first temporary suspension of Kogenate.
- **March 2001:** Bayer announces it has discovered bacterial traces in initial production stages of Kogenate, but that all of the product released so far is safe; head of unit is forced to resign.
- **June 2001:** Bayer calls global summit to explain how the problems occurred.
- **November 2001:** Bayer explains problems at National Hemophilia Foundation's annual conference, makes more provisions to distribute Kogenate to other sales and emergency channels; foundation lifts marketing boycott.

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