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2 Paths of Bayer Drug in 80's: Riskier Type Went Overseas

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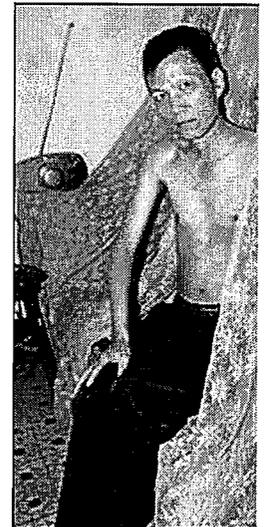
A division of the pharmaceutical company Bayer sold millions of dollars of blood-clotting medicine for hemophiliacs — medicine that carried a high risk of transmitting AIDS — to Asia and Latin America in the mid-1980's while selling a new, safer product in the West, according to documents obtained by The New York Times.

The Bayer unit, Cutter Biological, introduced its safer medicine in late February 1984 as evidence mounted that the earlier version was infecting hemophiliacs with H.I.V. Yet for over a year, the company continued to sell the old medicine overseas, prompting a United States regulator to accuse Cutter of breaking its promise to stop selling the product.

By continuing to sell the old version of the life-saving medicine, the records show, Cutter officials were trying to avoid being stuck with large stores of a product that was proving increasingly unmarketable in the United States and Europe.

Yet even after it began selling the new product, the company kept making the old medicine for several months more. A telex from Cutter to a distributor suggests one reason behind that decision, too: the company had several fixed-price contracts and believed that the old product would be cheaper to produce.

Nearly two decades later, the precise human toll of these marketing decisions is



Sam Yeh/Agence Presse, for The N

Lee Ching-Chang, so Taiwan farmer, teste positive for H.I.V. ir

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difficult, if not impossible, to document. Many patient records are now unavailable, and because an AIDS test was not developed until later in the epidemic, it is difficult to pinpoint when foreign hemophiliacs were infected with H.I.V. — before Cutter began selling its safer medicine or afterward.

But in Hong Kong and Taiwan alone, more than 100 hemophiliacs got H.I.V. after using Cutter's old medicine, according to records and interviews. Many have since died. Cutter also continued to sell the older product after February 1984 in Malaysia, Singapore, Indonesia, Japan and Argentina, records show. The Cutter documents, which were produced in connection with lawsuits filed by American hemophiliacs, went largely unnoticed until The Times began asking about them.

"These are the most incriminating internal pharmaceutical industry documents I have ever seen," said Dr. Sidney M. Wolfe, who as director of the Public Citizen Health Research Group has been investigating the industry's practices for three decades.

Bayer officials, responding on behalf of Cutter and its president at the time, Jack Ryan, declined to be interviewed but did answer written questions. In a statement, Bayer said that Cutter had "behaved responsibly, ethically and humanely" in selling the old product overseas.

Cutter had continued to sell the old medicine, the statement said, because some customers doubted the new drug's effectiveness, and because some countries were slow to approve its sale. The company also said that a shortage of plasma, used to make the medicine, had kept Cutter from manufacturing more of the new product.

"Decisions made nearly two decades ago were based on the best scientific information of the time and were consistent with the regulations in place," the statement said.

The medicine, called Factor VIII concentrate, essentially provides the missing ingredient without which hemophiliacs' blood cannot clot. By injecting themselves with it, hemophiliacs can stop bleeding or prevent bleeds from starting; some use it as many as three times a week. It has helped hemophiliacs lead normal lives.

But in the early years of the AIDS epidemic, it became a killer. The medicine was made using pools of plasma from 10,000 or more donors, and since there was still no screening test for the AIDS virus, it carried a high risk of passing along the disease; even a tiny number of H.I.V.-positive donors could contaminate an entire pool.

In the United States, AIDS was passed on to thousands of hemophiliacs, many of whom died, in one of the worst drug-related medical disasters in history. While admitting no wrongdoing, Bayer and three other companies that made the concentrate have paid hemophiliacs about \$600 million to settle more than 15 years of lawsuits accusing them of making a dangerous product.

The Cutter documents — a few of them have surfaced in recent years in television and newspaper reports about Cutter's marketing practices — were gleaned from that litigation. But because the documents did not relate directly to the suits, most went uninvestigated.

The documents — internal memorandums, minutes of company marketing meetings and telexes to foreign distributors — reveal and chronicle Cutter's decision to keep



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exporting the older product after it began making the new one, which was heat-treated to kill H.I.V. The heat treatment rendered the virus "undetectable" in the product, according to a government study. (There are few available records documenting the actions and decisions of the three other American-based companies that also sold unheated concentrate after offering a heated product.)

Doctors and patients contacted overseas said they had not known of the contents of the Cutter documents. Bayer and other blood-product companies, though admitting no wrongdoing, have already made some payments to foreign hemophiliacs. It is unclear if Bayer could now face legal liability specifically for selling the older product after a safer one was available.

Federal regulators helped keep the overseas sales out of the public eye, the documents indicate. In May of 1985, believing that the companies had broken a voluntary agreement to withdraw the old medicine from the market, the Food and Drug Administration's regulator of blood products, Dr. Harry M. Meyer Jr., summoned officials of the companies to a meeting and ordered them to comply. "It was unacceptable for them to ship that material overseas," he said later in legal papers.

Even so, Dr. Meyer asked that the issue be "quietly solved without alerting the Congress, the medical community and the public," according to Cutter's account of the 1985 meeting. Dr. Meyer said later that he could not recall making that statement, but another blood-product company's summary of the meeting also noted that the F.D.A. wanted the matter settled "quickly and quietly." Dr. Meyer died in 2001.

Whether Cutter was behaving ethically became an issue in internal company discussions. "Can we in good faith continue to ship nonheat-treated coagulation products to Japan?" a company task force asked in February 1985, fearing that some of its plasma donors might be H.I.V. positive. The decision, records show, was yes.

Taken together, the documents provide an inside view of Cutter's bottom-line strategizing and efforts to manage the flow of information amid growing public anxiety about the safety of its product.

When a Hong Kong distributor in late 1984 expressed an interest in the new product, the records show, Cutter asked the distributor to "use up stocks" of the old medicine before switching to its "safer, better" product. Several months later, as hemophiliacs in Hong Kong began testing positive for H.I.V., some local doctors questioned whether Cutter was dumping "AIDS tainted" medicine into less-developed countries.

Still, Cutter assured the distributor that the unheated product posed "no severe hazard" and was the "same fine product we have supplied for years."

Li Wei-chun said her son, who died in 1996 at the age of 23, was one of the hemophiliacs in Hong Kong who got AIDS after using that product. "They did not care about the lives in Asia," Ms. Li said in a recent interview. "It was racial discrimination."

How It Started

Discovery That Blood Spreads the Disease

At the beginning of the epidemic, more than two decades ago, fear over what would later be known as AIDS was centered mostly among gays and intravenous drug users.

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But that changed on July 16, 1982, when the federal Centers for Disease Control reported that three hemophiliacs had acquired the disease.

This gave epidemiologists a strong reason to believe that the disease was being spread through blood products. And that belief carried grave implications for the many thousands of hemophiliacs who routinely injected themselves with concentrate made from giant pools of donated plasma.

Because an AIDS test had not yet been developed, federal health officials had no idea how many plasma donors carried the disease.

By March of 1983, the C.D.C. went so far as to warn that blood products "appear responsible for AIDS among hemophilia patients."

The unfolding story had not gone unnoticed at Cutter headquarters. Back in January, Cutter's manager of plasma procurement had acknowledged in a letter: "There is strong evidence to suggest that AIDS is passed on to other people through . . . plasma products."

With sales of concentrate beginning to slip, Cutter got more bad news in May 1983: after learning that a Cutter rival had begun to make heated concentrate, France decided to halt all imports of clotting concentrate until it could figure out what to do.

Fearing a loss of customers, Cutter conceived a marketing plan that stopped well short of full disclosure. "We want to give the impression that we are continuously improving our product without telling them we expect soon to also have a heat-treated" concentrate, an internal memo said.

Several weeks later, Cutter tried to minimize the danger hemophiliacs faced when using blood products. "AIDS has become the center of irrational response in many countries," the company said in a June 1983 letter to distributors in France and 20 other countries. "This is of particular concern to us because of unsubstantiated speculations that this syndrome may be transmitted by certain blood products."

The French decided to keep using unheated concentrate, and Cutter said it sold them more of the unheated product in August 1983. Later, two French health officials were sent to prison for continuing to use up old stocks of unheated concentrate in 1985, when a heated product was available.

Cutter finally received United States approval to sell heated concentrate on Feb. 29, 1984, the last of the four major blood product companies to do so. Though some doctors and patients held out against the heated product, a safer era had clearly begun for hemophiliacs in the United States.

Market Considerations

Bayer Says Some Wanted Old Product

For five months more, until August 1984, Cutter said it continued to make the old, unheated medicine. The records suggest that the company hoped to preserve the profit margin from "several large fixed-price contracts." But in its statements to The Times, Bayer also said that some customers still wanted the old medicine, initially believing — incorrectly, it turned out — that heating the concentrate could leave it less effective and possibly dangerous.

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The new product, meanwhile, was selling briskly, leaving Cutter with a problem: "There is excess nonheated inventory," the company noted in minutes of a meeting on Nov. 15, 1984.

"They needed to get the return for what they invested," explained Michael Baum, a Los Angeles lawyer who has represented dozens of United States hemophiliacs in suits against blood-product companies. "They paid the donors. They had processed the plasma, put it into vials, kept it in warehouses — and all that expense had already been incurred." (One vial is roughly equivalent to a small dose, though more may be needed to stop severe bleeding.)

At the November meeting, the minutes show, Cutter said it planned to "review international markets again to determine if more of this product can be sold." And in the months that followed, it had some success, exporting more than 5 million units (a typical vial might contain 250 units) in the first three months of 1985, documents show.

"Argentina has been sold 300,000 units and will possibly order more, and the Far East has ordered 400,000 units," according to a March 1985 Cutter report. Two months later, the company reported that "in Taiwan, Singapore, Malaysia and Indonesia, doctors are primarily dispensing nonheated Cutter" concentrate.

By then, while there were still a small number of buyers in the United States, nearly all of the unheated concentrate was being sold abroad, available records show. All told, Cutter appears to have exported more than 100,000 vials of unheated concentrate, worth more than \$4 million, after it began selling its safer product.

Gary Mull, an international product manager for Cutter at the time, said no one at the company had ordered him to sell the unheated concentrate as a way of avoiding a write-off. "If I had reason to personally believe, let alone the company" that any of the material was highly infectious, "we wouldn't have sent it out," he said.

Mr. Mull, who now works for another blood-product company, added, "I wasn't the shipping person, but I would still be the person in charge of queueing it up."

Bayer, which is based in Germany, said in its statement that an overall plasma shortage in 1985 had kept Cutter from making more heated medicine. But Cutter may actually have contributed to that shortage — by using some its limited plasma supplies to continue making the old product.

Bayer's response also emphasized that some countries were slow to approve its new product. For example, Bayer said "procedural requirements" imposed by Taiwan had delayed its "ability to apply for registration" and had led to other delays as well.

But an official at Taiwan's health department, Hsu Chien-wen, said recently that Cutter had not applied for permission to sell the new, safer medicine until July 1985, about a year and a half after it began doing so in the United States.

In one case, records show, Cutter officials even discussed trying to delay Japan's approval of heated concentrate so the company could shed stocks of the older product. Bayer said Cutter did not act on that idea.

Officials from the three other American-based companies that continued to sell