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## Baxter's Heparin Killed Mother and Son, Family Says (Update2)

By Justin Blum - Apr 10, 2008

April 10 (Bloomberg) -- Bonnie Hubley, 65, died in December. A month later, so did her 47-year-old son.

Both suffered from an inherited kidney disease, and relatives at first assumed they died from years of health complications. The family also suspected that Randy, who lived three miles from his parents in Toledo, Ohio, was so devastated by his mother's death that he lost the will to survive.

``We thought he's in a better place," said Randy's widow, Colleen Hubley, 45. ``His body was, maybe, just too worn out. That gave me comfort knowing that."

The comfort faded days later when [Baxter International Inc.](#) recalled its blood-thinner heparin, a drug the family says mother and son received, as did thousands undergoing dialysis for failed kidneys. U.S. regulators later said the main ingredient in Baxter's heparin, made from pig intestines and imported from China, was contaminated with a cheaper substance. The Food and Drug Administration this week raised the death toll linked to heparin allergic reactions to 62.

Baxter's heparin sent Bonnie and Randy Hubley, already vulnerable because of other medical conditions, into a fatal tailspin, according to the family, which has filed two lawsuits against Baxter. The FDA won't name those who may have died from heparin or say whether the Hubleys are among them.

``Both of them have been through so many things," said Colleen Hubley, Randy's wife, who is a dialysis nurse. ``Fight, fight, fight. They were strong fighters. They had always made it through." She added: ``I do believe that the heparin was the accelerant."

### Still Taking Heparin

Family members said they're still upset and worried, especially since one of Bonnie Hubley's daughters, a year younger than Randy, gets dialysis -- and heparin -- for the same kidney disease.

The Hubleys assert in complaints filed in U.S. District Court in Toledo that Baxter was negligent. The suits contend that Bonnie and Randy Hubley suffered allergic symptoms consistent with those the FDA associated with the recalled heparin. They had nausea, diarrhea and weakness, family members said.

``He didn't have to die," said Colleen Hubley of her husband. ``I was actually getting to the point that I could actually function again when I heard about the heparin. It knocked me down so hard."

### Evidence Lacking, Baxter Says

Since January 2007, 62 people who had taken heparin died after suffering allergic reactions or low blood pressure, side effects consistent with those associated with the Baxter recall, the FDA said this week.

Baxter, which sold about half of the heparin in the U.S., hasn't conclusively linked any deaths to the contaminated medicine, said [Erin Gardiner](#), a spokeswoman. The company, based in Deerfield, Illinois, identified four cases in which heparin patients suffered reactions that may have contributed to their deaths, and the Hubleys aren't among them, Gardiner said.

Baxter knows of a dozen heparin-related legal complaints against the company, including the Hubleys', and all lack ``credible medical information" for the company to determine whether its drug was to blame, Gardiner said.

Baxter rose 80 cents, or 1.3 percent, to \$60.70 at 4:02 p.m. in New York Stock Exchange composite trading.

Regulators are investigating whether the contaminant, found in some of the Baxter heparin that was tested, was added intentionally to boost profit. The FDA says it hasn't concluded where in the supply chain the material was introduced. Baxter and its supplier of raw heparin, Scientific Protein Laboratories Inc., say the contaminant wasn't added in their factories and must have been introduced earlier.

### So Mad'

One of the Hubley lawsuits also names Scientific Protein, based in Waunakee, Wisconsin, with plants there and in China. Scientific Protein won't comment on the lawsuits, said spokesman [Wayne Pines](#).

Scientific Protein, majority owned by [American Capital Strategies Ltd.](#), also sold the product to other companies, prompting recalls by [Covidien Ltd.](#) and B. Braun Medical Inc. Recalls or warnings also have been issued in Australia, Switzerland, Germany, Italy, Denmark and Japan.

``I just try to put it out of my mind," said LeRoy Hubley, 71, Bonnie's husband and Randy's father. ``It makes me so mad I can't even think about it."

Family members say they're tormented by the FDA's disclosure in February that the agency failed to inspect a Chinese plant that makes the raw ingredient in heparin because the agency confused the company name.

## Staple of Dialysis

Hubley family members suffer from [polycystic kidney disease](#), a genetic disorder that can cause cysts that limit the kidneys' ability to filter waste from blood. About 600,000 people in the U.S. have the disease, which can lead to kidney failure and require a transplant or dialysis.

Bonnie Hubley's mother had the disease, and Bonnie passed it to Randy and her two daughters, Dawn and Barbara, said LeRoy Hubley. Bonnie Hubley's brother and half-brother also get dialysis for the illness, LeRoy Hubley said.

For years after they wed in 1959, Bonnie Hubley's health was good. She raised her family and worked as a waitress and restaurant manager. The disease began to take a toll in the 1980s, her husband said.

Bonnie Hubley had a kidney transplant more than a decade ago. Last year, that kidney began failing, forcing her back to dialysis in October, LeRoy Hubley said. She spent hours lying in dialysis centers.

Heparin, approved by the FDA in 1939, is a staple of dialysis, preventing blood clots in tubes that connect people's blood vessels with the machine that filters their blood and returns it. The drug also is routine in open-heart surgery.

## End to Suffering

The medicine gained notoriety last year when actor [Dennis Quaid](#) said a hospital gave his newborn twins a heparin overdose while they were treated for infection in November.

Soon after starting dialysis last year, Bonnie Hubley developed a fever and was sent to the hospital, said her daughter, Barbara Patton, 43, of Toledo. She needed heart bypass surgery.

Weeks later, after she resumed traveling to the dialysis center, fever forced her back into the hospital, her husband said. There, tests uncovered ailments including a growth in a heart valve, family members said. Doctors told relatives the prognosis was poor and suggested removing her breathing tube to end her suffering.

LeRoy Hubley concurred. Relatives gathered in the hospital room with Christmas music playing softly as LeRoy Hubley stroked his wife's hair and told her everything would be fine. Her eyes closed. The causes of death included septicemia, the presence of bacteria in the blood, according to her death certificate.

## Hot Wheels Collector

Randy Hubley, the couple's oldest, discovered his kidney disease when he tried to sign up for the armed forces at age 21, according to Patton.

He met his wife, the dialysis nurse, during treatments. After he received a kidney transplant in 2002 and was no longer a dialysis patient, they began dating, according to Colleen Hubley.

They married in 2004. From a previous marriage, he had three children and a grandchild. He spent free time restoring a vintage Ford Falcon and collecting toy Hot Wheels cars.

As his health deteriorated, he had to quit working as a manager of a retail battery store. He underwent surgery for an [aneurysm](#) in his brain and, in January, began dialysis treatments at the same Toledo center where his mother had gone.

‘They Poisoned Them’

After a session in which he was given heparin, he came home with diarrhea, vomiting and severe stomach pain, according to his wife. For several days, he was sick with a headache, sore throat and shoulder pain.

On Jan. 15, he awoke at 2 a.m. and collapsed on the floor. He was pronounced dead at the hospital, from causes that included a probable electrolyte imbalance, according to his death certificate. That condition can be caused by kidney disorders.

Patton, Bonnie Hubley's daughter and Randy Hubley's sister, shares the family's polycystic kidney disease and hasn't developed symptoms. She blames Baxter for the deaths of her mother and brother.

‘‘They poisoned them -- that's what it feels like,’’ Patton said. ‘‘It was unnecessary for either one of them to die.’’

Dawn Turk, 46, Bonnie and LeRoy Hubley's older daughter, wonders if she's next even though the FDA said it has taken steps to ensure the safety of heparin now in use.

Turk, who lives in Findlay, about 50 miles from family members in Toledo, needs dialysis six or seven days a week. Her husband, David, administers it at home. He uses heparin to keep her blood flowing.

‘‘You see her looking like a deer in the headlights,’’ said David Turk, 42.

‘‘I'm definitely going to die next,’’ he said his wife told him. ‘‘My mother is gone. My brother is gone.’’

‘‘I'm next.’’

To contact the reporter on this story: [Justin Blum](#) in Washington at [jblum4@bloomberg.net](mailto:jblum4@bloomberg.net).

To contact the editor responsible for this story: [Reg Gale](#) at [rgale5@bloomberg.net](mailto:rgale5@bloomberg.net).