

## KY Jury Awards \$7.2M for Defective Hearing Aid

BRETT BARROUQUERE - Associated Press

A central Kentucky family won a \$7.24 million verdict after a jury concluded that a company that makes implantable hearing aids knowingly sold a defective device that shocked a 6-year-old girl.

The jury in federal court in Louisville awarded \$6.25 million in punitive damages and \$994,000 in compensatory damages on Wednesday to the family of Breanna Sadler of Vine Grove. Sadler's family sued Advanced Bionics in 2011 — about three years after the girls' cochlear implant made her ill and sent her into convulsions when moisture seeped into the device.

Attorney Ronald Johnson, who represents the Sadler family and focuses on medical device litigation, said the company was "defiant" about whether it had done anything wrong in handling the hearing aid.

"This is, without a doubt, the worst conduct I've ever seen by a corporation, especially when dealing with such a vulnerable population," Johnson said.

The Swiss parent company of Advanced Bionics, Sonova, said in a written statement that it will consider appealing the judgment. In court records, the company said the devices complied with all federal regulations and recalls were issued appropriately.

The jury's award is the third largest in the western district of Kentucky since 1998, said Shannon Ragland, who runs the Kentucky Trial Court Review, a publication that monitors jury verdicts and awards.

A cochlear implant, sometimes called a bionic ear, is a device that is surgically placed into the bone of a patient's skull. Wires attach it to a magnet, which rests on the person's skull. When the magnet is engaged, the device gives a profoundly deaf or hard of hearing person a sense of sound.

The device has gained popularity among parents who have children with profound hearing issues, such as the one suffered by Breanna Sadler.

Breanna was 4 in 2006 when her family decided to have the cochlear device implanted.

"It worked pretty well," Johnson said. "It was a big surgery and they had it."

Breanna Sadler's device malfunctioned on Dec. 29, 2008. Johnson said her mother heard the girl screaming and found Breanna rubbing her head on the carpet and having convulsions. After calming the girl down, the mother removed the magnet from the device.

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Published on Medical Design Technology (<http://www.mdtmag.com>)

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"When she did, the convulsions stopped," Johnson said.

A doctor reattached the magnet, prompting more illness, screaming and convulsions, Johnson said. Six weeks later, Breanna underwent surgery to remove the Advanced Bionics device and have a new brand implanted.

Tests later showed that the device inside Breanna Sadler's ear had over 30 percent moisture. The allowable amount of moisture is .5 percent.

"She was at 60 times the allowable amount," Johnson said.

Advanced Bionics first became aware of problems with the implant in 2004 and conducted a limited, six-week recall in which they ceased shipping the devices. In March 2006, the company recalled devices that hadn't been implanted because of the issue of excessive moisture seeping into the device.

The company shipped roughly 4,000 implants between the 2004 recall and the 2006 recall. The Food and Drug Administration cited Advanced Bionics in 2007 for failing to get approval for a new supplier of a component to keep moisture out of the device. The FDA and Advanced Bionics settled the charges in 2008 for \$1.1 million.

"It was too late for Breanna," Johnson said.

To date, more than 1,000 have malfunctioned — a failure rate of about 40 percent. Johnson said the rate could rise to as high as 50 percent.

"If they're lucky, they just won't be able to hear anymore," Johnson said.

Breanna is now 11-years-old and the impact of the two surgeries and malfunctioning have taken a toll on her, Johnson said.

"Anytime she hears anything, she jumps out of her skin. She's very, very apprehensive," Johnson said. "She's just a very, very fearful little girl now."

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