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bill goes
down

GENETIC TESTING

Families Sue Hospital, Scientist For Control of Canavan Gene

A successful partnership between parents and a scientist to combat a deadly genetic disease has dissolved into a bitter legal battle over the commercial tests used to identify people with dangerous mutations in their genes. The lawsuit, filed on 30 October in Chicago federal court, is the latest dispute in the growing controversy over who controls and who benefits from human genetics research.

Thirteen years ago, the father of two children suffering from Canavan disease—a fatal illness whose symptoms begin appearing 3 months after birth—approached a scientist named Reuben Matalon and persuaded him to begin developing molecular probes to trace the disease to its source. They also set up a registry of families and helped recruit tissue donors. The disease, which affects 1 in 6400 Ashkenazi Jewish children, is caused by a mutation on chromosome 17 that leads to a deficiency of the enzyme aspartoacylase, gradually destroying the central nervous system. With the families' support, Matalon found a Canavan gene in 1993 and developed a genetic test. Matalon's employer at the time, Miami Children's Hospital (MCH), obtained a patent on the gene in 1997, and the next year began licensing a test that could identify lethal Canavan mutations.

The terms of that license are the focus of the suit, filed by four parents and three non-profit groups. They charge that Matalon and MCH are guilty of "misappropriation of trade secrets" based on their use of the children's blood and tissue, without consent, to secure a gene patent and develop a commercial test. Laurie Rosenow, an attorney at the Chicago-Kent College of Law in Chicago, Illinois, who helped prepare the complaint, says that this is the first time tissue donors have taken researchers to court for control of a gene. "It's a unique case" that could shape future genetic research partnerships, she adds.

Other patient groups are trying to head off such clashes by working out legal agreements in advance. For example, a support group for families with pseudo-xanthoma elasticum (PXE), an inherited disease that causes calcification of connective tissue, has been negotiating the terms of tissue donation with researchers since a gene was discovered in February. Sharon Terry, president of PXE International in Sharon, Massachusetts, hopes to sign an agreement soon with the gene discoverers and their employer, the University of Hawaii, to share control of patents. The support group has promised to pick up the patent application costs.

But there was no such agreement to clarify the roles of researchers and tissue donors when Daniel Greenberg, father of a child with Canavan disease, visited Matalon in 1987 to propose a collaboration. Greenberg heads the list of plaintiffs in the Canavan suit, which includes the Canavan Foundation of New York City, Dor Yeshorim of Brooklyn, New York, and the National Tay-Sachs & Allied Diseases Association Inc. of Brighton, Massachusetts. The suit seeks to block MCH's commercial use of the Canavan gene and recover damages of more than \$75,000 derived from royalties collected on the Canavan test.

The plaintiffs object to the \$12.50 royalty fee MCH is charging. In addition, accord-

ing to the complaint, they claim that MCH has tried to restrict access and promote a lead test center by setting a limit on the number of tests that can be performed by each licensee. The Canavan Foundation was forced to stop offering free genetic screening, according to the complaint, after being advised that it would have to pay royalties and comply with other licensing terms.

Matalon, who now works at the University of Texas, Galveston, says he has no stake in the dispute. "I get no royalties, no benefit from it," he says. "My interests have nothing to do with patents."

Matalon acknowledges that the Canavan parents helped him to get started by contributing tissue and "seed money" amounting to no more than \$100,000. But MCH provided \$1 million a year, he says, and in return asked him to turn over any marketable intellectual property. "They say, 'Let us know [about discoveries], and we will decide about the patent.'"

The parents' complaint includes a copy of a 12 November 1998 letter from MCH's chief financial officer, David Carroll, to a clinic testing for Canavan disease. Noting that users of the test must obtain a license from MCH, Carroll wrote, "We intend to enforce vigorously our intellectual property rights relating to carrier, pregnancy, and patient DNA tests."

MCH spokesperson Cynthia Gutierrez declined to discuss the case, citing the ongoing litigation. The Canavan parents also have decided not to comment.

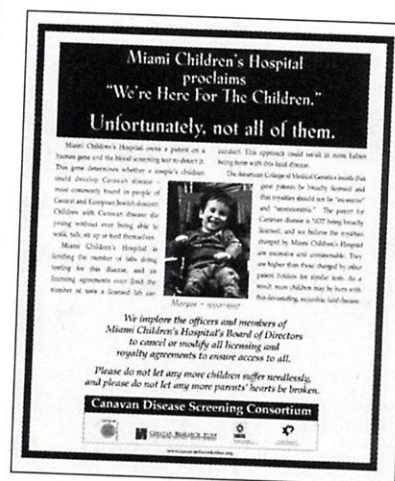
The suit highlights the key role that families can play in helping scientists with their research. Judith Tsipis, a biologist and genetic counselor at Brandeis University in Waltham, Massachusetts, who lost a son to Canavan disease, notes that the

Canavan families identified families at risk and collected tissues. The legal battle, she insists, "is not about the Canavan families wanting a piece of the pie," but about having a say in how their contributions are used.

—ELIOT MARSHALL

"I get no royalties. ... My interests have nothing to do with patents."

—Reuben Matalon



Media blitz. Parents of children with Canavan disease bought newspaper ads last year to promote access to genetic tests.