

SINCE 1854

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# Judge OKs punitives claim in suit over Adrenalin safety

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Pharmaceutical giant Warner-Lambert Co. will face a claim for punitive damages in Cook County Circuit Court next month for allegedly failing to warn of potential dangers to fetuses when its product Adrenalin is administered to pregnant women.

Circuit Judge Susan F. Zwick has ruled that plaintiffs in a lawsuit brought on behalf of a severely mentally retarded and disabled boy against Warner-Lambert can seek punitive damages when the case goes to trial Aug. 18.

In an order issued last week, Zwick found there is sufficient evidence to support the plaintiffs' theory of intentional wrongdoing by Warner-Lambert and to warrant a trial for punitive damages.

The boy, Daniel Valdovinos, sustained brain damage in the womb after his mother was given a shot of Adrenalin to treat symptoms of asthma at a Chicago clinic in 1984, according to plaintiff attorney Robert A. Holstein. Holstein said he will seek an award of \$40 million to \$50 million in punitive damages against Warner-Lambert.

The punitive damages are warranted because there is strong evidence that the company deliberately failed to inform the public that Adrenalin can cut off the oxygen supply to the brain of a fetus when administered to a pregnant woman, according to Holstein, of Robert A. Holstein & Associates.

"They have not warned of the danger to fetuses, even though they've known about it for at least five years prior to this occurrence," Holstein said. "The prod-

uct constricts the arteries of the uterus and cuts off the oxygen going to the child's brain."

Adrenalin, a synthetic form of the hormone produced naturally by the human adrenal gland, is a Warner-Lambert brand name for the generic drug epinephrine. The drug was developed by Warner-Lambert in 1901 and has been manufactured by its subsidiary, Parke-Davis & Co.

Jeff Baum, spokesman for New Jersey-based Warner-Lambert, said there is "simply no evidence" linking Adrenalin to birth defects in fetuses when the drug is administered to pregnant women. He also denied that the boy's mother, Marta Valdovinos, was treated with the company's brand of epinephrine.

"First of all, our product, Adrenalin,

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was not used — a generic form of epinephrine was used in that case," Baum said. "Secondly, and most importantly, there is no credible evidence that epinephrine given through an injection for an asthma attack could cause birth defects in a fetus."

Holstein disputed Baum's contention that Adrenalin was not used in the case, saying that the doctor who administered the drug to Valdovinos has testified that she used the Parke-Davis brand.

Another plaintiff attorney in the case, Thomas A. Zimmerman Jr. of Schneider & Schneider P.C., said Warner-Lambert has known at least since 1962 that Adrenalin causes fetal anoxia, or the deprivation of oxygen to the fetus, in pregnant women. Additionally, he charged that the company misled the U.S. Food and Drug Administration by failing to disclose that information.

"There is evidence that Warner-Lambert defrauded the FDA and medical profession by stating in Adrenalin's labeling that there are no studies on humans when, in fact, Warner-Lambert had knowledge of a 1962 study showing Adrenalin causing fetal anoxia in pregnant women," Zimmerman said.

Although Adrenalin and other brands of epinephrine have been widely used in the medical field for years, Warner-Lambert has never registered the product with the FDA since the agency's inception in 1934, according to Holstein. The FDA told the company to submit the drug for review in 1976, "and they never did and they still haven't since this case was filed," he said.

Holstein said the FDA is investigating allegations that Warner-Lambert failed to disclose the dangers that Adrenalin poses to fetuses.

Holstein said the FDA used its criminal powers for the first and only time in 1995 when the agency issued an indictment against Warner-Lambert for failing to notify it of a bad batch of another drug that it manufactured, Dilantin. The company settled the charges by agreeing to pay a \$10 million fine. Dilantin is a sister product of Adrenalin, Zimmerman said.

Warner-Lambert is represented in the Cook County case by John D. Cassidy of the Chicago law firm of Cassidy, Schade & Gloor.

No judge has yet been assigned to hear the case. *Valdovinos v. Parke-Davis & Co., et al.*, No. 91 L 8973.