

Top court revives lead poisoning suits

By Joe Surkiewicz
 Daily Record Legal Affairs Writer

For the second time in a month, a prestigious health research institution in Baltimore is being criticized for faulty research standards and ethical lapses with studies involving human subjects — and this time, the faultfinding comes from the state’s top court.

The Court of Appeals yesterday revived two lawsuits against Kennedy Krieger Institute brought by lead-poisoned children, rejecting the institute’s claim that their parents consented to their participation in a study of abatement techniques.

“[P]arents, whether improperly enticed by trinkets, food stamp, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous non-therapeutic research surroundings, than do researchers,” Judge Dale R. Cathell wrote. “In such cases, parental consent, no matter how informed, is insufficient....

“Children, it should be noted, are not in our society the equivalent of rats, hamsters, monkeys, and the like.”

A lower court had thrown the cases out, finding no relationship that would require the researchers to warn of potential harm to the children.

Reversing that decision, the Court of Appeals found the research relationship could create duties to the children, which Kennedy Krieger may have breached by not fully informing their parents of inherent dangers of potential blood lead poisoning.

“Such research programs normally create special relationships and/or can be of a contractual nature, that create duties,” the court held, remanding the case for trial. “The breaches of such duties may ultimately result in viable negligence actions.”

The court also found that federal regulations could impose such a duty on Kennedy Krieger, which it may have breached by not fully informing families enrolled in the project of risks and foreseeable dangers of lead poisoning in Baltimore’s rental properties. The study was funded by the U.S. Environmental Protection Agency.

“It is not in the best interest of a specific child, in a nontherapeutic research project, to be placed in a research environment, which might possibly be, or which proves to be, hazardous to the health of the child,” Cathell wrote for the court in a 101-page opinion. “We have long stressed that the ‘best interests of the child’ is the overriding con-

cern of this Court in matters relating to children.”

The top court criticized the Johns Hopkins University-affiliated Kennedy Krieger’s Institutional Review Board (IRB) only a month after the federal government suspended human medical experiments at Hopkins for widespread lapses in safety procedures.

The suspension, which lasted three days, came after the death in June of a healthy young woman participating in an asthma study. The federal Office for Human Research Protections ordered Hopkins’ Institutional Review Boards to reconsider about 2,000 studies that they had approved.

In the Kennedy Krieger study, two children suffered elevated blood lead levels and, according to their attorneys, suffer irreversible brain damage.

“Here, the IRB, whose primary function was to insure safety and compliance with applicable regulations, encouraged the researchers to misrepresent the purpose of the research in order to bring the study under the label of ‘therapeutic’ and thus under a lower safety standard of regulation,” the opinion noted. “The IRB’s purpose was ethically wrong, and its understanding of the experiment’s benefit incorrect.”

Judge Irma S. Raker concurred with the result only.

“Unfortunately, the majority chooses to go far beyond the narrow question presented in these appeals and addresses a number of ancillary issues in *dicta*,” Raker wrote. “Such sweeping holdings are far beyond the question presented in these appeals, and their resolution by the Court, at this time, is inappropriate.”

Chief Judge Robert M. Bell recused himself from the case for undisclosed reasons. Retired Judge Robert L. Karwacki served as the seventh member of



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jects who became lead poisoned during the study, also agreed with yesterday’s opinion.

“It appears that because of recent events, this is a very important decision of first impression for the entire country,” attorney Suzanne C. Shapiro said. “The court sent a message that it seriously views research on human subjects — and not just researchers, but the institutional review boards that oversee the research. The court’s concern is especially heightened when children are involved.”

Attorneys for Kennedy Krieger did not return phone calls seeking comment.

Angus R. Everton, who wrote an amicus brief on behalf of Kennedy Krieger by the National Center for Lead-Safe Housing, said his client is “profoundly disappointed” by the opinion.

“In terms of a lot of the *dicta* in there, I agree much more with what Judge Raker said,” Everton said. “The court made a lot of statements not necessary for the resolution of the case. Now it will be virtually impossible to conduct nontherapeutic research involving children.”

The Kennedy Krieger study began in 1994, when more than 100 families participated in the research effort, known as the Lead-Based Paint Abatement and Repair and Maintenance Study. Myron and his mother Catina moved into a house on East Federal Street in May 1994 and were soon recruited to the

the court.

One observer praised the opinion yesterday, saying it could be a model for other states.

“I think the court wisely recognized that the end doesn’t always justify the means,” said Michele E. Gilman, a University of Baltimore law professor and head of UB Law’s community law clinic. “It showed the legal profession in its finest hour. Scientists working for prestigious health care institutions didn’t see anything wrong with what they were doing. The court had to draw the line and say you can’t expose a healthy child to risk.”

The attorney for 11-year-old plaintiff Myron Higgins, one of the two test sub-

study.

Like other rental units in the research effort, the house had been identified as containing lead paint. The landlord agreed to have Kennedy Krieger assign one of three levels of lead-paint abatement repair to the house and to recruit families with children between the ages of 6 months and 47 months old.

Kennedy Krieger asked the families if investigators could periodically test the levels of lead in the house dust and draw blood samples from the children to monitor if they became lead-poisoned over time. The families, many of whom lived in economically deprived and minority neighborhoods, were offered incentives such as money, food and clothing to participate.

The court rejected Kennedy Krieger’s assertion that the parents of the children gave informed consent to participate in the study.

“Otherwise healthy children, in our view, should not be enticed into living in, or remaining in, potentially lead-tainted housing and intentionally subjected to a research program, which contemplates the probability, or even the possibility, of lead poisoning or even the accumulation of lower levels of lead in blood, in order for the extent of the contamination of the children’s blood to be used by scientific researchers to assess the success of lead paint or lead dust abatement measures,” the court said.

Cathell wrote that when it comes to children in nontherapeutic research that are subject to health risks, “we will not defer to science to be the sole determinant of the ethicality or legality of such experiments.

“The reason, in our view, is apparent from the research protocols at issue in the case at bar,” Cathell continued. “Moreover, in nontherapeutic research using children, we hold that the consent of a parent alone cannot make appropriate that which is innately inappropriate.”

Vulnerable subjects

While differing from the Tuskegee Syphilis Study, intentional exposure of soldiers to radiation, exposure of Navajo miners to radiation, and the secret administration of LSD to soldiers by the CIA and the Army, those studies present problems similar to the Kennedy Krieger study, the opinion said.

“These programs were somewhat alike in the vulnerability of the subjects; uneducated African-American men, debilitated patients in a charity hospital, prisoners of war, inmates of concentration camps and others falling within the custody and control of the agencies conducting or approving the experiments,” Cathell wrote.

“In the present case, children, especially young children, living in lower economic circumstances, albeit not as vulnerable as the other examples, are nonetheless, vulnerable as well,” Cathell added.

What the court held

Case: Ericka Grimes v. Kennedy Krieger Institute Inc., CA No. 128, Sept. Term 2000. Reported. Opinion by Cathell, J. Raker, J. concurs in result only. Filed Aug. 16, 2001.

Issue: Did the trial court err in ruling on a motion for summary judgment that as a matter of law a research entity conducting an ongoing non-therapeutic scientific study does not have a duty to warn a minor volunteer participant and/or his legal guardian regarding dangers present when the researcher has knowledge of the potential for harm to the subject and the subject is unaware of the danger?

Holding: Yes; summary judgment vacated and remanded for trial. Such research programs normally create special relationships and/or can be of a contractual nature that create duties. The breaches of such duties may ultimately result in viable negligence actions.

Counsel: Suzanne C. Shapiro and Kenneth W. Strong appellants; Michael I. Joseph for appellee.

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The state’s highest court yesterday revived two lead-poisoning lawsuits against Kennedy Krieger Institute, with harsh words about the research project that exposed children to the risk of brain damage. ‘The court sent a message that it seriously views research on human subjects - and not just researchers, but the institutional review boards that oversee the research,’ said Suzanne Shapiro, a plaintiff’s attorney in one of the suits.