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A Question of Consent

The study's goal was laudable: Finding the best way to stop lead poisoning in Baltimore's rental stock. But did Kennedy Krieger's researchers put children at risk?

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Did Baltimore's Kennedy Krieger Institute violate the basic tenets of human subject research by failing to inform adequately families with young children of risks and foreseeable dangers in a study on lead poisoning in Baltimore's rental housing?

Or was the internationally recognized clinical and research institute not legally obligated to warn participants in the non-therapeutic study, funded by the Environmental Protection Agency to evaluate the cost-effectiveness of various lead-paint reduction strategies?

Those arguments, which pit claims of ethical misconduct against well-meaning intentions to stem an endemic health problem that affects tens of thousands of children in Baltimore and beyond, will be heard by the Court of Appeals May 31.

The attorney for 11-year-old Myron Higgins and his family will argue that the Baltimore City Circuit Court erred last year when it granted KKI's motion for summary judgment — and that Myron, who became lead-poisoned during the study, should have a chance to present his case to a jury.

"The court below decided KKI didn't owe any type of duty to warn," said Suzanne C. Shapiro, Myron's attorney. "We're arguing there is a researcher and a subject, and because of that relationship the researcher owes a duty to really inform subjects of the true nature of the study and the risks."

Only if that's done, Shapiro added, can the subject make an informed choice about whether to participate in the study: "You can't have free will without being fully informed."

Countering that argument is one of KKI's attorneys, S. Allan Adelman, who said the case is over the question of duty owed by a researcher in a study that only collected data. "We're saying a passive study didn't create an additional relationship between the subjects of the study and [KKI]," Adelman said.

Prevention plan

The lawsuit's beginnings go back to 1994, when KKI began a study to evaluate the cost-effectiveness of different lead-paint abatement methods in preventing lead poisoning in young children. More than 100 families in Baltimore participated in the KKI 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 study. (Another case pending before the top court, *Grimes v. Kennedy Krieger Institute*, also alleges that child research subjects became lead-poisoned while participating in the study.)

Like other rental units in the research effort, the Higginses' house had been identified as containing lead paint. The landlord agreed to have KKI 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.

KKI 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 Higgins house was assigned a "level two" intervention, which cost $3,500. Repairs included replacing the entryway mat, reducing friction in the window sashes against the window jambs, making floors smooth and cleanable, re-hanging doors so they wouldn't scrape against the floor and "removal of loose and peeling paint to the limit of the funding budget," according to the Higgins brief.

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>
> Angus R. Everton

Catina Higgins was unaware the house contained lead-based paint, and Myron was not diagnosed with elevated blood lead levels before the family moved in, the brief noted.

After the house was tested for lead a second time in July 1994 and KKI determined several areas had lead-dust levels above Maryland's clearance criteria, "[KKI] did not share the results of this dust test until almost two months later," the brief said. "By that time, Myron Higgins was already exposed to high levels of lead in dust and was found to have an elevated blood lead reading."

"The issue is whether KKI owed a duty, breached that duty and a foreseeable injury resulted," said Shapiro, the family's lawyer. "They knew there was lead paint in the house and the dust. It was their belief the lead in the dust would increase, and they didn't explicitly express that to the family. They had an expectation some children would be poisoned."

A trusted name

Shapiro added that Catina Higgins put trust in the name and reputation of Kennedy Krieger.

"They're known for helping children with lead poisoning," she said. "When they introduced themselves to the Higginses, they said, 'We're from the lead poisoning prevention program.'"

The attorney rejected KKI's contention that the researchers were only passive observers collecting data.

"We say they set up a situation where children move in and set up a trap to see what will happen next," Shapiro said. "I don't think KKI's intent was evil. I believe it is foreseeable that they were going to cause unreasonable harm, and that is unethical. All ethical codes say researchers owe a duty to their subjects to protect them from harm."

In an amicus brief filed in support of the Higgins family, the Public Justice Center, a nonprofit public interest law firm in Baltimore, also argued that KKI had a duty to protect Myron and other human subjects.

"Especially because the study was non-therapeutic and scientific, there would be a duty to protect participants from unreasonable harm," said Deborah Thompson Eisenberg, the PJC attorney who wrote the friend-of-the-court brief.

"When they discovered the high lead levels in the dust in the Higgins house, KKI should have told the mother immediately, because there are high correlations between dust and blood lead levels," Eisenberg said.

Shades of shame

In its amicus brief, the PJC recounted the historical exploitation of blacks for medical research in the United States and principles of ethically sound research that emerged in response to Nazi atrocities during World War II.

It also drew a parallel with the infamous Tuskegee Syphilis Study, a U.S. Public Health Service project that investigated the effects of untreated syphilis in black men.

"Despite original good intentions, the [Tuskegee] investigators did not inform participants of the purpose of the study, and misled them into believing that they were being treated for syphilis," the brief said. "Research-related procedures, such as lumbar punctures, were described as 'special free treatments,'" and the study continued long after penicillin became widely available to treat the disease.

Suzanne C. Shapiro represents an 11-year-old boy who sustained lead poisoning during the course of the EPA-funded study, and now wants his day in court. 'The court below decided [Kennedy Krieger] didn't owe any type of duty to warn,' she said. 'You can't have free will without being fully informed.'

"Tuskegee teaches the danger of elevating the long-term goals of scientific research over the duty to protect the wellbeing of human research subjects," the PJC's brief noted.

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KKI dismissed those arguments, pointing out in its brief to the top court that Catina Higgins signed a lease addendum containing a warning the house contained lead paint and further "explicit" warnings in KKI's consent form.

Furthermore, KKI "substantially diminished the risk" of lead-paint dust poisoning by repairing the house, which reduced, but did not eliminate, lead in the house as part of the study.

Supporting those arguments is an amicus brief on behalf of KKI by the National Center for Lead-Safe Housing.

"Comparing this to the Tuskegee experiment is shameful. You can't make that comparison," said Angus R. Everton, the brief's author.

"If you read the appellant's brief, it's not clear what KKI was to warn," Everton said. "The Higginses also signed the informed consent form for the study. There's even a signature for Myron. To the extent the mother was able to give informed consent, she did so. The house wasn't held out to be lead-free."

Everton said the purpose of the study was to find practical ways to remove lead paint. "We can't remove all the lead from all the properties in Baltimore, and the only way to do it is to perform studies," he said.

Furthermore, the duty to obtain informed consent applies, for example, when a physician is going to perform a procedure, Everton added. "Courts have never recognized a general duty to inform the public of environmental dangers at large," he said.

Nor did he accept the argument made in the Higgins reply brief that unsophisticated subjects like the Higgins family are particularly vulnerable to inducements from respected institutions such as KKI and that the consent form was too difficult to understand.

"The consent form was in plain English," Everton said. "I'm personally not willing to accept the position that people like the Higginses are too stupid to understand a consent form. That's racist, and the court won't accept that. You have to assume people are intelligent enough to understand and accept responsibility."

One legal expert, however, questioned the validity of the warnings.

"There is an issue of whether a parent *could* ever consent to exposing a child to that kind of danger," said Michele E. Gilman, a law professor at the University of Baltimore and head of UB Law's community development clinic. "Wouldn't that be child abuse? A jury should be allowed to consider that."

Gilman called the case important.

"It's like putting children in the middle of the street to see what kinds of cars hit them and saying there's always a danger in crossing the street," she said. "I'm shocked this case was dismissed on summary judgment. [KKI] knowingly put them in the position of inhaling and eating lead paint."

> "Such a duty … would have a really chilling effect on research in this country."
>
> S. Allan Adelman

Chilling effect

Another legal expert said both sides in *Higgins v. Kennedy Krieger Institute* are making good points.

"In general, when you enroll someone in a study, consent forms are at a college level, not a sixth-grade level," said Diane Hoffman, a professor at the University of Maryland School of Law and head of its law and health care program. "Often the research is complex, and you need to take additional time to explain. So that's a valid concern."

But KKI is attempting to do something good in the study — "and the data may show that the EPA can't get to a level of abatement that's sufficient, and you need total abatement," Hoffman said.

"The appellants have a hard argument," the law professor added. "If [KKI] had disclosed the information earlier, would [the Higgins] have moved out of the house or taken [Myron] to a doctor? It's a question of whether they would have done something different."

There's another drawback if the Court of Appeals imposes the obligation the Higgins family seeks, said KKI's attorney: It would "obliterate" the research project to the "great detriment of our society."

"If the duty were imposed it would have a really chilling effect on research in this country," Adelman said. "It could very well negate some of this research."

The Higgins family, however, is not asking for anything unusual in their quest to get their case to a jury, their attorney said.

"It's just basic Maryland tort law on informed consent, plus complying with federal regulations and medical bioethics codes," Shapiro said. "Plus, the Hippocratic oath — First, do no harm."