

'My Kids Were Used as Guinea Pigs'

Lead Paint Study Adds To Debate on Research

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Saturday, August 25, 2001; Page A01

The plastic cylinders of green cleaning powder kept showing up at Jacqueline Martin's row house during that anxious summer of 1994. Every time she complained about the increasing lead levels in the blood of her 2-year-old daughter, Anquetette Carpenter, she would get another supply of cleanser from the woman she still calls "Miss Ruth," a researcher with the renowned Kennedy Krieger Institute.

Mix it with water and the lead dust will go away, Martin remembers being told. Clean the windowsills. Clean the floors. Everything will be okay.

But it wasn't. Anquetette's lead levels got worse. Soon, Martin began to hate that green powder, which came to represent so much to her.

"I felt betrayed," said Martin, whose other daughter, 5-year-old Ashley Partlow, also lived in the row house. "I felt like my kids were used as guinea pigs."

There is now a pitched debate about the ethics of the mid-1990s Kennedy Krieger study that encouraged landlords to rent lead-contaminated homes to Martin's family and many of the 107 other poor, Baltimore families with young children in the research project. The study, overseen by Johns Hopkins University, was denounced last week by Maryland's highest court, which compared it to the infamous Tuskegee, Ala., experiments that withheld treatment from black men infected with syphilis.

The court's outraged opinion -- which also accused Kennedy Krieger of inadequately informing parents of the study's risks and, in effect, using their children as "canaries in the mine" -- is further shaping the complex debate about the rights of human research subjects.

Baltimore judges had dismissed two lawsuits filed against Kennedy Krieger by mothers of children in the study even before lawyers could finish gathering information. Now that Maryland's highest court has reversed those decisions and ordered trials, the study's methods will finally get a public airing, offering a window into the veiled world of high-stakes human research.

At the same time, the Kennedy Krieger study also is being scrutinized by the agency that last month halted for five days federally funded research involving human subjects at Hopkins after the death of a healthy volunteer in an asthma experiment. The probe is being watched eagerly by the single mothers who filed suit against Kennedy Krieger: Catina Higgins, Martin's roommate, and former West Baltimore resident Viola Hughes. Martin's attorneys also are preparing a suit.

The federal probes -- by the Office for Human Research Protections, an agency of the U.S. Department of Health and Human Services -- into the lead paint and asthma studies have focused in large part on the actions of the panels of Hopkins faculty members, known as institutional review boards, which are charged with scrutinizing the methodology of medical studies. In his scathing opinion last week for the Maryland Court of Appeals, Judge Dale R. Cathell leveled blunt criticisms

<http://www.washingtonpost.com/ac2/wp-dyn/A59479-2001Aug24?language=printer> 8/25/01

at the review board that oversaw the lead paint study, saying "the medical and scientific communities" should no longer be given sole authority for research involving children.

Hopkins and Kennedy Krieger have close ties but are independently run. Kennedy Krieger is allowed to conduct human studies because it has been listed as an affiliate on Hopkins's federal human research permit.

The lead paint study focused on the hardscrabble neighborhoods in West and East Baltimore, where Kennedy Krieger researchers estimate that 95 percent of the thousands of row houses built before World War II are contaminated by lead paint. The purpose of the study was to determine the minimum amount of lead cleanup that could be undertaken and still protect the health of children.

The researchers split their subjects into four groups of row houses, each receiving varying degrees of lead cleanup. Kennedy Krieger's lawyers, S. Allan Adelman and Michael I. Joseph of Rockville, have said in court papers that the homes the children were to live in had to have elevated lead levels to be included.

A fifth group lived in modern homes with no lead paint.

The researchers doled out grants for cleanup work in the contaminated homes to landlords, who were given instructions to rent the homes to families with small children. Some occupied homes also were included in the study, as long as there were small children living there. The children could not be mentally disabled or have sickle cell anemia. All of the children in the study were tested to measure the effectiveness of the different cleanup methods.

Hughes lived in a house that Kennedy Krieger's lawyers said had undergone a complete cleanup before she moved in, though her attorneys contend that test results showing high lead levels in the house were withheld from her. Higgins and Martin moved into a home that had been given a partial cleanup, which included established lead removal techniques such as using sealants to make floors easier to clean and installing aluminum covers on door trims.

Lawyers for Higgins and Martin say it was unfair that their clients moved into a home that had received only a partial cleanup when others in the study got more extensive cleanup.

Kennedy Krieger officials say placement was a matter of chance. When houses in the study were available, landlords placed ads. Sometimes the houses had received major cleanup work, sometimes not.

Without Warning

Kennedy Krieger Chief Executive Gary W. Goldstein and Mark Farfel, the study's supervising researcher, have adamantly defended the research methods, though they have declined to talk in detail about the cases of the women who have sued. Goldstein and Farfel say the three-year research effort took an innovative approach by identifying rental homes that might have been abandoned by landlords concerned about high cleanup costs.

"We would feel very differently if somehow we looked at it and said 'We really screwed up here,' " Goldstein said this week. "But we didn't do that."

Lawyers for Higgins, Martin and Hughes have argued that Kennedy Krieger did not do enough to warn their clients about the risks of the study, an accusation that was affirmed in Cathell's opinion. The women signed consent forms that stated "lead poisoning in children is a problem in Baltimore," but the forms made no mention of specific health effects or that the researchers expected children in the study to accumulate lead in their blood.

Kennedy Krieger's lawyers have argued that the institute did not have a legal obligation to warn the study's subjects about the risks, saying the consent forms signed by participants are not binding contracts.

Such positions, relying on technical interpretations of the law, have drawn the ire of groups that advocate reforms.

"There is a culture that has grown up among researchers; it puts science above human beings -- and that's a very dangerous thing," said Vera Hassner Scharav, of the Alliance for Human Research Protection, a privately funded New York advocacy group.

Dangerous Levels

When the Kennedy Krieger study started, the children of Higgins, Martin and Hughes all had lead levels below or slightly above the 10 microgram per deciliter safety standard set by the Centers for Disease Control and Prevention, according to the children's attorneys. But those levels rose quickly.

In seven months, the levels for Myron Higgins, now 11, went from six micrograms to 21, according to Suzanne C. Shapiro, who represents the Higgins family. The levels for Hughes's daughter, Ericka Grimes, went from 9 micrograms to 32, her attorney, Kenneth W. Strong, said; the levels for Martin's daughter Anquetette, whose name was recently changed to Charnice, went from 10.7 micrograms to 24, said Shapiro, who also represents the Martins. No test results are available for Martin's other daughter, Ashley.

Lead levels of 20 or above have been shown in studies to lead to reduced IQs, while levels of 24 or above have been shown to increase the chances of mental retardation, according to the American Academy of Pediatrics.

Goldstein and Farfel say rising lead levels were not the norm in the study. They said researchers tracked declining lead levels for most children who registered above 15 on the contamination scale and that children with blood levels around 10 did not get worse.

New Opportunities

Hughes, Higgins and Martin were all poor and had bounced between welfare and low-paying jobs. Hughes, who has a general studies degree from Baltimore City Community College, is the only one who graduated from college.

Hughes, 29, lived in a row house about 3 1/2 miles from the home that Martin and Higgins shared. She moved there in 1990, with her sister and mother, after years living on the 11th floor of the

Lafayette Gardens public housing development, with its constant presence of guns and drugs.

The \$425-a-month row house on North Monroe Street sat between a funeral home and a liquor store on a busy street, but it was a big improvement over the squalid environment at Lafayette Gardens, which has since been torn down.

Hughes's daughter, Ericka, was born in 1992. The next year, a Kennedy Krieger representative signed up the young mother for the lead paint study.

At first, the study seemed like a great idea -- free testing and only a little inconvenience -- and she certainly didn't mind getting the \$5 or \$15 payments each time she filled out questionnaires or brought in little Ericka for testing.

But, like Martin, Hughes said she was getting increasingly worried during late 1993 and the summer of 1994. The reports she got from Kennedy Krieger showed rising lead levels in Ericka's blood. Hughes also turned to Miss Ruth. But the problem persisted.

Kennedy Krieger did not respond to requests to interview Miss Ruth, and her last name could not be confirmed.

Now, Hughes wonders whether the lead is responsible for her daughter's learning disabilities, attention problems and troubles at George Washington Elementary School, where Ericka had to repeat the second grade. Hughes wonders most on the days when Ericka comes home crying and asks: "Mommy, I'm stupid?"

"I'm like, 'No, baby, you're not stupid. We just have to work harder,' " Hughes said this week.

Martin, 27, said her children also have struggled at school, especially Ashley, who was 5 when the study started.

"She's slow. She's not on the level she should be," Martin said.

Higgins could not be reached to discuss the case.

Martin and Hughes said that while the study was being conducted they accepted small gifts from Kennedy Krieger when they took their children in for testing. Martin remembers Ashley and Anquetette getting a few stuffed animals and some stickers. Hughes was given vouchers for free food at a Baltimore farmers market.

"I thought it was just an incentive," Hughes said. "A lot of people pay you to take surveys. I didn't know a whole lot about it."

'My Kids Were in Danger'

Their homes also were being tested. There is much dispute about the testing of Hughes's home, in particular, because Kennedy Krieger gave her test results that showed low levels of contamination and withheld results that showed high levels.

Strong accuses Kennedy Krieger of hiding critical information, but the hospital's lawyers say the high-level results were not disclosed because they were measured with an experimental device.

Throughout the study, the mothers of children with high lead levels were being told by Kennedy Krieger to share the test results with their doctors, court documents state.

But such referrals were little comfort for Martin and Hughes. Eventually, they decided to move, each leaving in 1995.

"I knew my kids were in danger," said Martin, who now lives with her mother. "I needed to get out of that house. I even tried to get subsidized housing."

Keeping It Quiet

Kennedy Krieger will not release the names of the study subjects, citing the confidentiality of medical records. Farfel and Goldstein say no attempts have been made to contact them though the lawsuits have raised questions about the safety of the experiment. The hospital's last contact with study subjects was about 1 1/2 years ago for routine follow-ups, Farfel said.

Some lawyers who have represented human subjects say the hospital should be reaching out.

"There's a moral, an ethical and a legal obligation to notify the people, and if they don't notify the people, to notify the press so they can notify the people," said Alan Milstein, a New Jersey lawyer.

But Goldstein and Farfel said no notifications are necessary and that the study already has improved the lives of most participants. They describe poor Baltimore neighborhoods as awash in lead hazards. If the study subjects hadn't moved into homes linked to the Kennedy Krieger research, Goldstein said, they would have ended up in other contaminated homes, maybe ones that were receiving no treatments.

"It's not that we intercepted people who were on their way to some treasure trove of lead-safe houses in Baltimore and directed them to houses with lead paint," Goldstein said.

Asked whether he would change anything about the study, Goldstein thought for a moment, then said, "I don't think so."

Then, he paused again, adding, "That's not to say a mistake couldn't have been made."

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