Preemie Study Sparks Debate Over Risks of Research

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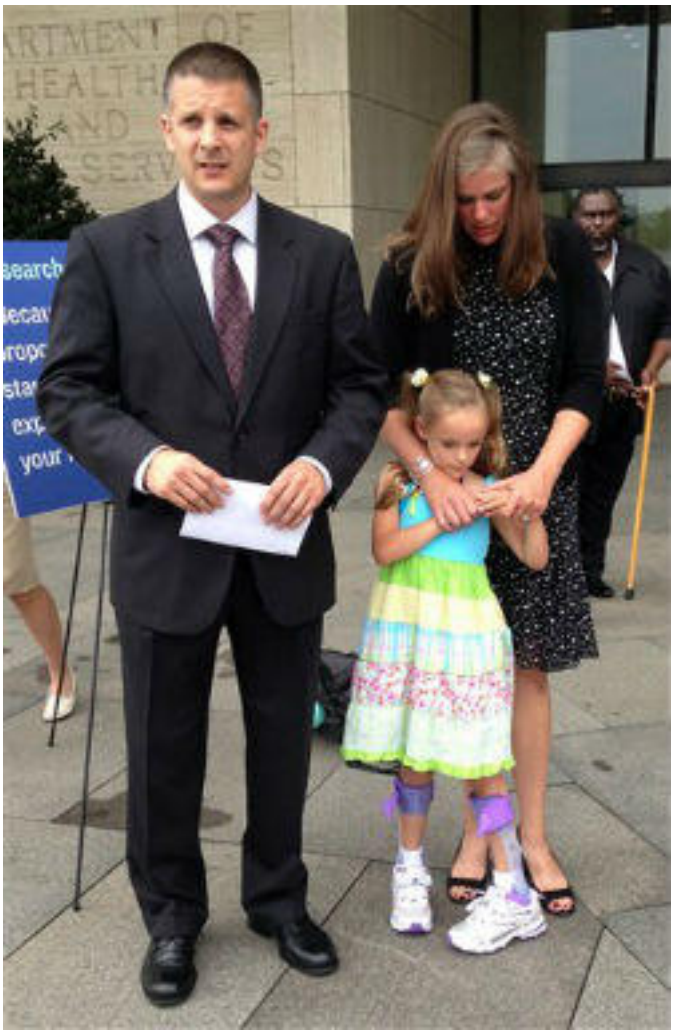

Dagen Pratt's parents enrolled their tiny premature baby in a study of oxygen treatment believing she'd get the best possible care. They didn't understand it was an experiment to test what dose works best. No one mentioned any risks.

Now 6, Dagen struggles with cerebral palsy, and they wonder: Is that long-ago study to blame?

"Tell me that the Support study did not hurt Dagen in any way," her father, Shawn Pratt, challenged a government panel on Wednesday as his daughter, dressed in a bright sundress, stood quietly by.

A major controversy has erupted over what sounds like a straightforward question: How much should patients be told about the potential risks before they're enrolled in certain kinds of medical research?

The issue isn't about how to study a brand-new, unapproved therapy. All sides agree that those studies must fully inform participants that there's no guarantee the experiment will work, or even be safe.

Instead, the debate is about one of modern medicine's dirty little secrets: Doctors frequently prescribe one treatment over another without any evidence to know which option works best. There's no requirement that they tell their patients when they're essentially making an educated guess, or that they detail the pros and cons of each choice.

Researchers are supposed to outline all the risks when they study which commonly used option is best. But could that mislead patients into thinking research is riskier than their own doctor's best guess?

Federal health officials put that question to the public Wednesday, as they debate how strictly to regulate this type of research — a debate sparked by that study of premature babies who included Dagen Pratt of Kingwood, W.Va.

The tiniest preemies face serious risks, including death and disabilities.

Oxygen has been a mainstay of treating them, but doctors didn't know just how much to use. Too much causes a kind of blindness called retinopathy of prematurity. Too little can cause neurologic damage, even death. So hospitals used a range of oxygen, with some doctors opting for the high end and some for the low.

The Support study, conducted between 2005 and 2009, aimed to settle which end of that range was the best dose. It randomly assigned about 1,300 preemies at 23 hospitals to a lower or higher oxygen dose. To researchers' surprise, slightly more babies who got the lower dose died, a finding that has led to new standards for the care of preemies.

The problem: A government watchdog agency last spring ruled that researchers violated federal regulations that required them to spell out the risks of the study for parents. Nowhere in the consent forms that parents had to sign was death mentioned.

"This was a very, very important study to do," Dr. Jerry Menikoff, head of the Office for Human Research Protections, stressed Wednesday. "All we were asking for," he added, "is a couple of sentences to say there were risks."

He agreed with consumer advocates that a similar study in New Zealand phrased the issue more appropriately, saying the question is whether the lower dose "is safe and effective in reducing serious vision and lung problems without increasing mortality or neurodevelopmental disability."

But critics, including the head of the National Institutes of Health, argued that back in 2005, doctors didn't think the lower dose really posed a survival risk — the question was more about which dose did a good-enough job at saving their vision.

In fact, preemies who didn't enroll in the study — and got whatever range of oxygen their doctors deemed best — turned out to have a higher risk of death, said NIH Deputy Director Kathy Hudson.

Dr. John Lantos, a bioethicist at Children's Mercy Hospital in Kansas City, Mo., knows that firsthand. His twin grandsons were born during the Support study but weren't given an opportunity to enroll. One died soon after birth. The other today is thriving but suffered severe retinopathy and has poor vision.

"Nonvalidated therapy is often more dangerous than careful research," Lantos said, adding that the consent forms should make that clear as well. "Doctors just hate to say they don't know something. When they do say it, we should listen."

While the experts debated how to explain research risks, two families who traveled to Washington for the unusual meeting outlined a bigger hurdle: Reeling from the stress of having a vulnerable preemie, they simply didn't understand that they were participating in an experiment. And they still haven't been told what dose of oxygen their children received, and it's impossible to say whether lingering health problems are a consequence of the study or of being extremely premature.

Yet, they now wish they hadn't participated.

"I unknowingly placed my son in harm's way," said Sharissa Cook of Attalla, Ala., who wonders if vision problems experienced by her 6-year-old, Dreshan Collins, were caused by the study or from weighing less than 2 pounds at birth. "The only thing a mother wants is for her baby to be well."

Dagen's mother, Carrie, was more blunt with reporters: "Why is omitting information not considered lying?" she said. "We were told they would give her the best care every day."