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Father of volunteer who died in medical research pushes for people to learn all the facts before volunteering

MELISSA McDERMOTT, anchor:

Good morning. I'm Melissa McDermott. There's more ahead on THE EARLY SHOW and this CBS station.

First, assessing the risks in medical research. Each year, millions of volunteers take part in studies they hope will someday lead to cures, and some have faced unexpected danger. Sharyl Attkisson reports.

SHARYL ATTKISSON reporting:

For Jesse Gelsinger, turning 18 meant he was finally old enough to volunteer for a study that could lead to a cure for newborns with the worst form of a rare liver disorder he suffered. Jesse's father says it meant a lot.

Mr. PAUL GELSINGER (Volunteer's Father): I mean, how do you say no to helping dying babies?

ATTKISSON: The study was said to be safe, but after one experimental treatment, Jesse got sicker and sicker; not from his disease, but from the injection he got as part of the study.

Mr. GELSINGER: So four days after getting this supposedly safe treatment, my boy was dead from it.

ATTKISSON: The FDA says the lead scientist misled his own ethical review board and volunteers. For example, his consent forms didn't disclose that monkeys had died from similar treatments. The scientist also had a possible conflict of interest by standing to profit from the treatment he was testing.

That was five years ago, but patient advocates say Jesse's case exposed dangerous weaknesses in the oversight of human research studies, weaknesses that still haven't been fixed.

Up to 19 million Americans are recruited to test new drugs and therapies each year. Adil Shamoo has advised the government on human research and says because of poor reporting, nobody knows just how many volunteers are hurt in studies.

Do you think more people are injured and even killed in these studies than we know about?

Mr. ADIL SHAMOO (Citizens for Responsible Care and Research): I have no doubt in my mind that there are more adverse events, and including death, is not reported.

ATTKISSON: He analyzed official reports and found only eight deaths reported in 10 years, a number he says is implausibly low.

Arthritis researcher Dr. David Borenstein says studies shouldn't get a bad rap.

Dr. DAVID BORENSTEIN (Arthritis Researcher): The kinds of research we do really can save people's lives and make them more comfortable.

ATTKISSON: He says most studies are incredibly safe and crucial to the advance of medicine.

Dr. BORENSTEIN: We have to be willing to accept the fact that some person may not have a good outcome, but that overall, the benefit to the vast majority of people is really a really great benefit.

ATTKISSON: Today, it's Jesse's dad who's volunteering for a new campaign to educate potential research volunteers. It includes this brochure which highlights what the researchers might be leaving out and suggests asking questions like 'What risks are known?' and 'Who stands to benefit financially?'

Mr. GELSINGER: I encourage everyone, anyone thinking about participating that they ask all the right questions.

ATTKISSON: He knows that Jesse's part in the study didn't help cure any newborns, but it did something else pretty big: It exposed weaknesses in a system that many are now pushing to change. Sharyl Attkisson, CBS News, Baltimore, Maryland.

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