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## *Medical Treatment vs. Experimentation is the Focus of Lawsuit*

*Doctors say the patient, now disabled, understood the risks; his wife alleges malpractice, conspiracy and fraud. Trial is set for next year.*

**(Note: A confidential settlement was reached in this case in 2000.)**

George Phillips had a dangerous tangle of blood vessels in his brain when he went to see a team of doctors from Thomas Jefferson University.

The doctors decided to take a novel approach and treat the abnormality with multiple doses of radiation. Phillips, an auto mechanic from Upper Darby with three small children, had six radiation treatments in January 1995.

Today he lies in a Delaware County nursing home. He cannot do anything for himself. He cannot speak. His wife, Nancy, says she does not know how much her husband, 35, comprehends.

Now at issue is whether Phillips' doctors subjected him to an experimental treatment without his knowledge and without proper oversight, in violation of standards set by the federal government.

His doctors dispute the allegations, saying that they had little else to offer Phillips and that his treatment did not cross the threshold of experimentation. Nancy Phillips contends in a lawsuit that her husband was a "human guinea pig" for unauthorized research and that doctors never informed him that the procedure was being tested on him. "They took it upon themselves to make that decision for George" with catastrophic results, Nancy Phillips said in a recent interview. Not only did the doctors mislead her husband, she alleges, but Thomas Jefferson University and its hospital, as well as Wills Eye Hospital, where the treatment was done, failed to monitor the research.

Phillips' doctors say they treated Phillips with the therapy they believed would offer him the most benefit. "The treatment given to Mr. Phillips was his only treatment option for an otherwise untreatable, inoperable fatal brain lesion," according to a court filing on behalf of David



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Nancy Phillips visits her husband, George, in the Chester Care Center in Chester several times a week. He formerly worked as a mechanic. They have three children, whom she also brings to see him.

Andrews and Robert Rosenwasser, Phillips' neurosurgeons. The therapy was "not a radical departure from the standard treatment for his condition," contends Thomas Jefferson University Hospital and several radiation oncologists named in the suit. It "represented an incremental change."

Spokesman and attorneys for Jefferson, Wills, the neurosurgeon and radiation oncologists declined to be interviewed for this story. The stakes in the case got higher recently when Philadelphia Common Pleas Court allowed the Phillipses to take the unusual step of amending their malpractice complaint to include allegations of civil conspiracy, fraud and punitive damages. A trial date has been set for early next year.

The Phillips case is being reviewed by the U.S. Office of Protection from Research Risks (OPRR), which is charged with safeguarding the rights of patients involved in research experiments. Under federal rules, patients must be fully informed of the nature of the research and give their consent before being included in a study. OPRR which has about 90 cases pending nationwide, declined to comment on the Phillips case.

At the heart of the case lie a few questions: How much did Phillips know about Andrews' treatment plan? How much did he understand? When does medical innovation become medical experimentation? In September 1994, George Phillips developed a bad headache and numbness in his right arm. His speech became slurred. Tests showed he had an abnormal and life-threatening tangle of blood vessels in his brain, an arteriovenous malformation (AVM) - and it had bled. Left untreated, AVM patients face a 2 to 4 percent annual chance of a hemorrhage, according to documents filed in the lawsuit.

Phillips' AVM was large and in a hard-to-reach part of his brain. Rosenwasser ruled out two treatment options for Phillips: removing the AVM with surgery or choking off its blood supply, according to court documents. He referred Phillips to his Jefferson colleague Andrews, who had experience using another approach - stereotactic radiosurgery. The technique focuses a beam of radiation at the AVM to shrink it.

A risk is that the radiation can destroy healthy brain tissue along with the AVM. At the time, the approach had been used successfully by other doctors around the country to treat some types of brain tumors and some AVMs. Andrews testified that before January 1995, he had treated between 30 and 40 patients with AVMs, using a single radiation dose approach. According to Nancy Phillips' deposition, when Andrews met with the Phillipses in October 1994, he recommended one radiation session, predicting an "80 percent chance" of obliterating the AVM.

But that recommendation changed in early November. Nancy Phillips learned in a phone conversation with Andrews' nurse that instead of one radiation treatment, her husband would get multiple radiation sessions, she testified. The decision to switch treatments came after his case was reviewed by a group of Jefferson neurosurgeons and radiation oncologists who met weekly to discuss patients. The group had decided as a "policy" to treat certain AVM patients with multiple - or fractionated - doses, according to the testimony of Walter Curran, Jefferson's chairman of radiation oncology, who also is named in the suit. Spreading out the radiation treatments would be "more beneficial and less risky" than a single dose, Andrews testified. The

Phillipses' lawsuit contends that the procedure entered the realm of the experimental when the doctors decided to fractionate it.

With tumors, said Stephen Tatter, a neurosurgeon and AVM expert at Wake Forest University Baptist Medical Center in North Carolina, fractionation works because healthy brain tissue bombarded by radiation can heal between sessions, while the tumor is progressively destroyed. Tatter said it was still an open question whether the technique worked on AVMs. He does not use it, but he said Andrews' approach seemed reasonable. Phillips had the six treatments in January 1995.

He tried to return to his mechanic's job but was confused, disoriented and had headaches, his wife testified. In early February, he was admitted to the hospital, where doctors treated swelling in his brain. Back home, he grew worse. He grew more confused, he had seizures, he had trouble sleeping. "He couldn't learn anything new," Nancy Phillips testified. "He only knew what was already in his mind, but to comprehend, to have a conversation with somebody, he was not able to do."

In November 1995, he suffered a massive stroke, according to the lawsuit, and Nancy Phillips contends it was connected to the radiation treatments. Rosenwasser and Andrews denied in their recent court filing that Phillips' "injuries are solely from the treatment rendered by any of the defendants." The two sides also disagree about how much the Phillipses were told in advance.

In the lawsuit, Nancy Phillips says that the Jefferson team omitted important information that "created a false sense of security" for her husband and her. When she learned in October 1995 that her husband was a medical pioneer, Nancy Phillips said in her deposition, she was "speechless." Her husband, she said, "could not believe it," either. In their recent court filing, Andrews and Rosenwasser said the Phillipses were given "a detailed description of the nature, risks, complications and alternatives of the treatment." They each reviewed it, according to the doctors, and the Phillipses signed a form, giving consent for him to undergo the procedure. A handful of other patients received the same fractionated treatment.

Karen Isnardi's husband, John, underwent the radiation treatment for an AVM in late 1995 at age 26. She said in an interview that the doctors were candid and thorough with them. "They saved his life," she said. "It was drilled into our heads this is not something that has been practiced very long," said Isnardi, a Lakewood, N.J., social worker. "This was a new way. And they were learning as they went." Most major American medical research centers, including Jefferson and Wills in Philadelphia, require researchers to submit proposals to an institutional review board (IRB) before they begin experiments. These institutions have pleaded to the federal government to protect patients in research trials.

Andrews, the Phillipses' suit contents, went to the research board after he had started his "experimental research." In the fall of 1994, the suit alleges, Andrews had two drafts of a research protocol outlining the same procedure given to Phillips. "These drafts or any final version were never submitted for approval to the IRB" until January 1996 - a year after Phillips was treated, according to the family's complaint." Andrews presented the results of his treatment of Phillips and other patients at a scientific conference in December 1996, the lawsuit alleges.

"George Phillips was treated under a human experiment research protocol which was not made known to the patient and not made known to the university," said Tom Kline, the Phillipses' lead attorney. In other court documents, Jefferson and the radiation oncologists deny the treatment was "research." It "was not designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge."

The doctors said that as they treated more patients like George Phillips, they decided to turn their technique into an experimental study. "It was a therapy which I subsequently submitted simply to formalize a protocol and a policy that we have set forth," Andrews testified. Tatter, the Wake Forest neurosurgeon, declined to comment on the case but said that was often how neurosurgeons worked. "We do things that are, in essence, experimental without having a formal experimental protocol," he said. "We do it on a compassionate basis. We don't have anything else to offer the patient." Tatter said because surgeons try out new techniques on rare disorders, it is hard to test the techniques in the same way as new drugs - by recruiting patients and then comparing the drug's effects with a placebo. Rather, he said, surgeons frequently treat a few patients with a new technique and only then decide to publish their findings as "research." Robert Daroff, professor of neurology at Case Western Reserve University Medical School in Cleveland and editor in chief emeritus of the journal *Neurology*, said it could be a gray area where research begins and when doctors should go to their hospital's institutional review boards. "My rule of thumb is, if there's any question about what's research, get IRB approval."

Meanwhile, Nancy Phillips visits her husband several times a week. She often takes their young children. Patients, she cautioned one recent afternoon at the nursing home, "should be really careful and make sure whatever their situation is, they know all the facts before they get into something that will change the rest of their lives."