



University Medical Center v. Shwab, 628 S.W.3d 112 (Ky. 2021)

Topics Covered: Abusive Litigation Against Physicians

Outcome: Favorable

Issue

The issue in this case was whether an explanation of medical risks by three doctors and a nurse, plus the signing of a 16-page informed consent form, was sufficient to obtain informed consent for an experimental medical procedure.

AMA Interest

The AMA supports efforts to curb lawsuit abuse against physicians.

Case Summary

Reagan Shwab needed a kidney transplant. She was referred to Dr. Kadiyala Ravindra, who was part of an organ transplant team. Mrs. Shwab's husband, Hugh Shwab, offered to donate one of his kidneys.

While consulting with the Shwabs about the possible transplant, Dr. Ravindra mentioned that he was involved in a Phase 1 clinical trial involving bone marrow infusion in advance of a kidney transplant. The hoped-for result of the experiment would be that the infusion of the donor's stem cells before the donation would decrease the likelihood of rejection of the donated kidney. The Shwabs asked to participate in the clinical trial.

Before beginning the clinical trial, the Shwabs met with two other physicians and a nurse, who explained the trial procedures and the possible side effects and risks associated with the stem cell infusion. The Shwabs signed a 16-page consent form, which detailed the study, the possible side effects, and the risks.

Over a course of three months, Ms. Shwab received the stem cell infusion and then the actual kidney transplant. For the next year, her white blood cell count remained low, and she felt ill. Eventually, she was diagnosed with blood cancer, which might have been caused by the clinical trial.

The Shwabs sued Dr. Ravindra, the two other physicians with whom they had consulted, and the University of Louisville Hospital. They claimed that they had not been properly informed of the risks associated with the clinical trial. The defendants moved for summary judgment, asserting that the consent form sufficiently informed Ms. Shwab of all known or reasonably anticipated risks associated with the clinical trial. The Shwabs opposed the motion, asserting

that the adequacy of the informed consent was a jury issue. The trial judge granted the defense motion and entered summary judgment for the defendants.

The Shwabs appealed to the Kentucky Court of Appeals, the intermediate level appellate court, which found that the defendants could not rely solely on the written consent form. They had to explain the risks in understandable language, consistent with the standards of the medical profession. The Court of Appeals reversed the summary judgment and remanded for additional proceedings.

On August 26, 2021, the Kentucky Supreme Court reversed the court of appeals decision, finding that the defendants had complied with the appropriate informed consent requirements. This was a favorable result, consistent with the position of the Litigation Center brief.

Litigation Center Involvement

The Litigation Center joined with the Kentucky Medical Association in an *amicus* brief in the Kentucky Supreme Court, which supported the defendants.

Kentucky Supreme Court Brief