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Commonwealth of Kentucky

Court of Appeals

NO. 2018-CA-001188-MR

REAGAN BROOKE SHWAB AND
HUGH MCNEILLY SHWAB, IV APPELLANTS

APPEAL FROM JEFFERSON CIRCUIT COURT
v. HONORABLE BRIAN C. EDWARDS, JUDGE
ACTION NO. 10-CI-006202

KADIYALA V. RAVINDRA, M.D.;
UNIVERSITY MEDICAL CENTER, INC.,
D/B/A JAMES GRAHAM CANCER CENTER;
UNIVERSITY MEDICAL CENTER,
D/B/A UNIVERSITY OF LOUISVILLE HOSPITAL;
ROGER HERZIG, M.D.; AND
CRAIG L. SILVERMAN, M.D. APPELLEES

OPINION
REVERSING AND REMANDING

** ** ** ** **

BEFORE: GOODWINE, SPALDING AND L. THOMPSON, JUDGES.

L. THOMPSON, JUDGE: Reagan Shwab and Hugh Shwab appeal from an order granting summary judgment in favor of the collective Appellees. Appellants argue

that they raised genuine issues of material fact that made summary judgment inappropriate. We agree and reverse and remand.

FACTS AND PROCEDURAL HISTORY

In 1996, Ms. Shwab was diagnosed with a kidney disease. In 2007, Ms. Shwab's kidney disease became so severe that she began dialysis. Shortly after beginning dialysis, her doctor told her that her kidneys had failed and that she would need a kidney transplant. Ms. Shwab was referred to Dr. Kadiyala Ravindra and the organ transplant team at Jewish Hospital for a kidney transplant. Mr. Shwab was eligible to donate a kidney to Ms. Shwab.

The Shwabs met with Dr. Ravindra to discuss the process for a transplant and the need to take immunosuppressants after the transplant. They also discussed the possible complications related to immunosuppressants. During the consultation, Ms. Shwab broached the subject of a Phase 1 clinical trial involving bone marrow infusion in advance of kidney transplant. As a Phase 1 study, this was the first time these protocols were being tested in humans. Phase 1 studies are meant to determine the safety of the protocol. Dr. Ravindra was involved with the clinical trial as the principal investigator.

The protocol for the trial was as follows: the patient would receive chemotherapy for three days to suppress the immune system; the following day, the patient would undergo total body irradiation; the day after the radiation, the

patient would receive an infusion of stem cells from the kidney donor; and one to two months later, the patient would receive the kidney transplant. The hopeful outcome of this process was to make the body more receptive to the donated kidney and negate the need for anti-rejection and immunosuppressant drugs after the transplant.

Appellee Dr. Craig Silverman, a radiation specialist, was a coinvestigator in the study. Appellee Dr. Roger Herzig, a bone marrow specialist, was also a coinvestigator. They were each responsible for their respective portions of the protocol process. Elizabeth Reed was a clinical nurse manager who also participated in the process but was not named in the underlying cause of action.

Appellants eventually met with all the individuals involved in the study. What was discussed during these meetings is somewhat disputed. What is clear is that Appellants were given a 16-page consent form which detailed the study and possible side effects. It was alleged by Appellees that Nurse Reed explained the consent form to Appellants. The consent form indicated that the methods used in the study had been untested in humans and that there were extreme risks involved. Some risks included cancer, loss of fertility, and death. Appellants claimed that they were verbally told by Nurse Reed that there were virtually no side effects to be expected in the trial. Appellants testified that they were also told that the worst-case scenario was that the trial would not work and

Ms. Shwab would have to undergo a traditional kidney transplant. Appellants alleged that the doctors involved in the trial made similar statements or did not discuss the risks at all. Appellants also alleged that they were told the study had been successful in five other patients; however, this was not true.

Ms. Shwab began treatment under the clinical trial in March of 2008. The kidney transplant was performed in June of 2008. For over a year after the transplant, Ms. Shwab's white blood cell count remained low and she continued to feel ill. Appellees could not determine what was wrong with her. Ms. Shwab eventually travelled to Northwestern University in Chicago to obtain a second opinion. In September of 2009, doctors at Northwestern diagnosed her with myelodysplastic syndrome (MDS). MDS is a blood cancer. One of the doctors at Northwestern indicated that the MDS could have been caused by the trial. Dr. Ravindra also testified that the trial could have caused the MDS.

Ms. Shwab sought treatment for the MDS at the University of Texas MD Anderson Cancer Center in Houston, Texas. She also sought treatment at the Fred Hutchinson Cancer Research Center in Seattle, Washington. She underwent further bone marrow transplants in order to treat the disease. It was also discovered that Ms. Shwab's body had rejected the kidney transplant.

Appellants sued Appellees for negligent failure to adequately inform Ms. Shwab of the risks of participating in the clinical trial. They claimed that had

they been properly and adequately informed of the risks of the trial, then Ms. Shwab would not have participated. Depositions of Appellants and the medical professionals involved with the trial were taken during discovery. Appellants also identified an expert witness, Dr. Lee Levitt. Dr. Levitt is a semi-retired doctor and professor of hematology and oncology. Dr. Levitt testified via deposition about the standard of care for obtaining informed consent from a patient. He testified that a written document is required, but also that a detailed oral conversation with the patient be had that describes the risks and benefits of a procedure. Dr. Levitt testified that he believed Appellees violated this standard. He also believed that the written document was flawed because it was long and hard to follow. Additionally, he claimed the form should have mentioned the specific risks regarding bone marrow, such as stem cell damage, leukemia, and MDS. Dr. Levitt claimed MDS is a known side effect when total body irradiation and chemotherapy are used in conjunction, as occurred in this case, and this risk should have been included in the consent form.

Appellees eventually moved for summary judgment. They argued that the consent form signed by Ms. Shwab sufficiently informed her of all known or reasonably anticipated risks associated with the clinical trial. Appellants opposed the motion. They argued that the adequacy of their informed consent was a jury issue. The trial court ultimately granted summary judgment in favor of

Appellees. The court held that the consent form satisfied Kentucky statutory authority and requirements set forth by the Federal Food and Drug Administration (FDA) regarding consent forms in clinical trials. The court also held that the form adequately explained the foreseeable risks associated with participating in the clinical trial. This appeal followed.

ANALYSIS

> The standard of review on appeal of a summary judgment is whether the trial court correctly found that there were no genuine issues as to any material fact and that the moving party was entitled to judgment as a matter of law. . . . The record must be viewed in a light most favorable to the party opposing the motion for summary judgment and all doubts are to be resolved in his favor. Summary judgment is only proper where the movant shows that the adverse party could not prevail under any circumstances. Consequently, summary judgment must be granted [o]nly when it appears impossible for the nonmoving party to produce evidence at trial warranting a judgment in his favor[.]

Scifres v. Kraft, 916 S.W.2d 779, 781 (Ky. App. 1996) (citations and internal quotation marks omitted). "Because summary judgment involves only legal questions and the existence of any disputed material issues of fact, an appellate court need not defer to the trial court's decision and will review the issue *de novo*." *Lewis v. B & R Corporation*, 56 S.W.3d 432, 436 (Ky. App. 2001).

> This case revolves around the issue of informed consent.
>
> In any action brought for treating, examining, or operating on a claimant wherein the claimant's informed

> consent is an element, the claimant's informed consent shall be deemed to have been given where:
>
> (1) The action of the health care provider in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with the accepted standard of medical or dental practice among members of the profession with similar training and experience; and
>
> (2) A reasonable individual, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedure and medically or dentally acceptable alternative procedures or treatments and substantial risks and hazards inherent in the proposed treatment or procedures which are recognized among other health care providers who perform similar treatments or procedures;
>
> (3) In an emergency situation where consent of the patient cannot reasonably be obtained before providing health care services, there is no requirement that a health care provider obtain a previous consent.

Kentucky Revised Statute (KRS) 304.40-320. Subsection three is not involved in this case; therefore, we will focus only on KRS 304.40-320(1) and (2). Appellants argue on appeal that they presented sufficient evidence to support their claim that Appellees breached their duty to get informed consent from Ms. Shwab. They claim that they presented evidence that indicates Appellees violated KRS 304.40-320(1) and (2); therefore, this case should be heard by a jury. We agree.

"[I]t is a well-established principle of law that, as an aspect of proper medical practice, physicians have a general duty to disclose to their patients in

accordance with accepted medical standards the risks and benefits of the treatment to be performed." *Sargent v. Shaffer*, 467 S.W.3d 198, 206 (Ky. 2015) (footnote omitted).

> Construed in accordance with its plain terms and obvious meaning, it is readily apparent that, in an applicable civil action where informed consent is an issue, a medical treatment provider has satisfied the duty to obtain the patient's consent only if both provisions are met. Not only must the physician's action in disclosing the risks be "in accordance with the accepted standard of medical . . . practice among members of the profession with similar training and experience" as stated in Subsection (1), it is further required that the information imparted by the physician be stated so as to provide "a reasonable individual" with "a general understanding of the procedure . . . [any] acceptable alternative[s] . . . [the] substantial risks and hazards inherent in the proposed treatment or procedures which are recognized among other health care providers who perform similar treatments or procedures."

Id. at 207-08 (quoting KRS 304.40-320). "[A] breach of the statutory standard may be established by proving that the medical provider failed to meet either one of the two subsections of KRS 304.40-320." *Argotte v. Harrington*, 521 S.W.3d 550, 556 (Ky. 2017).

Here, we conclude that Appellants provided enough evidence to show that there were genuine issues of material fact that must be determined by a jury. Appellants provided evidence that Appellees may have breached both KRS 304.40-320(1) and (2).

As to KRS 304.40-320(1), Appellants' expert, Dr. Levitt, testified during his deposition that it was his opinion that Appellees breached the standard of care in gaining informed consent. He believed that the consent form should have mentioned the specific risks regarding bone marrow, such as stem cell damage, leukemia, and MDS. Dr. Levitt also claimed MDS is a known side effect when total body irradiation and chemotherapy are used in conjunction, and this risk should have been included in the consent form. While Appellees presented evidence to the contrary, the conflicting evidence made this an issue for the jury.

As for KRS 304.40-320(2), Appellees argue that the consent form stated all known risks and that a reasonable person would have understood those risks. They also argued that each of them discussed the clinical trial with Appellants and also discussed the risks and alternatives to the trial. Appellants testified that no one explained the possibility that there could be extreme risks associated with this trial. They stated that the only information they were verbally given was that, at most, the trial would not work, and Ms. Shwab would have to undergo a traditional kidney transplant. They also alleged that they were rushed and did not have time to fully examine the consent form. Dr. Levitt also testified that he believed the consent form was too long and confusing.

"[V]alid consent to medical treatment is to be gleaned from evidence of the circumstances and discussions surrounding the consent process." *Kovacs v. Freeman*, 957 S.W.2d 251, 255 (Ky. 1997).

> Consent is a process, not a document. Authorization for treatment is the culmination of a discussion between a patient and a health care provider, the disclosure of risk and benefit information, the disclosure of reasonable alternative forms of care, and the posing of questions and answers by both the patient and the provider. Once the patient has agreed to a specific course of treatment, the process is over . . . . The documentation, the so-called consent form, is not the consent, for that lies instead in the conclusion of the discussion between the patient and the physician.

Id. at 254 (citation omitted). While a signed consent form may in some circumstances give rise to a presumption that patients read and understand the terms of the consent form, *Hoofnel v. Segal*, 199 S.W.3d 147, 151 (Ky. 2006), we believe that Appellants presented enough evidence to potentially convince a jury that Appellees did not give them enough information to reasonably understand the clinical trial or the potential risks associated. In fact, Appellants testified that they were given information that contradicted the consent form. Appellants admit that Ms. Shwab signed the form; however, they testified that they relied primarily on what they were told by the medical professionals. Examining this issue in a light most favorable to Appellants, the evidence presented by Appellants makes the KRS 304.40-320(2) issue one for the jury.

We note that Appellees raise an argument in their briefs that the informed consent statute should not apply to clinical trials. This issue was not decided upon by the trial court; therefore, we will not address it. An issue not raised or ruled upon in the trial court cannot be examined by an appellate court. *Fischer v. Fischer*, 197 S.W.3d 98, 102 (Ky. 2006).

CONCLUSION

Based on the foregoing, we conclude that Appellants presented evidence to raise genuine issues of material fact as to whether Appellees breached the standard set forth in KRS 304.40-320(1) and (2); therefore, summary judgment was inappropriate. We reverse and remand for additional proceedings.

ALL CONCUR.

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