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Supreme Court of Kentucky

2019-SC-0641-DG

UNIVERSITY MEDICAL CENTER, INC. D/B/A JAMES GRAHAM BROWN CANCER CENTER; CRAIG L. SILVERMAN, M.D.; ROGER H. HERZIG, M.D.; AND UNIVERSITY MEDICAL CENTER, INC. D/B/A UNIVERSITY OF LOUISVILLE HOSPITAL — APPELLANTS

V.

ON REVIEW FROM COURT OF APPEALS
NO. 2018-CA-1188
JEFFERSON CIRCUIT COURT NO. 10-CI-006202

REAGAN BROOKE SHWAB AND HUGH MCNEILLY SHWAB, IV — APPELLEES

OPINION OF THE COURT BY JUSTICE HUGHES

REVERSING AND REMANDING

Reagan Brooke Shwab (Brooke) was diagnosed with a kidney disease which became severe in 2007, necessitating a kidney transplant. Interested in avoiding the need for lifetime immunosuppressant drugs following the transplant, Brooke consented to participate in a Phase I clinical trial that had as its goal participants achieving tolerance of a transplanted kidney and avoiding a continuing regimen of immunosuppressant drugs. Shortly after participating in the clinical trial, Brooke developed myelodysplastic syndrome (MDS), a rare form of blood cancer.

Brooke and her husband filed suit against the clinical trial's medical providers alleging that her consent to the medical treatment involved in the trial was invalid pursuant to Kentucky Revised Statute (KRS) 304.40-320, the statute that provides the framework for determining when informed consent has been properly given in an action involving medical care. After eight years of discovery, the trial court found that the informed consent in this case complied with Kentucky statutory authority and federal regulations and granted summary judgment to the medical defendants. The Court of Appeals reversed, holding that the Shwabs presented enough evidence to potentially convince a jury that the medical defendants did not give them enough information to reasonably understand the clinical trial or the potential risks. After careful review, we reverse the Court of Appeals and reinstate the trial court's judgment.

FACTS AND PROCEDURAL HISTORY

In 1996 Reagan Brooke Shwab was diagnosed with IgA nephropathy, a kidney disease in which antibodies build up and damage kidney tissues.[1] In 2007 the disease became so severe that she began dialysis. Shortly after beginning dialysis her kidneys began failing and she needed a transplant. Brooke's nephrologist, Dr. Sanford Reikes, referred her to Dr. Kadiyala Ravindra and the organ transplant team at Jewish Hospital in Louisville,

[1] *IgA nephropathy (Berger's disease)*, MAYO CLINIC (May 17, 2019), https://www.mayoclinic.org/diseases-conditions/iga-nephropathy/symptoms-causes/syc-20352268.

Kentucky. The transplant team determined that Brooke was a transplant candidate and her husband, Hugh "Mack" Shwab, was an eligible donor.

The Shwabs, both college-educated individuals, met with Dr. Ravindra on January 24, 2008 to discuss the transplant process and her need to take immunosuppressant drugs after the transplant. They also discussed possible complications related to the immunosuppressant drugs. During this meeting the Shwabs asked about a clinical trial involving bone marrow transfusion that Mack's mother had heard about on the radio. Dr. Ravindra, the trial's principal investigator and transplant specialist, explained the trial and its past results.

In 2003 the Institute of Cellular Therapeutics (ICT) and the James Graham Brown Cancer Center at the University of Louisville partnered with the Northwestern School of Medicine to conduct a Phase I clinical trial involving kidney transplants.[2] The trial's ultimate goal was to allow a subject's body to develop "tolerance" to the transplanted kidney and thereby avoid the need for long-term anti-rejection drug therapy. The clinical trial used a combination of a stem cell transplant and kidney transplantation from the same donor, along with sequential chemotherapy and total body irradiation.[3] The trial began in

[2] The study was called "Induction of Donor Specific Tolerance in Recipients of Live Donor Kidney Allografts by Donor Stem Cell Infusion" (hereafter referred to as Phase I clinical trial or clinical trial).

[3] Total body irradiation, as explained in the materials provided to Brooke, is radiation therapy involving the use of high energy x-rays directed to the entire body. The purpose of total body irradiation is to kill cancer or abnormal cells and suppress the immune system before transplantation with healthy bone marrow.

2003 and was sponsored by Dr. Suzanne Ildstad, a professor of transplantation and surgery at the University of Louisville who focused her research on ways to induce tolerance in transplant patients.

Clinical trials range from Phases I through IV.[4] A Phase I trial is an initial safety trial on a new medicine or treatment, usually done with a small group of people to begin identifying unknown side effects.[5] Phase I trials are focused on establishing tolerability, i.e., whether the patient tolerates the medication or procedure, primarily looking for indices of safety.[6] Because a Phase I clinical trial's process and procedures are previously untested in humans, toxicity is unknown, and safety cannot be guaranteed.[7]

Several meetings occurred between the Shwabs and various medical providers regarding the clinical trial. After their initial discussions about the clinical trial Dr. Ravindra introduced the Shwabs to Elizabeth Reed, the trial's clinical nurse manager. Reed spoke with the Shwabs for approximately fifteen to twenty minutes and explained the nature of a Phase I trial and the trial protocol.

The protocol for the trial proceeded as follows: the patient would receive chemotherapy for three days to suppress the immune system; the following

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[4] There are five phases of clinical trials: Early Phase 1 (formerly known as Phase 0), Phase I, Phase II, Phase III and Phase IV. U.S. National Library of Medicine, *Learn About Clinical Studies,* https://clinicaltrials.gov/ct2/about-studies/learn (last updated Mar. 2019).

[5] *Id.*

[6] *Id.*

[7] *Id.*

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.[8] The goal of the trial was to make the participant's body more receptive to the donated kidney and negate the need for anti-rejection and immunosuppressant drugs after the transplant.

The Food and Drug Administration (FDA), tasked with ensuring the protection of the rights, safety and welfare of human subjects who participate in clinical trials, reviewed the clinical trial protocol and consent form. 21 United States Code (U.S.C.) Chapter 9. Because the clinical trial was regulated, in part, by the FDA, the clinical trial had to satisfy federal regulations governing the protection of human subjects. 21 Code of Federal Regulations (C.F.R.) Part 50. The clinical trial was funded in part by the United States Department of Defense, which also reviewed the protocol and informed consent form. In addition, the Department of Defense requires the use of a Data Safety Monitoring Board which consists of a group of independent scientists who monitor the safety and integrity of a clinical trial.[9]

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[8] Brooke was one of the first participants to undergo this specific protocol. The trial originally began in 2003 and involved simultaneous conditioning, bone marrow transplant, and kidney transplant. Over four years approximately twelve participants underwent the protocol, but it was relatively unsuccessful. Immediately prior to Brooke's participation, the protocol was changed to a sequential approach. The trial's investigators believed there would be a benefit to doing the conditioning regimen and bone marrow transplant separately so that participants would have time to recover and heal prior to receiving the kidney transplant.

[9] U.S. National Library of Medicine, *Learn About Clinical Studies,* https://clinicaltrials.gov/ct2/about-studies/learn (last updated Mar. 2019). A Data Safety Monitoring Board can recommend to the sponsor that a trial be stopped if it is

Also, an Institutional Review Board (IRB) reviewed the protocol and consent form and monitored the clinical trial.

When the Shwabs met with Elizabeth Reed to discuss the clinical trial initially, Dr. Ravindra was present for part of the discussion. Dr. Ravindra also discussed the risks and benefits of the clinical trial. Reed later testified that she gave the Shwabs the sixteen-page consent form to take home and read, a form which detailed the trial and possible side effects, including cancer, infertility and death. She also provided a brochure prepared by Dr. Ildstad describing the trial. Mack later claimed that the couple was not given the consent form to take with them. At this point the Shwabs expressed interest in participating in the trial.

In their depositions the Shwabs stated that Reed told them that they could expect virtually no side effects and that the worst-case scenario was that the trial would not work and Brooke would need a traditional kidney transplant. Additionally, Brooke testified that no one explained that the purpose of the trial was to determine whether the protocol was safe and effective. Mack also testified in his deposition that Reed explained that the worst that had happened to anyone in the trial was that they had to take more anti-rejection medication, but that most people who underwent this process

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ineffective, is harming participants, or is unlikely to serve its scientific purpose. Dr. Ildstad testified that the Data Safety Monitoring Board includes highly respected experts who are completely independent of the study. The Board routinely meets twice a year to review all subject data and study protocols.

achieved tolerance of the donor kidney. Conversely, Dr. Ravindra testified that as of the date of his conversation with the Shwabs, January 24, 2008, no participants had achieved tolerance and that he personally gave the Shwabs that information.

Brooke had a follow-up appointment with her nephrologist, Dr. Sanford Reikes, who was treating her for end-stage renal disease. They discussed the trial and Dr. Reikes described the potential benefits as substantial. He also informed Brooke that the risk of recurrence of her particular type of kidney disease in the transplanted organ may not be known. The Shwabs had several follow-up appointments with Dr. Ravindra in February 2008 primarily focused on Mack's candidacy as a kidney donor. The clinical trial was mentioned at these meetings, and Dr. Ravindra encouraged the Shwabs to meet with all of the members of the trial before deciding whether to participate.

On February 26, 2008, the Shwabs met with Dr. Craig Silverman, a professor of radiation oncology at the University of Louisville. Dr. Silverman's only involvement in the clinical trial was administering the total body irradiation and he did not collaborate with Drs. Ildstad, Ravindra, and Roger Herzig in developing the protocol or the sixteen-page informed consent form. Dr. Silverman discussed the purpose of the total body irradiation, the technique, and the side effects, including potential "second cancers," such as blood cancers, leukemia, lymphomas, and bone cancers. Dr. Silverman had a separate consent form, "Explanation of and Consent to Radiation Therapy," on which he handwrote the words "second cancer" during this February 26, 2008

discussion. Dr. Silverman also provided two pamphlets that detailed radiation therapy and total body irradiation, identifying potential side effects, for the Shwabs' review. After this meeting Brooke signed the consent form and agreed to participate in the clinical trial.

The Shwabs also met with Dr. Herzig, a professor of hematology and oncology at the University of Louisville and a clinical trial co-investigator, on March 10, 2008 for an evaluation and discussion of the trial. Dr. Herzig reviewed the trial's regimen and potential complications with the Shwabs. Dr. Herzig indicated that he spent an "extended period of time" with the Shwabs. He discussed the clinical trial informed consent form, focusing mostly on the portion of the protocol with which he was involved. Following this meeting, Brooke signed a revised consent form.[10] Excerpts from that consent form include:

> The purpose of this study is to determine if this procedure is safe . . . . (p. 2)
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> This is a Phase I research study. Phase I is research in which the safety of the procedure is evaluated. . . . However, the approach in this study using X-ray therapy and facilitator cells has not been done before. This procedure is investigational, which means it has not been approved by the U.S. Food and Drug Administration (FDA). (p. 2)
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> This combined bone marrow procedure is basically untested in humans. . . . The safety and effectiveness of this study procedure will be evaluated. . . . (p. 2)

[10] The March 10, 2008 consent form is the most recent version. While Brooke originally consented to participate in the trial on February 26, 2008, the consent form was amended because the Department of Defense provided funding and free care was provided to trial participants at government facilities. The initial consent form provided for care at Jewish Hospital. The February 26, 2008 consent form is not in the record, but the parties agree the March 10, 2008 consent form is controlling.

. . . .

> Presently, drugs are required to prevent rejection of a transplanted kidney. The drugs used to treat rejection have many side effects. Besides weakening your body's ability to fight infection, they can also cause high blood pressure, kidney damage, and possible cancer. (p. 4)
>
> . . . .
>
> Each of the different parts of this study may result in increased risks of serious complications, including death. (p. 5)
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> . . . .
>
> There is also a very low risk of developing cancer related to the radiation during the course of your lifetime. (p. 5)
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> . . . .
>
> It is not possible to be informed of every possible complication or risk. (p. 6)
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> . . . .
>
> Other risks: [associated with the use of Mycophenolate mofetil (MMF), an immunosuppressant drug] – lymphoma (cancer of the lymph nodes) . . . . (p. 7)
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> . . . .
>
> There may be unknown risks, which are not known at this time. (p. 7)
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> . . . .
>
> These delayed effects may include certain types of cancer. (p. 8)

The Shwabs allege that Reed verbally told them they could expect virtually no side effects, that the worst-case scenario was that the clinical trial would be unsuccessful and that Brooke would have to undergo a traditional kidney transplant; that the doctors involved in the trial made similar

statements or did not discuss the risks at all; and that they were told the clinical trial had been successful in five other patients, which was not true. Although Mack testified that they were told the trial had achieved success in five people,[11] Dr. Ildstad testified that at the time Brooke entered the clinical trial no participants had achieved the study's goal of avoiding the need for immunosuppressants.

Brooke began her treatment in the clinical trial in March 2008 and her kidney transplant was performed in June 2008. For over a year after the transplant, Brooke's white blood cell count remained low and she continued to feel ill. The clinical trial's medical providers could not determine what was wrong, so she travelled to Northwestern University in Chicago to obtain a second opinion. There she was diagnosed with MDS. One of the doctors at Northwestern University and Dr. Ravindra indicated that the trial could have caused the MDS. After seeking treatment for MDS, Brooke learned that her body had rejected the kidney transplant she received during the clinical trial.

On September 2, 2010, the Shwabs filed a complaint against Dr. Ravindra, Dr. Silverman, Dr. Herzig, Dr. Ildstad, the University Medical Center and the ICT (the medical defendants)[12] for negligent failure to adequately

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[11] Mack explained that the information about the successes in five people in the trial were from various trials. Reed testified that, as a clinical research manager for the ICT, she managed four trials—two kidney trials, one heart trial, and a sickle cell study at a children's hospital.

[12] On September 23, 2010, the Shwabs filed a separate action against Jewish Hospital claiming negligence, lack of informed consent and loss of spousal consortium. On January 10, 2011 that action was consolidated with the Shwabs' claim against all other medical defendants. Jewish Hospital filed a motion for summary judgment on October 23, 2014 because none of the individuals involved in the clinical trial were

inform Brooke of the risks of participating in the clinical trial.[13] They claimed that had they been properly and adequately informed of the risks, then Brooke would not have given consent.

The Shwabs named two experts in support of their claims. Dr. Lee Levitt, a retired board-certified hematologist and oncologist, testified by deposition that the informed consent for the trial was deficient. Dr. Levitt opined that the Shwabs did not understand the nature of a Phase I clinical trial or the potential toxicity of this particular trial. He did not believe that the alternatives were highlighted to the extent they should have been. He also opined that the informed consent form should have included more specific information about the risk of cancer, specifically MDS, and that the informed consent process made the risks seem relatively modest. Additionally, Dr. Levitt believed that Brooke should have been informed that there were alternatives, such as a traditional kidney transplant from her husband in which she had an

agents or employees of Jewish Hospital. While Jewish Hospital was listed as a site for the clinical trial on the informed consent form, the only procedure performed at Jewish Hospital was the removal of one of Mack's kidneys. The Shwabs did not object to summary judgment and their claims as to Jewish Hospital were dismissed on March 27, 2014.

[13] The Shwabs named the University Medical Center as a defendant in its capacity as the James Graham Brown Cancer Center and as the University of Louisville Hospital. The ICT filed a motion for summary judgment because it is not a separate legal entity. Rather, the ICT is simply a designated institution within the University of Louisville itself, approved by the University of Louisville Board of Trustees. In short, the ICT is part of the University of Louisville. The Shwabs did not oppose the motion. The trial court dismissed the ICT from the action on April 26, 2012 and Dr. Ildstad, the Director of the ICT, on April 29, 2013. Dr. Ildstad never met, treated or had any contact with the Shwabs.

estimated 85% chance of success, albeit with the necessity of immunosuppressant drugs.

The Shwabs also identified another expert, Dr. Guillermo Garcia-Manero, who treated Brooke for MDS at MD Anderson Cancer Center in Houston. His testimony focused on the cause of the MDS and he opined that the chemotherapy and radiation Brooke underwent in conjunction with the bone marrow transplant were most likely the cause. He spoke extensively about the difficulty of diagnosing MDS and determining its cause. Dr. Garcia-Manero did not testify regarding informed consent.

On April 21, 2017, the remaining medical defendants collectively filed a motion for summary judgment arguing that the Shwabs failed to prove their claim of improper informed consent. The defendants asserted that the consent form Brooke signed sufficiently informed her of all known or reasonably anticipated risks associated with participation in the clinical trial. The Shwabs opposed the motion and argued that the adequacy of Brooke's informed consent was a jury question.

On July 10, 2018, the trial court granted summary judgment in favor of the medical defendants. The trial court concluded that the lengthy consent form Brooke signed complied with Kentucky statutory authority and federal regulations. While the form did not explicitly include MDS as a risk, it stated that participation could result in a risk of "various cancers" and listed a multitude of risks and side effects. Brooke was given ample opportunity to review the form and consult with medical providers prior to giving consent.

The trial court noted Brooke was the first known individual to have developed MDS following participation in the clinical trial or similar study and thus MDS was not a reasonably known risk. Because it found no genuine issues of material fact regarding her claim that the medical defendants failed to properly inform her of the reasonably known risks associated with the clinical trial, the trial court granted summary judgment to the defendants.

The Court of Appeals reversed the trial court's opinion and order because it believed that the Shwabs presented enough evidence to defeat a motion for summary judgment. The appellate court focused on the deposition testimony of Dr. Levitt, who opined that the medical defendants used a deficient informed consent form, a form that should have, but did not, mention certain specific risks, such as stem cell damage, leukemia and MDS. He also claimed that MDS is a known side effect when total body irradiation and chemotherapy are used in conjunction. While the medical defendants presented evidence to the contrary, the Court of Appeals concluded that conflicting evidence made the adequacy of the informed consent an issue for the jury. Additionally, that court noted that the Shwabs testified that no one explained the possibility that there could be extreme risks associated with the trial and that they were only told that, at worst, the trial would not work. Ultimately the Court of Appeals concluded that the Shwabs presented enough evidence to potentially convince a jury that the medical defendants did not give them enough information to reasonably understand the trial or the potential risks.

Having granted discretionary review, heard oral arguments and carefully considered the record, we reverse the Court of Appeals.[14] Given the undisputed facts and applicable law, the trial court properly granted summary judgment.

ANALYSIS

On appeal, we review a summary judgment *de novo*. *Shelton v. Ky. Easter Seals Soc'y, Inc.,* 413 S.W.3d 901, 905 (Ky. 2013). We must consider whether the trial court "correctly determined that there were no genuine issues of material fact and that the moving party was entitled to judgment as a matter of law." *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 59 (Ky. 2010). To defeat summary judgment, the Shwabs must have presented affirmative evidence that a genuine issue of material fact exists. *Steelvest, Inc. v. Scansteel Serv. Ctr., Inc.*, 807 S.W.2d 476, 480 (Ky. 1991).

Turning to the substantive law of informed consent, "it 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). KRS 304.40-320 provides the informed consent standard:

> 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:

[14] Dr. Ravindra did not move this Court for discretionary review and is not a party in this appeal.

> (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**
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> (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 . . . .[15]

(Emphasis added.) Examining the contours of informed consent, this Court has noted that "[t]he two subsections perform very different functions and address two different aspects of 'informed consent.'" *Sargent,* 467 S.W.3d at 209. A physician must comply with both subsections in order to satisfy the statutory standard for obtaining informed consent. *Id.* at 207. Therefore, a breach of the statutory standard for informed consent can be established by proving that a medical care provider failed to meet either subsection of KRS 304.40-320. *Argotte v. Harrington,* 521 S.W.3d 550, 556 (Ky. 2017).

I. The Actions of the Medical Care Providers Satisfied Subsection One of the Informed Consent Statute.

The requirements of each subsection of KRS 304.40-320 were explained in *Sargent,* 467 S.W.3d at 209 (quoting KRS 304.40-320(1)):

> Subsection (1) covers the means employed by the health care provider to obtain the patient's consent. The "action of the health care provider" in obtaining consent must be "in accordance with

[15] KRS 304.40-320(3) provides requirements for obtaining informed consent in emergency situations; that subsection is inapplicable in this case.

> the accepted standards of [the relevant] medical or dental practice[.]"

Thus, to meet the requirements of the first subsection the Shwabs must show that the process by which the medical defendants obtained her consent did not comply with "accepted standards" within the medical profession.

As this Court has expressly recognized, informed consent "is a process, not a document." *Kovacs v. Freeman,* 957 S.W.2d 251, 254 (Ky. 1997). Over the course of several weeks in early 2008 Brooke met with five medical care providers, four providers associated with the clinical study plus her own nephrologist, for what the medical defendants estimate was a total of 120 minutes. During these meetings Brooke was informed of the trial's lack of success, substantial risks, and potential complications. The Shwabs also had the opportunity to ask questions and receive answers from the medical specialists. In addition, during their initial discussions about the clinical trial, they were given the detailed informed consent form to take home and review.[16] Although informed consent is a process, the detailed informed consent document Brooke signed is highly relevant in our analysis.

> The existence of a signed consent form gives rise to a presumption that patients ordinarily read and take whatever other measures are necessary to understand the nature, terms and general meaning of consent. To hold otherwise would negate the legal significance to written consent forms

[16] As noted, Mack disputes that they were allowed to take the consent form home. Reed testified that she gave it to them because it was required by the protocol for the clinical trial. Dr. Ravindra also testified that providing a copy of the consent form was part of Reed's typical routine when explaining the clinical trial to a candidate.

> signed by the patient and render the consent form completely unreliable.

Hoofnel v. Segal, 199 S.W.3d 147, 151 (Ky. 2006).[17] Our review of the record reflects that Brooke had ample opportunity to review the consent form and ensure that she understood its contents.

> **Dr. Ravindra** met with the Shwabs on January 24, 2008 to discuss Brooke's candidacy for a kidney transplant. Dr. Ravindra described the Shwabs as "very intelligent, very sharp" people. As noted, Mack's mother first brought up the trial, stating that she heard about it on the radio. Dr. Ravindra later testified that he explained chimerism,[18] avoiding immunosuppression and that chimerism was not achieved in the nine participants who had taken part in the clinical trial. He recalled that the Shwabs had concerns about graft versus host disease and he explained that it was a serious complication and that their fears were genuine. Dr. Ravindra also encouraged the Shwabs to meet with Dr. Herzig and Dr. Silverman to help ensure they understood the clinical trial prior to deciding on whether to participate. In his second meeting with the Shwabs, the Shwabs asked a number of questions about what Mack would have to do for the trial. Dr. Ravindra testified that at the time he ceased his involvement in the clinical trial when he left for a position at Duke University it was unclear whether MDS was related to the trial.
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> **Elizabeth Reed** met with the Shwabs to discuss the clinical trial on January 24, 2008, with Dr. Ravindra present for part of that initial meeting. Reed was the trial's clinical research manager, having been in that role for a few months following prior experience at Jewish Hospital and eighteen years at the Kentucky Organ Donor Affiliates. She recalled

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[17] While *Hoofnel* involved a claim of medical battery arising from surgery for removal of a colon tumor wherein the patient disputed also giving consent for removal of her ovaries and uterus if necessary, this recognition of the importance of an informed consent document applies equally in a medical negligence/informed consent case. The consent form signed by Brooke is crucial to the analysis of the informed consent process.

[18] Chimerism means that the transplant recipient has a mixture of the donor and recipient's immune systems. The informed consent form explains that Brooke would receive a stem cell transplant from her kidney donor, Mack. Therefore, Brooke would have two types of bone marrow, hers and Mack's, called "mixed chimerism." *See also Stedmans Medical Dictionary* (2014) ("Chimerism" is defined as "the state of being chimera" and "chimera" is defined as "[a]n organism that has received a transplant of genetically and immunologically different tissue, such as bone marrow.).

this first meeting and stated that she had the informed consent form with her because she used it as an educational tool to describe the trial. The Shwabs asked Reed questions and she estimated that she spent fifteen to twenty minutes with them this first time. Reed testified that she discussed the risks listed in the informed consent form in great detail and emphasized to the Shwabs that in a Phase I trial the researchers do not know what may happen. Importantly, she testified that she gave the Shwabs the informed consent form to take home and read because their protocol required her to do so. She explained that, because it was a Phase I clinical trial with unknown risks, it was important that patients fully understand the informed consent. She also gave them the brochure created by Dr. Ildstad that described the clinical trial.

Reed denies that she ever told the Shwabs that the worst thing that could happen is that the protocol would not work, and that Brooke would have to take anti-rejection medication. She estimated that on March 10, 2008 when she met with Brooke to sign the consent form that the process took approximately one hour. When questioned about her knowledge regarding obtaining informed consent, Reed also explained that before she began managing the study she was given the trial protocol and informed consent form, reviewed it, and was able to ask her predecessor questions about it. Reed also shadowed her predecessor while she obtained informed consent for the various clinical trials sponsored by the ICT. She had received additional training on how to obtain informed consent from Jewish Hospital and her former employer, Kentucky Organ Donor Affiliates. She also had discussed the clinical trial protocol and informed consent process during meetings with Drs. Ildstad, Ravindra and Herzig.

Dr. Herzig testified that when he met with Brooke he reviewed issues with her that were included in the informed consent. On the day Brooke signed the consent form Dr. Herzig meet with her for an "extended period of time." He described the process and explained that when he met with the Shwabs on March 10, 2008 they had already met with Dr. Ravindra and discussed the protocol. He explained the trial's regimen to the Shwabs and discussed the potential complications involved. He also explained that the protocol had not yet been successful. As for his training in the informed consent process generally, he also testified that he had discussions with Dr. Ildstad, Dr. Ravindra and Reed about how to obtain informed consent for the trial.

Dr. Silverman testified that he had a lengthy discussion with Brooke about the purpose, technique and side effects of radiation. Dr. Silverman testified that it was routine procedure to give patients two pamphlets, one that detailed the radiation procedure and another pamphlet that discussed total body irradiation (TBI). The TBI pamphlet listed "second cancer" as a possible side effect. The purpose of providing the pamphlets was to allow patients to take the materials home to review

> and ask questions prior to the procedure. Dr. Silverman specifically wrote "second cancer" on the list of possible side effects in the TBI consent form and stated that the risk of a second cancer was one of the many things he explained to Brooke.[19]

Dr. Levitt, the only expert witness the Shwabs disclosed relating to the consent process, provided his opinions about the informed consent form and process. He stated that written consent is required but that there should also be a detailed oral conversation with the patient that describes the risks and benefits of a procedure, as well as available alternatives. Dr. Levitt testified that these components of obtaining informed consent are even more important in the context of a Phase I clinical trial. He testified that he believed the medical defendants in this case used a flawed written consent form because it was too lengthy and difficult to follow. Conversely, Dr. Levitt further opined that the form was not detailed enough because it should have mentioned specific risks regarding bone marrow, including stem cell damage, leukemia and MDS. He claimed that MDS is a known side effect when total body irradiation and chemotherapy are used in conjunction and therefore the risk should have been included in the consent form.

Most of Dr. Levitt's criticism of Brooke's consent to participate in the trial stems from the Shwabs' testimony that they were not given all the necessary information and simply did not understand the extent of the risks. Notably,

[19] "Second cancer" was referenced because Dr. Silverman primarily used total body irradiation for patients with either advanced lymphoma or leukemia. Brooke was one of only three non-cancer patients he had ever treated with TBI. In twenty-two years of administering TBI he had never seen a patient develop a second cancer.

Dr. Levitt did not criticize how the medical defendants conducted the consent process but instead focused his deposition testimony on the content of the information as described by the Shwabs in their respective depositions.

In essence, Dr. Levitt believed the Shwabs came away with the idea that there was not much bad that could happen from the trial. However, they received, reviewed and signed the consent form that listed numerous potential risks and side effects, making it difficult to conceive how the Shwabs (or anyone for that matter) could believe nothing bad could happen. The numerous listed risks and side effects also make it difficult to conceive that any of the medical care providers they met with would have told them nothing bad would happen, especially given the definition and very nature of a Phase I clinical trial. As the first page of text in the consent form relates, the trial was to evaluate "the safety of the procedure"; "the approach . . . has not been done before"; the "procedure is investigational" and therefore not approved by the FDA; and the "combined bone marrow procedure is basically untested in humans."

Leaving aside Dr. Levitt's primary reliance on the Shwabs' deposition testimony, his review of the informed consent process was largely incomplete. While Dr. Levitt reviewed the Shwabs', Dr. Garcia-Manero's and Elizabeth Reed's depositions, he acknowledged that he did not read Drs. Ravindra's, Herzig's, Silverman's and Ildstad's depositions. As noted *supra*, the Shwabs also met with Dr. Silverman, Dr. Herzig and Dr. Ravindra to discuss the trial before Brooke consented to participate and all of these individual defendants

were deposed. Dr. Ildstad, the trial's sponsor involved with drafting the consent form and materials about the clinical trial, was also deposed. Dr. Levitt did not consider any of these fact witnesses' depositions and thus was unaware of Drs. Ravindra's, Herzig's and Silverman's sworn testimony regarding their conversations with the Shwabs. When questioned, he admitted that review of those depositions "could be" pertinent to his opinion regarding the discussions they had with the Shwabs about the clinical trial and risks. He even agreed that it would be important to know what everyone says about the consent process, not just the Shwabs. Although Reed engaged in discussions with the Shwabs about the clinical trial and was important to the informed consent process, she did not operate solo. Significantly, Dr. Levitt failed to review the depositions of the three medical care providers who discussed the clinical trial with the Shwabs, all of whom were deposed at least three years prior to Dr. Levitt.

Returning to the law of informed consent, the crucial component of a claim under KRS 304.40-320(1) is evidence that a medical care provider's actions did not comply "with the accepted standard of medical or dental practice among members of the profession with similar training and experience." "Ordinarily, the failure to comply with a medical profession standard can only be proven by expert testimony." *Argotte,* 521 S.W.3d at 556. While Dr. Levitt expressed his own personal criticism of the informed consent form and process, i.e., the informed consent form does not give a patient a sense of the degree of risk involved and MDS specifically should have been

included as a risk and discussed with the Shwabs, he did not testify to an accepted standard of medical practice and thus did not testify as to a breach of that standard. It was incumbent upon the Shwabs to "show the physician's actions for obtaining consent fell outside 'the accepted standard of medical . . . practice.'" *Argotte,* 521 S.W.3d at 556 (quoting KRS 304.40-320(1)). In addition to not testifying that the medical defendants deviated from an accepted standard of care, Dr. Levitt lacked a proper basis for such testimony given that he did not review depositions of three medical defendants (in fact the three physicians involved) who discussed the clinical trial with Brooke and actually provided medical treatment pursuant to the clinical trial protocol.

While Dr. Levitt noted his substantial clinical trial experience, including his participation in trials that studied leukemia and MDS, he was unable to specifically cite any medical literature to support his assertions that the informed consent process was deficient. The medical defendants' counsel specifically asked Dr. Levitt for citations to medical literature that more accurately reflected the risk of MDS or leukemia. Dr. Levitt stated that he had not "specifically reviewed the medical literature with regard to this" but that textbooks on radiation medicine reviewed data on total body irradiation, MDS and leukemia. He generally referenced studies that reviewed the incidence of MDS and the increase in incidence when chemotherapy is added. He also suggested that "most of the literature" indicates that the combination of total body irradiation and chemotherapy causes an increased risk of leukemia and MDS but did not cite any particular medical treatise or publication.

Stated simply, Dr. Levitt's testimony failed to qualify as expert testimony necessary to satisfy KRS 304.40-320(1). He did not possess all the relevant information regarding the various discussions with medical care providers and instead resorted almost entirely to the Shwabs' testimony regarding the informed consent process. KRS 304.40-320(1) requires more than one physician's personal opinion regarding how he believes informed consent should work. Dr. Levitt's testimony simply does not constitute evidence that "the [medical defendants'] actions for obtaining consent fell outside 'the accepted standard of medical . . . practice.'" *Argotte*, 521 S.W.3d at 556 (quoting KRS 304.40-320(1)).

While the Shwabs did not meet their burden under KRS 304.40-320(1), we note that it would be a difficult task for any plaintiff given the extra vetting that occurs where informed consent is sought in the context of a clinical trial subject to federal regulation. Title 21 C.F.R. § 50.25 outlines the information that must be contained within a valid informed consent form:

> (a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:
>
> > (1) A statement that the trial involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
> >
> > (2) A description of any **reasonably foreseeable risks** or discomforts to the subject.
> >
> > (3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

> (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
>
> (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
>
> (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
>
> (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
>
> (8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(Emphasis added.) The clinical trial Brooke participated in would not have been allowed to proceed absent compliance with this regulation. Particularly of note in the context of this litigation is subsection (2) requiring disclosure of all "reasonably foreseeable risks."

As for the particular informed consent form Brooke signed, the record reflects that Dr. Ildstad, Dr. Ravindra and Dr. Herzig collaborated to draft the consent form at an eighth-grade reading level to make it easy to understand. The initial draft of the consent form was then provided to the FDA for review. The form was next sent to a local IRB, which is a group formally designated to

review and monitor biomedical research involving human subjects.[20] An IRB has the authority to approve, require modifications, or disapprove research. The U.S. Department of Defense's own IRB also reviewed the informed consent form because the Department of Defense provided funding for the clinical trial. The Department of Defense reviewed the consent form and trial protocol to ensure both were in accordance with federal regulations.

Dr. Ildstad's testimony that the informed consent form was "very thoroughly reviewed" through a "very tedious process" is not surprising given the various layers of oversight in a clinical trial. In sum, Brooke signed a consent form that was drafted and reviewed not only by three medical care providers in Kentucky but also reviewed and approved by the FDA, two IRBs and the U.S. Department of Defense. Given these circumstances, the prospect of a deficient informed consent form that did not conform with the "accepted standard of medical . . . practice," KRS 304.40-320(1), is miniscule, at best. In any event, the record reflects no expert testimony regarding the accepted standard of medical practice and a breach of that standard and, as a result, the trial court properly granted summary judgment as to the medical defendants' compliance with KRS 304.40-320(1).

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[20] *Institutional Review Boards Frequently Asked Questions,* FDA (January 1998), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions. The local IRB that reviewed the informed consent is based in Olympia, Washington and serves as the IRB for the University of Louisville.

II. The Information Conveyed by the Medical Defendants Satisfied Subsection Two of the Informed Consent Statute.

KRS 304.40-320(2) requires that the medical defendants provide information that would give "a reasonable individual . . . a general understanding of the procedure" and also "medically . . . acceptable alternative procedures or treatments and substantial risks and hazards inherent in the proposed treatment" as "recognized among other health care providers who perform similar treatments or procedures." The *Sargent* Court explained that

> [s]ubsection (2) covers the content of "the information provided," and it sets forth **the objective standard** that "a reasonable individual" must have from that information a "general understanding" of the risks "recognized among health care providers who perform similar treatments[.]" KRS 304.40-320(2).

467 S.W.3d at 209 (emphasis added). Pursuant to the statute the medical defendants were required to inform Brooke of the **substantial risks** inherent in the clinical trial treatment and the information provided must be evaluated from the standpoint of "a reasonable individual," not Brooke's subjective understanding or memory.

The consent form warned that "[t]here may be unknown risks, which are not known at this time"; "[i]t is not possible to be informed of every possible complication or risk"; that the procedure was "basically untested in humans"; that she would "be one of the first groups to be treated"; and that "the approach in this trial using X-ray therapy and facilitator cells has not been done before." (pp. 2, 6 and 7.) The consent form further plainly identified cancer as a potential risk of the trial, including listing cancer as a risk under

the total body irradiation section as well as the stem cell transplantation section of the consent form. The form also included the following statements:

> [b]esides weakening your body's ability to fight infection, they can also cause high blood pressure, kidney damage, and **possibly cancer**. (p. 4)
> . . . .
>
> There is also a very low risk of **developing a cancer** related to the radiation during the course of your lifetime. This risk is estimated based on studies of one time exposure to low levels of radiation to be less than or equal to 2%. (p. 5)
>
> . . . .
>
> These delayed effects may include **certain types of cancer**. (p. 8)

(emphasis added). The form specifically informed the Shwabs that participation in the trial was voluntary and that they could "choose not to enter the trial and instead receive standard therapy" for Brooke's condition. In the separate consent form for the radiation therapy Brooke acknowledged that "second cancer" was a potential risk of the treatment. From an objective viewpoint, the multiple references during the consent process through the written form and discussions adequately conveyed that cancer was a risk of the treatment protocol.

The fact that MDS was not specifically listed in the consent form, despite Dr. Levitt's testimony that it should have been included as a risk, does not render the informed consent invalid. No other patient who participated in the trial had developed MDS.[21] Additionally, expert testimony established that

[21] The Shwabs assert that Brooke was the very first research subject in this Phase I clinical trial. At the time Brooke participated in the trial it had been ongoing since 2003 and had ten to twelve participants prior to Brooke. When Brooke

MDS is typically developed by older males, not young females like Brooke. The Shwabs' own expert witness, Dr. Garcia-Manero, testified that "not everyone that is exposed to these chemoradiation therapies will get this disorder. . . . It's actually a minority" of "less than five percent of patients." The Leukemia and Lymphoma Society states that, "[a] small number of patients who have received chemotherapy and/or radiation therapy in the past for another cancer have a small risk of developing treatment-related MDS. Generally, the chance of developing a myelodysplastic syndrome as a result of treatment for another cancer is very low."[22] Given the low prevalence of MDS and the fact that no other patient in the trial or similar studies had developed MDS, this specific cancer could not constitute a substantial risk under Kentucky informed consent law and, in fact, no expert testified as such.[23]

The Shwabs insist that the issue of "substantial risk" is for the jury and does not require expert testimony. We briefly review the two cases relied on to clarify the law. In *Sargent,* the trial court erroneously instructed the jury by failing to incorporate the requirements of KRS 304.40-320 applicable to a medical provider's duty to obtain informed consent. 467 S.W.3d at 212. The

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participated in the trial in 2008 she was the first subject under the particular protocol which used the sequential method of total body irradiation and fludarabine.

[22] *Myelodysplastic Syndromes*, LEUKEMIA AND LYMPHOMA SOCIETY, https://www.lls.org/booklet/myelodysplastic-syndromes (last updated 2019).

[23] *See Goodman v. U.S.,* 298 F.3d 1048, 1058 (9th Cir. 2002), where a clinical research study participant was not informed of the complication from which she ultimately died. The federal appellate court held that the physicians had no reason to know there was a risk of that complication as no study participants had previously suffered that complication. The record supported "the conclusion that the NIH doctors were not, and could not reasonably have been, aware . . ." of the unperceived risk. *Id.*

Court explained that jurors can apply the "reasonable individual" and "general understanding" standards provided in subsection (2) of KRS 304.40-320, but that "evidence on whether the 'risks and hazards' involved are among those 'recognized among other health care providers who perform similar treatments or procedures'" is required. *Id.* at 209. Notably, the majority in *Sargent* failed to state "**substantial** risks and hazards," the language of the statute, in explaining what is required in the medical evidence. This Court's reference to the ability of the jurors to apply the law, moreover, was focused on determining if a reasonable individual would have a general understanding of the information provided not on their ability to know whether a particular risk was substantial or not. In *Argotte*, a 4-3 decision, the majority stated that proving a failure to comply with KRS 304.40-320 "requires an expert opinion only as needed to establish "whether the 'risks and hazards' involved [in the plaintiff's claim] are among those 'recognized among other health care providers who perform similar treatments or procedures.'" 521 S.W.3d at 556 (quoting KRS 304.40-320(2)). Once again the majority omitted "substantial," which is crucial to correct application of the statute.

As Justice Keller explained in a separate opinion (joined by two other Justices) in *Argotte,* KRS 304.40-320(2) expressly states that the risks to be disclosed must have been "substantial risks." 521 S.W.3d at 562 (Keller, J., concurring in part and dissenting in part). The dissenters did not believe "a jury of laypersons, without guidance from providers who perform similar treatments or procedures, *i.e.*, expert witnesses, can independently determine

whether a risk is substantial." *Id.* Indeed, determining whether a particular risk is substantial is not only a matter best addressed by the medical community and therefore an element requiring expert testimony, but that is what a plain reading of KRS 304.40-320(2) requires, i.e., "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." To the extent that *Sargent* and *Argotte* suggest that the substantiality of a risk is a jury question that does not depend on medical evidence those holdings are overruled. Under the informed consent statute, the Shwabs' claim, premised on a failure to disclose the risk of MDS, required expert testimony establishing that MDS was a recognized substantial risk and they had no such testimony. In any event, to the extent that cancer generally was a substantial risk associated with the treatment in the clinical trial, that risk was appropriately disclosed numerous times.

Dr. Levitt testified that the Shwabs did not understand the risks involved in the clinical trial, relying on the Shwabs' subjective testimony. In *Sargent*, however, this Court emphasized that subsection (2) of KRS 304.40-320 creates an objective standard: "Meeting the standard does not require that patient's *actual* understanding of the risks; it only requires that the risks be explained so that 'a reasonable individual' would gain a general understanding of the risks." 467 S.W.3d at 208 n.10. Thus our informed consent law does not require a determination of how the plaintiff-patient claims to have understood the consent form, procedure and risks but rather how a reasonable

person would have understood the information.[24] Consequently, the standard in subsection (2) is not met by a plaintiff-patient, after the fact, simply claiming they were not properly informed or that, had they known of the specific risk that resulted in actual harm, they would not have consented to the treatment or procedure.[25]

As noted in the concurring in result only opinion in *Sargent*, 467 S.W.3d at 218, KRS 304.40–320 was enacted as part of a tort-reform effort and was produced by the Governor's Hospitals and Physicians Professional Liability Insurance Advisory Committee in 1975. In the Committee's Majority Report, they describe the statute (Section 13 of their proposal and eventually Section 4 of Senate Bill 248 in the 1976 Session of the General Assembly) as follows:

> This section will legislatively require that "informed consent" cases be proven by expert testimony relating to accepted standards of practice of the profession in providing information, and further require that an objective standard be applied in determining whether that information would likely have resulted in any different decision by the plaintiff. The purpose of this section is to eliminate the possibility of (1) a jury's speculating after the fact that the health care provider should have told the plaintiff of a given risk even though accepted professional standards would not require such advance information, and (2) a plaintiff's testifying

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[24] Some jurisdictions have held that under an objective approach, a patient's hindsight testimony is relevant, but not controlling. *See Goldberg v. Boone,* 912 A.2d 698, 702 (Md. 2006)*; Roybal v. Bell*, 778 P.2d 108, 112 (Wyo. 1989).

[25] If the informed consent standard were subjective then a plaintiff-patient's testimony would control. Proof of causation, i.e., that adequate disclosure would have caused the patient to decline treatment because of the risk that resulted in actual harm, viewed under a subjective standard "would ultimately turn on the credibility of the hindsight of a person seeking recovery after he had experienced a most undesirable result. Such a test puts the physician in 'jeopardy of the patient's hindsight and bitterness.'" *Sard v. Hardy*, 379 A.2d 1014, 1025 (Md. App. 1977) (quoting *Canterbury v. Spence,* 464 F.2d 772, 790-91 (D.C. Cir. 1972)) (internal citation omitted).

> that had he known of an unforeseeable or unlikely injury he would not have consented to the recommended health care.

As this passage reflects, the informed consent statute was enacted, at least in part, to prevent the type of hindsight scenario present in this case.

The Shwabs did not present evidence that the information given to Brooke failed to provide a reasonable person a "general understanding" of any "substantial risks" that were "recognized among other health care providers" performing similar research and treatment. Moreover, our own review, like the trial court's, satisfies us that no issue of material fact exists as to the applicability of subsection (2) of KRS 304.40-320 to this case. MDS was not a "substantial risk" at the time Brooke entered the trial given its low prevalence generally in young females, and the fact that no other patient in the clinical trial or similar study had developed MDS. In any event, a reasonable person would certainly understand from even a casual reading of the informed consent form that developing cancer (of which MDS is one type) was a risk of the clinical trial procedure and treatment.

III. KRS 304.40-320 Is Clear in Its Application to Any Action Wherein Informed Consent Is an Element and Thus Applies Even if Medical Treatment Occurs in a Clinical Trial.

The medical defendants and *amici curiae* American Medical Association and Kentucky Medical Association emphasize the importance of clinical trials for the advancement of medicine and the chilling effect that a subjective approach to liability, as reflected in the Court of Appeals' opinion in this case, would have on medical professionals' participation in studies essential for improving medical care. In recognition of the unique nature of clinical trials,

the medical defendants encourage this Court to conclude that Kentucky's informed consent law does not apply to clinical trials because no physician-patient relationship exists. We decline because we conclude that a physician-patient relationship clearly does exist, at least in the circumstances presented here, and our Kentucky informed consent law, tied to standards of accepted medical practice and an objective assessment of the information provided to the patient, adequately protects the interests of both patients and medical care professionals participating in a clinical trial.

In *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, the case relied on by the medical defendants, the federal court observed that "[m]edical consent law does not apply to medical researchers." 264 F. Supp. 2d 1064, 1069 (S.D. Fla. 2003). However, the facts of that case are significantly different from cases such as this one which entail receiving medical treatment in the context of a clinical trial. *Greenberg* involved the families of children with a rare genetic condition who donated tissue samples to a medical researcher in hopes of identifying the gene responsible for their disorder. *Id.* at 1066. Once the researcher identified the genes, he applied for a patent and began restricting any activity related to the disorder, including testing, treatments and research. *Id.* at 1067. The *Greenberg* plaintiffs filed suit alleging they were never informed that the medical researcher intended to seek a patent on the research or of his intentions to commercialize the research. *Id.* at 1068. The suit included a claim of lack of informed consent, among other claims. *Id.* The court acknowledged that the question of informed consent in

the context of medical research was relatively novel in Florida but concluded that while "in certain circumstances a medical researcher does have a duty of informed consent" no such duty existed there. *Id.* at 1070. The Shwabs assert that *Greenberg* is inapplicable because it involved a dispute over financial proceeds of non-therapeutic testing. *Id.* at 1068-69. We agree *Greenberg* is distinguishable and find the Kentucky informed consent statute on its face applies to a clinical trial involving medical treatment.[26]

The informed consent statute plainly applies to "**any action** brought for treating, examining, or operating on a claimant wherein the claimant's informed consent is an element." KRS 304.40-320 (emphasis added). KRS 304.40-260(4) includes "patient" in its definition of "claimant" and "patient" is defined as "a natural person who receives health care from a licensed health care provider under a contract, express or implied." KRS 304.40-260(3). Health care is defined as "any act, or treatment performed or furnished, or which should have been performed or furnished, by any health care provider to a patient during that patient's care, treatment, or confinement for a physical or mental condition. . . ." KRS 304.40-260(7).

Brooke qualifies as a claimant and the treatment she received during the clinical trial undeniably constitutes health care. The language in KRS 304.40-

[26] The Court of Appeals declined to review this issue, stating that it was not decided upon by the trial court and citing *Fischer v. Fischer,* 197 S.W.3d 98, 102 (Ky. 2006). While the trial court did not discuss this issue in its order granting summary judgment, the medical defendants presented the argument in their motion for summary judgment and the issue has been briefed to this Court.

320 and 304.40-260 is clear and unequivocal. Where a statute is clear and unambiguous, "we are not free to construe it otherwise . . . ." *MPM Fin. Grp., Inc. v. Morton*, 289 S.W.3d 193, 197 (Ky. 2009). While the Kentucky General Assembly could have deferred to federal authorities such as the FDA in defining the informed consent duty in a clinical trial or articulated a different standard for informed consent in clinical trials, it did not. Because the judiciary's role in statutory construction cases is to see that "the will of the legislature" is applied, *Allstate Ins. Co. v. Smith*, 487 S.W.3d 857, 861 (Ky. 2016), we decline to impose a different standard of informed consent for clinical trials.

CONCLUSION

As the trial court stated in its order granting summary judgment, this is "an unquestionably tragic situation for Ms. Shwab and her family," but for the reasons we have discussed the Shwabs do not have a viable informed consent claim under Kentucky law. Thus, we reverse the Court of Appeals and remand to the trial court for reinstatement of the summary judgment in favor of the Appellants.

All sitting. All concur.

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