**STATE OF LOUISIANA**
**COURT OF APPEAL, THIRD CIRCUIT**

**03-351**

**HARWARD SOILEAU, ET AL.**

**VERSUS**

**MED-EXPRESS AMBULANCE SERVICE, INC., ET AL.**

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APPEAL FROM THE
TWENTY-SEVENTH JUDICIAL DISTRICT COURT,
PARISH OF ST. LANDRY, NO. 00-4883,
HONORABLE ALONZO HARRIS, DISTRICT JUDGE

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**MICHAEL G. SULLIVAN**
**JUDGE**

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Court composed of Oswald A. Decuir, Michael G. Sullivan, and Elizabeth A. Pickett, Judges.

**AFFIRMED.**

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SULLIVAN, Judge.

Harward Soileau and his children, Sheila Soileau Corbin, Phyllis Soileau Dodson, and Montie Soileau, appeal the judgment of the trial court which dismissed their medical malpractice claims against Dr. Robert T. Casanova, Casanova Eye Care, and Med-Express Ambulance Service, Inc. (Med-Express) for the wrongful death of Vivian Soileau, their wife and mother. For the following reasons, we affirm.

***Facts***

On February 3, 1998, Mrs. Soileau went to Dr. Casanova's office to have a fluorescein angiogram performed on her left eye. Tragically, she had an adverse reaction to the fluorescein dye used for the test. Attempts by Dr. Casanova and Med-Express to revive Mrs. Soileau were unsuccessful, and she died. Her husband and children filed this lawsuit, alleging that she died as a result of malpractice on the part of the defendants. They also alleged that Dr. Casanova did not properly inform her of the risks associated with the test and did not have her consent to perform the test.

Mrs. Soileau first saw Dr. Casanova on April 8, 1997. At that time, she complained of dry eyes and a black spot moving in one of her eyes, and that her glasses kept slipping on her nose. Prior to examining Mrs. Soileau, Dr. Casanova obtained a medical history from her, which included allergies and asthma. Mrs. Soileau's vision at that time was 20/20 with glasses. After examining Mrs. Soileau, Dr. Casanova diagnosed her as having early cataracts and age-related macular degeneration. He also suspected that she was developing glaucoma. In July 1997, Mrs. Soileau returned to Dr. Casanova, complaining of seeing a black spot in her left eye for seven days. Examination on that date revealed that she had a peripheral retinal detachment in her left eye. Dr. Casanova referred her to Dr. J. Culotta for repair of the detached retina. She underwent three surgeries by

Dr. Culotta. As a result, she was legally blind in her left eye because the lens in that eye had been removed during surgery.

On January 27, 1998, Mrs. Soileau returned to Dr. Casanova, complaining of blurry vision in her left eye. Attempts to improve the vision with glasses were unsuccessful. Dr. Casanova suspected that her poor vision was the result of swelling of the macula, the area of the eye that provides our real fine vision. During this visit, he performed three tests to see if the macula was swollen. However, the tests did not reveal any swelling of the macula or any other cause of Mrs. Soileau's poor vision. Dr. Casanova explained to Mrs. Soileau that there may have been swelling or another abnormality not revealed by the tests he performed that day that a fluorescein angiogram would show.

Mrs. Soileau had a follow-up appointment scheduled with Dr. Culotta a few months later, and she told Dr. Casanova that she would discuss the possibility of the additional test with him at that time. Yet, two days later she called Dr. Casanova with continued complaints. After that conversation, Dr. Casanova contacted Dr. Culotta regarding the fluorescein angiogram, and he agreed that the test was appropriate for Mrs. Soileau. Dr. Casanova gave Mrs. Soileau the option of having him or Dr. Culotta perform the test. She indicated that she wanted him to do it, and she returned to his office February 3, 1998 for that purpose.

In preparation for the angiogram, Dr. Casanova's nurse, Patricia Hardy, explained the procedure and obtained Mrs. Soileau's consent to perform it. Nurse Hardy testified that she read the consent form "word for word" to Mrs. Soileau until she reached the portion of the form which refers to adverse reactions, at which time she verbally explained that the most common symptoms of such reactions are nausea,

vomiting, and itching. She then explained to Mrs. Soileau that very rarely a patient may have a severe adverse reaction which can lead to death. Before Mrs. Soileau signed the consent form, Dr. Casanova came to the procedure room and asked her if she had any questions regarding the test. She did not ask any questions and signed the consent form.

Nurse Hardy then began the angiogram. She testified that, when she injected the dye into the intravenous line in Mrs. Soileau's right hand, she did not see anything unusual happen. After she finished injecting the dye, she placed Mrs. Soileau's chin on the angiogram machine and prepared to take photographs of her eye. Mrs. Soileau started slightly coughing. At that time, Nurse Hardy told her to sit back. As she sat back in the chair, Mrs. Soileau asked for her asthma inhaler, which Nurse Hardy handed to her. Nurse Hardy summoned Dr. Casanova, who immediately administered oxygen, but Mrs. Soileau's breathing worsened. His staff called 911 and the hospital. Dr. Casanova then administered Benadryl and Epinephrine, but Mrs. Soileau did not respond. Instead, she continued to worsen and quit breathing. Dr. Casanova began administering CPR and continued his efforts until Med-Express personnel arrived and relieved him. Their efforts were unsuccessful, and Mrs. Soileau died.

Mrs. Soileau's family had an autopsy performed. Dr. Emil Laga, the pathologist who performed the autopsy, testified that Mrs. Soileau died due to an acute deprivation of oxygen to her body and that there was an acute and diffused, asthma-like reaction in her lower airways. He described the reaction as an anaphylaxis and testified that Mrs. Soileau's lower airways were almost 100% blocked by "slimy materials."

As previously noted, Mrs. Soileau had a history of allergies and asthma. Dr. Bernard Fruge, her treating physician for these conditions, testified that when he first saw her, she related a history of allergies and asthma for fifteen years. On her first visit with him in 1996, her lung function was restricted but not obstructed as a result of these conditions. She last saw him in October 1997 at which time her lung function had improved to normal, and she was asymptomatic. He testified that the autopsy findings on her were consistent with anaphylactic reaction. In his opinion, Mrs. Soileau experienced a fatal bronchial spasm, which caused mucus to plug her lower airways. This, together with inflammation, prevented her from ventilating. He further testified that Mrs. Soileau's history of allergies and asthma was not a contraindication for the angiogram, explaining that there was no predictor of a person's response to fluorescein dye, if they had never received it before. However, he agreed that her reaction was more severe than what the general population's response would be because her lower airways were more restrictive.

Prior to trial, the Soileaus filed a motion in limine to exclude the testimony of Nurse Hardy and Dr. Casanova regarding the verbal warnings that Nurse Hardy gave to Mrs. Soileau before the fluorescein dye was injected. As reflected above, the trial court denied the motion, and they were allowed to testify that it was Nurse Hardy's standard practice to supplement the written consent form with a verbal warning, as she did in this case.

The matter was tried to a jury for four days. At the conclusion of the trial, the jury found no malpractice on the part of the defendants and did not award damages to the Soileaus. On appeal, the Soileaus assign as error the trial court's admission of Dr. Casanova's and Nurse Hardy's testimony to modify the terms of the written

consent form. They also assign as error the jury's finding that Mrs. Soileau's consent to the angiogram was informed and the jury's failure to award damages.

***Nurse Hardy's Verbal Warnings***

The Soileaus contend that the trial court erred in denying their motion in limine which sought to prevent Dr. Casanova and Nurse Hardy from testifying regarding the verbal warnings that she gave to Mrs. Soileau. La.R.S. 40:1299.40 governs the consent which must be obtained from a patient before a medical procedure is rendered. Subsections (A)(1), (B), and (C) of La.R.S. 40:1299.40, are at issue herein. They provide:

> A. (1) Notwithstanding any other law to the contrary, *written consent* to medical treatment means a handwritten consent to any medical or surgical procedure or course of procedures which: sets forth in general terms the nature and purpose of the procedure or procedures, *together with the known risks, if any, of death,* brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, of disfiguring scars associated with such procedure or procedures; acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner; and is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent by a person who has legal authority to consent on behalf of such patient in such circumstances. *Such consent shall be presumed to be valid and effective, in the absence of proof that execution of the consent was induced by misrepresentation of material facts.*
>
> B. *Except as provided in Subsection A of this Section*, no evidence shall be admissible to modify or limit the authorization for performance of the procedure or procedures set forth in such written consent.
>
> C. Where consent to medical treatment from a patient, or from a person authorized by law to consent to medical treatment for such patient, is *secured other than in accordance with Subsection A* above, the explanation to the patient or to the person consenting for such patient *shall include the matters set forth in Paragraph (1) of Subsection A* above, and an opportunity shall be afforded for asking questions concerning the procedures to be performed which shall be answered in a satisfactory manner. Such consent shall be valid and effective and is subject to proof according to the rules of evidence in ordinary cases.

(Emphasis added.)

Relying on Subsection (B), the Soileaus contend that when there is written consent no evidence regarding oral warnings given by the health care provider to the patient is admissible. They correctly point out that the interpretation of a statute begins with the language of the statute itself. However, after a close reading of Subsections (A) and (B) and review of the jurisprudence interpreting these provisions, we find that their interpretation is incorrect.

Subsection (A) defines written consent as "handwritten consent" which sets forth the nature and purpose of the medical procedure and "the known risks, if any, of death, . . . the loss or loss of function of any organ," acknowledges disclosure of the information and that all questions have been answered, and is signed by the patient. *Id.* "Such consent," i.e., written consent which satisfies this definition, creates a rebuttable presumption that a patient has consented "to encounter risks adequately described in the consent form," *Hondroulis v. Schuhmacher*, 553 So.2d 398, 417 (La.1988), and limits the introduction of evidence to situations in which "execution of the consent was induced by misrepresentation of material facts." La.R.S. 40:1299.40(A).

Subsection (B) prohibits the admission of evidence "to modify or limit" the authorization for the procedure set forth in "such written consent." The Soileaus argue that parol evidence should not have been allowed regarding the risks not specified on the written consent form. Therefore, we must determine whether "such written consent" in this section is a reference to all written consent, as the Soileaus argue, or just certain written consent. Subsection (B)'s introductory reference to Subsection (A) and its placement immediately following Subsection (A) leads to the

conclusion that the phrase "such written consent" is a reference to written consent which satisfies the requirements of Subsection (A). Accordingly, only written consent which sets forth "the known risks" of the procedure to be performed on the patient are governed by Subsection (B).

This conforms with the supreme court's conclusion in *Hondroulis,* 553 So.2d 398, that La.R.S. 40:1299.40 addresses the patient's burden of proof in an informed consent claim. In *Hondroulis*, the supreme court recognized that La.R.S. 40:1299.40 is not clear and precise, then conducted a thorough review of the jurisprudence on informed consent and the statute to determine the effect of the statute. Analyzing the requirements of La.R.S. 40:1299.40, the court explained:

> In our opinion, under the statute, (1) if it is proved that the patient *signed a document purporting to warn him of a risk involved* in the proposed surgery or treatment, (2) it is presumed that the patient understood and consented to encounter whatever risk a reasonable person, in what the doctor knew or should have known to be the patient's position, would have apprehended from the written consent form, and (3) the patient cannot disprove the presumed fact except by showing that his consent was induced by misrepresentation.

*Id.* at 417 (emphasis added).

Acknowledging the uncertainty of the effect of the statute on the existing jurisprudence regarding informed consent, the court continued its analysis:

> The statute may be interpreted reasonably as a modest amendment to the informed consent doctrine, rather than as a cryptic restatement of the whole body of law severely burdening or interfering with the rights of patients to make intelligent medical choices. Prior to this enactment our courts attached no particular legal significance to a medical consent merely because it happened to be in writing. . . . Consequently, a patient could introduce virtually any kind of relevant evidence to prove lack of consent or to rebut the doctor's evidence that the patient had consented to the therapy. Therefore, the statute may be viewed reasonably as having as its principal object a change in the law providing that, notwithstanding any other law to the contrary, a written consent to encounter the risks disclosed therein may not be rebutted except by a showing that consent was induced by misrepresentation.

> Since the statute does not expressly define or redefine the cause of action for failure to obtain informed consent, such an intention should not be read into its provisions. *Its aim is simply to affect the burden borne by the plaintiff who would controvert the disclosure or consent set forth in the consent form.* . . .
>
> For these reasons, we conclude that, notwithstanding prior judicial expressions, the legislature by enacting La.R.S. 40:1299.40, did not intend to make substantive alterations in the informed consent doctrine. More particularly, the legislature did not intend to change the law with respect to major elements of the cause of action such as the doctor's duty to disclose material information (including reasonable alternative therapy) or the patient's burden to prove the materiality of any risk not disclosed. That the statute does not contain an express restatement of these principles is due simply to their being integral parts of the jurisprudential doctrine that the legislature tacitly accepted in accomplishing its limited purpose of regulating proof of lack of informed consent. . . .

*Id.* at 418 (emphasis added) (citations omitted).

In light of *Hondroulis*, we interpret La.R.S. 40:1299.40 to provide that, if a written consent identifies the risk at issue, there is a presumption that the patient was informed of and accepted that risk, and the patient cannot introduce evidence to rebut that presumption, unless he proves that his "consent was induced by misrepresentation of material facts." However, if the written consent does not identify the risk at issue, there is no presumption that the patient was informed of and accepted the risk at issue, and the physician must prove that he informed the patient of the risk at issue and that the patient consented to the surgery or procedure at issue. *See LeBlanc v. Krupkin* (La.App. 1 Cir. 1989), 555 So.2d 600, *writ denied*, 558 So.2d 603 (La.1990).

Consent that does not meet the requirements of Subsection (A) is valid if it includes "the matters set forth in Paragraph (1) of Subsection (A)" and the patient is allowed to ask questions which are answered. La.R.S. 40:1299.40(C). An oral explanation and oral consent are acceptable under this provision. *Id.* *See also*

*Distefano v. Bell*, (La.App. 1 Cir.), 544 So.2d 567, *writ denied*, 550 So.2d 650 (La.1989). Consent obtained in accordance with either Subsection (A) or (C) is valid consent. *Capel v. Langford*, 98-1517 (La.App. 3 Cir. 4/28/99), 734 So.2d 835, *writ denied,* 99-2080, 99-2086 (La. 10/29/99), 749 So.2d 637, 638.

While the precise issue presented here has not been previously addressed, there are cases in which written consent that was supplemented with the testimony of the physician was found to be informed consent. *See Ardoin v. Mills*, 00-1257 (La.App. 3 Cir. 3/8/01), 780 So.2d 1265, *writ denied*, 01-1003 (La. 6/15/01), 793 So.2d 1242; *Leger v. La. Med. Mut. Ins. Co.*, 98-1098 (La.App. 3 Cir. 3/31/99), 732 So.2d 654, *writ denied*, 99-1253 (La. 6/18/99), 745 So.2d 30*; Bourgeois v. McDonald*, 622 So.2d 684 (La.App. 4 Cir.), *writ denied*, 629 So.2d 1177 (1993).

The written consent form signed by Mrs. Soileau does not satisfy the requirements of Subsection (A) because it does not identify death as a "known risk" of a fluorescein angiogram; therefore, Subsections (A) and (B) are inapplicable. Subsection (C) governs the issue presented herein, and the trial court's admission of Dr. Casanova's and Nurse Hardy's testimony regarding the manner in which Nurse Hardy orally supplemented the written consent form was not error.

***Informed Consent***

In their second assignment of error, the Soileaus assert that the jury's determination that Mrs. Soileau's consent to the fluorescein angiogram was informed was erroneous. They contend that because of her history of asthma, which included one emergency room visit, she should have been informed that respiratory distress and/or an anaphylactic reaction were material risks of the fluorescein angiogram and that the procedure could have been performed in the hospital.

In *Hondroulis,* the supreme court explained the concept of material risk in the context of informed consent:

> The determination of materiality is a two-step process. The first step is to define the existence and nature of the risk and the likelihood of its occurrence. "Some" expert testimony is necessary to establish this aspect of materiality because only a physician or other qualified expert is capable of judging that risk exists and the likelihood of occurrence. The second prong of the materiality test is for the trier of fact to decide whether the probability of that type harm is a risk which a reasonable patient would consider in deciding on treatment. The focus is on whether a reasonable person in the patient's position probably would attach significance to the specific risk.

*Hondroulis* at 412. To be successful on their claim, the Soileaus must prove that respiratory distress and/or anaphylactic reaction occurred, and that had these risks been disclosed to Mrs. Soileau, she would not have had the angiogram performed. *Id.* The disclosure requirement is an objective standard which was adopted "[b]ecause of the likelihood of a patient's bias in testifying in hindsight on this hypothetical matter." *Id.*

Dr. Raymond Records, the Soileaus' expert, was qualified as a medical expert, specializing in ophthalmology. He testified that fluorescein dye is old and very, very safe. He also testified that he considered asthma and allergies to be risk factors with fluorescein angiograms and that he generally did not do fluorescein angiograms on patients with a history of asthma in his office.

Dr. Kurt Gitter, an ophthalmic and retinal surgeon, was Dr. Casanova's expert. He testified that the possibility of an anaphylactic reaction to fluorescein dye is very, very rare. Dr. Gitter testified that the only statistics on fluorescein angiograms reflect that severe reactions to the dye occur in only 115 of every 220,000 performed, which is .05%. He also testified that the fluorescein angiogram is the gold standard for diagnosing CME. According to him, it is one of the safest and most used of all

diagnostic tests in ophthalmology when other forms of "interventional testing" are considered. He further testified that, during the course of his practice of approximately forty years, he has performed fifty to 100 fluorescein angiograms per week and never had an episode like Mrs. Soileau's or an anaphylactic response occur. He explained that those patients who did react to the fluorescein were easily and quickly treated with no further complications. He also testified that it is the standard of care for these tests to be performed in offices rather than in hospitals.

In *Ardoin,* 780 So.2d 1265, the plaintiff developed an infection after surgery which resulted in the loss of use of his arm. He claimed that he would not have had an arthrogram procedure performed if he knew that he could lose the use of his arm as a result of the procedure. The defendant doctor testified that he had informed the plaintiff that bleeding, infection, and allergic reaction are risks associated with the procedure. He argued that "the standard of care did not require that he then explain the potential complications of these risks, *i.e.*, the potential that infection could lead to the loss of the use of his arm." *Id.* at 1270. This court found no error with the jury's conclusion that the defendant doctor did not breach the standard of care, stating: "We disagree that the jury was required to find that the potential of loss of function of the arm was a material risk of the operation. The jury repeatedly heard expert testimony indicating that the physician is expected to reveal material risks of the operation, but not every potential complication." *Id*.

The situation here is similar. Mrs. Soileau was advised that severe allergic reaction, including death, was a risk of the angiogram, but she was not advised that respiratory distress or anaphylactic reaction are also risks. Dr. Bernard testified that an anaphylactic reaction *is a systemic allergic reaction*. He testified that such a

reaction can affect the lungs and cause wheezing or bronchial spasms and that he believed that Mrs. Soileau experienced a fatal bronchial spasm.

A jury's finding of fact may not be reversed absent manifest error or unless clearly wrong. *Stobart v. State, Through Dep't of Transp. and Dev*., 617 So.2d 880 (La.1993). "[A] reviewing court must do more than simply review the record for some evidence which supports or controverts the trial court's findings. [It must] review the record in its entirety to determine whether the trial court's finding was clearly wrong or manifestly erroneous." *Id.* at 882 (citation omitted). "[T]he issue to be resolved . . . is not whether the trier of fact was right or wrong, but whether the fact finder's conclusion was a reasonable one." *Id*.

Considering the testimony of Dr. Gitter, the jury may have concluded that, even though Mrs. Soileau had allergies and asthma, the risk of respiratory distress and/or anaphylactic reaction were not material risks that Dr. Casanova should have disclosed. Additionally, Dr. Fruge's testimony may have led the jury to conclude that an anaphylactic reaction is an allergic reaction which may include respiratory distress and that these responses were encompassed in the warning she was given. Dr. Gitter's and Dr. Fruge's testimony may have also led the jury to conclude that, even if Dr. Casanova had advised Mrs. Soileau of these risks, she would not have decided against having the procedure performed by him in his office.

Our determination on this issue pretermits the need to address the Soileau's third assignment of error.

***Disposition***

The judgment of the trial court is affirmed. All costs of this proceeding are assessed to the Soileaus.

**AFFIRMED.**