

**ELAINE DEROUCHE AND
GERALD DEROUCHE**

*

NO. 2013-CA-0979

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VERSUS

COURT OF APPEAL

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**RIAN M. TANENBAUM, M.D.,
METROPOLITAN
GASTROENTEROLOGY
ASSOCIATES, AND C.B.
FLEET COMPANY, INC.**

*

FOURTH CIRCUIT

STATE OF LOUISIANA

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APPEAL FROM
CIVIL DISTRICT COURT, ORLEANS PARISH
NO. 2012-02749, DIVISION "L-6"
Honorable Kern A. Reese, Judge

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Judge Max N. Tobias, Jr.

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(Court composed of Chief Judge James F. McKay, III, Judge Max N. Tobias, Jr.,
Judge Madeleine M. Landrieu)

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AFFIRMED.

DECEMBER 18, 2013

The plaintiffs, Elaine and Gerald Deroche, appeal a summary judgment dismissing their medical malpractice action against the defendant, Rian M. Tanenbaum, M.D., with prejudice. For the following reasons, we affirm.

I.

On 16 January 2008, Elaine Deroche filed a complaint with the Louisiana Patients' Compensation Fund ("LPCF") alleging that Dr. Tanenbaum, a gastroenterologist, deviated from the prevailing standards of care when he ordered her to follow the instructions prepared by Metropolitan Gastroenterology Associates ("MGA")¹ for the use of a Fleet Phospho-Soda preparation ("FPS prep")² that was "contrary to the instructions" of the manufacturer prior to her scheduled colonoscopy in February 2007.³

¹ MGA is the medical group with whom Dr. Tanenbaum practices medicine.

² Fleet Phospho-Soda is manufactured and distributed by C.B. Fleet Company ("Fleet"), which is also a defendant in the instant litigation.

³ Mrs. Deroche's complaint with the LPFC further averred that MGA breached the prevailing standard of care when one of its nurses improperly advised her to ingest a second dose of the FPS prep on the morning of the procedure, which allegedly caused her to sustain permanent kidney damage. MGA moved for summary judgment, which motion was denied. Thus, the Deroches' allegations asserted against MGA are not currently before the court on this appeal.

Elaine Deroche was initially treated by Dr. Tanenbaum in 1998 for irritable bowel syndrome.⁴ In 2004, she underwent her first colonoscopy⁵ performed by Dr. Tanenbaum. Prior to the 2004 procedure, Dr. Tanenbaum instructed Mrs. Deroche to use the same FPS prep at issue in the instant case, which she did without incident or difficulty.

Mrs. Deroche returned to Dr. Tanenbaum on 23 January 2007 upon referral by her family physician following complaints of blood-tinged diarrhea. Blood work performed by the referring physician the previous day indicated Mrs. Deroche was not dehydrated at that time. Given her history of loose bowels for approximately three weeks duration, Dr. Tanenbaum recommended and had his staff schedule Mrs. Deroche for a colonoscopy for 7 February 2007 to take place at MGA's facilities. According to Dr. Tanenbaum, because Mrs. Deroche had used the same FPS prep prior to her 2004 colonoscopy and done very well with it, he determined that the FPS prep would likewise be an appropriate bowel preparation for her colonoscopy in 2007. Dr. Tanenbaum discussed the procedure with Mrs. Deroche, explained why he was recommending she undergo the procedure, and explained what she needed to do in preparation for the procedure, including utilizing the FPS prep.⁶ Dr. Tanenbaum admittedly did not discuss with Mrs.

⁴ At that time, Mrs. Deroche underwent a flexible sigmoidoscopy, a procedure used prior to colonoscopies, performed by Dr. Tanenbaum, which revealed a "mild inflammatory reaction of the colon." Based upon this finding, Dr. Tanenbaum diagnosed Mrs. Deroche as suffering from irritable bowel syndrome.

⁵ Dr. Tanenbaum described a colonoscopy as "an evaluation of the large intestine with an endoscopic or a fiber-optic scope to aid in evaluation and treatment of the patient."

⁶ The record contains a "Consent for Medical Procedure and Acknowledgement of Receipt of Information" executed by Mrs. Deroche prior to undergoing the colonoscopy.

Deroche the rare complication regarding potential renal failure and nephrotoxicity as a consequence of taking the FPS prep.⁷

Mrs. Deroche was given written instructions prepared by MGA that provided a step-by-step process for using the FPS prep that she was to complete during the days immediately preceding her scheduled colonoscopy.⁸ As per the written instructions, Mrs. Deroche was to avoid certain foods and medication beginning three days prior to the procedure. The instructions further instructed her to drink one quart of Gatorade two days prior to the colonoscopy and another quart the day before the procedure. Regarding the day of her colonoscopy (scheduled for 12:30 p.m.), the instructions directed Mrs. Deroche to consume “½ bottle (1½ oz.) of Fleet Phospho-soda to one-half glass (4 oz.) of clear liquid” at 6:00 a.m., followed “with one full glass (8 oz.) of clear liquid.” At 9:00 a.m., the instructions stated that Mrs. Deroche was to “add the remaining [FPS] (1½) to one-half glass (4 oz.) of clear liquid,” also followed “with one full glass (8 oz.) of clear liquid.” At 9:30 a.m., the instructions directed Mrs. Deroche to use a Fleet enema. The written instructions also advised what the patient should expect while taking the FPS prep. Additionally, the instructions directed the patient to call the physician if any vomiting occurred while taking the FPS prep.⁹

⁷ Dr. Tanenbaum testified that, while he was aware of the risk of acute renal failure associated with the use of the FPS prep, he did not discuss the possibility with her because, in his medical opinion and based upon Mrs. Deroche’s prior use of the same prep without incident, he believed Mrs. Deroche was not a part of the at-risk population, especially had she followed the MGA written instructions and been properly hydrated during the course of the preparation for the colonoscopy.

⁸ Dr. Tanenbaum explained that the protocol or written instructions for the FPS prep given to Mrs. Deroche were drafted by MGA based on recommendations from various medical sources and the PDR (Physician’s Desk Reference) regarding administering the FPS prep. Dr. Tanenbaum participated in the drafting of these instructions.

⁹ It is undisputed that the instructions for taking the FPS prep prepared by MGA differed from Fleet’s instructions and warnings regarding the use of the FPS prep that were in effect at

In her deposition, Mrs. Deroche testified that she purchased a single three-ounce bottle of FPS prep, but did not read or retain the package insert. She claimed that after measuring half of the bottle and mixing it with apple juice, she took the first dose at 6:00 a.m. on the morning of the procedure, which caused her to immediately regurgitate. She explained that due to her nausea and vomiting, she was unable to drink the required eight ounces of liquid following the first dose as directed.

Mrs. Deroche testified that she telephoned Dr. Tanenbaum's office at MGA to report having vomited the first dose and left a message with MGA's answering service.¹⁰ According to Mrs. Deroche, within 15 to 30 minutes, a MGA nurse returned her call and advised her to proceed with taking the second dose of the FPS prep since she had regurgitated the first dose. She could not recall telling the MGA nurse that she had not consumed any liquids after ingesting the first dose. Mrs. Deroche testified that she then took the second FPS prep dose at approximately 6:30 a.m. (rather than at 9:00 a.m. pursuant to the written instructions), followed by an eight-ounce glass of apple juice.

It is undisputed that Dr. Tanenbaum was not notified at any time prior to performing Mrs. Deroche's colonoscopy – by Mrs. Deroche or anyone else – that she was nauseous, had vomited the morning of the procedure, or that she had taken

the time of Mrs. Deroche's colonoscopy. Specifically, instead of the three-hour lapse between the first and second doses espoused by Dr. Tanenbaum and MGA, Fleet recommended ten to twelve hours between doses. Dr. Tanenbaum admitted in his deposition that he was unaware of Fleet's revisions to its instructions regarding the change in the timeframe. Despite the Fleet package instructions, however, Dr. Tanenbaum was of the medical opinion that the three-hour span for taking the preparation was sufficient and appropriate.

¹⁰ Whether Mrs. Deroche actually made the call to MGA and eventually spoke with a MGA nurse remains a fact in contention. But this unresolved factual issue is not relevant to the issues regarding the alleged negligence or malpractice of Dr. Tanenbaum. MGA's motion for summary judgment, which is not before this court on appeal, was denied on this basis.

both doses of the FPS prep within 30 minutes of one another without hydration in-between doses contrary to the written instructions.

Dr. Tanenbaum conceded that he did not know for a fact whether Mrs. Deroche was dehydrated before she ingested the FPS prep. However, based upon the results of blood work performed two weeks earlier by the referring physician (indicating that after several weeks of diarrhea she had not become dehydrated as a result of her symptoms), and his personal evaluation of her in his office, he opined that even if Mrs. Deroche's symptoms had persisted from the date of the blood test to the date of the colonoscopy, she would not have been dehydrated prior to ingesting the FPS prep. Moreover, Dr. Tanenbaum stated that, given the above, unless Mrs. Deroche informed him that there had been a change in her symptoms (which she did not), and assuming she properly hydrated according to MGA's written instructions while taking the FPS prep, he had no reason to believe that she was dehydrated prior to performing the colonoscopy.

According to Dr. Tanenbaum, Mrs. Deroche's colonoscopy was performed under moderate sedation without complications. He did not find any abnormalities; to the naked eye, the colon looked completely normal. Biopsies were obtained for further analysis.¹¹ Mrs. Deroche was then discharged home with her husband. Further written instructions were provided and Mr. Deroche was advised to make sure that his wife had plenty of fluids to drink that evening.¹² Though Mrs. Deroche contends she continued to feel nauseous even after the colonoscopy was completed, she confirmed that she failed to report this to either

¹¹ Mrs. Deroche's biopsy report later revealed a diagnosis of "collagenous colitis," which Dr. Tanenbaum explained is a microscopic colitis that cannot be detected with visualization of the colon, but only by biopsy.

Dr. Tanenbaum or to anyone at MGA. Moreover, she concedes that, contrary to the discharge instructions to drink plenty of fluids that evening, she only managed to ingest a few sips of juice before going to bed for the night.

On the day following the procedure, Mrs. Deroche experienced difficulty urinating. She contacted Dr. Tanenbaum's office and was instructed to go to the hospital. She presented to the emergency room at West Jefferson Medical Center and was thereafter admitted to the hospital with a diagnosis of dehydration and, based on elevated blood urea nitrogen (BUN) and creatinine levels, acute renal failure and nephrocalcinosis.¹³ Mrs. Deroche was discharged on 1 March 2007 once her renal function was stabilized.

The Deroches filed a complaint with the LPCF in January 2008¹⁴ alleging that Dr. Tanenbaum breached the standard of care for gastroenterologists when he instructed Mrs. Deroche to follow MGA's prepared instructions for taking the FPS prep which were contrary to the instructions of Fleet in preparation for her colonoscopy.¹⁵ The medical review panel convened four years later on 28 February 2012 and unanimously determined that Dr. Tanenbaum (and MGA) complied with all prevailing standards of care.

¹² In her deposition, Mrs. Deroche testified that following the procedure, she specifically recalls being told to drink plenty of fluids that evening.

¹³ Nephrocalcinosis is a condition in which calcium levels in the kidneys are increased.

¹⁴ Also in January 2008, after filing their complaint with the LPCF, the Deroches filed a product liability action against Fleet in federal court alleging that the FPS prep was unreasonably dangerous and caused Mrs. Deroches' acute kidney failure. In January 2009, Fleet filed a motion for summary judgment, seeking dismissal of the Deroches' claims on the basis that they failed to present any medical expert testimony to prove them. On 18 February 2009, the Deroches moved to voluntarily dismiss their claims against Fleet without prejudice.

¹⁵ The complaint also alleged that MGA breached the applicable standard of care resulting in Mrs. Deroche's acute renal failure and nephrocalcinosis.

The Deroches subsequently filed the instant state court action against Dr. Tanenbaum, MGA, and Fleet in March 2012. Specifically, the Deroches' petition alleged that Dr. Tanenbaum deviated from the prevailing standard of care for gastroenterologists in providing medical care to Mrs. Deroche when he negligently: (1) failed to determine if Mrs. Deroche was dehydrated prior to instructing her to take the FPS prep; (2) failed to inform her of the potential risk of nephrotoxicity associated with taking the FPS prep; (3) instructed her to use the FPS prep contrary to the instructions and warnings provided by Fleet; and (4) advised Mrs. Deroche to immediately take the second dose of FPS despite her having regurgitated after ingesting the first dose. The plaintiffs further averred that Mrs. Deroche's acute renal failure and nephrocalcinosis was directly caused by Dr. Tanenbaum's breach of the applicable standard of care.

Dr. Tanenbaum and MGA answered the plaintiffs' petition. In November 2012, they moved for summary judgment seeking dismissal of the Deroches' claims on the basis that the plaintiffs failed to identify any expert medical witness to establish the applicable standard of care and/or to establish their claim that Dr. Tanenbaum's actions deviated from that standard of care causing Mrs. Deroche's acute renal failure. In support of his motion for summary judgment, Dr. Tanenbaum submitted a copy of the expert opinion of the medical review panel¹⁶ which had determined that the evidence did not support the conclusion that he failed to meet the applicable standard of care as charged by the plaintiffs. Specifically, the panel unanimously concluded:

1. There was no reason to suspect the patient was dehydrated prior to [taking] the [FPS] prep.

¹⁶ The medical review panel consisted of Drs. James Smith, John Harrington, and Sean Connolly.

2. The patient did not have any contra-indications for the use of Fleet Phospho-Soda prep.
3. The prescribed prep was within the variations that were considered appropriate at the time of this procedure.
4. While disputed as to whether there was a telephone call, the panel finds that it was appropriate to let the patient take a second dose of Fleet Phospho-Soda prep after immediately vomiting the first dose.

In further support of his motion, Dr. Tanenbaum attached a copy of MGA's written instructions for the colonoscopy preparation with FPS prep; a copy of Mrs. Deroche's deposition; excerpts from the deposition of Dr. J. Kevin Modisette, Mrs. Deroche's treating nephrologist;¹⁷ a chart access record for Mrs. Deroche; and Dr. Tanenbaum's responses to the plaintiffs' third set of interrogatories.

Mrs. Deroche's deposition testimony established that she had used a bowel cleansing prep prior to her colonoscopy in 2004 without incident and about which she had no complaints. According to Dr. Tanenbaum, the prep Mrs. Deroche used in 2004 colonoscopy was the same FPS prep he instructed her to use in preparation for her 2007 colonoscopy. Mrs. Deroche's deposition testimony further established that prior to her colonoscopy in 2007, Dr. Tanenbaum's assistant discussed with her MGA's written instructions for taking the FPS prep. Specifically, the assistant went over the importance of hydration and the need to drink a quart of green Gatorade on each of the two days preceding the procedure, as well as drinking the specified amounts of clear liquids during the course of the preparation. Despite those instructions, Mrs. Deroche advised that she did not

¹⁷ A nephrologist is a medical doctor who specializes in kidney care and diseases.

drink any fluids between the two doses of the FPS prep.¹⁸ Mrs. Deroche further stated that immediately following the colonoscopy, she was instructed regarding the need to drink fluids that evening. Again, despite those instructions to hydrate, Mrs. Deroche testified that she ingested only a few sips of juice before retiring for the night.

The deposition testimony of Dr. Modisette supports Dr. Tanenbaum's contention that the instructions given to Mrs. Deroche prior to her colonoscopy regarding the use of FPS prep were appropriate. Specifically, Dr. Modisette testified as follows:

Q. Do you have any criticism of the instruction to the patient to drink a quart of green Gatorade on Monday, another quart of green Gatorade on Tuesday, and on Wednesday to take half a bottle, one and a half ounces of Fleet Phospho-Soda mixed with a four-ounce glass of clear liquid, followed up with a full glass of eight-ounce clear liquid and then waiting three hours for the second half of the dose?

A. No. That seems to be actually more appropriate than the company recommendations based on what I've read. That is a low dose prep and it sounds like if she was, in fact, told to drink that much Gatorade, they were trying to protect against dehydration.

In opposition to Dr. Tanenbaum's motion, the Deroches submitted a photocopy of the affidavit of Dr. Karen Kim, an expert retained by Fleet to defend against the prior product liability action the Deroches brought against Fleet in federal court, which action was dismissed in 2009.¹⁹ Dr. Kim's affidavit was prepared for and presented in the federal court action. The plaintiffs presented no

¹⁸ Mrs. Deroche testified that because of her nausea, she was unable to drink the requisite eight ounces of fluid following the first dose of the FPS prep.

¹⁹ Notably, Dr. Kim was retained by Fleet as its expert in the earlier federal product liability action to discuss Fleet's compliance with FDA regulations and the safety of its product, and whether Fleet properly informed the medical community of the risks and benefits of their product and its subsequent labeling changes.

other expert witness testimony, countervailing affidavit, or supporting documentation to rebut the expert opinion of the medical review panel.

Dr. Tanenbaum's motion for summary judgment came for hearing in January 2013, nearly five years from the date the Deroches' instituted their initial claim against Dr. Tanenbaum with the LPCF. Following oral argument, the trial court granted Dr. Tanenbaum's motion, without written reasons, dismissing the Deroches' suit against him with prejudice.

The Deroches' timely filed a motion to set aside the judgment and for new trial. In support of their motion, the plaintiffs again attached a photocopy of the affidavit of Dr. Kim, in addition to the deposition of Dr. Tanenbaum, a copy of the PDR's instructions and warnings for FPS prep, a copy of Dr. Tanenbaum's instructions for colonoscopy preparation with FPS prep, and various medical records of Mrs. Deroche. The motion was orally argued before the trial court on 22 March 2013, and denied in a written judgment of 23 April 2013.

The Deroches perfected this appeal, arguing that issues of fact remain as to whether they have satisfied their burden under La. R.S. 9:2794 by demonstrating that Dr. Tanenbaum deviated from the applicable standard of care when he failed to use reasonable care and diligence in his treatment of Mrs. Deroche, and as to whether his breach caused Mrs. Deroche to sustain acute renal failure.

II.

An appellate court utilizes a *de novo* standard to review the granting or denial of a motion for summary judgment. *Independent Fire Ins. Co. v. Sunbeam Corp.*, p. 7 (La. 2/29/00), 755 So.2d 226, 230. A motion for summary judgment will be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no

genuine issue of material fact, and that the mover is entitled to judgment as a matter of law.” La. C.C.P. art. 966 B.

The burden of proof is on the movant. But if the movant will not bear the burden of proof at the trial of the matter, the movant is not required to negate all essential elements of the adverse party’s claim, but rather to point out an absence of factual support for one or more essential elements. Thereafter, if the adverse party fails to provide factual evidence to establish that he will be able to satisfy his evidentiary burden of proof at trial, no genuine issue of material fact exists, and summary judgment is properly granted. La. C.C.P. art. 966 C(2).

In a ruling on a motion for summary judgment, the trial court’s role is not to evaluate the weight of the evidence or to determine the truth of the matter, but instead to determine whether a genuine issue of triable fact remains. *Hines v. Garrett*, 04-0806, p. 1 (La. 6/25/04), 876 So.2d 764, 765. Factual inferences reasonably drawn from the evidence must be construed in favor of the party opposing the motion, and all doubt must be resolved in the opponent’s favor. *Willis v. Medders*, 00-2507, p. 2 (La. 12/8/00), 775 So.2d 1049, 1050. Because it is the applicable substantive law that determines materiality, whether a particular fact in dispute is “material” for summary judgment purposes can be seen only in light of the substantive law applicable to the case. *Richard v. Hall*, 03-1488, p. 5 (La. 4/23/04), 874 So.2d 131, 137.

La. R.S. 9:2794 A provides that a plaintiff in a medical malpractice action against a physician bears the burden of proving by a preponderance of the evidence: (1) the applicable standard of care expected of physicians in his medical specialty, (2) a violation of that standard of care, and (3) a causal connection between the alleged negligent treatment and the plaintiff’s injuries resulting

therefrom. *Pfiffner v. Correa*, 94-0924, 94-0963, 94-0992, p. 8 (La. 10/17/94), 643 So.2d 1228, 1233; *Farmer v. Reyes*, 95-0734, pp. 3-4 (La. App. 4th Cir. 11/16/95), 665 So.2d 129, 131. All three elements must be proven in order for a plaintiff to successfully maintain a cause of action sounding in medical malpractice. Expert medical testimony is generally required to establish the applicable standard of care and whether or not that standard was breached, except where the negligence is so obvious that a lay person can infer negligence without guidance of expert testimony. *Pfiffner*, 94-0924 at pp. 9-10, 643 So.2d at 1234.

In the instant case, Dr. Tanenbaum does not dispute that Mrs. Deroche sustained acute renal failure and nephrocalcinosis following the colonoscopy he performed. The medical records contained in the record on appeal, as well as Dr. Tanenbaum's deposition testimony, confirm this. At issue, however, is whether, as a matter of law, in accordance with the burden of proof requirements in a medical malpractice action as set forth in La. R.S. 9:2794 and *Pfiffner*, the Deroches have satisfied their burden of establishing the applicable standard of care of physicians in Dr. Tanenbaum's field of expertise when preparing patients for a colonoscopy, that Dr. Tanenbaum deviated from that standard of care, and that his deviation caused Mrs. Deroche's acute renal failure.

The Deroches argue that Dr. Tanenbaum's own deposition testimony raises an issue of fact as to whether he breached the standard of care of gastroenterologists. Specifically, the Deroches contend that because of Mrs. Deroche's history of several weeks of persistent diarrhea, Dr. Tanenbaum should have ordered another blood test immediately prior to performing the colonoscopy to ensure that she was properly hydrated. According to the Deroches, pursuant to Fleet's instructions for the FPS prep, "in patients such as Mrs. Deroche," a baseline

and post-treatment sodium, potassium, chloride, bicarbonate, phosphate, blood urea nitrogen, and creatinine values should have been obtained. The plaintiffs apparently seek to have us infer a breach of the applicable standard of care from Dr. Tanenbaum's failure to conduct an additional blood test prior to Mrs. Deroche's colonoscopy in order to obtain her baseline electrolyte levels. The plaintiffs posit that other than Dr. Tanenbaum's deposition testimony, no additional expert testimony is needed to support their contention that Dr. Tanenbaum's reliance on the previous doctor's blood work rather than performing his own constituted negligence resulting in Mrs. Deroche's acute renal failure.

Though conceding the importance of obtaining a baseline electrolyte level in an at-risk patient before prescribing FPS prep, Dr. Tanenbaum does not dispute that he relied on the blood work of the referring physician instead of conducting his own blood test before proceeding with Mrs. Deroche's colonoscopy. According to Dr. Tanenbaum, the "at-risk" population associated with the FPS prep was identified to include those patients with pre-existing kidney disease, congestive heart failure, colitis, and patients that were on certain types of medications such as diuretics or ace inhibitors. Contrary to the unsubstantiated assertions by the plaintiffs that Mrs. Deroche fell into this "at-risk" category, in Dr. Tanenbaum's medical opinion, her ongoing bowel issues did not place her "at-risk" such that additional blood work was necessary. Consequently, Dr. Tanenbaum argues that his reliance on the referring physician's blood work was proper, and no reason existed for him to believe Mrs. Deroche was dehydrated prior to his performing the colonoscopy.²⁰

²⁰ Dr. Tanenbaum testified in his deposition as follows:

We find that the Deroches have failed to present any expert medical evidence establishing the applicable standard of care in the field of gastroenterology addressing what pre-procedure evaluation is required for a colonoscopy, what laboratory work is indicated, and/or whether any contraindications for the FPS prep exists. We also find the record devoid of evidence establishing that, *prior* to her 2007 colonoscopy, Dr. Tanenbaum had any reason to opine that Mrs. Deroche fell into the “at-risk” patient population for

Q. Would it be fair to say [sic] you, based on your experience of doing these colonoscopies and instructing people to take these difference types of bowel preps, you knew that before 2007, specifically that you don't want to give this product Fleet Phospho-Soda to somebody that's dehydrated?

A. Yes.

Q. If you had information that the patient was possibly dehydrated, that would be the appropriate protocol to do before giving them this Fleet product, do a baseline blood test on them?

A. Yes.

Q. Did you do a baseline blood test on Ms. Deroche before giving her this product Fleet Phospho-Soda?

A. Yes.

Q. You did?

A. The doctor that saw the patient before I did did a baseline.

Q. I saw that in the medical records. If you can find that in the records for me, do you know the date that was given?

A. January 22, 2007.

Q. The actual colonoscopy was on February 7, 2007, correct?

A. Yes.

Q. So we're taking approximately, what, two weeks?

A. Yes.

Q. Can someone get dehydrated within a two-week period?

A. If you're asking me if the patient had a change in her symptoms, which she had for three weeks prior to seeing me and her blood work did not show dehydration, the patient at the time of the procedure did not notify me of any changes of those symptoms, the answer is that the baseline on 1/22 would suffice.

* * *

Q. So diagnostically we don't know if she was dehydrated or not back in February 7, 2007?

A. A blood test was performed on the 22nd of 2007 after the patient had been having several weeks of diarrhea documenting whether the patient would have been having any dehydration from her symptoms which had not changed and the patient did not let me know that at the time of her colonoscopy.

which the FPS prep was contraindicated. Our finding is bolstered by the uncontroverted expert medical testimony from three gastroenterologists, establishing that no reason existed for Dr. Tanenbaum to suspect that Mrs. Deroche was dehydrated prior to the prep and that she was an appropriate candidate for the FPS prep.

Next, the plaintiffs claim that Dr. Tanenbaum breached the applicable standard of care by failing to inform Mrs. Deroche of the potential risk of nephrotoxicity and/or acute renal failure associated with taking the FPS prep. The plaintiffs present no expert medical testimony to establish this aspect of their claim. The record contains a consent form executed by Mrs. Deroche disclosing the risks associated with a colonoscopy, which included the loss of function of an organ. It is undisputed that Mrs. Deroche experienced acute renal failure, or loss of kidney function, following her colonoscopy.²¹ In Louisiana, a physician is not charged with the duty of informing a patient of any and all known risks however slight or immaterial, but rather, a physician has the duty to disclose all material risks of the proposed treatment. *See Hondroulis v. Schumacher*, 553 So.2d 398, 418-19 (La. 1988). 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 what risks exists and the likelihood of occurrence. *Id.* at 412. In the instant case,

²¹ In Louisiana, an executed consent form presents a presumption of informed consent, which may be rebutted by proving the following: (1) a material risk exists which the physician has a duty to disclose; (2) the physician failed to inform the patient about a material risk; (3) the material risk was realized; and, (4) a causal connection exists between the failure to inform the patient of the risk and realization of the risk. *See Hondroulis v. Schumacher*, 553 So.2d 398,

while it is not disputed that nephrotoxicity and/or acute renal failure were potential risks associated with the FPS prep and that in 2007 Dr. Tanenbaum was aware of these potential risks, the Deroches offer no expert testimony to prove these risks were “material.” Their failure to do so is fatal to their claim. Moreover, the FPS prep package insert provided by the plaintiffs identify the risk of renal failure as a “rare” risk affecting persons falling into the at-risk population (*i.e.*, patients with previous kidney problems, heart conditions, or taking medications affecting kidney function such as drugs for hypertension or diuretics, et cetera). Additionally, Dr. Tanenbaum testified that, in his medical opinion based upon the blood work obtained by her referring physician and his examination of Mrs. Deroche, she did not present with a medical history or have symptoms placing her into the at-risk category. The medical review panel agreed.

The second prong of the materiality test requires proof that a reasonable person in the patient’s position would have attached significance to the risk in deciding whether or not to forgo the proposed treatment. *Id.* at 412. While this determination of materiality does not require expert testimony, our review of the summary judgment evidence indicates that the plaintiffs cannot carry their burden. The record establishes that Mrs. Deroche used the same FPS prep without incident prior to her colonoscopy in 2004. Consequently, absent evidence to the contrary, it reasonably follows that even had Dr. Tanenbaum informed her of the potential for the rare risk of renal failure to occur she, or a reasonable person in her position, would not have withheld consent to use of the FPS prep. Accordingly, we reject the plaintiffs’ argument that Dr. Tanenbaum breached the applicable standard of

405 (La. 1988); *In re Medical Review Panel of Morris*, p. 5 (La. App. 4 Cir. 12/5/01), 802 So.2d 999, 1002.

care by failing to inform Mrs. Deroche of the rare risk of renal failure associated with use of FPS prep.

The Deroches next argue that Dr. Tanenbaum breached the standard of care by providing Mrs. Deroche outdated instructions that were contrary to Fleet's directives and warnings regarding the taking of FPS prep. Offering no expert medical testimony, the plaintiffs refer to the PDR's instructions and warnings for FPS prep to support their position.²² We note that a similar argument, *i.e.*, that Dr. Tanenbaum improperly prescribed FPS prep to Mrs. Deroche, was previously reviewed by the medical review panel. Specifically, the expert medical opinion of the panel was that Dr. Tanenbaum's instructions complied with the applicable standard of care: "[T]he prescribed prep was within the variations that were considered appropriate at the time of this procedure."

The medical review panel rejected the plaintiffs' contention and, absent expert medical testimony to the contrary, so do we. We specifically hold that a manufacturer's labeling and package insert standing alone is insufficient to establish the prevailing medical standard of care required by La. R.S. 9:2794. Similarly, we find that a physician's medical decision to deviate from a manufacturer's labeling also does not *ipso facto* establish a breach of the applicable standard of care.

The plaintiffs aver that the affidavit of Dr. Kim, a gastroenterologist, further supports a finding that, by providing Mrs. Deroche with outdated instructions for taking FPS prep, Dr. Tanenbaum breached the applicable standard of care and placed her at an unnecessary risk for her resulting renal failure. We disagree. Our

review of Dr. Kim's affidavit (which itself contains no opinions, but rather, authenticates an attached expert report she authored) reveals that it is silent regarding the prevailing medical standard of care for gastroenterologists and in no way supports a contention that Dr. Tanenbaum breached the applicable standard of care. Accordingly, because Dr. Kim's affidavit does not establish the applicable standard of care at issue in this case and contains no evidence of a breach of thereof, we find it fails to defeat Dr. Tanenbaum's motion for summary judgment.

The absence of expert medical testimony in this case to support the plaintiffs' various theories of liability against Dr. Tanenbaum is the death knell of the Deroches' claims against him. Reviewing the record *de novo*, we find the evidence adduced by the plaintiffs is insufficient to prove the applicable standard of care, its breach, or causation. Summary judgment dismissing their claims was proper.

III.

For the reasons assigned, we affirm the judgment of the trial court.

AFFIRMED.

²² The instructions Dr. Tanenbaum provided to Mrs. Deroche directed her to take the second dose of the FPS prep three hours after ingesting the first dose. Fleet's instructions recommend 10 to 12 hours between doses.