STATE OF LOUISIANA

COURT OF APPEAL

FIRST CIRCUIT

NUMBER 2013 CA 2009

LOY M. McCORKLE, TWEETY M. DUFRENE AND MATTHEW E. McCORKLE

VERSUS

WAYNE D. GRAVOIS, M.D.

Judgment Rendered: JUN 06 2014

Appealed from the
Nineteenth Judicial District Court
In and for the Parish of East Baton Rouge, Louisiana
Docket Number C609248

Honorable Kay Bates, Judge Presiding

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BEFORE: WHIPPLE, C.J., WELCH AND CRAIN, JJ.

WHIPPLE, C.J.

Plaintiffs appeal the trial court's judgment, granting the defendant physician's motion for summary judgment and dismissing with prejudice their wrongful death and survival action based on alleged medical malpractice. For the following reasons, we affirm.

FACTS AND PROCEDURAL HISTORY

On January 13, 2010, Harvey McCorkle visited Dr. Wayne Gravois, a family medicine physician, with complaints of insomnia and work-related stress. In addition to providing McCorkle with educational materials about management of stress and insomnia, Dr. Gravois also gave McCorkle eight to ten samples of the medication Lunesta to aid with sleep, instructing him to take one pill at bedtime. Dr. Gravois told McCorkle to call or return to the clinic if he had any problems with the medication.

McCorkle began taking the Lunesta on January 13 and continued to take it for the next three nights. At around 3:00 a.m. in the early morning hours of January 17, 2010, McCorkle's wife found him lying in their driveway with a gunshot wound to the head. McCorkle later died from his self-inflicted injuries.

A medical review panel was convened, and ultimately the panel rendered its decision, finding that Dr. Gravois's actions in prescribing Lunesta were appropriate and that the evidence did not support a finding that Dr. Gravois had failed to meet the applicable standard of care in his treatment of McCorkle. Mrs. McCorkle and McCorkle's children, Tweety Dufrene and Matthew McCorkle, then filed the instant suit in district court against Dr. Gravois on February 14, 2012.

Plaintiffs contended that, while under the influence of, and as a direct cause of taking Lunesta, McCorkle either hallucinated or fell into the depths

of depression and unintentionally took his own life. Plaintiffs further alleged that Dr. Gravois failed to exercise the degree of knowledge and skill or degree of care ordinarily exercised by health care professionals in his field by prescribing Lunesta to McCorkle in light of McCorkle's history of depression and contemporaneous signs of depression, including anxiety and disturbed sleep.

Additionally, plaintiffs alleged that the manufacturer of Lunesta provided to physicians instructions approved by the Food and Drug Administration (the FDA), stating that certain instructions must be given to patients in order for the drug to be used safely. According to plaintiffs, Dr. Gravois failed to inform himself of critical manufacturer directions for the safe administration of Lunesta. Plaintiffs further contended that Dr. Gravois failed to inform McCorkle of certain instructions provided by the manufacturer and that, as a direct result of this failure, McCorkle continued to take Lunesta, which ultimately caused him to take his own life.

On April 10, 2013, Dr. Gravois filed a motion for summary judgment, contending that there were no genuine issues of material fact and that he was entitled to judgment as a matter of law dismissing plaintiffs' claims against him. (R. 31). Specifically, Dr. Gravois contended that in addition to the medical review panel unanimously concluding that the evidence did not support the conclusion that he had failed to meet the applicable standard of care in his treatment of McCorkle, plaintiffs' own expert, Dr. Matthew Abraham, testified that Dr. Gravois did not breach the applicable standard of care. Thus, Dr. Gravois contended that plaintiffs had no expert to opine that he had breached the applicable standard of care and, accordingly, could not establish the essential elements of their claims against him.

In a reply memorandum in support of his motion, Dr. Gravois also contended that plaintiffs could not meet their burden of establishing the other elements of their claim. Specifically, he averred that plaintiffs could not establish the applicable standard of care by relying solely on the Physicians' Desk Reference (PDR) and, further, that they could not meet their burden of establishing that any alleged breach by him caused McCorkle's death.

In opposition to the motion for summary judgment, plaintiffs contended that the package inserts that are included with prescription medication by the manufacturer can establish the standard of care, asserting that jurisprudence within this state provides that package inserts can establish a *prima facie* case of negligence. Moreover, they contended: (1) that the Lunesta package insert and related PDR reference, which they submitted among other things in opposition to the motion for summary judgment, instruct the prescribing physician to provide certain information to his patients, including an instruction that the patient should "read the accompanying Medication Guide with each new prescription and refill"; and (2) that Dr. Gravois's actions in failing to provide the instructions listed in the Lunesta package insert, and instead providing a generalized instruction that McCorkle should call him if he had any problems, violated the standard of care as established by the Lunesta package insert and resulted in McCorkle's death.[1]

[1]Notably, in opposing the motion, plaintiffs did not specifically assert that Dr. Gravois breached the standard of care in **prescribing** Lunesta to McCorkle, stating in this regard only that Dr. Gravois prescribed Lunesta despite the fact that McCorkle had symptoms suggesting that he might be depressed, but averring in the same sentence that hallucinations, and not depression, caused his death. Rather, plaintiffs focused their argument on the contention that Dr. Gravois breached the standard of care in **failing to provide** McCorkle with the **instructions** listed in the Lunesta package. Indeed, no expert opined that Dr. Gravois's action in prescribing Lunesta was a breach of the applicable standard of care.

After a hearing on the motion, the trial court concluded that plaintiffs had failed to establish that they could meet their burden of proof at trial, stating that "plaintiffs do not have an expert witness who will testify that Dr. Gravois breached the standard of care, assuming that they can establish the applicable standard of care." Accordingly, by judgment dated August 15, 2013, the trial court granted Dr. Gravois's motion for summary judgment and dismissed plaintiffs' claims against him with prejudice. From this judgment, plaintiffs appeal, contending that the trial court erred in: (1) granting Dr. Gravois's motion for summary judgment for no other reason than plaintiffs had no expert to establish the standard of care; and (2) ruling on an issue that was not before the court, i.e., whether plaintiffs needed an expert to establish that Lunesta caused McCorkle to take his life, where three experts concluded that it had.

BURDEN OF PROOF AND STANDARD OF REVIEW FOR SUMMARY JUDGMENT

A motion for summary judgment is properly granted if the pleadings, depositions, answers to interrogatories, and admissions, together with affidavits, if any, admitted for purposes of the motion, show that there is no genuine issue as to material fact and that the mover is entitled to judgment as a matter of law. LSA-C.C.P. art. 966(B). The summary judgment procedure is expressly favored in the law and is designed to secure the just, speedy, and inexpensive determination of non-domestic civil actions. LSA-C.C.P. art. 966(A)(2).

The mover bears the burden of proving that he is entitled to summary judgment. LSA-C.C.P. art. 966(C)(2). However, if the mover will not bear the burden of proof at trial on the subject matter of the motion, he need only demonstrate the absence of factual support for one or more essential

elements of his opponent's claim, action, or defense. LSA-C.C.P. art. 966(C)(2). If the moving party points out that there is an absence of factual support for one or more elements essential to the adverse party's claim, action, or defense, then the nonmoving party must produce factual support sufficient to satisfy his evidentiary burden at trial. LSA-C.C.P. art. 966(C)(2). If the mover has put forth supporting proof through affidavits or otherwise, the adverse party may not rest on the mere allegations or denials of his pleadings, but his response, by affidavits or otherwise, must set forth specific facts showing that there is a genuine issue for trial. LSA-C.C.P. art. 967(B).

In 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 there is a genuine issue of triable fact. Hines v. Garrett, 2004-0806 (La. 6/25/04), 876 So. 2d 764, 765. Despite the legislative mandate that summary judgments are now favored, 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, 2000-2507 (La. 12/8/00), 775 So. 2d 1049, 1050.

In determining whether summary judgment is appropriate, appellate courts review evidence *de novo* under the same criteria that govern the trial court's determination of whether summary judgment is appropriate. East Tangipahoa Development Company, LLC v. Bedico Junction, LLC, 2008-1262 (La. App. 1st Cir. 12/23/08), 5 So. 3d 238, 243-244, writ denied, 2009-0166 (La. 3/27/09), 5 So. 3d 146.

ANALYSIS

In their first assignment of error, plaintiffs contend that the trial court erred in concluding that they were required to present the testimony of a medical expert to establish the standard of care, in light of the instructions provided by the manufacturer of Lunesta in the package insert and in the PDR.[2] Plaintiffs assert that the standard of care need not be established in every case by testimony of a medical expert and that when it comes to the administration of medicines, the pharmaceutical manufacturer's instructions to the physician can serve that purpose. Thus, plaintiffs assert that the Lunesta package insert establishes the standard of care with regard to the information that a prescribing physician should communicate to his patient.

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[2]At the outset, we note that while plaintiffs contend on appeal that the trial court erred in finding that they could not establish the applicable standard of care herein because they had no expert witness to establish the standard of care, the trial court did not actually make such a finding. Rather, the trial court found that the **breach** of the standard of care by the defendant doctor must be established through expert testimony, stating in oral reasons for judgment that "the plaintiffs do not have an expert witness who will testify that Dr. Gravois **breached the standard of care, assuming that they can establish the standard of care**." (Emphasis added).

Nonetheless, we note that the factual finding regarding breach of standard of care is so intertwined with the applicable standard of care that we cannot consider the issue of whether the trial court correctly determined that plaintiffs could not carry their burden of establishing a breach of the standard of care without first considering plaintiffs' argument that they met their burden of establishing the standard of care.

Indeed, none of the physicians whose testimony was presented in the proceedings below stated that the package insert and related PDR reference established the standard of care for a prescribing physician. If, in fact, the standard of care can be established by the instructions listed in package inserts, then the experts' failure to accept that as the standard could raise questions about their opinions that the standard was not breached herein or at the very least create an issue of fact as to whether the standard of care was breached. See generally Fournet v. Roule-Graham, 00-1653 (La. App. 5th Cir. 3/14/01), 783 So. 2d 439, 445, writ denied, 2001-0985 (La. 6/15/01), 793 So. 2d 1242 (wherein the appellate court noted that the expert opinion directly contradicted the warnings in the PDR and concluded that nothing in the record established that the PDR was wrong and should not be relied upon); see also Terrebonne v. Floyd, 99-0766 (La. App. 1st Cir. 5/23/00), 767 So. 2d 758, 763, writ not considered, 2000-1931 (La. 9/29/00), 769 So. 2d 549 (wherein this court determined that whether the plaintiffs could use the manufacturer's specific warning with regard to administration of a drug and the defendant physician's admitted failure to adhere to that warning as *prima facie* proof of negligence was "a matter seriously unresolved" and rendered the granting of summary judgment inappropriate).

Moreover, given our role on appeal of reviewing summary judgments *de novo*, we will address the issue of whether plaintiffs failed to demonstrate that they can satisfy their burden of proving the applicable standard of care as to Dr. Gravois in prescribing Lunesta by reliance on the Lunesta package insert and related PDR reference.

A plaintiff in a medical malpractice case has the burden of proving the applicable standard of care, its breach, and a causal connection between the physician's alleged negligence and the patient's injuries. Pfiffner v. Correa, 94-924, 94-963, 94-992 (La. 10/17/94), 643 So. 2d 1228, 1233. The Louisiana Supreme Court has held that expert medical testimony is generally required to establish the applicable standard of care and whether the standard was breached, except where the negligence is so obvious that a lay person can perceive negligence without guidance of expert testimony. Pfiffner, 643 So. 2d at 1234. Examples of situations where expert medical testimony would not be required include: (1) the physician performs an obviously careless act, such as fracturing a leg during an examination, amputating the wrong arm, dropping a knife, scalpel or acid on a patient, or leaving a sponge in a patient's body, from which a lay person can infer negligence; (2) the defendant/physician testifies as to the standard of care and his breach thereof; or (3) the alleged negligence consists of violating a statute and/or the hospital's bylaws. Pfiffner, 643 So. 2d at 1233-1234. The Court further explained:

> Though in most cases, because of the complex medical and factual issues involved, a plaintiff will likely fail to sustain his burden of proving his claim under LSA-R.S. 9:2794's requirements without medical experts, there are instances in which the medical and factual issues are such that a lay jury can perceive negligence in the charged physician's conduct as well as any expert can, or in which the defendant/physician testifies as to the standard of care and there is objective evidence, including the testimony of the defendant/physician, which demonstrates a breach thereof.

Pfiffner, 643 So. 2d at 1234.

In the instant case, the uncontested testimony establishes that when Dr. Gravois gave McCorkle samples of Lunesta, he did not give McCorkle a

copy of the Lunesta package insert.[3] Nonetheless, Dr. Gravois instructed McCorkle to call the clinic if he had any problems at all with the medication.[4] After the first night he took the Lunesta sample, McCorkle related to his wife that he had experienced a vivid dream about his deceased mother, a dream which he talked about until his death. Additionally, after the second night of taking Lunesta, McCorkle had difficulty concentrating at work, which was very disturbing to him, and he made a mistake of some significance in a calculation that day. However, McCorkle did not communicate these occurrences to Dr. Gravois. After taking Lunesta on the fourth night, McCorkle fatally shot himself.

In support of his motion for summary judgment, Dr. Gravois submitted the opinion of the medical review panel, which concluded that the evidence did not support the conclusion that Dr. Gravois had failed to meet the applicable standard of care, as alleged.[5] Moreover, he offered the deposition testimony of Dr. Matthew Abraham, a board-certified physician in the field of sleep medicine, who was initially retained by plaintiffs to provide an expert opinion herein. While in an earlier affidavit Dr. Abraham had attested that a patient to whom Lunesta is prescribed should be instructed by the physician or his staff that "should he experience any unusual or disturbing thoughts or behavior, which can be early warnings of

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[3]Dr. Gravois explained that only one package insert is included in a box of samples provided to a physician.

[4]While Dr. Gravois specifically testified that he told McCorkle to call the clinic with any problems at all with the medication and with any problems whatsoever, defense counsel later asked him, "[a]nd part of your instruction about if [the patient] ha[s] any problems with medications is to **stop taking the medications** and come see me or call me," to which Dr. Gravois responded "yes." (Emphasis added). However, Dr. Gravois had not previously testified that he included within his instructions the statement that the patient should stop taking the medication if he had any problems.

[5]While the panel concluded that the evidence did not support a finding that Dr. Gravois had breached the standard of care herein and that it was appropriate for Dr. Gravois to prescribe Lunesta to McCorkle, sadly, all three expert physicians also believed that it was likely that Lunesta did in fact cause McCorkle to take his own life.

potential parasomnias, he should stop the medicine and call the physician," in his deposition, he testified he did not realize he had specifically written that in his affidavit. Moreover, he acknowledged that he does not give such a detailed instruction, but instead, usually recommends that the patient be instructed to "contact the office if there is any problem associated with the medication."

Additionally, when asked to compare the instructions recommended in the Lunesta package insert to the instructions he actually gives to patients to whom he prescribes Lunesta, Dr. Abraham stated that he gives his patients "way less instruction" than what the package insert provides, candidly admitting that his instructions are "severely less ... to where it's not even a comparison." He also testified that he never discusses suicide with a patient to whom he prescribes Lunesta.

With regard to the standard of care for a family practitioner or sleep medicine practitioner in prescribing this medication, Dr. Abraham testified that the PDR does not establish the standard of care, but, rather, in his opinion, the standard of care would be "to make sure the patient has the understanding to communicate with the physician if there's any changes related to medications." Thus, Dr. Abraham opined that if Dr. Gravois told the patient to call with any problems whatsoever, then he did not breach the standard of care.

While noting that Dr. Abraham had "basically disowned" an earlier affidavit in which he had allegedly concluded that Dr. Gravois had deviated from the standard of care if he failed to give his patient appropriate instructions on the administration of Lunesta, plaintiffs nonetheless contended in opposition to the summary judgment and again on appeal that they can establish the applicable standard of care and Dr. Gravois's breach

thereof through the manufacturer's package insert and the related PDR excerpt for Lunesta. The Lunesta package insert and related PDR excerpt, while listing no "contraindications" to the use of Lunesta, do state in the "warnings" section that, in primarily depressed patients, worsening of depression, including suicidal thoughts and actions, has been reported in association with the use of sedative/hypnotics. Moreover, the "precautions" section of the product information and related PDR excerpt contain, in part, the following statement:

> **Patients should be instructed to read the accompanying Medication Guide with each new prescription and refill. The complete text of the Medication Guide is reprinted at the end of this document.** Patients should be given the following information:
> 1. Patients should be instructed to take LUNESTA immediately prior to going to bed, and only if they can dedicate 8 hours to sleep.
> 2. Patients should be instructed not to take LUNESTA with alcohol or with other sedating medications.
> 3. Patients should be advised to consult with their physician if they have a history of depression, mental illness, or suicidal thoughts, have a history of drug or alcohol abuse, or have liver disease.
> 4. Women should be advised to contact their physician if they become pregnant, plan to become pregnant, or if they are nursing.

(Emphasis added). The Medication Guide, which the package insert and PDR excerpt recommend the patient should be instructed to read, lists the following "possible serious side effects" of Lunesta, among others: "getting out of bed while not fully awake and do[ing] an activity that you do not know you are doing" and "abnormal thoughts and behavior," including more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.

Thus, plaintiffs contend that the applicable standard of care herein required Dr. Gravois, as directed by the Lunesta package insert, to instruct McCorkle to read the Medication Guide for Lunesta, which listed the above-

mentioned possible side effects of Lunesta and that Dr. Gravois's failure to do so constituted a breach of the applicable standard of care and resulted in McCorkle's death.

The FDA, pursuant to congressional directives, has developed a regulatory procedure to inform the medical profession about prescription drugs and, as such, requires that package inserts accompany shipments of prescription drugs by pharmaceutical manufacturers. 21 U.S.C. § 301 et seq.; 21 C.F.R. § 201.1 et seq; David Carl Minneman, Annotation, *Medical Malpractice: Drug Manufacturer's Package Insert Recommendations as Evidence of Standard of Care*, 82 A.L.R. 4th 166, § 1[a] (1990). These package inserts form the basis of the FDA's notification system concerning composition, dosage, indications, contraindications, potential side effects, and adverse reactions of drugs. The PDR is an annual publication that compiles product information about pharmaceuticals. The information contained in the PDR, which is provided by drug manufacturers, is substantially similar, if not identical, to the material contained in the drug package inserts. David Carl Minneman, Annotation, *Medical Malpractice: Drug Manufacturer's Package Insert Recommendations as Evidence of Standard of Care*, 82 A.L.R. 4th 166, § 2[a] (1990); see also Cagnolatti v. Hightower, 95-2598 (La. App. 4th Cir. 12/11/96), 692 So. 2d 1104, 1110.

Federal regulations specifically require manufacturers of prescription drugs to include sections in their labeling information entitled Contraindications, Warnings, and Precautions, among other information.[6]

[6]Newer prescription drugs must also include a "Boxed Warning," where applicable, which if required by the FDA, must contain certain contraindications or serious warnings, particularly those that may lead to death or serious injury. 21 C.F.R. §§ 201.56(d) & 201.57(a)(4) & (c)(1).

21 C.F.R. § 201.56(d) & (e). The "Contraindications" section of the product labeling must describe any situations in which the drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit. 21 C.F.R. §§ 201.57(c)(5) and 201.80(d). The "Warnings" section must describe significant adverse reactions and potential safety hazards, and the "precautions" must include, among other information, any special care to be exercised by the practitioner for safe and effective use of the drug.[7] 21 C.F.R. §§ 201.57(c)(6) & 201.80(e) & (f).

Package inserts and the PDR have been used in medical malpractice cases *in conjunction with expert medical testimony* to establish the applicable standard of care and breach thereof. See e.g. Jones v. Bick, 2004-0758 (La. App. 4th Cir. 12/15/04), 891 So. 2d 737, 744-746, writ denied, 2005-0142 (La. 3/24/05), 896 So. 2d 1043, Bailey v. State, Department of Health and Human Resources, 96-2797 (La. App. 4th Cir. 5/21/97), 695 So. 2d 557, 560-561, and Cagnolatti, 692 So. 2d at 1110-1111. However, the determination of whether the package insert or PDR, either alone or where contradicted by expert medical testimony, may be used to establish the applicable standard of care and breach thereof is more complex and more problematic.

In support of their argument that they should be allowed to prove the applicable standard of care herein through the Lunesta package insert and related PDR reference, plaintiffs rely on the cases of Terrebonne v. Floyd,

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[7]For newer drugs (which include prescription drug products for which a new drug application was approved by the FDA between June 30, 2001, and June 30, 2006; those with pending applications on June 20, 2006; and those for which an application is submitted on or after June 20, 2006, 21 C.F.R. § 201.56(b)(1)), the "Warnings" and "Precautions" are combined into one section, whereas they are separate sections in the labeling of older drugs. 21 C.F.R. §§ 201.57(c)(6) and 201.80(e) & (f). Moreover, while for older drugs, the "Precautions" section must also include information for patients necessary for them to use the drug safely and effectively, 21 C.F.R. § 201.80(f)(2), the same information is required for newer drugs under the "Patient counseling information" section. 21 C.F.R. §201.57(c)(18).

99-0766 (La. App. 1st Cir. 5/23/00), 767 So. 2d 758, writ not considered, 2000-1931 (La. 9/29/00), 769 So. 2d 549; Fournet v. Roule-Graham, 00-1653 (La. App. 5th Cir. 3/14/01), 783 So. 2d 439, writ denied, 2001-0985 (La. 6/15/01), 793 So. 2d 1242; and Christiana v. Sudderth, 02-1080 (La. App. 5th Cir. 2/25/03), 841 So. 2d 911.

In Terrebonne, this court noted that the case therein may have presented the first instance in Louisiana where a plaintiff sought to rely *solely* on an admitted deviation from a manufacturer's **specific warning** to establish the standard of care. Terrebonne, 767 So. 2d at 763. In opposition to the defendant/physician's motion for summary judgment, the plaintiff in Terrebonne relied upon the **warnings section** in the package insert that the drug was to be administered ***only*** at certain times within a woman's menstrual cycle to establish the applicable standard of care and further argued that the physician's admitted use of the drug contrary to the manufacturer's instructions constituted *prima facie* evidence of negligence. Terrebonne, 767 So. 2d at 760.

In addressing the issue, this court first noted the Louisiana Supreme Court's holding in Pfiffner that expert testimony is not necessary to establish the applicable standard of care and breach thereof in instances in which the medical and factual issues are such that a lay jury can perceive negligence in the complained-of conduct as well as any expert can. Terrebonne, 767 So. 2d at 762, quoting Pfiffner, 643 So. 2d at 1233-1234. Additionally, this court considered and cited with favor the Minnesota Supreme Court's opinion in Mulder v. Parke Davis & Company, 288 Minn. 332, 181 N.W.2d 882 (1970).

In Mulder, the defendant/physician prescribed a lower-than-recommended dosage of a medication, thus allegedly prolonging the need

for continued use of the medication by the decedent patient. In addition to recommending the dosage to be prescribed, the manufacturer's package insert and the PDR reference contained a "**Warning** section," which **warned** that serious and even fatal disorders could occur after use of the drug and, thus, gave the precaution that adequate blood studies during treatment with the drug were "essential." Mulder, 288 Minn. at 334, 181 N.W.2d at 884-885. In reversing a directed verdict in favor of the prescribing physician, the Court held that "[w]here the dosage is prescribed by the manufacturer, testimony of the physician's failure to adhere to its recommendation is sufficient evidence to require him to explain the reason for his deviation," which the Court said was "particularly true where the manufacturer's warning puts the doctor on notice of potentially lethal effects." Mulder, 288 Minn. at 339, 181 N.W.2d at 887.

Moreover, on rehearing, the Court expanded its decision to hold as follows:

> Where a drug manufacturer recommends to the medical profession (1) the conditions under which its drug should be prescribed; (2) the disorders it is designed to relieve; (3) the precautionary measures which should be observed; and (4) warns of the dangers which are inherent in its use, a doctor's deviation from such recommendations is ***prima facie*** **evidence** of negligence if there is competent medical testimony that his patient's injury or death resulted from the doctor's failure to adhere to the recommendations. [8]

Mulder, 288 Minn. at 339-340, 181 N.W.2d at 887 (*per curiam* on rehearing) (emphasis added).

This court in Terrebonne also noted that the Mississippi Supreme Court in Thompson v. Carter, 518 So. 2d 609, 613 (Miss. 1987), held that

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[8]Notably, in Mulder, the plaintiff had also presented physicians' testimony and was not relying solely on the package insert. Mulder, 288 Minn. at 336-337, 181 N.W. 2d at 886-887.

information contained in package inserts and the PDR constituted *prima facie* proof of the proper use of a drug.[9] Terrebonne, 767 So. 2d at 763.

This court then stated that the Louisiana Supreme Court's pronouncements in Pfiffner as well as the above-referenced jurisprudence from other jurisdictions "soundly points [sic] in favor of considering such evidence sufficient to make a *prima facie* showing of negligence." However, without expressly holding that a **specific warning** in a manufacturer's package insert alone could establish the applicable standard of care or that a physician's admitted deviation from that specific warning was sufficient to establish *prima facie* evidence of negligence, this court then concluded that "whether plaintiffs may use the evidence they intend to offer as *prima facie* proof of [the physician's] negligence is itself a matter seriously unresolved; and the granting of summary judgment under the circumstances was inappropriate." Terrebonne, 767 So. 2d at 763.

In Fournet, which involved a physician's alleged negligence in prescribing a drug when it was contraindicated and her failure to inform the patient of the risk associated with prescribed medication, the plaintiff was prescribed a medication even though the PDR listed a **contraindication** for prescribing it to a patient with a history of a disorder that the plaintiff had.[10] Fournet, 783 So. 2d at 441. Despite the contraindication contained in the PDR, the defendant/physician testified that it was "standard practice" for physicians in her field to prescribe the drug even to patients with a known

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[9]In Thompson, the Mississippi Supreme Court held that the package insert was "some evidence of the standard of care, but it is not conclusive evidence." However, the Court then stated that the physician could rebut this "implication" and explain his deviation from the manufacturer's recommended use on dosage, noting that the holding would shift the burden of persuasion to the physician to provide a sound reason for his deviation. Thompson, 518 So. 2d at 613.

[10]The court noted that a "contraindication" means "it is inadvisable to prescribe a particular drug when a patient suffers from one or more enumerated conditions." Fournet, 783 So. 2d at 441.

history of this disorder. The defendant/physician appealed the trial court's judgment in favor of the plaintiff, contending that the trial court erred in basing its decision solely on the contraindications contained in the PDR. Fournet, 783 So. 2d at 442. In affirming the trial court, the Fifth Circuit Court of Appeal stated that it "cannot ignore the fact that there is a source of information, the PDR, which **definitively states** that [the drug prescribed] should not have been prescribed for a patient with [the plaintiff's condition]."[11] Fournet, 783 So. 2d at 442-443.

Additionally, in rejecting the defendant/physician's argument that the plaintiff had failed to prove lack of informed consent, the court noted that under the Informed Consent Doctrine, where circumstances permit, a patient should be told the nature of the pertinent condition, the general nature of the proposed treatment, the risk involved in the proposed treatment, the risks of failure to undergo any treatment or procedure at all, and the risks of any alternative method of treatment. Fournet, 783 So. 2d at 444. While the defendant/physician testified that the majority of doctors in her specialty "simply do not believe that there is any risk of harm in prescribing" the drug she prescribed to a patient with the plaintiff's condition, the appellate court noted that "[s]uch an opinion directly contradicts the warnings in the PDR" and concluded that "there is nothing in the record that convinces us the PDR is wrong and should not be relied on as an authoritative medical source." Fournet, 783 So. 2d at 445.

Finally, in Christiana, the Fifth Circuit Court of Appeal reversed a

[11]However, the court therein noted that unlike the plaintiff in Terrebonne, the plaintiff in Fournet was **not attempting to rely solely on the contraindication contained in the PDR** to establish the standard of care. Nevertheless, the court stated that Terrebonne was instructive because it demonstrated that other courts have considered the PDR as an authoritative medical source in a medical malpractice case. Fournet, 783 So. 2d at 443.

summary judgment in favor of the defendant/hospital, noting that the affidavits of three physicians as to the proper use of a medical stapler did not address the manufacturer's instructions under "**Contraindications**" as to the size of staple to use. Christiana, 841 So. 2d at 915-916. In reversing, the court relied upon Fournet and Terrebonne and held that "[a] health-care provider's deviation from a manufacturer's warning may be negligence for which expert testimony is not required to establish the applicable standard of care, because such evidence may be sufficient to make a *prima facie* showing of negligence."[12] Christiana, 841 So. 2d at 916.

A review of Terrebonne, Fournet, and Christiana reveals that the package inserts and related PDR references relied upon in those cases contained **specific contraindications or warnings** that in clear and specific language directed the manner or timing in which a drug or device was to be used and warned against uses in certain specified situations, language from which a lay jury could readily perceive a standard of care. Moreover, those cases involved physicians administering, using or prescribing the medication or device in direct contradiction to the manufacturer's contraindications or warnings, actions from which a *prima facie* case of negligence could be inferred, see Terrebonne, 767 So. 2d at 763, and Christiana, 841 So. 2d at

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[12]See also LW v. Delta Clinic of Baton Rouge, Inc., 2006-0134, p. 6 n.5 (La. App. 1st Cir. 2/23/07), 2007 WL 866478 at 3 n.5 (unpublished), wherein this court, citing Terrebonne and Fournet, stated that "[c]ourts have approved the use of the PDR and the manufacturer's labeling and instructions for a prescription drug to establish the standard of care owed by a physician and a *prima facie* showing of negligence." The alleged malpractice in LW involved the intravenous injection of a drug at an allegedly higher concentration than specified in the PDR. However, the facts in LW are distinguishable from the facts herein in that the defendant/physician acknowledged that the PDR is commonly accepted and recognized in the field of prescription drugs and, additionally, referred to the PDR in his testimony to establish the standard of care. However, while the defendant/physician contended that he had complied with the PDR by injecting a higher concentration of the drug over a longer interval of time, the plaintiff claimed he had injected the drug in a "matter of seconds." Thus, this court reversed a summary judgment in favor of the defendant/physician, finding that "conflicting evidence raise[d] questions of fact and credibility concerning the issue of whether [the defendant/physician] complied with the relevant portions of the PDR." LW, 2006-0134 at pp. 6-8, 2007 WL 866478 at 3-4.

916, and, ultimately, from which a factfinder could perceive a deviation from the standard of care as well as any expert. See generally Fournet, 783 So. 2d at 443-445.

On the other hand, in Deroche v. Tanenbaum, 2013-0979 (La. App. 4th Cir. 12/18/13), 131 So. 3d 400, 411, in affirming the granting of the defendant/physician's motion for summary judgment and resulting dismissal of the plaintiffs' claim against him, the Fourth Circuit Court of Appeal specifically held 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" and 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." In Deroche, the plaintiffs contended that the physician had breached the applicable standard of care in providing the patient with instructions on taking a Fleet Phospho-Soda preparation that were contrary to the manufacturer's instructions as set forth in the PDR. Deroche, 131 So. 3d at 402-403. The plaintiffs offered no expert medical testimony to support this contention, instead referring to the PDR's instructions and warnings. Finding that this evidence was insufficient to establish the standard of care and a breach thereof, the court affirmed the granting of summary judgment and dismissal of the plaintiffs' case against the physician given the absence of expert medical testimony to support this theory of liability, among others. Deroche, 131 So. 3d at 411-412.

Moreover, in Robin v. Hebert, 2012-1417, p. 8 (La. App. 3rd Cir. 5/1/13), ___ So. 3d ___, ___, 2013 WL 1809821, the Third Circuit Court of Appeal concluded that the plaintiffs' reliance on the Xanax product labeling alone, without expert testimony, was insufficient to establish the applicable

standard of care where the case presented complex medical issues including a cardiologist's standard of care for medical decision-making, determining the appropriate medication to prescribe, and clinical evidence as to the patient's actual cause of death, which were not the types of issues where a lay jury could infer negligence. Accordingly, because the plaintiff had not opposed the motion for summary judgment with expert testimony as to these issues, the court affirmed the dismissal of the plaintiffs' claims against the cardiologist on summary judgment.[13] Robin, 2012-1417 at p. 8, __ So. 3d at __.

In the instant case, the "warnings" section of the Lunesta package insert and related PDR reference contained only a general warning that in primarily depressed patients, worsening of depression, including suicidal thoughts and actions, had been reported in association with "the use of sedative/hypnotics" and the "precautions" section **recommended** that patients "**should**" be instructed to read the accompanying Medication Guide "with each new prescription and refill." It did not list any **contraindications** to this medication being prescribed to a patient such as McCorkle, nor did it provide any **specific warning** that in clear and explicit language directed a manner in which the drug should be administered that differed from those actions taken by Dr. Gravois. Thus, we conclude that in the absence of a specific contraindication or warning in the package insert and PDR, the

[13]Similarly, in Ekendahl v. Louisiana Medical Mutual Insurance Company, 48,374 (La. App. 2nd Cir. 8/28/13), 124 So. 3d 461, 468-469, the Second Circuit Court of Appeal concluded that a manufacturer's warning is evidence, but not conclusive evidence, of a standard of care. The court concluded that the trial court was not manifestly erroneous in accepting the testimony of medical experts, which conflicted with the manufacturer's recommendations as to the administering of a medical test and that the plaintiff's argument that the standard of care should be set by the manufacturer "is contrary to well-settled law" that generally requires expert testimony to establish the standard of care and breach thereof in the absence of obvious negligence. Ekendahl, 124 So. 3d at 469 & n.21. Notably, however, Ekendahl involved a manifest error review of a trial court's decision, following trial on the merits, to credit the testimony of medical experts instead of relying upon the manufacturer's instructions and recommendations.

plaintiffs could not satisfy their burden of establishing the applicable standard of care, nor establish a *prima facie* case of negligence, by relying upon the package insert and PDR alone, but instead, needed expert testimony.

In so holding, we note the admonition of the New Jersey Supreme Court in Morlino v. Medical Center of Ocean County, 152 N.J. 563, 578, 580, 706 A.2d 721, 728, 729-730 (1998), wherein it cautioned that drug manufacturers do not design package inserts and PDR entries to establish a standard of medical care, as follows:

> **Manufacturers write drug package inserts** and PDR warnings **for many reasons including** compliance with FDA requirements, advertisement, the provision of useful information to physicians, and **an attempt to limit the manufacturer's liability**. After a drug has been on the market for a sufficient period of time, moreover, physicians may rely more on their own experience and the professional publications of others than on a drug manufacturer's advertisements, inserts, or PDR entries.
>
> Those considerations highlight the reasons expert testimony must accompany the introduction of PDR warnings to establish the applicable standard of care in prescribing a drug. Additionally, expert testimony often is needed to explain the information contained in package inserts or the PDR. Drug manufacturers write explanations and warnings for doctors, not the general public. Comprehension of the terms and their significance may depend on medical expertise.
>
> Accordingly, we hold that package inserts and PDR references alone do not establish the standard of care. It follows that a physician's failure to adhere to PDR warnings does not by itself constitute negligence. Reliance on the PDR alone to establish negligence would both obviate expert testimony on an issue where it is needed and could mislead the jury about the appropriate standard of care.
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> * * *
>
> **Allowing the admission of PDR warnings without accompanying expert testimony could transform drug manufacturers into judges of acceptable medical care. The**

> **effect would be to force doctors to follow the PDR's recommendations or run the risk of liability for malpractice.**[14] [Emphasis added, citations omitted.]

Accordingly, we find no error in the trial court's judgment granting Dr. Gravois's motion for summary judgment and dismissing plaintiffs' claims against him. Because of our conclusions with regard to the issues of standard of care and breach thereof, we pretermit consideration of plaintiffs' second assignment of error with regard to causation.

CONCLUSION

For the above and foregoing reasons, the trial court's August 15, 2013 judgment, granting Dr. Gravois's motion for summary judgment and dismissing plaintiffs' claims against him, is affirmed. Costs of this appeal are assessed against plaintiffs, Loy McCorkle, Tweety Dufrene, and Matthew McCorkle.

AFFIRMED.

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[14]The New Jersey Supreme Court held that product package inserts and PDR references alone do not establish the standard of care and that a jury may consider package inserts and parallel PDR references to determine the appropriate standard of care in a medical malpractice case *only when* they are supported by expert testimony. Morlino, 152 N.J. at 578, 580, 706 A.2d at 728, 730.