STATE OF LOUISIANA

COURT OF APPEAL

FIRST CIRCUIT

NO. 2014 CA 1797

JEAN COOPER

VERSUS

CVS CAREMARK CORPORATION, ET AL.

Judgment Rendered: JUN 17 2015

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On Appeal from
The 22nd Judicial District Court,
Parish of Washington, State of Louisiana
Trial Court No. 101426
The Honorable Allison H. Penzato, Judge Presiding

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BEFORE: McDONALD, CRAIN, AND HOLDRIDGE, JJ.

CRAIN, J.

In this proceeding, a party who purchased expired allergy medicine filed suit against the retailer and certain related entities, seeking injunctive relief, damages, and class certification. The trial court granted summary judgment to the defendants dismissing all claims, and the plaintiff appeals. Finding that the plaintiff failed to present sufficient evidence to warrant injunctive relief, damages, or class certification, we affirm.

FACTS

Jean Cooper purchased over-the-counter allergy medicine at a CVS store; however, before consuming any of the medicine, she noticed that the expiration date on the product had passed. Cooper did not request a refund, could not remember if she complained to the store, did not take any of the medicine, and, by her own admission, did not suffer any damages as a result of the purchase.

Cooper filed a petition against several CVS entities, including CVS Caremark Corporation, Louisiana CVS Pharmacy, L.L.C., and CVS Pharmacy (collectively "CVS"), alleging that the defendants had "a long history of selling out-of-date medications, baby formula, and food" and that her purchase of the expired allergy medicine had "exposed her to health risks." Cooper requested injunctive relief to remedy "violations of law" and an order requiring CVS "to comply with the law by ceasing to sell expired products," to notify purchasers of the "true characteristics of the products sold," and to preserve all records evidencing the sale of expired products. Cooper sought certification of her suit as a class action and requested that she be confirmed as the representative of the putative class. In addition to the injunctive relief, Cooper requested an award of damages to her and the class.

The defendants answered, denied a history of selling expired products, and alleged that they make substantial efforts to keep expired products off their shelves. CVS also affirmatively pled that the expiration date was clearly printed on the packaging of the product purchased, that Cooper failed to give them an opportunity to repair the alleged defect through a refund or replacement product, and that Cooper did not sustain any damages.

After the parties conducted discovery, CVS filed a motion for summary judgment asserting that the defendants were entitled to judgment as a matter of law, dismissing the suit in its entirety. CVS maintained that Cooper did not have legal standing to pursue injunctive relief and could not prove irreparable injury, because her claims were based exclusively on past purchases, and she admitted that she did not intend any future purchases of over-the-counter medicines at a CVS store. In support of the summary dismissal of the claim for damages, CVS cited admissions by Cooper in her deposition that she did not have any damages and that she did not tender the expired product for a refund or replacement. CVS also argued that the expiration date was clearly marked on the product package. The exhibits in support of the motion included excerpts from the deposition of Cooper and an affidavit from an executive with CVS Caremark Corporation, who confirmed that all CVS stores provide a refund or replace any product purchased after the expiration, "sell by," or "use by" date stamped on the product.

In opposition to the motion for summary judgment, Cooper asserted that she was not required to prove irreparable injury to obtain injunctive relief, because the sale of expired over-the-counter medication by CVS violated a prohibitory law, 21 U.S.C.A. Section 331, of the Food, Drug, and Cosmetic Act (FDCA). Section 331, in pertinent part, prohibits the introduction or delivery into interstate commerce of an "adulterated" drug. Cooper argued that expired over-the-counter medication is

an adulterated drug and relied on 21 U.S.C.A. Section 351(a)(2)(B), which provides that a drug shall be deemed to be adulterated if

> it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . . .

Although this definition is limited to actions that do not conform to "current good *manufacturing* practice" (emphasis added), Cooper maintained that the provision should nevertheless be interpreted to include the retail sale of expired over-the-counter medication. She cited no jurisprudence or regulations in support of this position, but Cooper did introduce a "Memo" from the Food and Drug Administration, Center for Drug Evaluation and Research, captioned 'HUMAN DRUG CGMP NOTES." The Memo is dated June of 1995 and addresses a number of questions, including whether the sale of expired over-the-counter drugs by a retailer violates the FDCA. In somewhat contradictory fashion, the Memo initially provides that "[w]e regard expired drug products to be adulterated within the meaning of Section 501(a)(2)(B)," (referencing the section of the FDCA appearing at 21 U.S.C.A. Section 351(a)(2)(B)); however, the Memo later instructs:

> It should be noted that it would *not be appropriate to cite a retailer* for deviations from the CGMP [current good manufacturing practice] regulations in 21 CFR Parts 210 and 211, because the CGMP regulations apply to drug product *manufacturers*. [Emphasis added.]

In addition to the Memo, Cooper introduced an affidavit from an individual who "investigated" CVS stores for expired over-the-counter medications and expired infant or baby formula. The affiant visited 63 CVS stores and confirmed that "expired products were purchased and/or documented" at those stores,

although sales associates at six of the stores refused to sell some or all of the expired products that the affiant attempted to purchase.

After hearing arguments and taking the matter under advisement, the trial court issued written reasons for judgment finding that Cooper failed to establish that she will be able to meet her burden of proof at trial to obtain injunctive relief, damages, or class certification. The trial court found that Cooper failed to establish irreparable injury or that the cited provisions from the FDCA established a prohibitory law that supported the claim for injunctive relief. The trial court noted that the Memo was not appropriate summary judgment proof and was unpersuasive. In finding no factual support for the damage claim, the trial court recognized that Cooper testified in her deposition that she was not seeking damages in this case. A judgment was signed thereafter that granted summary judgment to the defendants and dismissed Cooper's claims, with prejudice and at her cost.

On appeal Cooper asserts the trial court erred in finding that she failed to establish (1) a prohibitory law supporting her claim for injunctive relief, when, according to Cooper, the FDCA prohibits the sale of expired, over-the-counter medications; (2) irreparable injury where a "shopping study" conducted on behalf of Cooper demonstrated that the vast majority of CVS stores visited in the study were continuing to offer expired over-the-counter products for sale; and (3) that Cooper lacked standing to request class-wide injunctive relief. Cooper also assigns as error the granting of summary judgment when discovery was purportedly limited to non-merits, class certification issues.

DISCUSSION

A motion for summary judgment shall be granted only if the pleadings, depositions, answers to interrogatories, and admissions, together with the

affidavits, if any, admitted for purposes of the motion for summary judgment, show that there is no genuine issue as to material fact, and that the mover is entitled to judgment as a matter of law. La. Code Civ. Pro. art. 966B(2). The party seeking summary judgment has the burden of proving an absence of a genuine issue of material fact. La. Code Civ. Pro. art. 966C. If the movant satisfies the initial burden, the burden shifts to the party opposing summary judgment to present factual support sufficient to show he will be able to satisfy the evidentiary burden at trial. *See* La. Code Civ. Pro. art. 966C(2); *Suire v. Lafayette City–Parish Consolidated Government,* 04-1459 (La. 4/12/05), 907 So. 2d 37, 56. The summary judgment procedure is favored and is designed to secure the just, speedy, and inexpensive determination of every action. *See* La. Code Civ. Pro. art. 966A(2). 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. *In re Succession of Beard*, 13-1717 (La. App. 1 Cir. 6/6/14), 147 So. 3d 753, 759-60.

According to her petition, the primary relief sought by Cooper is an injunction. An injunction shall be issued in cases where irreparable injury, loss, or damage may otherwise result to the applicant, or in other cases specifically provided by law. La. Code Civ. Pro. art. 3601A; *City of Baton Rouge/Parish of East Baton Rouge v. 200 Government Street, LLC*, 08-0510 (La. App. 1 Cir. 9/23/08), 995 So. 2d 32, 35, *writ denied,* 08-2554 (La. 1/9/09), 998 So. 2d 726. A showing of irreparable injury is not required in cases where the conduct sought to be restrained is unlawful, such as when the conduct constitutes a direct violation of a prohibitory law. *City of Baton Rouge/Parish of East Baton Rouge*, 995 So. 2d at 35-36.

Cooper contends that the retail sale of expired over-the-counter medication is a direct violation of Section 331 of the FDCA. The merit of that claim depends entirely upon whether such medication is an "adulterated" drug within the meaning of Section 351(a)(2)(B). As previously quoted, Section 351(a)(2)(B) deems a drug to be adulterated if "the methods used in . . . its manufacture, processing, packing, or holding do not conform to . . . current good manufacturing practice . . . ." In the final paragraph of the statute, Section 351 further provides:

> For purposes of paragraph (a)(2)(B), the term 'current good manufacturing practice' includes the implementation of oversight and controls over the *manufacture of drugs* to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products. [Emphasis added.]

The language of these statutes does not support the interpretation proposed by Cooper. The starting point for interpretation of any statute is the language of the statute itself. *Rando v. Anco Insulations, Inc.,* 08-1163 (La. 5/22/09), 16 So. 3d 1065, 1075. When a law is clear and unambiguous and its application does not lead to absurd consequences, the law is applied as written, and no further interpretation may be made in search of legislative intent. La. Civ. Code art. 9. A statute must be applied and interpreted in a manner that is logical and consistent with the presumed fair purpose and intent of the legislature in enacting it, and the principal rule is the text of a statute is considered the best evidence of legislative intent or will. *Harrah's Bossier City Investment Company, LLC v. Bridges,* 09-1916 (La. 5/11/10), 41 So. 3d 438, 447. The interpretation of a statute is a question of law that may be decided by summary judgment. *Louisiana Workers' Compensation Corporation v. Landry*, 11-1973 (La. App. 1 Cir. 5/2/12), 92 So. 3d 1018, 1021, *writ denied*, 12-1179 (La. 9/14/12), 99 So. 3d 34.

Cooper cites no particular language in Sections 331 or 351 of the FDCA in support of her argument that statutes governing the "manufacture of drugs" should

be construed to regulate the retail sale of over-the-counter medication. She likewise cites no federal regulations or jurisprudence supporting her proposed interpretation. Cooper relies solely on the 1995 Memo, which is considered a "guidance document" under federal regulations. *See* 21 C.F.R. § 10.115(b). As such, the Memo is not binding on the public or the FDA, and it does not establish legally enforceable rights or responsibilities. *See* 21 C.F.R. § 10.115(d). While the Memo does state that the FDA regards expired drug products to be adulterated, it also states that retailers should not be cited for deviations from current good manufacturing practice regulations, because the regulations only "apply to drug product manufacturers."

The trial court found that the Memo was "not appropriate summary judgment proof . . . nor . . . persuasive authority." We initially note that the document is deemed admitted for purposes of the motion for summary judgment, because it was attached to a memorandum filed in opposition to the motion for summary judgment, and no objection was raised to its admissibility. *See* La. Code Civ. Pro. art. 966F(2) and (3). This court must therefore consider the Memo in determining whether summary judgment is appropriate.

Given the express language of the applicable federal statutes, we are not persuaded by the Memo to extend the scope of the statutes to the retail sale of over-the-counter medication. Through the definition of "adulterated drug," the statutes are limited to actions that do not conform to "current good manufacturing practice." That phrase, in turn, is defined to include the implementation of oversight and controls over the "manufacture of drugs." *See* 21 U.S.C.A. §§ 331 and 351. This court cannot disregard such clear statutory language in search of legislative intent. *See* La. Civ. Code art. 9. The record contains no evidence that CVS is engaged in the manufacture of drugs or that CVS is otherwise required to

conform to any proscribed current good manufacturing practice. Therefore, Sections 331 and 351(a)(2)(B) are not applicable to the facts of this case.

Cooper also briefly cites a state administrative regulation, Section 2501 of Title 46, Part LIII of the Louisiana Administrative Code, which mandates that expired drugs shall not be dispensed and shall be removed from a pharmacy's drug inventory. However, Section 2501 governs "prescription drugs," not over-the-counter medications, and is therefore not applicable to the present matter. *See* LAC 46:LIII:2501A.

Based upon the foregoing, we find no error in the trial court's determination that Cooper failed to establish a violation of prohibitory law. This assignment of error has no merit.

Cooper alternatively argues that the sale of expired over-the-counter medication will cause her irreparable injury because she was "duped into buying unreliable expired medicine." Irreparable injury is a loss that cannot be adequately compensated in money damages or is not susceptible of measurement by pecuniary standards. *In re Interdiction of Wright*, 13-0862 (La. App. 1 Cir. 3/27/14), 144 So. 3d 7, 12, *writ denied*, 14-0832 (La. 6/20/14), 141 So. 3d 810.

The evidence in this case of any loss suffered by Cooper, irreparable or otherwise, is limited. She presented no evidence of any physical, mental, or emotional injury resulting from her purchase of the expired allergy medicine, and she conceded that she is not pursuing a claim for damages. She did not attempt to return the medicine for a refund, and she admitted that she has no intention of purchasing medicine at CVS stores in the future. Although Cooper cites a printout from the CVS website that indicates that expired medicine "may" be less effective, she did not offer any proof that the medicine she purchased was, in fact, less effective. She did not consume any of the expired medicine and presented no

evidence of any adverse health effects from not taking the medicine. The "shopping study" establishes only that certain CVS stores sold expired products; that evidence does not prove how the sale of those items will cause irreparable injury to Cooper. The only potential loss identifiable from the record is the purchase price paid by Cooper for the expired medicine; however, that loss is compensable in money damages and is susceptible of measurement by pecuniary standards. Based upon the evidence in the record, the trial court did not err in determining that Cooper failed to present sufficient evidence to establish that she would be able to meet her burden of proving irreparable injury at trial. This assignment of error is without merit.

In her third assignment of error, Cooper contends the trial court erred in finding that she lacked standing to request class-wide injunctive relief. Although Cooper frames the trial court's finding as one of a lack of standing, the trial court's written reasons actually state that Cooper "failed to produce factual support sufficient to establish that she will be able to satisfy her evidentiary burden of proof at trial with regard to her claim for class certification; thus there is no issue of material fact." The trial court appears to have reached the same conclusion with respect to Cooper's claim in both her individual capacity and in her representative capacity on behalf of the putative class: Cooper failed to carry her burden of proof in opposition to the motion for summary judgment. Based upon that finding, the trial court dismissed all of Cooper's claims.

We initially note that the trial court made this determination without ruling on the motion to certify the proceeding as a class action. However, a trial court may decide the merits of a case regardless of whether it is certified as a class action. *Clark v. Shackelford Farms Partnership*, 38,749 (La. App. 2 Cir. 8/18/04), 880 So. 2d 225, 228. Consequently, the court may consider and grant a

defendant's motion for summary judgment prior to a class certification hearing. *Clark*, 880 So. 2d at 228.

Cooper requested injunctive relief in her individual capacity and as representative of a putative class and, therefore, was obligated to present evidence in opposition to the motion for summary judgment establishing that she would be able to meet her burden of proof at trial. *See* La. Code Civ. Pro. art. 966C(2). For the reasons already provided, Cooper failed to present sufficient evidence to support an award of injunctive relief. The record contains no evidence of a violation of a prohibitory law or proof of irreparable injury to Cooper or any other purported member of the putative class. The trial court did not err in granting summary judgment and dismissing Cooper's claims, both individually and on behalf of the putative class. This assignment of error is without merit.

In her final assignment of error, Cooper contends that the trial court erred in granting summary judgment when discovery was purportedly limited to non-merits, class certification issues. Although the record on appeal contains no order, minute entry, or other indication of any limitation on discovery by the trial court, Cooper claims that the trial court provided instructions to that effect during a discovery conference. Cooper did not present this argument to the trial court in opposition to the motion for summary judgment, and she did not request a continuance of the motion to allow for additional discovery, as authorized by Louisiana Code of Civil Procedure article 967C. We further note that the record contains extensive written discovery propounded by Cooper that addresses the merits of the case. We find no error in the trial court granting summary judgment under these circumstances. This assignment of error is without merit.

CONCLUSION

We affirm the summary judgment in favor of the defendants, CVS Caremark Corporation, Louisiana CVS Pharmacy, L.L.C., and CVS Pharmacy, dismissing the claims of the plaintiff, Jean Cooper, with prejudice. All costs of this appeal are assessed to Cooper.

AFFIRMED.