STATE OF MINNESOTA
IN COURT OF APPEALS
A23-0060

Joyce Walsh, et al.,
Appellants,

vs.

Upsher-Smith Laboratories, Inc.,
Respondent,

John Does 1-50,
Defendants.

Filed October 2, 2023
Affirmed
Bratvold, Judge

Hennepin County District Court
File No. 27-CV-20-6531

Brendan J. Flaherty, Oft Law, PLLC, Minneapolis, Minnesota; and

Samuel Cole (pro hac vice), Sam Cole Legal Services, PLLC, Richardson, Texas (for appellants)

Kay Nord Hunt, Lommen Abdo, P.A., Minneapolis, Minnesota; and

Richard G. Morgan, Cameron R. Woods, Lewis Brisbois Bisgaard & Smith LLP, Minneapolis, Minnesota (for respondent)

Considered and decided by Reyes, Presiding Judge; Smith, Tracy M., Judge; and Bratvold, Judge.

NONPRECEDENTIAL OPINION

BRATVOLD, Judge

Appellants are a group of 101 individuals alleging damages for personal injury or wrongful death caused by taking a prescribed generic drug for a heart condition not indicated on the manufacturer's medication guide. A prescription of this type is commonly called "off-label" use. Appellants sued the drug manufacturer, alleging that, among other theories, it failed to warn patients and their physicians of the risks associated with the drug's off-label use. The district court granted summary judgment in favor of the drug manufacturer after determining it was undisputed that the manufacturer discharged its duty to warn patients by complying with federal requirements for medication guides that are provided to pharmacies. The district court concluded that the drug manufacturer was not required to show "that it satisfied its duty to warn patients through another method, such as warning their doctors."

Appellants challenge the district court's summary-judgment decision, arguing that their claims for failure to warn physicians survive the dismissal of their claims for failure to warn patients via compliance with medication-guide regulations. Appellants contend that the district court erred because compliance with federal regulations on medication guides is not sufficient to establish that the drug manufacturer adequately warned physicians. Appellants add that the record evidence presents a genuine issue of material fact as to whether the manufacturer adequately warned physicians about the dangers of prescribing this generic drug for off-label use.

Appellant's principal brief does not dispute that the drug manufacturer's medication guide complied with federal regulations and adequately warned patients. Although appellant's reply brief attempts to revive a challenge to patient warnings, we reject that attempt. Based on existing Minnesota law, a drug manufacturer's duty to warn runs to the patient. Therefore, a drug manufacturer discharges its duty to warn patients by complying with federal regulations for medication guides—in part because state law does not impose a duty to warn patients by another method, i.e., separately warning the patient's physician. For these reasons, the district court correctly determined that the drug manufacturer was entitled to summary judgment as a matter of law. Thus, we affirm without considering additional issues raised by the parties.

FACTS

This appeal concerns patients who were prescribed a generic drug as an off-label treatment for a stable cardiac condition even though the drug's approved use was to treat life-threatening cardiac arrhythmias. The following summarizes the district court record as relevant to the issue on appeal.

General Background

The United States Food and Drug Administration (FDA) oversees the labeling of prescription drugs. Federal regulations require that "human prescription drug products" have an FDA-approved label if "it is necessary to the patients' safe and effective use of drug products," primarily when the prescription drugs are "used on an outpatient basis without direct supervision by a health professional." 21 C.F.R. § 208.1(a), (b) (2022). Generic drug manufacturers have a duty to ensure that the generic warning label is the same

as the brand-name warning label, known as the "duty of sameness." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011).[1]

FDA regulations also require drug manufacturers to provide "medication guides," defined in 21 C.F.R. § 208.3(h) (2022) and governed by 21 C.F.R. § 208.20-.26 (2022). Federal regulations detail what type of information a drug manufacturer must include in a medication guide and describe a manufacturer's obligation to provide medication guides to distributors, such as pharmacies. 21 C.F.R. § 208.20, .24.

The FDA approved the use of amiodarone hydrochloride (amiodarone) in 1985 under the trade name Cordarone®, which is manufactured by a pharmaceutical company not party to this appeal. Respondent Upsher-Smith Laboratories Inc. (Upsher-Smith) is a pharmaceutical manufacturer that makes a generic version of amiodarone.[2] The FDA approved Upsher-Smith's application to manufacture and sell this generic version of amiodarone in 1998.

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[1] The supreme court in *PLIVA* stated:

> The FDA . . . tells us that it interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.' The FDA's views are controlling unless plainly erroneous or inconsistent with the regulation[s] or there is any other reason to doubt that they reflect the FDA's fair and considered judgment.

564 U.S. at 613 (quotation and citation omitted).

[2] Upsher-Smith's version of amiodarone is called Pacerone®. This opinion will refer to the drug manufactured by Upsher-Smith as amiodarone.

The FDA-approved label for Upsher-Smith's amiodarone states that it is "indicated for the treatment of documented, life-threatening recurrent ventricular fibrillation and life-threatening recurrent hemodynamically unstable tachycardia in adults who have not responded to adequate doses of other available antiarrhythmics or when alternative agents cannot be tolerated." The prescribing information for amiodarone also warns that amiodarone can cause "pulmonary toxicity" at rates reported "as high as 17% and is fatal in about 10% of cases." The medication guide for amiodarone warns patients that amiodarone "should only be used to treat people who have been diagnosed with life-threatening heartbeat problems called ventricular arrhythmias" and lists "lung problems" as a serious side effect.

Complaint and Motion to Dismiss

Appellants are a group of 101 plaintiffs. Some are patients who were prescribed amiodarone by their physicians, and others are wrongful-death trustees and family members of patients who died after being prescribed amiodarone. Appellants allege that doctors prescribed amiodarone off-label to treat atrial fibrillation, a stable cardiac arrythmia commonly referred to as "a-fib," and that use of amiodarone led to injury to the plaintiff or death of the decedent. As mentioned above, amiodarone's indicated use is for ventricular fibrillation, or "v-fib."

In April 2020, appellants sued for damages, alleging that Upsher-Smith failed to warn the patients and their physicians of the harmful and deadly side effects of amiodarone's off-label use for a-fib. Appellants' complaint alleged seven causes of action: (1) strict products liability for a failure to warn, (2) negligence for a failure to warn,

(3) negligence in marketing and sales, (4) negligence per se, (5) strict liability for a manufacturing defect, (6) fraud and deceit, and (7) wrongful death. In September 2020, appellants filed a first amended complaint that generally included the same factual allegations and legal claims and added more plaintiffs.

In July 2020, Upsher-Smith moved to dismiss under Minn. R. Civ. P. 12.02(e), arguing that appellants' claims were preempted by federal law, failed as a matter of law, or were inadequately pleaded. In January 2021, the district court granted Upsher-Smith's motion to dismiss in part. The district court agreed that many of appellants' claims were preempted by federal law or inadequately pleaded and, on that basis, dismissed appellants' claims that alleged a failure to report adverse events to the FDA, manufacturing defects, fraud and deceit, and negligent misrepresentation.

The district court then turned to appellants' failure-to-warn claims, discussed *Wyeth v. Levine*, 555 U.S. 555 (2009), and concluded that preemption did not bar appellants' failure-to-warn claims under state law. The district court rejected Upsher-Smith's argument that "the existence of a federal duty [to warn] negates the existence of a parallel state duty" to warn. The district court emphasized that appellants "are not asking for warnings additional to or different from those already required by the FDA," relying on our analysis in *Angeles v. Medtronic, Inc*., 863 N.W.2d 404, 409 (Minn. App. 2015).

The district court determined that appellants' failure-to-warn claims alleged that Upsher-Smith failed to warn (1) patients by violating federal medication-guide regulations and (2) physicians by failing to provide FDA-approved medication information. The district court reasoned that appellants' theories addressed ways a drug manufacturer could

discharge its duty to warn and rejected Upsher-Smith's argument that appellants were "attempting to require more warnings than the FDA did." The district court pointed out that appellants' position was "not asking for warnings additional to or different from those required by the FDA." The district court concluded that appellants adequately pleaded their failure-to-warn-via-medication-guide and failure-to-warn-physicians claims. Therefore, appellants' failure-to-warn claims based on strict liability and negligence survived Upsher-Smith's motion to dismiss.

Summary-Judgment Motions

In May 2021, Upsher-Smith moved for summary judgment under Minn. R. Civ. P. 56.01, seeking to dismiss appellants' remaining failure-to-warn claims. Upsher-Smith argued that it was entitled to judgment as a matter of law because it provided adequate prescribing information to physicians and it complied with all federal regulations about providing medication guides to distributors, such as pharmacies.

In October 2021, the district court denied Upsher-Smith's summary-judgment motion.[3] The district court first determined that appellants raised a genuine issue of material fact as to whether Upsher-Smith used effective "methods of warning physicians about the dangers of [off-label] prescriptions." The district court concluded that, "[o]n the present record, the Court cannot find, as a matter of law, that Upsher-Smith satisfied its duty to warn [appellants'] physicians." Second, the district court determined that

[3] Upsher-Smith petitioned this court for discretionary review of the district court's October 2021 denial of the summary-judgment motion, which we denied in December 2021. *Walsh v. Upsher-Smith Lab'ys, Inc.*, No. A21-1455 (Minn. App. Dec. 14, 2021) (order).

appellants' medication-guide claims were not "ripe for summary judgment" because appellants had "not yet had an opportunity to depose" an Upsher-Smith employee and thus had made a sufficient showing of their need for "specific additional discovery."

In June 2022, Upsher-Smith filed a renewed motion for summary judgment. Upsher-Smith first argued that, under Minnesota law, Upsher-Smith's duty to warn runs to the patient and may be satisfied by providing adequate warnings to *either* the patient *or* the patient's physician. Upsher-Smith reasoned that its compliance with the federal medication-guide regulations was undisputed and that it therefore satisfied its duty to warn patients under state law. Upsher-Smith emphasized that "compliance with the federal Medication Guide regulations is the sole issue presented in this [summary-judgment] motion." And Upsher-Smith urged that "once Upsher-Smith shows it has complied with its duty to warn patients by complying with medication guide regulations, it need not also prove that it complied with that duty by warning the patient's doctors."

In November 2022, the district court granted Upsher-Smith's summary-judgment motion and dismissed appellants' failure-to-warn claims. The district court examined the record evidence and legal arguments in detail and determined that there was no genuine issue of material fact regarding whether Upsher-Smith complied with federal regulations on providing medication guides as stated in 21 C.F.R. § 208.24(b).

The district court next considered whether summary judgment on appellants' "medication guide claims disposed of this case." The district court first reasoned that appellants' failure-to-warn claims were based on Upsher-Smith's failure to warn patients via compliance with medication-guide regulations, failure "to provide FDA warnings to

doctors," or failure "to do both." The district court also noted that, in its January 2021 order, it determined that appellants' failure-to-warn claims corresponded to the alternative ways a drug manufacturer could discharge its duty to warn. The district court decided it would "not reconsider" that determination on summary judgment.

The district court stated that appellants, in response to Upsher-Smith's motion to dismiss, "acknowledge[d] that if Upsher-Smith complied with the Medication Guide regulations, it would have no liability on their state-tort claims." Because record evidence established that Upsher-Smith had complied with the medication-guide regulations and "Upsher-Smith is not also required to show that it satisfied its duty to warn patients through another method, such as warning their doctors," the district court determined that no genuine issue of material fact remained for trial. The district court concluded that Upsher-Smith had satisfied its duty to warn patients and granted summary judgment in Upsher-Smith's favor.

This appeal follows.

DECISION

Appellants argue that the district court erred when it granted summary judgment in favor of Upsher-Smith on appellants' failure-to-warn-physicians claims. Upsher-Smith argues that the district court properly granted summary judgment because Upsher-Smith discharged its duty to warn patients by complying with federal medication-guide regulations, and thus, it did not also need to warn physicians. Alternatively, Upsher-Smith argues that summary judgment may be affirmed because appellants failed to produce any

evidence that federally approved warnings were unknown to or unavailable to their physicians.

An appellate court "review[s] the grant of summary judgment de novo to determine 'whether there are genuine issues of material fact and whether the district court erred in its application of the law.'" *Montemayor v. Sebright Prods., Inc.*, 898 N.W.2d 623, 628 (Minn. 2017) (quoting *Stringer v. Minn. Vikings Football Club, LLC*, 705 N.W.2d 746, 754 (Minn. 2005)); *see also* Minn. R. Civ. P. 56.01. "In doing so, [an appellate court] must not weigh facts or determine the credibility of affidavits and other evidence." *Montemayor*, 898 N.W.2d at 628 (quotation omitted). Summary judgment is "inappropriate when reasonable persons might draw different conclusions from the evidence presented." *Id.* (quoting *Osborne v. Twin Town Bowl, Inc.*, 749 N.W.2d 367, 371 (Minn. 2008)). An appellate court "need not adopt the reasoning of the district court" and "may affirm a grant of summary judgment if it can be sustained on any grounds." *Doe v. Archdiocese of St. Paul*, 817 N.W.2d 150, 163 (Minn. 2012).

In their principal brief, appellants do not challenge the district court's determination that Upsher-Smith complied with federal medication-guide regulations or that, in doing so, Upsher-Smith discharged its duty to warn patients. To the extent appellants attempt to resurrect their failure-to-warn-patients claims in their reply brief, we reject that attempt, as is discussed in more detail below. In short, the issue presented is whether appellants' failure-to-warn-physicians claims survive summary judgment given that appellants no longer dispute that Upsher-Smith complied with federal medication-guide regulations.

We begin with a brief summary of relevant law. Minnesota recognizes a manufacturer's common-law duty to warn of foreseeable dangers posed by prescription drugs. *See Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 (Minn. 1970); *see also Lovejoy v. Minneapolis-Moline Power Implement Co.*, 79 N.W.2d 688, 693 (Minn. 1956) (stating that a "manufacturer of a chattel" may be liable if it "knows or should know that the chattel is apt to cause bodily harm if not used in a specific manner if [it] fails to furnish adequate warning as to the dangers inherent in its use").

Minnesota also recognizes that the manufacturer's duty to warn runs to the patient. *Gray v. Badger Mining Corp.*, 676 N.W.2d 268, 279 n.7 (Minn. 2004) (stating that a drug manufacturer has "a duty to warn the patient"). This duty to the patient is similar to the common-law duty to warn users of a product. *See Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977) ("[W]here the manufacturer or the seller of a product has actual or constructive knowledge of danger to users, the seller or manufacturer has a duty to give warning of such dangers."); *see also Mulder*, 181 N.W.2d at 885 & n.1 (discussing that "[t]he [drug] manufacturer has no duty to warn the lay public regarding prescription drugs" and noting that "the manufacturer is not liable" if the plaintiff's doctor was "fully aware" of the relevant hazard).

The district court relied on these principles in resolving Upsher-Smith's renewed motion for summary judgment. The district court first determined it was undisputed that Upsher-Smith complied with federal regulations to "ensur[e] that Medication Guides are available for distribution to patients" pursuant to 21 C.F.R. § 208.24(b)(2). Federal regulations require manufacturers to "ensur[e] that Medication Guides are available for

distribution to patients" by either "[p]roviding Medication Guides in sufficient numbers to distributors," such as pharmacies, or "[p]roviding the means to produce Medication Guides in sufficient numbers to distributors." 21 C.F.R. § 208.24(b).

After reviewing the parties' arguments and evidence in detail, the district court concluded that "no genuine issue of material fact remains for [appellants] to pursue on their Medication Guide claim." The district court reasoned that "Upsher-Smith presented evidence that it provided a website and a toll-free number to meet [the federal] regulation, and [appellants] produced no evidence that these means prevented any of their pharmacies from producing Medication Guides for amiodarone." The district court concluded that Upsher-Smith's compliance with the medication-guide regulations discharged its duty to warn patients. The district court next examined appellants' failure-to-warn-physicians claims, determining that "Upsher-Smith has shown that it complied with its duty to warn by complying with the Medication Guide regulation" and "is not also required to show that it satisfied its duty to warn patients through another method, such as warning their doctors."

In their principal brief to this court, appellants contend that "state common law negligence-based claims survive regardless of whether [Upsher-Smith] complied with the FDA's Medication Guide regulations" because "compliance with a federal regulation does not delimit the scope of liability under Minnesota law." Appellants cite two cases to support the proposition that a drug manufacturer's compliance with a federal regulation does not automatically satisfy a manufacturer's duty to warn. *Blasing v. P. R. L. Hardenbergh Co.*, 226 N.W.2d 110, 115 (Minn. 1975) (concluding evidence that a defendant "has complied with a statute or ordinance regulating conduct under the circumstances is not conclusive

that [they were] in the exercise of due care"); *Wendinger v. Forst Farms, Inc.*, 662 N.W.2d 546, 554 (Minn. App. 2003) ("A statutory standard is no more than a minimum, and it does not necessarily preclude a finding that the actor was negligent in failing to take additional precautions." (quotation omitted)), *rev. denied* (Minn. Aug. 5, 2003).

Appellants correctly state the rule of law applied in *Blasing* and *Wendinger*. But appellants' argument that Upsher-Smith's compliance with medication-guide regulations "does not mean that [Upsher-Smith] satisfied its duty to warn [appellants' physicians]" is unavailing for three reasons.

First, appellants' principal brief does not challenge the district court's determination that Upsher-Smith's medication guide complied with federal regulations and adequately warned patients.

Second, appellants' theory on appeal assumes that a drug manufacturer has a duty to warn physicians *in addition to* its duty to warn patients. On appeal, appellants argue that Upsher-Smith's "duty to warn [appellants' physicians] . . . is a core obligation in a prescription drug case." This is a different theory than the theory appellants advanced in district court. And a party may not "obtain review by raising the same general issue litigated below but under a different theory." *Thiele v. Stich*, 425 N.W.2d 580, 582 (Minn. 1988); *see also Pomush v. McGroarty*, 285 N.W.2d 91, 93 (Minn. 1979) (holding that plaintiffs could not raise a new negligence theory of recovery on appeal).

Throughout the proceedings before it, the district court described appellants' failure-to-warn arguments as alternative ways a drug manufacturer could discharge its duty to warn. For example, in the January 2021 order, the district court referred to one of the

failure-to-warn theories as appellants' "fall back claim." In the November 2022 order, the district court described the medication-guide claim as an "alternative method by which Upsher-Smith may satisfy its state-law duty to warn." Because appellants argue for the first time on appeal that drug manufacturers have a separate duty to warn physicians in addition to their duty to warn patients, we need not consider appellants' new theory. *See Thiele*, 425 N.W.2d at 582 (stating that we generally consider "only those issues that the record shows were presented and considered by the trial court" (quotation omitted)).

Third, even if we consider the merits of appellants' separate-duty-to-warn-physicians theory, we are not persuaded. Existing Minnesota law does not recognize that a drug manufacturer has a separate duty to warn physicians. Rather, Minnesota law recognizes that a drug manufacturer's duty to warn runs to the patient.[4] Appellants do not cite binding authority that holds a drug manufacturer has a separate duty to also warn physicians about prescription drugs, and we are not aware of any.[5] Here, Upsher-Smith discharged its duty to warn patients by complying with federal regulations

[4] Minnesota has recognized the "learned-intermediary defense," *Gray*, 676 N.W.2d at 275, whereby a drug manufacturer "is not liable if the [prescribing physician] was fully aware of the facts which were the subject of the warning," *Mulder*, 181 N.W.2d at 885.

[5] Some foreign caselaw has explicitly recognized a drug manufacturer's exclusive duty to warn physicians as opposed to patients. *See, e.g.*, *Carlin v. Super. Ct.*, 920 P.2d 1347, 1354 (Cal. 1996) ("[I]n the case of prescription drugs, the duty to warn runs *to the physician*, not to the patient."); *Presto v. Sandoz Pharm. Corp.*, 487 S.E.2d 70, 73 (Ga. Ct. App. 1997) (acknowledging the "settled 'learned intermediary rule' of Georgia law that the manufacturer of a prescription drug is not normally required to directly warn the patient of dangers in its use" and that "[o]rdinarily, in the case of prescription drugs, a warning as to possible danger in its use to the prescribing physician is sufficient" (emphasis omitted) (quotation omitted)).

to distribute medication guides, and appellants do not challenge this determination on appeal. In their principal brief to this court, appellants concede that Upsher-Smith "complied with the letter of the Medication Guide regulations." Additionally, appellants' attorney confirmed at oral argument that they "are only appealing [their physicians] claim."

Still, in their reply brief, appellants appear to shift positions and argue that, even if Upsher-Smith complied with the federal regulations for medication guides, it "did not exercise reasonable care in warning patients, and this issue was not even before the district court" in Upsher-Smith's renewed motion for summary judgment. Appellants' reply brief also asserts that their failure-to-warn-physicians claims "would be inapplicable only if [Upsher-Smith] discharged its duty to warn patients, but it did not."

Appellants' reply-brief arguments differ from those in their district court pleadings and memoranda. In district court, appellants consistently equated their failure-to-warn-patients claims to Upsher-Smith's failure "to ensure the Medication Guide [for amiodarone] was provided."[6] In appellants' response to Upsher-Smith's renewed motion for summary judgment, appellants argued that Upsher-Smith's "methods of

[6] Appellants' focus on the medication-guide regulation as the heart of their failure-to-warn-patients claims is seen in the first amended complaint, which alleged that Upsher-Smith violated its state-law duty to warn patients because Upsher-Smith was "responsible for ensuring that the appropriate warning labels and Medication Guide were provided." In their response to Upsher-Smith's motion to dismiss, appellants quoted *Jones v. Medtronic, Inc.*, No. A17-1124, 2018 WL 1462169, at *4 (Minn. App. Mar. 26, 2018), to argue that "*only* when a manufacturer complies with the Medication Guide regulation, has the manufacturer exercised 'reasonable care in giving adequate and accurate instructions as to the use of the product and a warning as to any dangers reasonably foreseeable in its intended use.'" Appellants further argued that federal regulations "require providing a Medication Guide to a distributor to ensure that the warning ultimately reaches the consumer."

distributing Medication Guides are inadequate to ensure consumers actually receive Medication Guides." Appellants also argued: "In failing to ensure that plaintiffs (or physicians) received Medication Guides in proper form, [Upsher-Smith] not only violated its duties under FDA regulations but also fell short of its duty to adequately warn under Minnesota state law."

The record shows that appellants' failure-to-warn-patients claims were synonymous with the allegation that Upsher-Smith failed to comply with federal medication-guide regulations. Indeed, appellants asserted that had they received the medication guides, "all the [appellants] would have declined to take [a]miodarone." Therefore, when the district court determined that Upsher-Smith complied with the federal medication-guide regulations as a matter of law, it necessarily concluded that Upsher-Smith discharged its duty to warn patients by meeting its obligation to "ensur[e] that Medication Guides are available for distribution to patients."

We need not, therefore, consider arguments in appellants' reply brief about whether compliance with federal medication-guide regulations satisfied Upsher-Smith's duty to warn patients. Appellants' principal brief does not challenge the district court's summary-judgment determination dismissing appellants' failure-to-warn-patients claims. And generally, we do not consider issues raised for the first time in a reply brief. *Moorhead Econ. Dev. Auth. v. Anda*, 789 N.W.2d 860, 887 (Minn. 2010).

Even if we were to consider appellants' new arguments in their reply brief, we would have an additional reason to reject them. Appellants cannot raise a new theory on appeal. *Thiele*, 425 N.W.2d at 582. Here, appellants' theory in district court was that "*only*

when a manufacturer complies with the Medication Guide regulation, has the manufacturer exercised 'reasonable care in giving adequate and accurate instructions as to the use of the product and a warning as to any dangers reasonably foreseeable in its intended use.'"

In sum, the district court's summary-judgment dismissal of appellants' failure-to-warn-patients claims is not before us; therefore, we accept the district court's determination that Upsher-Smith discharged its duty to warn patients by complying with the federal medication-guide regulations. State law does not impose a separate or additional duty on drug manufacturers to warn physicians once a manufacturer has discharged its duty by warning the patient. Thus, the district court did not err when it granted Upsher-Smith's summary-judgment motion on appellants' state-law failure-to-warn-physicians claims.

While appellants also contend that the record raises genuine issues of fact regarding whether Upsher-Smith adequately warned physicians and Upsher-Smith presents alternative grounds for affirmance, we need not consider either of these additional arguments.

Affirmed.