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IN THE

COURT OF APPEALS OF INDIANA

Joe Alcozar, *et al.*,

Appellants-Plaintiffs,

v.

Orthopedic & Sports Medicine Center of Northern Indiana, *et al.*,

Appellees-Defendants.

September 28, 2023

Court of Appeals Case No. 22A-CT-909

Interlocutory Appeal from the St. Joseph and Elkhart Superior Courts

The Honorable Jamie C. Woods, Judge

The Honorable Kristine Osterday, Judge

Trial Court Cause Nos.
71D06-1406-CT-181
71D06-1407-CT-257
71D06-1409-CT-320
71D06-1405-CT-136
20D01-1404-CT-72

Opinion by Judge Bradford
Judges May and Mathias concur.

Bradford, Judge.

Case Summary[1]

[1] Beginning in 2012, several patients in St. Joseph and Elkhart Counties ("Plaintiffs") were injured, and, in some cases, died, after being given injections of preservative-free methylprednisolone acetate ("MPA"), a steroid purchased from New England Compounding Pharmacy, Inc., a/k/a, the New England Compounding Center ("NECC"). Plaintiffs brought suit in St. Joseph and Elkhart Counties against ASC Surgical Ventures, LLC; Orthopedic and Sports Medicine Center of Northern Indiana; and OSMC (collectively, "ASC") and Anonymous Clinic. In 2016, we ruled that Plaintiffs' claims against Anonymous Clinic and ASC (collectively, "Defendants") were subject to the provisions of the Indiana Medical Malpractice Act ("the MMA").

[2] In 2018, Plaintiffs moved for preliminary determination/partial summary judgment on their prescription-law claims before the St. Joseph and Elkhart trial courts. Both trial courts denied Plaintiffs' partial-summary-judgment motions, concluding the cases first had to be presented to medical-review panels ("MRPs"). Further discovery, selection of MRP chairpersons and their members and submissions to MRPs were undertaken. The handling of those

[1] We held oral argument in this case on September 7, 2023, in the Court of Appeals of Indiana courtroom in Indianapolis. We commend counsel for the high quality of their written submissions and oral advocacy.

MRPs led to the filing of a motion for preliminary determination by ASC with the Elkhart trial court and a joint motion for preliminary determination with the St. Joseph trial court.

[3] The St. Joseph trial court concluded that Plaintiffs' claims of prescription-drug-law violations by Anonymous Clinic should be presented to the MRPs in each case and rejected its preemption argument. The St. Joseph trial court concluded that the decision in *Sherrow v. GYN, Ltd.*, 745 N.E.2d 880 (Ind. Ct. App. 2001), did not preclude the parties from discussing the prescription-drug laws in their MRP submissions.

[4] The Elkhart trial court denied Plaintiffs' motion for partial summary judgment, concluding that Plaintiffs were asserting fraud on the federal Food and Drug Administration ("the FDA"), a claim that was preempted by the federal Food, Drug, and Cosmetic Act ("the FDCA"). The Elkhart trial court further held that Plaintiffs' negligence *per se* claims based upon ASC's violations of Indiana's Food, Drug, and Cosmetic Act ("the IFDCA") were preempted. The Elkhart trial court entered summary judgment in favor of Defendants on Plaintiffs' claimed prescription-drug law violations. The Elkhart trial court concluded that *Sherrow* precluded the parties from discussing the prescription-drug laws in their MRP submissions and that the MRP chairpersons should not instruct the MRPs regarding Plaintiffs' prescription-drug-law claims.

[5] Plaintiffs argue that (1) Defendants violated various Indiana and federal laws pertaining to prescription drugs, (2) those violations establish negligence *per se*, (3) medical testimony is not necessary to establish the violation of a statute, (4)

their claims of medical negligence are not preempted by the FDCA, (5) discussion of statutes in a submission to a MRP is not prohibited when a plaintiff asserts a statutory violation, and (6) the trial courts erred in denying Plaintiffs' motions for partial summary judgment. Because we reject Plaintiffs' first, fifth, and sixth arguments, we need not address the others and affirm in part, reverse in part, and remand with instructions.

Facts and Procedural History

[6] We summarized the facts underlying this case in a previous appeal:

> Beginning in 2012, patients around the country began suffering meningitis after being injected with [MPA], a steroid purchased from [NECC]. It was soon discovered that some lots of MPA had become contaminated with fungus. This consolidated appeal concerns claims brought by injured patients (or those suing on their behalf) (collectively, "the Plaintiffs") against Anonymous Clinic in St. Joseph County and [ASC]. Plaintiffs contend that the Defendants were negligent in choosing to administer preservative-free MPA and in failing to properly evaluate NECC before using it as a supplier. Some of the Plaintiffs brought suit without using the procedures laid out in the [the MMA], and Defendants moved either for dismissal or summary judgment on the basis that Plaintiffs' claims were claims of medical malpractice.
>
> Stephen W. Robertson, acting in his capacity as Commissioner of Indiana Department of Insurance, which administers the Indiana Patient's Compensation Fund ("the PCF") intervened, arguing that Plaintiffs' claims were of general negligence and therefore not subject to the provisions of the MMA. The trial courts ultimately agreed with Defendants and Plaintiffs (who had reversed their initial position) that Plaintiffs' claims were governed by the MMA. In this consolidated appeal, the PCF contends that the trial courts erred in concluding that Plaintiffs' claims are claims of medical malpractice. Plaintiffs, Defendants, and *Amici Curiae* (health-care

> providers facing similar claims in other cases), contend that Plaintiffs' claims are subject to the MMA as they involve actions informed by the exercise of professional medical judgment. Because we conclude that Plaintiffs' claims are subject to the MMA, we affirm the judgments of the trial courts and remand for further proceedings consistent with this opinion.

Robertson v. Anonymous Clinic, 63 N.E.3d 349, 352 (Ind. Ct. App. 2016), *trans. denied*.

[7] Following our decision in *Robertson*, Plaintiffs moved for preliminary determination/partial summary judgment on their prescription-law claims before the St. Joseph trial court on November 21, 2018, and the Elkhart trial court on June 28, 2018. On July 23, 2019, both trial courts denied Plaintiffs' partial-summary-judgment motions, concluding the cases first had to be presented to MRPs.

[8] Further discovery, selection of MRP chairpersons and their members, and submissions to MRPs were undertaken. The handling of those MRPs led to the filing of a motion for preliminary determination by ASC with the Elkhart trial court on February 1, 2021, and a joint motion for preliminary determination with the St. Joseph trial court on March 26, 2021.

[9] The St. Joseph trial court held a hearing on January 13, 2022, and thereafter entered an order on February 17, 2022. A summary of that order is as follows:

> 1. The St. Joseph trial court concluded that Plaintiffs' claims of prescription-drug-law violations by Defendants should be presented to the MRPs in each case and rejected Defendants' preemption argument.

2. The St. Joseph trial court concluded that the decision in *Sherrow*, 745 N.E.2d at 880, did not preclude the parties from discussing the prescription-drug laws in their MRP submissions.

3. The St. Joseph trial court concluded that it was for the MRP to determine whether a violation of the prescription-drug laws by a healthcare provider constituted a violation of the standard of care, *i.e.*, negligence.

Appellants' App. Vol. XIV pp. 58–68.

[10] The Elkhart trial court held a hearing on June 2, 2021, on the motion for preliminary determination filed by ASC and on Plaintiffs' motion to reconsider the denial of Plaintiffs' motion for partial summary judgment. On June 18, 2021, the Elkhart trial court granted Plaintiffs' motion to reconsider. The Elkhart trial court entered its order on February 22, 2022. A summary of that order is as follows:

1. The Elkhart trial court denied Plaintiffs' motion for partial summary judgment concluding Plaintiffs were asserting fraud on the FDA claims and such claims were preempted by the FDCA. The Elkhart trial court further held that Plaintiffs' negligence *per se* claims based upon ASC's violations of Indiana prescription statutes were preempted.

2. On ASC's motion for preliminary determination, the Elkhart trial court concluded that the decision in *Sherrow* precluded the parties from discussing the prescription-drug laws in their MRP submissions. The Elkhart trial court further concluded that the MRP chairpersons should not instruct the MRPs regarding Plaintiffs' prescription-drug-law claims as the Elkhart trial court was entering summary judgment against Plaintiffs on those claims.

Appellants' App. Vol. XIII pp. 31–46.

[11] Motions to certify the St. Joseph and Elkhart trial courts' orders for interlocutory appeal were granted on March 28, 2022. On May 13, 2022, we accepted jurisdiction.

Discussion and Decision

[12] Plaintiffs argue that (1) Defendants violated various Indiana and federal laws pertaining to prescription drugs, (2) those violations establish negligence *per se*, (3) medical testimony is not necessary to establish the violation of a statute, (4) their claims of medical negligence are not preempted by the FDCA, (5) discussion of statutes in a submission to a MRP are not prohibited when a plaintiff asserts a statutory violation, and (6) the trial courts erred in denying Plaintiffs' motions for partial summary judgment.

[13] Defendant Anonymous Clinic argues that (1) the FDCA and Indiana's prescription-drug laws do not apply to Plaintiffs' claims, (2) Plaintiffs' claims are preempted by the FDCA, (3) Plaintiffs are improperly attempting to circumvent the MMA, and (4) Plaintiffs' motions for partial summary judgment are not properly before us in this appeal.

[14] Defendant ASC argues that (1) Plaintiffs' allegations amount to a claim of fraud on the FDA, (2) Plaintiffs cannot prevail on their claims of negligence *per se* because they cannot establish that any alleged violations of federal or state prescription-drug laws caused their injuries or, indeed, that Defendants even violated any federal or state prescription-drug laws, and (3) the Elkhart trial

court correctly determined that Plaintiffs are prohibited from making legal arguments before the MRPs.

[15] The Commissioner of the Indiana Department of Insurance argues that (1) we reserved determination of whether Defendants' conduct fell below the standard of care for MRPs, (2) the trial courts lacked jurisdiction to rule on issues of negligence *per se*, (3) the Elkhart trial court correctly ruled that Plaintiffs' claims are preempted, and (4) the medical-review process is not intended to be a mini-trial that involves legal arguments.

[16] Plaintiffs contend that Defendants violated various federal and Indiana laws related to prescription drugs, which, they allege, establishes negligence *per se*. The establishment of negligence *per se*, the argument continues, eliminates the need for MRP review, resulting in going straight to trial on the question of damages only.

A. Causation

[17] As an initial matter, ASC argues that Plaintiffs have failed to establish that any of the Plaintiffs' alleged violations of federal or state law, even if they occurred, caused Plaintiffs' injuries. ASC correctly points out that the statutory violations must still be shown to have been the proximate cause of the injury. *Lindsey v. DeGroot*, 898 N.E.2d 1251, 1260 (Ind. Ct. App. 2009).

> The violation of statutory duty is not actionable negligence unless it is also the proximate cause of the injury. The violation of a statute raises no liability for injury to another unless the injury was in some manner the result of such violation. In order to find that an injury was the proximate result of a statutory violation, the injury must have been a foreseeable consequence of the violation

> and would not have occurred if the requirements of the statute had been observed.

Id. at 1261 (cleaned up).

[18] Put another way, the "violation of a statute raises no liability for injury to another unless the injury was in some manner the result of such violation." *Conway v. Evans*, 549 N.E.2d 1092, 1095 (Ind. Ct. App. 1990). "In order to find that an injury was the proximate result of a statutory violation, the injury must have been a foreseeable consequence of the violation and would not have occurred if the requirements of the statute had been observed." *Inland Steel v. Pequignot*, 608 N.E.2d at 1378, 1383 (Ind. Ct. App. 1993), *trans. denied*; *see also McBride v. Cole Assocs., Inc.*, 753 N.E.2d 730, 738 (Ind. Ct. App. 2001) (concluding that there was no liability under a theory of negligence *per se* for failing to have a posted speed limit of forty-five miles per hour when there was no evidence the vehicles involved in the accident were traveling in excess of that speed).

[19] Plaintiffs allege the following violations of law:

- ASC ordered five vials of MPA at a time from NECC;
- ASC did not provide individual prescriptions;
- the prescriptions did not include the patients' addresses or dates of birth;
- prescriptions were not signed by the physician;
- vials of MPA did not contain NECC's address or phone number;
- the vials did not have a serial number but, instead, a lot number;

- the prescribing doctor's name was not on the vial;
- there were no instructions for use of the medication;
- there was no refill information; and
- there was no information concerning possible substitute medications.

[20] ASC argues that fulfilling each of these alleged requirements would not have changed anything, as none of them would have had any effect on NECC's failure to use sterile ingredients in compounding the MPA or maintain sterility in its compounding facility. We agree. None of these provisions, whatever their purpose or utility, have any connection whatsoever with the undisputed cause of the injuries in this case—contaminated MPA. Had Defendants done any—or all—of the things that Plaintiffs argue they were required to do, it would have changed nothing, as none of the alleged requirements have anything to do with the compounding of the MPA or its handling. Put another way, the allegedly illegal lack of information on labeled vials of MPA did not injure Plaintiffs, the contaminated drug within did. While we conclude that Plaintiffs cannot establish any causal connection between Defendants' alleged statutory violations and Plaintiffs' injuries, we nonetheless elect to address their specific allegations.

B. Federal Law

[21] The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any […] drug […] that is adulterated or misbranded." 21 U.S.C. § 331(a). A drug is misbranded if its "labeling is false or misleading in any particular." 21 U.S.C. § 352(a). Plaintiffs argue that Defendants ordered

and administered misbranded MPA to their patients in two respects: (1) the MPA administered by Defendants to Plaintiffs bore false labeling in that each vial indicated it was to be used by an identified person when, in fact, it was known by Defendants that it would be injected into a different patient and (2) Plaintiffs argue that the MPA administered by Defendants was misbranded because 21 U.S.C. § 352(f) specifies that a drug is misbranded "[u]nless its labeling bears (1) adequate directions for use" and the labeling on the vials containing MPA administered by Defendants to Plaintiffs contained no such directions. Plaintiffs also argue that Defendants improperly provided MPA that had not gone through the FDA's new-drug-approval process and, finally, that the prescription exemptions for misbranding and new-drug approval were not met in this case.

[22] We conclude, as a matter of law, that Plaintiffs have failed to establish any violations of FDCA labeling provisions. Put simply, 21 U.S.C. § 352(f)'s labeling requirements do not apply to the actions of Defendants in this case, *i.e.*, ordering MPA from NECC and then administering it to patients in a clinical setting. As for the alleged requirement that Defendants were required to order MPA from NECC by issuing a prescription that identified, *inter alia*, the name of the patient to whom it was to be administered, Plaintiffs are asking us to apply a requirement from a completely different scenario to one in which it makes no sense. It is, of course, true that had NECC been administering the MPA to Plaintiffs instead of Defendants, Defendants would have had to issue prescriptions to NECC with a specific patient's name, but that never occurred.

Plaintiffs point to no FDCA requirement that such information be included in an order for medicine to be delivered to the doctor who ordered it.

[23] Moreover, as ASC points out, because 21 U.S.C. § 353(b)(2) allows a drug to be administered by an oral prescription, it follows that doctors are, in fact, not required to provide patients with any of the labeling information specified in 21 U.S.C. § 352(f). This is not surprising, because, for one example, it would be nonsensical to require directions for patient use for a drug that is injected into the patient by a doctor in a clinical setting, such as MPA. Our conclusion is consistent with the court's decision in *United States v. Evers*, 643 F.2d 1043 (5th Cir. 1981), which correctly recognized that a prescription drug delivered by a physician is required to adhere to the provisions of 21 U.S.C. § 353(f) *only* if delivered to another physician. *Id*. at 1053. Put another way, if a doctor administers a prescription drug directly to a patient, the 21 U.S.C. § 352(f) use and warning labels are not required. *Id*.

[24] Plaintiffs' contention that Defendants illegally dispensed a new drug is also without merit. Pursuant to 21 U.S.C. § 355(a), "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." A drug prepared by a compounding pharmacy is considered a "new drug" unless the exemptions under the FDCA for a compounded prescription drug are met. *See* 21 U.S.C. § 353(b). Plaintiffs contend that neither the prescription nor compounded-drug exemptions operate to remove the requirement that MPA be treated as a new drug.

[25] Plaintiffs first argue that the prescription exemption does not help Defendants. Pursuant to 21 U.S.C. § 353(b),

> (1) A drug intended for use by man which--
>
> (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug[…]
>
> shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.
>
> (2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.

The provisions above, as with the labeling requirements addressed in the previous section, have no relevance to what occurred in this case: no MPA was "dispensed" by anyone—it was administered by Defendants. Consequently,

the requirements for dispensing drugs to a patient did not have to be met in this case.

[26] As for the compounded-drug exemption, Plaintiffs cite 21 U.S.C. § 353(a) for the proposition that labeling (and other) requirements apply under the circumstances of this case. This provision, however, only applies if "the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient[.]" *Id*. Here, the MPA was not compounded for identified patients based on the receipt of a prescription, it was ordered in bulk. Any suggestion that the FDCA required Defendants to provide additional information to NECC in connection with its MPA orders or to the patients to whom it was administered is entirely unsupported by any FDCA provision.

C. State Law

[27] Plaintiffs argue that Defendants also violated the IFDCA by obtaining MPA from NECC without issuing prescriptions for each individual patient to NECC. Plaintiffs cite authority for the proposition that a compounding pharmacist "may provide compounded drugs *to patients* only upon receipt of a valid prescription from a doctor or other medical practitioner licensed to prescribe medication." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002) (emphasis added). It is undisputed, however, that NECC never distributed any MPA to *any* patients, only to medical providers like Defendants.

[28] Anonymous Clinic argues that the only obligation it had under state law was to issue a prescription before administering MPA to a patient, not before ordering it from NECC. We agree. For the purpose of a physician treating a patient, Indiana defines "prescription" as follows: "'Prescribe or prescription' means to direct, order, or designate the use of or manner of using a drug, medicine, or treatment, by spoken or written words or other means and in accordance with IC 25-1-9.3 [which relates only to controlled substances.]" Ind. Code § 25-22.5-1-1.1(f). In other words, Indiana physicians are permitted to orally prescribe medication before administering it to a patient. This statute is consistent with the statutory authority for the Indiana Pharmacy Board, which acknowledges that a "prescription" may be transmitted in writing or by another form. *See* Ind. Code § 25-26-13-2. Anonymous Physician's injection of MPA during patient procedures meets this statutory definition of prescription for a physician, fulfilling Anonymous Clinic's statutory obligations. While it is true that Defendants would have had to issue a prescription to NECC in order for *NECC* to deliver or administer MPA to a patient, that has nothing to do with this case because all agree that NECC never delivered or administered MPA to any Plaintiff, Defendants did.

[29] ASC also argues that, although the Indiana Legend Drug Act, Ind. Code ch. 16-42-19, provides labeling requirements for prescription drugs, these requirements do not apply to drugs sold to practitioners. *See* Ind. Code §§ 16-42-19-11 (setting forth labeling requirements including patient name and instructions for use) and 16-42-19-21 (exempting drugs sold to practitioners

from the Ind. Code § 16-42-19-11 labeling requirements). Moreover, "practitioner" is defined to include physicians and other medical professionals with prescription licensure, so the Drug Legend Act's labeling requirements do not apply to Defendants. Ind. Code § 16-42-19-5.[2] Plaintiffs have failed to allege, much less establish, that Defendants violated any federal or state prescription laws.

Conclusion

[30] Because Plaintiffs cannot establish that Defendants' alleged statutory violations caused their injuries or, indeed, that Defendants have violated any federal or state prescription-drugs law whatsoever, any questions regarding negligence *per se* and preemption are moot. Even if we were to assume that an MMA plaintiff *could* discuss allegations of statutory violations in the MRP under certain circumstances (a question we leave for another day), Plaintiffs certainly cannot continue to press those claims in *this* case. We affirm the judgment of the Elkhart trial court in its entirety. We reverse the judgment of the St. Joseph trial court and remand with instructions to enter summary judgment in favor of Defendants on Plaintiffs' federal and state prescription-law claims. This opinion has no effect on Plaintiffs' ability to proceed with their MMA claims as

[2] It is apparent that the provisions Plaintiffs would like us to apply to Defendants—who administered a drug to patients in a clinical setting—are meant to regulate another transaction entirely, in which a doctor evaluates a patient, decides the patient needs a certain drug, and issues a prescription to a pharmacy, which then dispenses the drug to the patient.

they see fit; they may not, however, continue to pursue their allegations of statutory violations or mention them in the MRPs.

[31] We affirm the judgment of the Elkhart trial court. We reverse the judgment of the St. Joseph trial court and remand with instructions.

May, J., and Mathias, J., concur.