Illinois Official Reports

Appellate Court

Urbaniak v. American Drug Stores, LLC, 2019 IL App (1st) 180248

Appellate Court Caption	STEPHAN URBANIAK and SANDRA URBANIAK, Plaintiffs-Appellants and Cross-Appellees, v. AMERICAN DRUG STORES, LLC, d/b/a Osco Drug #3086, Defendant-Appellee and Cross-Appellant.
District & No.	First District, First Division Docket No. 1-18-0248
Filed	March 25, 2019
Decision Under Review	Appeal from the Circuit Court of Cook County, No. 14-L-13331; the Hon. William Gomolinski and the Hon. Kathleen Flanagan, Judges, presiding.
Judgment	Affirmed.
Counsel on Appeal	Michael T. Reagan, of Ottawa, and Bruce R. Pfaff, of Pfaff, Gill & Ports, Ltd., of Chicago, for appellants. Andrew Kopon Jr. and Colette L. Kopon, of Kopon Airdo, LLC, of Chicago, for appellee.
Panel	JUSTICE GRIFFIN delivered the judgment of the court, with opinion. Presiding Justice Mikva and Justice Walker concurred in the judgment and opinion.

OPINION

¶ 1 The learned intermediary doctrine is a fundamental tenet of pharmacological and negligence law in America. The doctrine generally absolves pharmacies and pharmaceutical companies from liability for failing to warn a patient about the potential side effects of prescription drugs. The logic behind the doctrine is to put the burden on the prescribing physician—a learned intermediary—to know the drug's side effects and any of the patient's relevant conditions before prescribing the drug.

¶ 2 In this case, a patient was prescribed and took a drug called Reglan for six years and developed severe movement disorders called tardive dyskinesia and dystonia. The prescribing physician admits that he was unaware of the risk that a patient might develop these movement disorders from the long-term ingestion of Reglan. The doctor has separately settled with the plaintiffs. This appeal concerns whether the pharmacy that filled the prescriptions and dispensed Reglan to plaintiff can be liable for failing to verbally warn him or his doctor about the medical risks associated with the long-term ingestion of Reglan. By operation of the learned intermediary doctrine, the pharmacy cannot be liable for such an alleged omission. We affirm the circuit court's entry of a judgment of no liability for the pharmacy.

¶ 3 I. BACKGROUND

¶ 4 In 2008, plaintiff Stephan Urbaniak was under the care of a gastroenterologist who prescribed him a prescription drug called Reglan to treat gastroparesis. Beginning in 2010, plaintiff's primary care physician, Dr. John Ross, took over writing plaintiff's prescription for the drug. Plaintiff took Reglan continuously from May 2008 to August 2014.

¶ 5 In August 2014, plaintiff was diagnosed with tardive dyskinesia and dystonia. Tardive dyskinesia and dystonia are well-known side effects from the prolonged ingestion of Reglan. Tardive dyskinesia is a serious movement disorder that causes involuntary movements of parts of the body. Dystonia is a similar movement disorder that causes involuntary and uncontrollable muscle contractions. There is no known cure for either disorder. Plaintiff is now unable to work and suffers from extensive disabilities.

¶ 6 In February 2009, after plaintiff was prescribed and began taking Reglan, the Food and Drug Administration (FDA) approved a black box warning for the drug. A black box warning is the strongest form of warning that the FDA requires for prescriptions, and it indicates that there is reasonable evidence that there are serious or life-threatening risks associated with taking the drug. The black box warning for Reglan, speaking in terms of its generic name, metoclopramide, addresses tardive dyskinesia directly.

> "WARNING: TARDIVE DYSKINESIA
>
> Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose.
>
> Metoclopramide therapy should be discontinued in patients who develop signs of symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.

> Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia."

¶ 7 For the six years he took Reglan, plaintiff had all of his prescriptions filled at Osco Drug (Osco)—a local retailer of defendant American Drug Stores, LLC. Osco receives Reglan in containers of 500 pills from the manufacturer and divides them up to distribute to consumers. The 500-pill containers it received during the period relevant to this case contained a package insert that included the FDA's black box warning. When dispensing Reglan, Osco distributed a medication guide to consumers. The medication guide for Reglan provided warnings and other information about the drug, including the warning about tardive dyskinesia from the FDA. However, Osco never verbally warned plaintiff about the risks associated with taking Reglan longer than 12 weeks.

¶ 8 During his time of prescribing Reglan to plaintiff, Dr. Ross was unaware of the tardive dyskinesia risks associated with the long-term use of Reglan. Thus, Dr. Ross never informed plaintiff of the risk of developing tardive dyskinesia, and he continued to write the prescriptions for the drug for years. Osco had frequent contact with Dr. Ross during the period plaintiff was taking Reglan, and it never informed the doctor of the risks associated with taking Reglan longer than 12 weeks.

¶ 9 Plaintiff filed this case against Dr. Ross, Dr. Ross's professional corporation, and the pharmacy. The doctor and his professional corporation settled the case for their insurance policy limits. Osco moved for summary judgment on the claims against it, arguing that it had no duty to warn plaintiff or his doctor about plaintiff being at risk of developing tardive dyskinesia and dystonia as a result of taking Reglan for longer than 12 weeks. Depositions and other discovery were taken, and the trial court entered summary judgment in Osco's favor, finding that it did not owe plaintiff the duty of care it was alleged to have breached. Plaintiff appeals.

¶ 10 II. ANALYSIS

¶ 11 Plaintiff appeals the trial court's order entering summary judgment in defendant's favor. Summary judgment is appropriate when the pleadings, depositions, admissions and affidavits, viewed in a light most favorable to the nonmovant, fail to establish that a genuine issue of material fact exists, thereby entitling the moving party to judgment as a matter of law. 735 ILCS 5/2-1005 (West 2012); *Fox v. Seiden*, 2016 IL App (1st) 141984, ¶ 12. We review a trial court's decision to grant summary judgment *de novo*. *Illinois Tool Works Inc. v. Travelers Casualty & Surety Co.*, 2015 IL App (1st) 132350, ¶ 8.

¶ 12 Defendant was granted summary judgment on the basis that it did not owe plaintiff the duty of care that it was alleged to have breached; namely that it was under no legal duty to warn plaintiff or his doctor about the risks of taking Reglan for a prolonged period. In cases where a pharmacy is alleged to be negligent for failing to warn a consumer about the risks of a drug it dispenses, Illinois courts look to the same factors reviewed in any typical negligence case to determine whether a plaintiff is owed the relevant duty of care. See *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 186-87 (2002). To determine whether a duty exists in a particular case, courts look to certain relevant factors, including (1) the reasonable foreseeability that the defendant's conduct may injure another, (2) the likelihood of an injury occurring, (3) the

magnitude of the burden of guarding against such injury, and (4) the consequences of placing that burden on the defendant. *Id.*

¶ 13 Frequently at issue in pharmaceutical cases, the "learned intermediary doctrine" has a role in this case. The learned intermediary doctrine helps courts to decide which participant in the chain of administering prescription drugs to consumers should be charged with the duty to warn patients about the potential adverse side effects. See *Hernandez v. Schering Corp.*, 2011 IL App (1st) 093306, ¶ 30. In its most basic form, the learned intermediary doctrine obligates drug manufacturers to warn only physicians about the potential risks of a drug, and then physicians are required to use medical judgment to determine which warnings to provide to patients to whom the drug is prescribed. *Martin v. Ortho Pharmaceutical Corp.*, 169 Ill. 2d 234, 238-39 (1996). The doctor acts as an intermediary of the information for the benefit of and on behalf of the patient. The learned intermediary doctrine applies to pharmacists in the same way that it does drug manufacturers—the duty to warn of side effects is not placed on the pharmacist, it is placed on the prescribing physician. *Leesley v. West*, 165 Ill. App. 3d 135, 143 (1988) (citing *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507, 524 (1987)).

¶ 14 A pharmacist owes just a duty of ordinary care in practicing his profession. *Eldridge v. Eli Lilly & Co.*, 138 Ill. App. 3d 124, 126 (1985). However, we have explained that a pharmacist's duty to its customers nonetheless requires "the highest degree of prudence, thoughtfulness and diligence, and it is proportioned to the danger involved." *Id.* Because of the learned intermediary doctrine, a pharmacist generally has no independent duty to warn a consumer about the potential dangers of a prescribed drug. *Jones v. Irvin*, 602 F. Supp. 399, 402 (S.D. Ill. 1985) (applying Illinois law); *Eldridge*, 138 Ill. App. 3d at 127. But a duty to warn, including in the pharmaceutical context, can be found where there is unequal knowledge of a dangerous condition and the defendant, possessed of that knowledge, knows or should know that harm might or could occur if no warning is given. *Kennedy v. Medtronic, Inc.*, 366 Ill. App. 3d 298, 304-05 (2006). The duty of care that pharmacists sometimes owe to their customers to warn them of the dangerous side effects of prescription drugs is still regarded as a narrow one. See *Happel*, 199 Ill. 2d at 189, 197.

¶ 15 To be clear in defining the issue in this case, it is not whether Osco had a generalized duty to warn plaintiff about the dangers of Reglan, because it did so in writing. The issue is whether Osco had a specific duty to verbally advise defendant about the risks of the prolonged ingestion of Reglan or to advise the prescribing physician about the risks of taking Reglan long term.

¶ 16 Plaintiff argues that he was legally entitled to be warned by Osco because "Osco's employees should have known that Stephan had taken the drug for years and that the risk of a serious neurological injury was cumulative." Plaintiff points out that it is "highly unusual" for a black box prescription warning to have a time limitation—12 weeks in this case—and that Osco's pharmacists "should have told Dr. Ross and Stephan about the 12 week warning so they could have evaluated whether to continue the drug."

¶ 17 Going through the factors our courts use to determine whether a duty exists in a particular case, plaintiff opines that it is reasonably foreseeable that injury will result from dispensing a drug for more than six years that is known to cause tardive dyskinesia when taken for more than 12 weeks. The likelihood of an injury occurring is supported by "reasonable evidence" according to the FDA, and the risk increases with the duration of treatment and the total cumulative dose. Plaintiff suggests that the magnitude of guarding against the injury is "slight" because there are very few drugs that have severe dangers based on the duration of their

administration. And plaintiff argues that the consequence of placing a duty to warn on pharmacies with regard to Reglan are limited and are already embraced by Osco's policy of providing "conscientious pharmaceutical care" by always using "professional judgment to accurately audit prescriptions."

¶ 18 The arguments submitted by plaintiff suggest a tacit acknowledgement that, were we to rule in his favor, we would be expanding any duty our courts have previously recognized for pharmacists in Illinois. Plaintiff asks that we find Osco to have had a duty "to be aware of the black box time limitation, to make sure that the refill does not exceed the limitation, and if it does, discuss that issue with the doctor or patient." Such a rule would require pharmacies to inquire into the doctor's judgment about, at a minimum, the duration of prescriptions when side effects could develop from long-term use. Plaintiff makes clear that he is not asking us to find a duty for pharmacists "to monitor every patient's prescriptions of every kind." Nonetheless, a proper application of the learned intermediary doctrine means that plaintiff cannot demonstrate that the pharmacy in this case was legally obligated to inform him about the potential side effects of the drug prescribed to him.

¶ 19 It is the pharmaceutical company's obligation to inform the doctor about potential adverse effects of a drug, and then it is the doctor's obligation to take that information into account, decide what drug to prescribe, and then to prescribe the drug and a regimen for delivering the drug: dosage, duration, and so on. See *Eldridge*, 138 Ill. App. 3d at 127. From the pharmacy's perspective, the prescribing physician is presumed to have knowledge of the potential adverse side effects of the drug he is prescribing. If the physician prescribes the drug in spite of the side effects he is presumed to know, it is the doctor's burden to warn the patient. See *Frye v. Medicare-Glaser Corp.*, 153 Ill. 2d 26, 34 (1992) ("consumers should principally look to their prescribing physician to convey the appropriate warnings regarding drugs, and it is the prescribing physician's duty to convey these warnings to patients"). Plaintiff wants us to allocate some of that burden to the pharmacist.

¶ 20 As we recently stated, we have "consistently declined to impose upon a pharmacy any duty to monitor patients, make medical decisions, or to warn a physician or a patient of 'excessive' prescribed doses." *Hernandez v. Walgreen Co.*, 2015 IL App (1st) 142990, ¶ 24. Illinois law imposes "no duty on a pharmacist to warn the customer or notify the physician that drugs are being prescribed in dangerous amounts, that the customer is being overmedicated or that various drugs in the prescribed quantities could have an adverse effect." (Internal quotation marks omitted.) *Id.* ¶ 25.

¶ 21 Osco also *did* warn plaintiff about the dangers of taking Reglan for longer than 12 weeks. It just did so in writing, and plaintiff argues that it should have been done verbally. That is not a theory of liability the court can accept. Osco passed along the warning from the FDA. Plaintiff admits that he never read the medication guide given to him with his prescription. Plaintiff posits that Osco should have waded further into the situation. But the learned intermediary doctrine dictates that pharmacists stay out of the physician-patient relationship. *Happel*, 199 Ill. 2d at 194-95. And, when it comes to prescription drugs, the extent of the warnings to be given to patients is within the discretion of the physician. *Frye*, 153 Ill. 2d at 34. The legal framework, through application of the learned intermediary doctrine, places the responsibility for providing medical advice on the doctor, not the pharmacist.

¶ 22 Osco was not required to inquire about Dr. Ross's medical judgments or question the physician's wisdom concerning the regimen for administering the drug; it was required to

dispense to the patient the drug that the doctor prescribed to the patient. Osco had no reason to know that the doctor was ignorant of the effects of the drug for which he wrote a prescription, and Osco had no independent duty to inquire into the doctor's pharmaceutical competence. Osco likewise had no reason to know that Reglan could be dangerous to plaintiff specifically as opposed to the general public.

¶ 23 The deposition testimony in this case revealed that the 12-week timetable for administering Reglan is by no means absolute. Dr. Lue, who prescribed Reglan to plaintiff in the first place, stated that he has a number of patients to whom he has prescribed Reglan and that many have taken it for far longer than 12 weeks. The black box warning itself does not say Reglan cannot or should not be prescribed or taken for more than 12 weeks; it just states that there are accompanying medical risks. Those are risks that must be considered by the doctor, not the one simply dispensing the medication. The decision to prescribe Reglan and to continue prescribing Reglan are medical decisions. Osco is fully entitled to presume that Dr. Ross knew about the potential consequences of Reglan and prescribed it to plaintiff in spite of those warnings. Putting any further burden on Osco would require it to question doctors' medical judgment or question their competency when, knowing almost nothing about the patient's medical condition, the patient presents a prescription that could be unwise or inadvisable for any number of reasons.

¶ 24 Plaintiff was prescribed Reglan for a number of years by two different doctors who were the ones in the position to verbally warn plaintiff about the risks of Reglan. The deposition testimony reveals that, obviously, plaintiff's primary care doctor could not have warned him about the relevant side effect of the drug because the doctor did not know about it himself. But because plaintiff's doctor fell short on his obligation to know about the drugs he was prescribing, plaintiff seeks to hold the pharmacy responsible for simply carrying out the doctor's directives and doing so as directed. The learned intermediary doctrine places the legal duty in such cases on the doctor, not the pharmacy.

¶ 25 It is the doctor's duty to know what he is prescribing, and it is the pharmacy's duty to give the patient what the doctor orders. *Fakhouri v. Taylor*, 248 Ill. App. 3d 328, 333 (1993). Plaintiff is asking that we require much more of the pharmacy. He asks us to have the pharmacy enter the realm of inquiring into what medication regimen is appropriate for a patient—a medical judgment best addressed to the doctor.

¶ 26 The parties have not pointed us to any case law directly addressing a pharmacist's duty related to administering a drug for a potentially unsafe duration, but a close analogue is presented in cases addressing a pharmacist's duty related to administering a drug in a potentially unsafe dose. Discussing Illinois law, the United States District Court for the Southern District of Illinois described the varying role of those involved in the pharmaceutical delivery system and how the primary burden is placed on the doctor and not the pharmacist.

> "It is the duty of the prescribing physician to know the characteristics of the drug he is prescribing, to know how much of the drug he can give his patient, to elicit from the patient what other drugs the patient is taking, to properly prescribe various combinations of drugs, to warn the patient of any dangers associated with taking the drug, to monitor the patient's dependence on the drug, and to tell the patient when and how to take the drug. Further, it is the duty of the patient to notify the physician of the other drugs the patient is taking. Finally, it is the duty of the drug manufacturer to notify the physician of any adverse effects or other precautions that must be taken in

> administering the drug. [Citation.] *Placing these duties to warn on the pharmacist would only serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability*." (Emphasis added.) *Jones*, 602 F. Supp. at 402.

¶ 27 Plaintiff advocates for a ruling that would require pharmacies to investigate the appropriateness of a prescription for the patient. Plaintiff is asking us to require the pharmacy to skeptically question the doctor's judgment and to delve into whether the doctor's judgment is being exercised prudently. That is precisely the result that the application of the learned intermediary doctrine precludes. The rationale behind the learned intermediary doctrine is that, because the prescribing physician has expert knowledge of the drugs he is prescribing and, more importantly, knowledge of his patient's medical history, it is the physician who is in the best position to prescribe drugs and monitor their use. *Happel*, 199 Ill. 2d at 193.

¶ 28 Our courts have already made clear that pharmacies do not have a duty to determine whether a prescription is "excessive" (see, *e.g.*, *Fakhouri*, 248 Ill. App. 3d at 330; *Hernandez*, 2015 IL App (1st) 142990, ¶ 44), and there is no basis to make a legal distinction between an excessive dose for a regular duration and a regular dose for an excessive duration. The rationale for not imposing a duty on the pharmacists in such cases is that the pharmacists did nothing more than fill prescriptions as ordered by physician. *Fakhouri*, 248 Ill. App. 3d at 331-32. To impose a duty to verbally warn on the pharmacist would be to place the pharmacist in the middle of doctor-patient relationship. See *id.* at 323-33.

¶ 29 Plaintiff relies heavily on our supreme court's decision in *Happel*, 199 Ill. 2d 179, for his position that Osco should be liable here. That case is readily distinguishable from the situation presented in this case. In *Happel*, the supreme court stated that a pharmacy could be liable for dispensing drugs to a customer where the pharmacy dispensed a drug to a customer despite that it *knew* of the customer's allergies, *knew* that the prescribed drug was contraindicated for a person with the customer's allergies, and *knew* that injury or death was substantially certain to result from the contraindication. *Id.* at 187-90. The supreme court held that the reasons for generally applying the learned intermediary doctrine were not present in that case because the pharmacy knew both that the customer had a drug allergy and that the prescription written for the customer was contraindicated and dangerous for someone with that allergy. *Id.* at 194.

¶ 30 Here, there is not any allegation that the pharmacy knew of any potential problems with plaintiff taking Reglan. Some of those working in the pharmacy did not even know about the warning, but again, it was plaintiff's physician's duty to know. In attempting to bring this case into some harmony with *Happel*, plaintiff presented evidence on "contraindications" like the drug allergy presented in *Happel*. Plaintiff argues that since he should have been warned about the risks of a longer-than-12-week Reglan treatment, "[f]or him, Reglan was 'relatively contraindicated' for six years."

¶ 31 Our supreme court addressed contraindications in *Happel* and stated that "[a] contraindication is a serious limitation on a drug's use, necessarily implying grave consequences if it is ignored." *Id.* at 189. The court continued by explaining that a court in another jurisdiction had noted that "a contraindication refers to 'a circumstance under which the drug must never be given.' " *Id.* (quoting *Hand v. Krakowski*, 453 N.Y.S.2d 121, 123 (App. Div. 1982)). Other courts have used the definition for contraindications used by the American Medical Association, that a "contraindication" is " '[a] factor in a person's condition that makes it inadvisable to participate in a particular treatment, such as taking a certain medication or undergoing surgery.' " *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 823 n.2 (7th Cir.

2010) (quoting American Medical Association Complete Medical Encyclopedia 404 (Jerrold B. Leikin & Martin S. Lipsky eds., 2003)).

¶ 32 Under either or any definition, contraindications refer to specific treatments that might be harmful to a specific patient—like where a specific drug should not be used for a specific person at a specific time. But plaintiff is really trying to make the case that Reglan should be considered contraindicated for *anyone* after 12 weeks of use. Contraindications speak in terms of specific patients and specific treatments. Reglan was not specifically contraindicated for plaintiff for any articulable reason. Plaintiff presented with no allergy, and there was no concern about the interaction of multiple drugs in this case. There is no specific reason that the pharmacy could have known about that would have made plaintiff specifically someone who could not be treated with Reglan longer than 12 weeks. In *Happel*, it was clear that the drug prescribed to the customer could have never been taken safely and no medical judgment to the contrary would change that. Here, the deposition testimony in the record is clear that Reglan can be and often is prescribed for and taken for a period longer than 12 weeks—it just requires an exercise of medical judgment.

¶ 33 While the supreme court in *Happel* found that the facts presented therein took the case "outside the purview of the learned intermediary doctrine," the facts presented here put the case squarely within the doctrine's purview. Osco did not owe plaintiff the duty of care that it is alleged to have breached. The circuit court properly granted summary judgment for Osco.

¶ 34 III. CONCLUSION

¶ 35 Accordingly, we affirm.

¶ 36 Affirmed.