

NOTICE: This order was filed under Supreme Court Rule 23(b) and is not precedent except in the limited circumstances allowed under Rule 23(e)(1).

IN THE
APPELLATE COURT OF ILLINOIS
SECOND DISTRICT

SANDRA MEINHART,)	Appeal from the Circuit Court
)	of De Kalb County.
Plaintiff-Appellant,)	
)	
v.)	No. 20 L 26
)	
HY-VEE, INC., d/b/a Hy-Vee Pharmacy; J.P.;)	
J.C.R.; SOLCO HEALTHCARE, US., LLC,)	
)	
Defendants)	
)	
(Hy-Vee, Inc, d/b/a Hy-vee Pharmacy;)	Honorable
and Solco Healthcare, US, LLC,)	Bradley J. Waller,
Defendants-Appellees).)	Judge, Presiding.

PRESIDING JUSTICE BRENNAN delivered the judgment of the court.
Justices McLaren and Jorgensen concurred in the judgment.

ORDER

- ¶ 1 *Held:* The trial court did not err in granting defendants' motions to dismiss plaintiff's fifth amended complaint with prejudice. Plaintiff's negligence and *res ipsa loquitur* counts against the supplier of a generic anti-epileptic-seizure medication and the pharmacy that dispensed plaintiff's prescription for the medication failed to state a claim. Plaintiff forfeited her argument that the trial court erred in dismissing her strict liability count. Affirmed.
- ¶ 2 Plaintiff, Sandra Meinhart, sued, *inter alios*, Hy-Vee, Inc., doing business as Hy-vee Pharmacy (Hy-Vee), and Solco Healthcare, US, LLC (Solco) for damages arising out of her

ingestion of an anti-epileptic-seizure medication packaged and distributed by Solco and dispensed by the pharmacy Hy-Vee. The trial court granted defendants' motions to dismiss the operative complaint with prejudice for failure to state a claim and on federal preemption grounds. Plaintiff timely appealed. The claims at issue on appeal are two negligence counts, premised upon theories of voluntary undertaking and *res ipsa loquitur*, and a strict liability count for defective product and failure to warn. For the reasons set forth below, we affirm.

¶ 3

I. BACKGROUND

¶ 4 Plaintiff initiated this lawsuit on April 14, 2020. The named defendants in the complaint, first amended complaint, and third amended complaint (there was no second amended complaint) were Hy-Vee (the pharmacy), "J.P." (Hy-Vee's registered pharmacist), and "J.C.R." (Hy-Vee's registered pharmacist's technician). J.P. and J.C.R. were never served and never appeared; they are not parties to this appeal. In the fourth and fifth amended complaints, plaintiff added Solco (the packager and distributor of the medication) as a defendant.

¶ 5 The complaints included, collectively and in relevant part, counts for negligence premised on a theory of voluntary undertaking, negligence premised on a theory of *res ipsa loquitur*, and strict liability based upon defective manufacturing and failure to warn. (Additional counts for negligent misrepresentation, breach of warranty, and violation of the Illinois Consumer Fraud and Deceptive Business Practices Act (815 ILCS 505/1 *et seq.* (West 2020)) were ultimately dismissed with prejudice and are not at issue in this appeal). While the operative complaint is the fifth amended complaint, to place the procedural history and the parties' arguments in context, we discuss, in relevant part as to the counts at issue on appeal, the iterations of the complaint, defendants' respective motions to dismiss, and the trial court's rulings thereon.

¶ 6

A. Complaint

¶ 7 Plaintiff alleged that she was prescribed and takes levetiracetam—a generic anti-epileptic-seizure medication. On March 6, 2019, Hy-Vee dispensed the prescription with pink levetiracetam pills rather than the yellowish-white levetiracetam pills Hy-Vee regularly provided. Plaintiff alleged that she asked the pharmacist if it was safe to take the pink pills and the pharmacist responded that it would be “o.k.”

¶ 8 Plaintiff alleged that, in late April 2019, after finishing her remaining yellowish-white pills, she began to take the pink pills. On April 30, 2019, plaintiff suffered three seizures and was admitted to the hospital. She suffered an additional seizure the next day, on May 1, 2019. Plaintiff alleged that, around this two-day time period, her levetiracetam level was 1.9—“well below the therapeutic range of 12-46 mcg/ml.” Plaintiff further alleged that the change in the levetiracetam source was the cause of her seizures. According to plaintiff, she had “always taken the ‘yellowish white’ Levetiracetam for the past ten (10) years and did well on it, and had been seizure free for seven (7) years prior to April 30, 2019.”

¶ 9 Regarding the negligence claim, plaintiff alleged that Hy-Vee had a duty to dispense the medication without a change in the source and to warn of dangers associated with the substituted source. Regarding the strict liability claim, plaintiff alleged that the levetiracetam “was, at the time it was sold, in a defective condition that was unreasonably dangerous when put to a reasonably anticipated use because the medication it contained was from a new, substituted source, that was different than prior dispenses, thereby preventing Plaintiff from receiving the therapeutic benefits of the Levetiracetam as prescribed for her by her physician.”

¶ 10 Hy-Vee moved to dismiss the initial complaint for failure to state a claim pursuant to section 2-615 of the Illinois Code of Civil Procedure (Code) (735 ILCS 5/2-615 (West 2020)) on the ground that plaintiff failed to plead a duty. Namely, Hy-Vee argued that substituting the source

of a prescription drug, unless prohibited by the prescribing physician, is expressly allowed by section 25 of the Illinois Pharmacy Practice Act (Act) (225 ILCS 85/25 (West 2020)). Moreover, Hy-Vee argued that, under the “learned intermediary doctrine,” the duty to warn of potential dangers associated with a prescription drug is placed on the prescribing physician, and generally not on the pharmacist.

¶ 11 Plaintiff responded that anti-epileptic medication is treated differently under the Act. Indeed, according to plaintiff, section 26 of the Act (225 ILCS 85/26 (West 2020)) places an independent duty on the pharmacist to provide written notice to the patient if the pharmacist substitutes anti-epileptic medication. Moreover, plaintiff argued that a duty arose under a voluntary undertaking theory based upon the allegation that the Hy-Vee pharmacist’s response that it would be “o.k.” to take the pink pills. According to plaintiff, an exception to the learned intermediary doctrine also applied given the pharmacist’s actual knowledge of a dangerous epileptic condition and the risk of serious harm from failure to warn of the substituted medication. See *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 197 (2002) (recognizing a “narrow” duty to warn where a pharmacy has patient-specific information about drug allergies and knows that the prescribed drug is contraindicated for the patient).

¶ 12 In reply, Hy-Vee pointed out, *inter alia*, that section 26 of the Act did not apply because there was no “do-not-substitute” instruction from plaintiff’s prescribing physician. See 225 ILCS 85/26(c) (West 2020) (“When the prescribing physician has indicated on the original prescription “may not substitute,” a pharmacist may not interchange an anti-epileptic drug or formulation of an anti-epileptic drug for the treatment of epilepsy without notification and the documented consent of the prescribing physician and the patient or the patient’s parent, legal guardian, or spouse.”). In addition, there was no allegation that a generic drug was substituted for a brand name drug. See

id. § 26(d) (“If a pharmacist substitutes any generic prescription in place of a brand-name anti-epileptic drug, then the pharmacist shall provide written notice to the patient no later than the time the prescription is dispensed.”). Rather, plaintiff alleged that one generic brand was substituted for another generic brand.

¶ 13 Following argument, the trial court granted Hy-Vee’s motion to dismiss and dismissed the complaint without prejudice and with leave to file an amended complaint. The trial court reasoned that Hy-Vee was shielded from liability under the learned intermediary doctrine and that plaintiff failed to plead the application of any exception to the doctrine. Specifically, trial court reasoned that “as alleged the answer with merely ‘okay’ does not create a voluntary undertaking.” Rather, Hy-Vee “did not undertake to do anything more than substitute generic for generic and the answer the word ‘okay’ does not create the duty contemplated by *Happel*.”

¶ 14 In addition, the trial court found no duty to warn under section 26(c) of the Act because there was no allegation that plaintiff’s physician indicated “may not substitute” on the prescription. The court also found no duty to warn under section 26(d) of the Act because there was no allegation that a generic drug was substituted for a brand name.

¶ 15 B. First Amended Complaint

¶ 16 In her first amended complaint, plaintiff realleged her negligence and strict liability claims against Hy-Vee. Plaintiff maintained the allegation that she asked the pharmacist if it was safe to take the pink pills but added that the pharmacist responded that it would be “o.k. to take” (as opposed to the response of “o.k.” alleged in the initial complaint). Plaintiff also added the allegation that substitution of the source of her prescribed levetiracetam was prohibited by section 26 and that Hy-Vee had a statutory duty to warn plaintiff of the increased danger posed by the medication from the substituted source. Plaintiff alleged that her treating physician was not

notified of the substitution and would not have documented her consent had she been notified. Plaintiff continued to allege that she had taken the yellowish-white pills for the past 10 years and had been seizure-free for 7 years prior to April 30, 2019.

¶ 17 Hy-Vee filed a motion to dismiss the first amended complaint pursuant to section 2-619.1 of the Code of Civil Procedure (735 ILCS 5/2-619.1 (West 2020)). Hy-Vee sought dismissal of the negligence count under section 2-615 on the basis that there is no duty in section 26 to warn of an increased danger from a substituted source. Hy-Vee also sought dismissal of the negligence and strict liability counts pursuant to section 2-619(a)(9) of Code of Civil Procedure (735 ILCS 5/2-619(a)(9) (West 2020)) on the basis that the claims were barred by other affirmative matter—namely, that plaintiff’s prescription refuted her allegation that Hy-Vee had a duty to dispense levetiracetam without changing the source. In support, Hy-Vee attached an affidavit from a pharmacist explaining that plaintiff’s prescription included the notation “DAW:0 No Product Selection Indicated,” which meant that there was no prohibition against a substituted source.

¶ 18 In response, plaintiff acknowledged the substitution code on the prescription but nevertheless relied upon an affidavit from her treating physician, who attested that, had the Hy-Vee pharmacist notified her of the medication change, she would not have documented her consent to the change. According to plaintiff’s treating physician, the change in source was more likely than not the cause of plaintiff’s seizures. Plaintiff also argued that her negligence and strict liability claims were sufficiently alleged “given the medication[’]s patent failure to maintain a therapeutic level of levetiracetam.”

¶ 19 Following argument, the trial court granted Hy-Vee’s motion to dismiss, dismissed the negligence count with prejudice, and the strict liability count without prejudice. The trial court found that the uncontroverted evidence established that substitutions were permitted; thus, there

was no duty to warn of any substitution under section 26. Regarding the strict liability claim, the trial court found that plaintiff had only alleged substitution of the drug, not that there was something wrong with “the drug in and of itself.”

¶ 20

C. Third Amended Complaint

¶ 21 In her third amended complaint against Hy-Vee, plaintiff maintained the strict liability count and added a count entitled “Res Ipsa Loquitar [*sic*].” Plaintiff no longer alleged that the levetiracetam was a do-not-substitute prescription. However, she alleged that the prescription was adulterated. In this regard, plaintiff further alleged that “[o]n March 6, 2019, [she] had a prescription for 500 MG of Levetiracetam, which was filled by Defendants. One bottle contained pills with materially less than 500 MG of Levetiracetam.” Plaintiff continued to allege that she had taken the yellowish-white pills for the past 10 years and had been seizure-free for 7 years prior to April 30, 2019. Plaintiff added the allegation that the adulterated pink pills caused her seizures.

¶ 22 Regarding the *res ipsa loquitar* count, plaintiff alleged that there was “an inference of negligence and causation” against Hy-Vee because: (1) the adulterated pills were under its management and control when manufactured; (2) plaintiff’s levetiracetam level could not have dropped below the therapeutic range but for negligence in the design, manufacture, inspection, or compounding of the pink pills sold to plaintiff on March 6, 2019; (3) Hy-Vee was solely responsible for all likely causes of the injury given the substantial deviation in levetiracetam levels after plaintiff’s consumption of the adulterated pills; and (4) plaintiff did not contribute to or cause her injury because she took the medication as prescribed as she had done for years prior. According to plaintiff, Hy-Vee’s negligence was a direct and proximate cause of her injuries by “sourcing pink pills in an adulterated state that were compounded in a form materially less than 500 mg.”

¶ 23 Hy-Vee filed a motion to dismiss pursuant to section 2-621 of the Code (735 ILCS 5/2-621 (West 1994)) on the ground that it was not the product manufacturer. See *Cassidy v. China Vitamins, LLC*, 2018 IL 122873, ¶¶ 1, n.1, 14 (section 2-621 “sets forth a scheme that allows a defendant that is not a manufacturer of the allegedly defective product at issue in a strict liability action to seek dismissal after it accurately certifies the identity of the product’s manufacturer”; upon the filing of a complaint that the manufacturer is required to answer, the trial is required to dismiss the strict liability claim against the certifying nonmanufacturer-defendant, in the absence of certain limitations). After entering and continuing the section 2-621 motion, the trial court granted plaintiff’s motion for leave to amend the complaint to add a new defendant.

¶ 24 D. Fourth Amended Complaint

¶ 25 Plaintiff added Solco as a defendant in her fourth amended complaint.¹ Plaintiff maintained the *res ipsa loquitur* and strict liability counts against both defendants. Plaintiff maintained the allegation that the March 6, 2019, prescription was adulterated in that “[o]ne bottle contained pills with materially less than 500 MG of Levetiracetam.” According to plaintiff, the bottle of pills, while labeled levetiracetam, “contained Levetiracetam from an adulterated source compound or make-up *** that was not bearing a ‘pink’ hue.” Plaintiff continued to allege that she had taken

¹Plaintiff alleged that Solco manufactured and supplied the levetiracetam pills. However, Solco stated that it is a packager and distributor of generic levetiracetam that is manufactured by Zhejiang Huahai Pharmaceutical Co., Ltd.—“a foreign company located in China” who “has not been served in this matter and is not joining in this motion.” Neither defendant makes any argument on appeal that dismissal of the strict liability count was warranted pursuant to section 2-621.

the yellowish-white pills for the past 10 years and had been seizure-free for 7 years prior to April 30, 2019.

¶ 26 Hy-Vee moved to dismiss the complaint for failure to state a claim pursuant to section 2-615, reiterating the arguments advanced in its previous motions to dismiss and arguing that the *res ipsa loquitur* count likewise failed to state a claim. Namely, Hy-Vee argued that plaintiff failed to establish the requisite elements of *res ipsa loquitur* by failing to plead either that she was injured in an occurrence that normally does not happen in the absence of negligence or that her prescription was within Hy-Vee's exclusive control.

¶ 27 Solco moved to dismiss the complaint on federal preemption grounds pursuant to section 2-619(a)(9). Solco also moved to dismiss the *res ipsa loquitur* count pursuant to section 2-615 on the basis that plaintiff's allegations were insufficient to meet the elements of the doctrine. Hy-Vee and Solco joined in each other's respective motions to dismiss.

¶ 28 In support of dismissal under section 2-619(a)(9), Solco attached the affidavit of its vice president and head of regulatory affairs, who attested that, on February 10, 2009, the United States Food and Drug Administration (FDA) found "Levetiracetam tablets 250 mg, 500 mg, 750 mg, and 1000 mg to be safe and effective for use as recommended in its submitted labeling and found it to be bioequivalent and therapeutically equivalent to the Branded Keppra tablet."

¶ 29 Solco argued that the FDA's approval of Solco's generic levetiracetam on the basis of its bioequivalency to Keppra meant the generic levetiracetam has the same ingredients, employs the same route of administration, and has the same dosage form, strength, and therapeutic effect as Keppra. In challenging the allegation that the pink pills were adulterated, Solco requested the trial court to take judicial notice of the FDA's "DailyMed website." The website reflects that Solco's generic levetiracetam 500 mg tablets are, and always have been, pink.

¶ 30 Solco argued that plaintiff was essentially attempting to advance a private enforcement action on the basis that the levetiracetam did not have the same active ingredient strength as the brand name Keppra. However, section 337(a) of the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 337(a) (2018)) provides that proceedings for enforcement, or to restrain violations, of the FDCA “shall be by and in the name of the United States.” Accordingly, the right to enforce the FDCA and the FDA regulations promulgated thereunder rests exclusively with the FDA. Thus, Solco argued that plaintiff’s claims are preempted under federal law.

¶ 31 Following argument, the trial court granted both motions to dismiss, dismissed the *res ipsa loquitur* claim with prejudice, and dismissed the strict liability claim without prejudice. Regarding the *res ipsa loquitur* count, the trial court reasoned that, without a surviving negligence count, “it doesn’t seem to me based upon the case law that [the *res ipsa loquitur* count] has a basis or a bearing under the law.” In any event, the trial court reasoned that plaintiff failed to allege that defendants had exclusive control of the medication—a requisite element of the *res ipsa loquitur* doctrine.

¶ 32 Regarding the strict liability count, the trial court found no allegation of the requisite knowledge of an unreasonably dangerous condition to support a failure to warn theory. The trial court also found the allegation that the pink pills had “materially less than 500 MG of Levetiracetam” to be insufficiently specific to support a manufacturing defect claim. Plaintiff failed to plead the amount of levetiracetam in the pills, and it was unclear what “materially” meant. The trial court acknowledged that a defect may be alleged through an inference. However, the trial court reasoned that the inference “must be based on defendant’s liability and not other potential causes such as here as alleged the delay in plaintiff taking the pills *** [and] the seven out of the

ten years where a seizure did and did not occur, so there are other factors or other causes that come into play here.”

¶ 33 In addition, the trial court found that, as alleged, plaintiff’s claims were preempted. After noting the FDA’s findings regarding the bioequivalence of the generic levetiracetam to the brand name drug Keppra and approval of the generic 500 milligram level for this drug, the trial court found that plaintiff’s allegations with respect to the pink hue of the drug did not amount to adulteration. Rather, taking judicial notice of the FDA’s guidelines, the trial court reasoned that “this drug has always been pink or a pink hue and unless there is more specificity regarding the adulteration of this particular drug during the manufacturing process *** or there is something that this pink color would somehow create a defect at this point[,] there is not sufficient specificity ***.” Accordingly, the trial court held that, “although I don’t believe I need to get to the 619 because I’ve ruled on the 615, I do find the 619 to be well-founded[,] but I am going to grant that but it’s going to be without prejudice ***.”

¶ 34 E. Fifth Amended Complaint

¶ 35 The sole surviving count at issue alleged in the fifth amended complaint against Hy-Vee and Solco was the strict liability count. The previously dismissed counts at issue were incorporated for appeal purposes.

¶ 36 In support of her failure-to-warn strict liability claim, plaintiff alleged:

“The bottles containing the pink pills had inadequate warnings. The packaging of the pink pills failed to warn Plaintiff that the pink pills would not deliver the amount of levetiracetam necessary to maintain healthy therapeutic levels.

[] Defendants knew the contents of the bottles due to their role in the manufacturing and packaging process. Defendants had unequal knowledge as compared to Plaintiff of

what Plaintiff's therapeutic levels of Levetiracetam would be if Plaintiff consumed the pink pills as prescribed."

¶ 37 With respect to the manufacturing defect claim, plaintiff eliminated the allegation that one bottle of pink pills contained pills with materially less than 500 milligrams of levetiracetam. Instead, she included five new allegations: (1) as of April 30, 2019, plaintiff's phenobarbital (the other anti-seizure medication she was taking) was within the therapeutic range; (2) plaintiff made no changes in sleep, diet, activity level, or lifestyle after switching to the pink pills and before suffering seizures on April 30, 2019, and May 1, 2019; (3) plaintiff has not suffered seizures since switching back to the yellow pills; (4) the number of seizures plaintiff suffered on April 30, 2019, and May 1, 2019, were the most she has experienced in a short time span, and she never had three seizures in one day before taking the pink pills; and (5) plaintiff's treating physician attributes the seizures to the pink pills.

¶ 38 Plaintiff eliminated the allegation that she had been taking levetiracetam for ten years and was seizure-free for seven years prior to April 30, 2019. Rather, plaintiff alleged:

"Plaintiff's physician prescribed Levetiracetam on a twice-daily basis in order to prevent seizures associated with epilepsy. Plaintiff's prescription called for 1,500 mg of Levetiracetam daily, taking 1,000 mg in the morning and another 500 mg at night. Based on this prescription regimen, Plaintiff had been seizure-free for seven (7) years prior to receiving the Levetiracetam prescription at issue in the present case on March 6, 2019."

¶ 39 Plaintiff alleged that, "[a]fter March 6, 2019, Plaintiff initially consumed her remaining yellowish-white pills of Levetiracetam. Around April 23, 2019, Plaintiff began consuming the pink pills that were filled and dispensed on March 6, 2019." Plaintiff further alleged that she "consumed the pink pills as prescribed in order to maintain her Levetiracetam levels within a therapeutic range,

which was necessary for prevention of seizures.” Plaintiff concluded that “[t]he Levetiracetam defect present in the pills that Plaintiff consumed prevented the Levetiracetam from metabolizing as was intended and expected.”

¶ 40 Hy-Vee and Solco jointly filed a section 2-619.1 motion to dismiss the fifth amended complaint. Regarding their request for dismissal under section 2-615, defendants argued that the failure-to-warn claim remained deficient given the conclusory allegation that defendants knew of the purported defect. Defendants likewise argued that the manufacturing-defect claim remained deficient. Defendants noted that plaintiff had been in possession of the pink pills for over two years with the ability to conduct testing of the levetiracetam pills, yet there was no direct allegation of any defect. While plaintiff may plead circumstantial evidence of a defect, the allegation must lead to an inference of probability that the defect existed. This inference, however, requires that plaintiff negate any secondary causes. According to defendants, plaintiff’s fifth amended complaint does the opposite. Namely, plaintiff continues to plead that she did not start her March 6, 2019, prescription until April 23, 2019, and that she was taking another anti-seizure medication (phenobarbital) at the time of the seizures. Accordingly, defendants argued that “[t]his establishes that other possible causes of her seizures could have been her underlying epilepsy condition or her own lack of use of the medication as prescribed which led to the seizures and low level of the active ingredient.”

¶ 41 Regarding their request for dismissal under section 2-619(a)(9), defendants maintained that plaintiff’s claims were preempted by federal law. As previously argued, the fact that Solco’s packaged levetiracetam 500 milligram tablets were pink is not a factual basis to allege adulteration.

¶ 42 Following argument, the trial court granted the motion to dismiss and dismissed the strict liability claim with prejudice.² The trial court reasoned that plaintiff failed to plead a duty to warn of a purported defect. Moreover, plaintiff failed to allege a particular defect in the pink levetiracetam pills; rather, her allegations were mere conclusory statements that did not specify the nature of the defect. The trial court reasoned that, based on the allegations, any inference of a defect in the pink pills was not appropriate. The trial court concluded that there is no “specific defect that’s alleged that would enable the plaintiff to state a cause of action for strict liability.”

¶ 43 In granting the dismissal with prejudice, the trial court found that there had been sufficient opportunity to allege a defect or facts from which a defect could be inferred. However,

“[A]t no time has there been any allegation that these particular pills or this medication were examined, were sent off to an independent laboratory *** to ascertain whether or not these pills were defective. In other words, did the pills have a sufficient amount of the active ingredient to metabolize appropriately, properly and to maintain the therapeutic level that would be medically mandated by the plaintiff’s physician. At no time has that been alleged, and it would seem to me that would be the hurdle to get over to really allege a viable cause of action. I don’t know that, but it would seem to me that an examination of these pills would have certainly been determinative as to whether or not the efficacy was there in the first instance. I’m no expert on that. None of us are, as far as I know, but that has never been alleged and that seems to me to have been a very, very

²In its written order, the trial court stated that the strict liability count directed against Hy-Vee was dismissed with prejudice pursuant to section 2-615 and that the strict liability count directed against Solco was dismissed with prejudice pursuant to section 2-615 and 2-619.

important issue, and I don't know how we get there without that being done and that hasn't been done for the entirety of this case.”

¶ 44 In addition, the trial court found that federal preemption was an affirmative matter that barred the strict liability claim. Consequently, dismissal with prejudice of the strict liability claim as it pertains to Solco was also warranted under section 2-619.

¶ 45 Plaintiff timely appealed.

¶ 46 II. ANALYSIS

¶ 47 Plaintiff challenges the dismissal of her negligence, *res ipsa loquitur*, and strict liability claims. As set forth above, the counts were dismissed under section 2-615 for failure to state a claim and under section 2-619(a)(9) on the basis of federal preemption.

¶ 48 A section 2-615 motion to dismiss challenges the legal sufficiency of the complaint. 735 ILCS 5/2-615 (West 2020); *Bjork v. O'Meara*, 2013 IL 114044, ¶ 21. “The essential question is whether the allegations of the complaint, when construed in the light most favorable to the plaintiff, are sufficient to establish a cause of action upon which relief may be granted.” *Cochran v. Securitas Security Services USA, Inc.*, 2017 IL 121200, ¶ 11. A section 2-619(a)(9) motion to dismiss admits the legal sufficiency of the complaint but asserts affirmative matter or a defense outside the pleadings to defeat the claim. See 735 ILCS 5/2-619(a)(9) (West 2020); *Bjork*, 2013 IL 114044, ¶ 21. The defendant bears the burden of proving an affirmative defense. *Norabuena v. Medtronic, Inc.*, 2017 IL App (1st) 162928, ¶ 14.

¶ 49 When ruling on a motion pursuant to section 2-615 or section 2-619, a court must accept as true all well-pled facts and any reasonable inferences therefrom. *Patrick Engineering, Inc. v. City of Naperville*, 2012 IL 113148, ¶ 31. Mere conclusions unsupported by specific facts cannot be accepted as true. *Id.* We review *de novo* orders granting section 2-615 and 2-619 dismissals.

Bjork, 2013 IL 114044, ¶ 21. We may affirm on any ground evident in the record. See *Norabuena*, 2017 IL App (1st) 162928, ¶ 36.

¶ 50 With these concepts in mind, we turn to the parties' arguments.

¶ 51 A. Negligence

¶ 52 The essential elements of a common law negligence action are the existence of a duty owed by the defendant to the plaintiff, a breach of that duty, and an injury to the plaintiff proximately caused by that breach. *Bell v. Hutsell*, 2011 IL 110724, ¶ 11. The issue in this case is whether plaintiff adequately pled a duty. "Unless a duty is owed, there can be no recovery in tort for negligence." *Id.* Plaintiff argues that Hy-Vee voluntarily undertook a duty to warn her about the safety of the pink levetiracetam pills. Hy-Vee disputes that plaintiff adequately alleged a voluntary undertaking and argues that the learned intermediary doctrine shields it from liability. We agree, as set forth below.

¶ 53 The learned intermediary doctrine provides that manufacturers of prescription drugs have a duty to warn prescribing physicians of a drug's known dangerous propensities. *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507, 517-19 (1987). The prescribing physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients. *Id.* at 517. In other words, the physician acts as an intermediary between the prescription drug manufacturer and the patient. *Id.* at 519. "The underlying rationale of the learned intermediary doctrine is that, with regard to prescription drugs, which are likely to be complex medicines, it is the prescribing physician who knows both the propensities of the drug and the susceptibilities of his patient, and who therefore is in the best position to prescribe a particular drug for the patient." *Happel*, 199 Ill. 2d at 191.

¶ 54 The learned intermediary doctrine generally extends to pharmacists. *Urbaniak v. American Drug Stores, LLC*, 2019 IL App (1st) 180248, ¶ 13. That is, the duty to warn of dangers involved in taking the drug is placed on the prescribing physician, not on the pharmacist. *Id.* To impose such a duty on the pharmacist “would require the pharmacist to learn the customer’s condition and monitor his drug usage” and thus be required to “interject himself into the doctor-patient relationship and practice medicine without a license.” *Eldridge v. Eli Lilly & Co.*, 138 Ill. App. 3d 124, 127 (1985); see also *Fakhouri v. Taylor*, 248 Ill. App. 3d 328, 332-33 (1993) (“To impose a duty to warn on the pharmacist would be to place the pharmacist in the middle of the doctor-patient relationship, *without* the physician’s knowledge of the patient.”) (Emphasis in original.).

¶ 55 However, a pharmacy has a “narrow” duty to warn where the pharmacy has “patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient.” *Happel*, 199 Ill. 2d at 197. Under such circumstances, “a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger.” *Id.* The narrow duty to warn recognized in *Happel* does not apply here. There was no allegation that the substituted pink levetiracetam was contraindicated for plaintiff. Indeed, on appeal, plaintiff appears to have abandoned reliance on this theory.

¶ 56 Rather, plaintiff argues on appeal that Hy-Vee removed itself from the protection of the learned intermediary doctrine by voluntarily undertaking a duty to advise plaintiff about the safety of the pink levetiracetam pills. According to plaintiff, Hy-Vee undertook this duty when its pharmacist stated that the pink pills were “o.k. to take.”

¶ 57 Hy-Vee responds that plaintiff forfeited her argument by advancing a cursory basis for reversal with a single citation to a case generally setting forth the elements of a voluntary undertaking. See Ill. S. Ct. R. 341(h)(7) (eff. Oct. 1, 2020) (an argument must “contain the

contentions of the appellant and the reasons therefor, with citation of the authorities and the pages of the record relied on”). Although we agree that plaintiff advances a perfunctory analysis of the issue, the deficiencies to which Hy-Vee cites are not so flagrant as to hinder or preclude review. We therefore decline to deem plaintiff’s argument forfeited. See *Carter v. Carter*, 2012 IL App (1st) 110855, ¶ 12 (“Although our review of [appellant’s] brief reveals that it fails to comply with Rules 341(h)(6) and (h)(7), we conclude that her violations of those rules do not hinder our review of the case ***.”)

¶ 58 Section 323 of the Restatement (Second) of Torts (“Negligent Performance of Undertaking to Render Services”), sets forth the voluntary undertaking theory of liability, providing:

“One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other’s person or things, is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if

- (a) his failure to exercise such care increases the risk of such harm, or
- (b) the harm is suffered because of the other’s reliance upon the undertaking.”

Restatement (Second) of Torts § 323 (1965); see also *id.* § 324A (“Liability to Third Person for Negligent Performance of Undertaking”); *Bell*, 2011 IL 110724, ¶¶ 12-13.

¶ 59 According to plaintiff, the Hy-Vee pharmacist voluntarily undertook to advise her that the pink pills were “o.k. to take” in response to plaintiff’s inquiry as to whether the pink pills were safe to take. This allegation does not amount to a voluntary undertaking. As the trial court reasoned, Hy-Vee did not undertake to do anything more than substitute generic for generic. The pharmacist’s alleged statement was a response to a question pertaining to the pills’ pink hue and does not equate to a gratuitous undertaking of a duty to warn about the safety of the pills.

¶ 60 Moreover, the voluntary undertaking theory of liability is narrowly construed. *Bell*, 2011 IL 110724, ¶ 12. Any duty Hy-Vee allegedly assumed was limited to the extent of the undertaking. See *id.* For instance, in *Kasin v. Osco Drug, Inc.*, 312 Ill. App. 3d 823, 827-29 (2000), this court held that, where a pharmacy voluntarily undertook a duty to warn a customer about the side effects of the prescription drug, that duty extended only to the information provided. In other words, the pharmacy removed itself from the protection of the learned intermediary doctrine, but only to the extent that the information supplied was accurate. *Id.* at 828. Accordingly, the pharmacy did not voluntarily assume a duty to reveal all possible side effects by listing only some of the side effects. *Id.* at 828-29 (citing *Frye v. Medicare-Glaser Corp.*, 153 Ill. 2d 26, 33-34 (1992) (the pharmacy did not assume a duty to warn of all side effects by placing a “may cause drowsiness” label on the prescription container)).

¶ 61 Plaintiff did not allege that the Hy-Vee pharmacist failed to exercise reasonable care in responding that the pink levetiracetam pills were “o.k. to take.” There was no allegation that the pharmacist knew or should have known that the levetiracetam level in the pink pills was allegedly not equivalent to the level in the yellowish-white pills. The pharmacist merely responded to plaintiff’s question about the color difference in the prescription, affirming that the prescription was in fact correctly filled. To hold otherwise would undermine the purpose of the learned intermediary doctrine by imposing a duty on the pharmacist that would require interjecting himself into the doctor-patient relationship. In sum, there was nothing pled that would remove Hy-Vee from the protection of the learned intermediary doctrine. Thus, the trial court properly dismissed the negligence claim.

¶ 62

B. Res Ipsa Loquitur

¶ 63 Our supreme court recently recounted the nature and purpose of the *res ipsa loquitur* doctrine (“ ‘the thing speaks for itself’ ”) as follows:

“ ‘When a thing which caused the injury is shown to be under the control or management of the party charged with negligence and the occurrence is such as in the ordinary course of things would not have happened if the person so charged had used proper care, the accident itself affords reasonable evidence, in the absence of an explanation by the party charged, that it arose from want of proper care. [Citations.] This in essence is the doctrine of *res ipsa loquitur*, and its purpose is to allow proof of negligence by circumstantial evidence when the direct evidence concerning cause of injury is primarily within the knowledge and control of the defendant.’ ” *Johnson v. Armstrong*, 2022 IL 127942, ¶ 33 (quoting *Metz v. Central Illinois Electric & Gas Co.*, 32 Ill. 2d 446, 448-49 (1965)).

¶ 64 Accordingly, plaintiff was required to plead (1) that she was injured in an occurrence that normally does not happen in the absence of negligence (the probability element) (2) by an agency or instrumentality within defendants’ exclusive control (the control element). See *id.* ¶ 35. “ [T]he requisite control is not a rigid standard, but a flexible one in which the key question is whether the probable cause of the plaintiff’s injury was one which the defendant was under a duty to the plaintiff to anticipate or guard against.’ ” *Id.* ¶ 42 (quoting *Heastie v. Roberts*, 226 Ill. 2d 515, 532 (2007)).

¶ 65 Plaintiff argues that the trial court failed to recognize *res ipsa loquitur* as a separate theory for proving negligence. This distinction, however, was not the basis of the trial court’s ruling. Rather, the trial court reasoned that, having failed to state the elements of a negligence claim (including the existence of duty), plaintiff could not state a *res ipsa loquitur* claim. We agree.

¶ 66 Importantly, “*res ipsa loquitur* is not a claim in and of itself; rather, it is an evidentiary doctrine that allows a plaintiff to prove negligence under a unique set of proofs.” *Id.* ¶ 23. That is, satisfaction of the *res ipsa loquitur* elements is not sufficient to establish a cause of action for negligence. *Id.* ¶ 55. A plaintiff still must establish the elements of a negligence claim apart from pleading *res ipsa loquitur*. *Id.*; see also *Spidle v. Steward*, 79 Ill. 2d 1, 7 (1980) (*Res ipsa loquitur* “will not apply unless a duty of care is owed by the defendant to the plaintiff.”); *Carroll v. Faust*, 311 Ill. App. 3d 679, 687 (2000) (“Initially, a trial court must decide whether, as a matter of law, the *res ipsa loquitur* doctrine is applicable, and it will not apply unless a duty of care is owed to the plaintiff.”).

¶ 67 Here, plaintiff failed to plead that defendants owed her a duty—an essential element of any negligence claim, regardless of the manner of evidentiary proof. See *Bell*, 2011 IL 110724, ¶ 11. A review of plaintiff’s *res ipsa loquitur* count reflects a litany of allegations regarding defendants’ control of the pink pills and plaintiff’s low levetiracetam level after taking the pills despite no changes in her daily regimen. These allegations merely spoke to the *res ipsa loquitur* elements, not to the existence of a duty. As set forth *supra*, plaintiff failed to allege that Hy-Vee voluntarily undertook a duty to warn her about the safety of the pink levetiracetam pills. With respect to Solco, plaintiff did not include an allegation that Solco owed her a duty. Moreover, plaintiff advances no argument on appeal with respect to the source of Solco’s duty and has therefore forfeited the argument pursuant to Rule 341(h)(7).

¶ 68 Having failed to allege that defendants owed her a duty, the trial court properly dismissed plaintiff’s *res ipsa loquitur* count. In light of our holding, we need not address defendants’ argument that the trial court properly dismissed the *res ipsa loquitur* claim on the additional basis

that plaintiff failed to plead sufficiently either the probability element or the control element of the doctrine.

¶ 69 C. Strict Liability

¶ 70 To recover in a strict product liability action, a plaintiff must establish that: (1) the injury resulted from a condition of the product; (2) the condition was unreasonably dangerous; and (3) the condition existed at the time the product left the manufacturer’s control. *Mikolajczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 525 (2008). A product may be found unreasonably dangerous based upon a physical defect in the product itself, a defect in the product’s design, or the manufacturer’s failure to warn of the danger or instruct on proper use of the product. *Id.* Plaintiff’s strict liability count raised failure to warn and manufacturing defect claims. We address each theory in turn.

¶ 71 1. Failure to Warn

¶ 72 “Under a failure to warn theory, a plaintiff must demonstrate that the manufacturer did not disclose an unreasonably dangerous condition or instruct on the proper use of the product as to which the average consumer would not be aware.” *Salerno v. Innovative Surveillance Technology, Inc.*, 402 Ill. App. 3d 490, 499 (2010). Thus, “ ‘[a] manufacturer has a duty to warn where the product possesses dangerous propensities and there is unequal knowledge with respect to the risk of harm, and the manufacturer, possessed of such knowledge, knows or should know that harm may occur absent a warning.’ ” *Id.* (quoting *Sollami v. Eaton*, 201 Ill. 2d 1, 7 (2002)).

¶ 73 Plaintiff argues that she stated a claim for strict liability failure to warn. Defendants respond that plaintiff forfeited this argument pursuant to Rule 341(h)(7) by advancing a mere one-sentence supporting basis—that she “explicitly alleged [in the fifth amended complaint] that the medication at issue contained inadequate warnings.” We agree that the argument is forfeited pursuant to Rule 341(h)(7). This court is “entitled to have issues clearly defined with pertinent authority cited and

cohesive arguments presented, and it is not a repository into which an appellant may foist the burden of argument and research.” (Internal quotation marks omitted.) *Velocity Investments LLC v. Alston*, 397 Ill. App. 3d 296, 297 (2010); see also *Hall v. Naper Gold Hospitality LLC*, 2012 IL App (2d) 111151, ¶ 12 (the plaintiff’s argument, which consisted of two conclusory paragraphs, was forfeited for failure to comply with Rule 341(h)(7)). Plaintiff fails to articulate a legal basis upon which to hold that she stated a failure to warn strict liability claim against defendants. Indeed, plaintiff not only neglects to address the elements of the claim but also fails to identify the basis for a duty to warn in the first instance given application of the learned intermediary doctrine. Accordingly, plaintiff forfeited her argument that the trial court erred in dismissing her failure to warn strict liability claim.

¶ 74

2. Defective Product

¶ 75 To establish strict liability for a manufacturing defect, a plaintiff must demonstrate: (1) a condition of the product that results from manufacturing; (2) the condition made the product unreasonably dangerous; (3) the condition existed at the time the product left the defendant’s control; (4) the plaintiff suffered an injury; and (5) the injury was proximately caused by the condition. *Salerno*, 402 Ill. App. 3d at 498. The central inquiry is whether the allegedly defective condition made the product unreasonably dangerous. *Id.*

¶ 76 Under the “*Tweedy* doctrine,” a plaintiff need not identify the specific defect in a product to recover under strict liability. *DiCosolo v. Janssen Pharmaceuticals, Inc.*, 2011 IL App (1st) 093562, ¶¶ 15-16 (citing *Tweedy v. Wright Ford Sales, Inc.*, 64 Ill. 2d 570, 574 (1976)). Rather, an inference of a product’s defectiveness may be created by evidence that: (1) there was no abnormal use of the product; (2) there was no reasonable secondary cause of the injury; and (3) the

product failed to perform in the manner reasonably to be expected in light of its nature and intended function. *Id.* (citing *Tweedy*, 64 Ill. 2d at 574).

¶ 77 Plaintiff argues that she stated a claim for strict liability manufacturing defect. Initially, defendants argue that plaintiff forfeited this argument as well by advancing a cursory basis for reversal and failing to address the *Tweedy*-doctrine in her opening brief. We agree. In her opening brief, plaintiff fails to articulate a legal basis upon which to hold that she stated a claim and simply recounts the allegations she added to her fifth amended complaint.

¶ 78 Indeed, failure to satisfy the *Tweedy*-doctrine was the crux of defendant's section 2-615 motion to dismiss the fifth amended complaint and the basis of the trial court's ruling. Yet in her opening brief, while never purporting to have identified the specific alleged defect in the pink levetiracetam pills, plaintiff does not cite *Tweedy* or its progeny and advances no argument as to satisfaction of the doctrine's elements. There is no discussion of the required lack of abnormal use of the product or secondary causes of the seizures. It is not until her reply brief that plaintiff addresses the *Tweedy*-doctrine. A party may not raise an argument for the first time in a reply brief. See Ill. S. Ct. R. 341(h)(7) (eff. Oct. 1, 2020) ("Points not argued are forfeited and shall not be raised in the reply brief ***."); *Berggren v. Hill*, 401 Ill. App. 3d 475, 479 (2010) ("Plaintiff also forfeited the argument that the contract was ambiguous because she did not raise this until her reply brief."). Accordingly, plaintiff forfeited her argument that the trial court erred in dismissing her manufacturing defect strict liability claim.

¶ 79 We turn to the preemption issue.

¶ 80 D. Preemption

¶ 81 Defendants argue in the alternative that federal law preempts plaintiff's strict liability claims. The preemption doctrine, derived from the supremacy clause of article VI of the United

States Constitution, provides that the laws of the United States “shall be the supreme Law of the Land; *** any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const., art. VI, cl. 2. Accordingly, “state law is null and void if it conflicts with federal law.” *Carter v. SSC Odin Operating Co.*, 237 Ill. 2d 30, 39 (2010). Preemption may be express or implied. *Id.* at 39-40. Namely, federal law preempts states in three distinct situations: (1) express preemption—where Congress has expressly preempted state action; (2) implied field preemption—where state law regulates conduct in a field that Congress intended the federal government to occupy exclusively through its implementation of a comprehensive regulatory scheme; or (3) implied conflict preemption—where the state law conflicts with federal law. *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990); *Norabuena*, 2017 IL App (1st) 162928, ¶ 17.

¶ 82 Defendants base their argument on the doctrine of implied conflict preemption under the theory that it would be impossible to comply with both state and federal requirements. See *English*, 496 U.S. at 79. Their argument centers on the principle that a manufacturer of a generic drug is expressly prohibited from unilaterally changing a drug’s label. See *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 486-89 (2013).

¶ 83 To begin, defendants point out that, under the FDCA, “a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate.” *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011) (citing 21 U.S.C. §§ 355(b)(1), (d) (2018) and *Wyeth v. Levine*, 555 U.S. 555, 567 (2009)). In turn, generic drugs may gain FDA approval by showing equivalence to an already FDA-approved brand-name drug. *Id.* Three forms of equivalence are required: chemical equivalence, bioequivalence, and identical labeling. *Bartlett*, 570 U.S. at 477; see also *PLIVA*, 564 U.S. at 612-13 (a generic drug must bear

the same labeling as the approved brand-name drug). “Once a drug *** is approved, the manufacturer is prohibited from making any major changes to the ‘qualitative or quantitative formulation of the drug product, including active ingredients ***.’ ” *Bartlett*, 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)). “Generic manufacturers are also prohibited from making any unilateral changes to a drug’s label.” *Id.* (citing 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10)).

¶ 84 Here, as set forth in the affidavit of Solco’s vice president and head of regulatory affairs, in 2009, the FDA approved the marketing of the generic levetiracetam in the United States. The FDA found 250 milligram, 500 milligram, 750 milligram, and 1000 milligram tablets to be safe and effective for use as recommended in the submitted labeling. In addition, the FDA found levetiracetam to be bioequivalent and therapeutically equivalent to Keppra (the brand-name tablet). Accordingly, defendants argue that, with respect to the failure to warn strict liability claim, any modification to the labeling on the generic levetiracetam to provide different warnings would have violated federal law, and, with respect to the manufacturing defect strict liability claim, any alteration to the composition of the drug would have violated federal law. Thus, defendants contend that plaintiff’s claims are impliedly preempted.³

¶ 85 Plaintiff essentially argues that the cases upon which defendants rely are inapposite because plaintiff did not seek stronger warnings for a known side effect despite FDA approval. Rather, she argues that her claim was that defendants “did not warn her the product would not work as intended,” *i.e.*, that “the pink Levetiracetam would fail to keep her Levetiracetam levels within a therapeutic range.”

³Plaintiff makes no argument that these principles are limited to manufacturers.

¶ 86 Citing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), plaintiff argues that her claims arise out of traditional state tort law principles that parallel federal safety requirements and are thus not preempted. In *Buckman*, the plaintiffs alleged that the manufacturer obtained FDA approval for its bone screws by making fraudulent representations to the FDA about the intended use of the device. *Id.* at 346-47. The manufacturer had unsuccessfully applied for approval for the use of the device in spinal surgery. *Id.* After the FDA rejected the initial application, the manufacturer revised the application to specify a different use (“long bone surgery”), which the FDA approved. *Id.* The plaintiffs alleged that they were injured due to the off-label use of the device in spinal surgery and would not have suffered damages but for the alleged misrepresentations to the FDA. *Id.*

¶ 87 In affirming dismissal of the claim, the United State Supreme Court characterized the allegations as a “fraud-on-the-FDA” claim and held that such a claim conflicts with and is therefore impliedly preempted by federal law given the FDA’s sole authority to enforce the FDCA. *Id.* at 348-49. The Court rejected the plaintiffs’ effort to characterize their claim as a parallel, state-law claim that would survive preemption, reasoning that the claim “exist[ed] solely by virtue of the FDCA disclosure requirements.” *Id.* at 352-53. Thus, the plaintiffs were not “relying on traditional state tort law which had predated the federal enactments in question.” *Id.* at 353. Accordingly, their claims were impliedly preempted. *Id.*

¶ 88 Plaintiff argues that her claims *do* arise out of traditional state tort law principles that parallel federal safety requirements. Plaintiff’s position is that she is not suing because the conduct violates the FDCA. Rather, plaintiff contends (without supporting record citation) that she “alleged the medication at issue was adulterated” and that “Solco failed to warn about the adulteration.” Thus, plaintiff argues that her strict liability claims for failure to warn and manufacturing defect

parallel the federal safety requirements prohibiting adulteration and misbranding (see 21 U.S.C. §§ 351-52 (2018)) and fall outside the scope of implied preemption. In support, plaintiff cites *Norabuena*, 2017 IL App (1st) 162928, ¶¶ 31-32 (state law claim against medical device manufacturer for failure to warn against risks of off-label uses in advertising the device paralleled the federal prohibition against misbranding and was not preempted), and *Bausch v. Stryker Corp.*, 630 F.3d 546, 556-58 (7th Cir. 2010) (state law manufacturing defect claim for an allegedly adulterated device used in the plaintiff's hip replacement surgery paralleled the federal safety requirement against adulteration and was not preempted).

¶ 89 However, unlike *Norabuena*, plaintiff did not allege failure to warn against risks of off-label uses. Moreover, as defendants point out, plaintiff did not allege adulteration because she never alleged that the composition of the generic levetiracetam deviated from the FDA-approved formulation. We point out that, while plaintiff affirmatively alleged in the third amended complaint and fourth amended complaint that the pink pills were “adulterated,” the allegation does not appear in the fifth amended complaint. While we must accept as true all well-pled facts and any reasonable inferences therefrom (see *Patrick Engineering*, 2012 IL 113148, ¶ 31), plaintiff fails to direct us to allegations of adulteration. Indeed, as noted, her argument lacks supporting record citation, in violation of Rule 341(h)(7).

¶ 90 At oral argument, plaintiff's counsel stated that the fifth amended complaint incorporated the counts previously dismissed and therefore incorporated the adulteration allegation. However, plaintiff pled the strict liability count anew in the fifth amended complaint. Further, the specific allegations of adulteration were set forth in the “Background and General Allegations” section of the third amended complaint and fourth amended complaint. These allegations were not included in the “Background and General Allegations” section of the fifth amended complaint and were

replaced with allegations that plaintiff made no changes to her sleep, diet, activity level, or lifestyle after taking the pink pills; her other anti-seizure medication remained in the therapeutic range; and that she had not suffered any additional seizures after resuming consumption of the yellowish-white pills.

¶ 91 In sum, plaintiff's strict liability count, as alleged, amounts to an attack on the FDA-approved labeling and composition of the levetiracetam pills. Plaintiff's arguments otherwise simply cannot be squared with the allegations in her fifth amended complaint. Accordingly, the trial court properly dismissed the entirety of the strict liability count on the additional basis that the claims are preempted by federal law. We therefore affirm the trial court's dismissal with prejudice of plaintiff's fifth amended complaint.

¶ 92

III. CONCLUSION

¶ 93 For the reasons stated, we affirm the judgment of the circuit court of De Kalb County.

¶ 94 Affirmed.