[Cite as *Sattelmyer v. Covidien, L.L.C.*, 2026-Ohio-527.]

IN THE COURT OF APPEALS OF OHIO

TENTH APPELLATE DISTRICT

Robyn E. Sattelmyer,	:	
Plaintiff-Appellant,	:	No. 25AP-319 (C.P.C. No. 22CV-8905)
v.	:	(REGULAR CALENDAR)
Covidien, LLC et al.,	:	
Defendants-Appellees.	:	

D E C I S I O N

Rendered on February 17, 2026

On brief: *Bey & Associates LLC*, and *Anita M. Washington*, for appellant. **Argued:** *Anita M. Washington*.

On brief: *Tucker Ellis LLP*, and *John A. Favret III*, for Covidien, LLC.

On brief: *Porter Wright Morris & Arthur LLP*, *C. Darcy Jalandoni*, *Sara C. Schiavone*, and *Jhay T. Spottswood-Harrison*, for Cardinal Health 200, LLC. **Argued:** *C. Darcy Jalandoni*.

Shook Hardy & Bacon LLP, and *Bryan T. Pratt*, for Covidien, LLC. **Argued:** *Bryan T. Pratt*.

APPEAL from the Franklin County Court of Common Pleas

EDELSTEIN, J.

{¶ 1} Plaintiff-appellant, Robyn E. Sattelmyer, appeals from the decision of the Franklin County Court of Common Pleas dismissing her product liability claims against defendants-appellees, Covidien, LLC ("Covidien"), Cardinal Health 200, LLC ("Cardinal Health"), and John Doe Corporations 1-5, pursuant to Civ.R. 12(B)(6). For the foregoing reasons, we reverse, in part, and remand.

I. FACTS AND PROCEDURAL BACKGROUND

{¶ 2} On December 20, 2022, Ms. Sattelmyer filed a complaint in the Franklin County Court of Common Pleas against Covidien, Cardinal Health, John Doe Corporations 1-5, and OhioHealth Corporation ("OhioHealth"). As pled in the complaint, Ms. Sattelmyer was injured on December 23, 2020 while using an Argyle Infant Heel Warmer during the course and scope of her employment with OhioHealth. The purpose of this product "is to help medical providers provide the right amount of heat to an infant's heel for blood sampling." (Dec. 20, 2022 Compl. at ¶ 12.) It is "activated at the point of care by squeezing the pouch," which "mixes the substrate inside the pouch causing an exothermic chemical reaction" that "warm[s] the pouch." (Compl. at ¶ 17, quoting Compl., Ex. 3.) As alleged in the complaint, Ms. Sattelmyer "squeezed the heel warmer to activate it when it exploded all over [her], the patient, and the exam room." (Compl. at ¶ 20.) The contents of the heel warmer flew into her eyes, causing her to suffer "serious and permanent injuries." (Compl. at ¶ 22.)

{¶ 3} Count One of the complaint alleged various claims, including manufacturing-defect, design-defect, and nonconformance with manufacturer's representations, under the Ohio Product Liability Act ("OPLA"), R.C. 2307.71 et seq. Generally, Ms. Sattelmyer alleged that Covidien, Cardinal Health, and John Doe Corporations 1-5 were business entities that "manufacture and/or make and/or sell medical products, including the infant heel warmer product at issue in this case." (Compl. at ¶ 2-3, 9.) However, as described more below, the complaint only alleged specific facts about Covidien's actions as the proximate cause for Ms. Sattelmyer's injuries. Count Two sought declaratory judgment against OhioHealth in connection with workers' compensation benefits.

{¶ 4} At issue in this case is the sufficiency of the product liability claims as pled in Ms. Sattelmyer's complaint.

{¶ 5} On January 24, 2023, Covidien and Cardinal Health (collectively, "appellees") jointly moved to dismiss Count One of Ms. Sattelmyer's complaint pursuant to Civ.R. 12(B)(6). They argued the complaint "is devoid of any factual allegations regarding what, if anything, was wrong with the design or manufacture of the [heel warmer], or how any alleged failure caused [Ms. Sattelmyer's] injuries." (Jan. 24, 2023 Joint Mot. at 2.) In opposing that motion, Ms. Sattelmyer argued her complaint sufficiently pled facts, in

conjunction with the attached exhibits, "to support the manufacturing defect, design defect, and failure to conform to representations claims" against Covidien and Cardinal Health. (Feb. 7, 2023 Memo Contra at 2-4.) Ms. Sattelmyer further contended that, despite only alleging Covidien's tortious conduct directly and proximately caused her to suffer serious permanent injures (Compl. at ¶ 26-30), the allegation in paragraph nine—that Covidien, Cardinal Health, and John Doe Corporations 1-5 were corporations "that manufactured, marketed, and sold medical products to customers . . . in the State of Ohio"—indicated her OPLA claims were also being made against Defendant Cardinal Health and John Doe Corporations 1-5. (*See* Feb. 7, 2023 Memo Contra at 3, fn. 1, citing Compl. at ¶ 9.)

{¶ 6} On April 3, 2023, the trial court issued a decision granting appellees' joint motion and dismissed Ms. Sattelmyer's OPLA claims, as alleged in Count One, with prejudice. However, this decision did not resolve Ms. Sattelmyer's remaining declaratory judgment claim against OhioHealth and the trial court did not include a Civ.R. 54(B) certification in its judgment entry permitting immediate review. Thus, the trial court's decision dismissing Ms. Sattelmyer's OPLA claims was not ripe for appellate review until March 17, 2025, when the trial court entered final judgment dismissing her remaining claim against OhioHealth without prejudice.

{¶ 7} Ms. Sattelmyer timely appealed from that judgment and now asserts the following two assignments of error for our review:

> [I.] THE TRIAL COURT ERRED BY DISMISSING PLAINTIFF'S CLAIMS AGAINST COVIDIEN, LLC AND THE "JOHN DOE" DEFENDANTS.
>
> [II.] THE TRIAL COURT ERRED BY DISMISSING PLAINTIFF'S CLAIMS AGAINST CARDINAL HEALTH 200, LLC.

II. ANALYSIS

{¶ 8} In Count 1 of her complaint, Ms. Sattelmyer alleged various product liability claims under the OPLA, including manufacturing defect (R.C. 2307.74), design defect (R.C. 2307.75), and nonconformance with manufacturer's representation (R.C. 2307.77). Covidien and Cardinal Health argued that Ms. Sattelmyer failed to plead any operative facts to support these claims and contended that the allegations in the complaint amount to no more than mere legal conclusions restating the required elements of the various statutes.

The trial court agreed, finding Ms. Sattelmyer's claims against Covidien, Cardinal Health, and John Doe Corporations 1-5 were too vague to even survive Ohio's notice pleading standards.

{¶ 9} In her first assignment of error, Ms. Sattelmyer argues the trial court erred in dismissing her OPLA claims against Covidien and John Doe Corporations 1-5 with prejudice. In her second assignment of error, Ms. Sattelmyer contends the trial court erred in dismissing her OPLA claims against Cardinal Health with prejudice. In the interest of efficiency, we address them together.

A. Ohio's Statutory Scheme for Product-Liability Claims

{¶ 10} "Products liability grew out of a public policy judgment that people need more protection from dangerous products than is afforded by the law of warranty." *E. River Steamship Corp. v. Transamerica Delaval*, 476 U.S. 858, 866 (1986), citing *Seely v. White Motor Co.*, 63 Cal.2d 9, 15 (1965).

{¶ 11} In 1988, the Ohio General Assembly enacted a statutory scheme for regulating product-liability claims, contained in R.C. 2307.71 et seq. Ohio law defines a "product liability claim" as any claim or cause of action "that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from" a defective design, a failure to warn, or a failure to conform to representations about the product. R.C. 2307.71(A)(13).

{¶ 12} The OPLA "abrogate[s] all common law product liability claims or causes of action." R.C. 2307.71(B). Instead, the OPLA defines exclusive theories of liability for recovery associated with product-related injuries: defective "design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product," R.C. 2307.71(A)(13)(a); failure to adequately warn or instruct about the product, R.C. 2307.71(A)(13)(b); and failure of the product to conform to a representation or warranty, R.C. 2307.71(A)(13)(c).

{¶ 13} OPLA claims can only be brought against a "manufacturer or supplier." R.C. 2307.71(A)(13). Relevant here, a "manufacturer" is broadly defined as an "individual, corporation, business trust, estate, trust, partnership, and association" including governmental entities, "engaged in a business to design, formulate, produce, create, make,

construct, assemble, or rebuild a product or a component of a product." *See* R.C. 2307.71(A)(9); R.C. 1.59.

B. Civil Rule 12(B)(6)

{¶ 14} We review a trial court's decision granting a motion to dismiss de novo. *State ex rel. Ohio Civ. Serv. Emps. Assn. v. State*, 2016-Ohio-478, ¶ 12, citing *Perrysburg Twp. v. Rossford*, 2004-Ohio-4362, ¶ 5.

{¶ 15} Under Civ.R. 12(B)(6), a motion to dismiss for failure to state a claim upon which relief can be granted is a procedural test of a civil complaint's sufficiency. *Cool v. Frenchko*, 2022-Ohio-3747, ¶ 13 (10th Dist.), quoting *Morrow v. Reminger & Reminger Co. LPA*, 2009-Ohio-2665, ¶ 7 (10th Dist.). Dismissal of a complaint pursuant to Civ.R. 12(B)(6) is appropriate "only if it appears beyond a doubt that the plaintiff can prove no set of facts entitling the plaintiff to recovery." *Bullard v. McDonald's*, 2021-Ohio-1505, ¶ 11 (10th Dist.).

{¶ 16} In determining whether dismissal is appropriate, the trial court "must presume all factual allegations contained in the complaint to be true and must make all reasonable inferences in favor of the plaintiff." *Bullard* at ¶ 11. "The trial court may only consider the complaint itself and [certain] written instruments attached thereto by the plaintiff." *McBroom v. Gertmenian*, 2018-Ohio-3884, ¶ 12 (10th Dist.), citing *Cline v. Mtge. Electronic Registration Sys., Inc.*, 2013-Ohio-5706, ¶ 9 (10th Dist.); *Brisk v. Draf Industries, Inc.*, 2012-Ohio-1311, ¶ 10 (10th Dist.); and *Park v. Acierno*, 2005-Ohio-1332, ¶ 29 (7th Dist.). Thus, attachments to the complaint are considered part of the complaint for all purposes. Civ.R. 10(C). A trial court may not, however, rely on allegations or evidence outside the complaint. *See, e.g.*, *State ex rel. Fuqua v. Alexander*, 79 Ohio St.3d 206, 207 (1997); *Schmitz v. Natl. Collegiate Athletic Assn.*, 2018-Ohio-4391, ¶ 10, citing *Loveland Edn. Assn. v. Loveland City School Dist. Bd. of Edn.*, 58 Ohio St.2d 31, 32 (1979); *State ex rel. Scott v. Cleveland*, 2006-Ohio-6573, ¶ 26. And the trial court will not "accept as true any unsupported and conclusory legal propositions advanced in the complaint." *Bullard* at ¶ 11. *See also State ex rel. Martre v. Reed*, 2020-Ohio-4777, ¶ 12 (noting that "legal conclusions, even when cast as factual assertions, are not presumed true for purposes of a motion to dismiss").

C. Civil Rule 8

{¶ 17} The basis of the trial court's dismissal under Civ.R. 12(B)(6) was that Ms. Sattelmyer's OPLA claims did not comply with Civ.R. 8.

{¶ 18} Ohio is a notice-pleading state. *Maternal Grandmother, ADMR v. Hamilton Cty. Dept. of Job & Family Servs.*, 2021-Ohio-4096, ¶ 10. Pursuant to Civ.R. 8, "[a] pleading that sets forth a claim for relief . . . shall contain (1) a short and plain statement of the claim showing that the party is entitled to relief, and (2) a demand for judgment for the relief to which the party claims to be entitled." Civ.R. 8(A). *See also Wells Fargo Bank N.A. v. Horn*, 2015-Ohio-1484, ¶ 13. "Each averment of a pleading shall be simple, concise, and direct. No technical forms of pleading or motions are required." Civ.R. 8(E)(1). The notice-pleading standard "does not require a plaintiff to prove her case at the pleading stage, but merely requires factual allegations that if proved would entitle the plaintiff to relief." *Maternal Grandmother, ADMR* at ¶ 21 (DeWine, J., concurring in judgment only), citing *Illinois Controls, Inc. v. Langham*, 70 Ohio St.3d 512, 526 (1994).

{¶ 19} Although a complaint need not state with precision all elements that give rise to a legal basis for recovery, fair notice of the nature of the action must be provided. *Bridge v. Park Natl. Bank*, 2003-Ohio-6932, ¶ 5 (10th Dist.). To constitute fair notice, the complaint must still allege sufficient underlying facts that relate to and support the alleged claim, and may not simply state legal conclusions. *See, e.g.*, *Regulic v. Columbus*, 2022-Ohio-1034, ¶ 23 (10th Dist.). The standard simply requires a plaintiff to allege in her complaint a set of facts which, if accepted to be true, would allow the plaintiff to recover. *York v. Ohio State Hwy. Patrol,* 60 Ohio St.3d 143, 145 (1991). This means that, outside of a few specific circumstances—such as claims involving fraud or mistake, *see* Civ.R. 9(B)—"a party will not be expected to plead a claim with particularity." *Maternal Grandmother, ADMR* at ¶ 10. Thus, unless expressly required otherwise, "a short and plain statement of the claim" is typically sufficient. *Id.*, citing Civ.R. 8(A). *See also York* at 145. This "standard relies on liberal discovery rules and summary judgment motions to define disputed facts and issues to dispose of nonmeritorious claims." *Vinicky v. Pristas*, 2005-Ohio-5196, ¶ 6 (8th Dist.), citing *Duff v. Coshocton Cty.*, 2004-Ohio-3713, ¶ 32 (5th Dist.) (describing "[t]he liberal notice pleading of Rule 8(a) [as] the starting point of a simplified pleading system, which was adopted to focus litigation on the merits of a claim").

{¶ 20} In contrast, the federal pleading standard generally requires that a complaint contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face' " in order to survive a motion to dismiss for failure to state a claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* While the "plausibility standard is not akin to a 'probability requirement,' " it does "ask[] for more than a sheer possibility that a defendant has acted unlawfully." *Id.* Thus, under the federal pleading standard, a plausible claim must do more than merely allege entitlement to relief; it must support the grounds for that entitlement with sufficient factual content. *See id.*

{¶ 21} Notwithstanding the heightened federal pleading standard established in *Twombly* and *Iqbal*, the Supreme Court of Ohio "has never adopted that standard." *State ex rel. Ware v. Booth*, 2024-Ohio-2102, ¶ 5, fn. 1, citing *Maternal Grandmother, ADMR* at ¶ 28 (DeWine, J., concurring in judgment only). Indeed, even after *Twombly* and *Iqbal* were decided in 2007 and 2009, respectively, the Court has continued to recognize that the heightened federal pleading standard does not apply in Ohio state courts. *See, e.g.*, *Ware* at ¶ 5, fn. 1; *Maternal Grandmother, ADMR* at ¶ 25-29 (DeWine, J., concurring in judgment only); *State ex rel. Mobley v. Chambers-Smith*, 2024-Ohio-1910, ¶ 10, fn. 1 (DeWine, J., concurring). We are bound by these decisions. *See, e.g. State v. Bruce*, 2022-Ohio-909, ¶ 40 (10th Dist.), quoting *State v. Tatom*, 2018-Ohio-5143, ¶ 24 (10th Dist.); *Zakel v. State*, 2022-Ohio-4637, ¶ 7 (8th Dist.).

{¶ 22} The trial court in this case correctly recognized Ohio is a notice-pleading state. (*See* Apr. 3, 2023 Decision and Entry at 5.) However, on review, we find the trial court applied a heightened pleading standard, akin to the federal *Twombly*/*Iqbal* plausibility standard. For the following reasons, we find no basis to hold Ms. Sattelmyer to a heightened pleading standard for her product liability claims asserted under the OPLA. And, under the precedent applicable in Ohio, we find no legal basis to do so.

D. Analysis

{¶ 23} On appeal, Ms. Sattelmyer contends she sufficiently alleged product-liability claims against Covidien, Cardinal Health, and John Doe Corporations 1-5 based on four

theories recognized by the OPLA: (1) defective manufacturing under R.C. 2307.74; (2) defective design under R.C. 2307.75; (3) nonconformance with representations made about the product under R.C. 2307.77; and (4) inadequate warnings or instructions under R.C. 2307.76. For the following reasons, we agree, in part, and disagree, in part.

{¶ 24} At the outset, we note that Ohio case law is limited in application of the notice-pleading standard to OPLA claims.[1] Appellees argue for application of a heightened pleading standard to claims brought under the OPLA, pointing to federal case law as persuasive authority. (*See* Appellees' Brief at 9, 13, 15-19.) While the decisions of federal courts interpreting a ***federal*** rule are persuasive authority for an Ohio state court interpreting a similar Ohio rule, these federal decisions are not binding on this court. *See, e.g.*, *Hope Academy, Broadway Campus v. White Hat Mgt., LLC*, 2022-Ohio-178, ¶ 32, fn. 6 (10th Dist.); *State v. Burnett*, 93 Ohio St.3d 419, 422-24 (2001).

{¶ 25} We ultimately find that, under the facts and circumstances of this case, appellees have not provided this court with a compelling reason to depart from the notice-pleading standard applicable to claims brought in Ohio courts. Given the obvious difficulties in obtaining relevant information about the manufacture of a product before a lawsuit is filed and the absence of a strong public policy argument, we see no reason for holding plaintiffs who bring product liability claims under the OPLA to the heightened pleading standard employed by the trial court below. *See, e.g.*, *York*, 60 Ohio St.3d at 145 ("Very often, the evidence necessary for a plaintiff to prevail is not obtained until the plaintiff is able to discover materials in the defendant's possession. If the plaintiff were required to prove his or her case in the complaint, many valid claims would be dismissed because of the plaintiff's lack of access to relevant evidence."). To the contrary, courts do not serve the interest of the public by ***preventing*** product liability claims from going

[1] As appellees note in their brief, the Eighth District Court of Appeals affirmed a trial court's dismissal of various OPLA claims under Civ.R. 12(B)(6) in *Allstate Ins. Co. v. Electrolux Home Prods.*, 2012-Ohio-90 (8th Dist.). But, contrary to appellees' contention otherwise, the complaint filed in that case is easily distinguishable from the complaint at issue here. (*See* Appellees' Brief at 14-15.) Significantly, the Eighth District Court of Appeals applied Ohio's notice-pleading standard—not the heightened federal standard—when reviewing the sufficiency of Allstate's two-page complaint containing 12 enumerated paragraphs. *See Allstate Ins. Co.* at ¶ 9-10. On review, the appellate court found the complaint—which alleged that because the defendant manufactured and designed gas dryers and Allstate's insured's gas dryer caught fire, the dryer was defective, and therefore defendant was liable for damages—was insufficient "under Ohio's notice pleading standard." *Id.* at ¶ 10. Unlike in this case, Allstate's complaint "merely recite[d] the elements of the law governing [design and manufacturing defects under the OPLA] as a legal conclusion" and did not "contain any facts or allegations that support[ed] its conclusions." *Id.* at ¶ 11.

forward merely because the injured party does not, before a lawsuit is commenced, have the ability to access information from the supplier or manufacturer about the design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of the product at issue.

{¶ 26} We decline to endorse a review process that permits state trial courts to use these information-access limitations as a bar to justice for OPLA claims at the pleading stage. Indeed, information about a product's "design specifications, formula, or [the] performance standards of the manufacturer" would generally be known only by the manufacturer. (Emphasis added.) *See* R.C. 2307.74. So, too, would information about whether a particular product deviated from other "identical units manufactured to the same design specifications, formula, or performance standards." R.C. 2307.74. And, information about whether and to what extent a design or formulation "conformed to any applicable public or private product standard that was in effect when the product left the control of its manufacturer" would likewise only be reasonably known by a manufacturer or supplier of a product—not the consumer. R.C. 2307.75(B)(4). The same is true for information regarding "[t]he technical and economic feasibility, when the product left the control of its manufacturer, of using an alternative design or formulation." R.C. 2307.75(C)(2).

{¶ 27} The fact that a plaintiff does not have access to information relevant—and even necessary—to proving (or disproving) an OPLA claim does not mean, for purposes of surviving a motion to dismiss under Civ.R. 12(B)(6), that a product's defective nature can never be apparent from the factual circumstances. To be sure, here, the fact that an ***infant*** heel warmer device exploded when it was activated in its intended manner (squeezing) (*see* Compl. at ¶ 16-18) surely suggests a defect in that product.

{¶ 28} In this case, Ms. Sattelmyer's complaint alleged that on December 23, 2020 (Compl. at ¶ 19), she "squeezed" the Argyle Infant Heel Warmer to "activate it" (Compl. at ¶ 19-20) at work (Compl. at ¶ 10, 32) in connection with patient care (Compl. at ¶ 20) "when it exploded" all over her, the patient, and the exam room (Compl. at ¶ 20), making contact with her eyes and clothing (Compl. at ¶ 21). The complaint also established that the infant heel warmer "is activated at the point of care by squeezing the pouch," thus alleging Ms. Sattelmyer used the product in its intended manner. (*See* Compl. at ¶ 17; Compl., Ex. 3.)

{¶ 29} Ms. Sattelmyer alleged that Covidien "designed, manufactured, and sold the 'Argyle Infant Heel Warmer' [she] was attempting to use at a Columbus, Ohio hospital at the time of the incident." (Compl. at ¶ 10, 26.) In support of that claim, she attached to her complaint photographs depicting the packaging of an Argyle Infant Heel Warmer with Covidien's branding. (*See* Compl. at ¶ 10-11; Compl., Ex. 1.) That packaging showed the FDA Product Code[2] for the Argyle Infant Heel Warmer as MH00002T. (Compl., Ex. 1.) Ms. Sattelmyer also attached to her complaint two U.S. Food and Drug Administration ("FDA") Recall Notices about the heel warmer product at issue in this case, identified as product code MH00002T, that were issued before and after the heel warmer exploded on her in December 2020. (Compl. at ¶ 13-18.)

{¶ 30} The 2015 FDA Recall Notice, naming Covidien as the manufacturer of the heel warmer (product code MH00002T), cautioned that the product's packaging design "may break during activation resulting in spillage of the contents on patients or healthcare workers causing potential skin/eye irritations." (Compl. at ¶ 13-15; Compl., Ex. 2.) The 2021 FDA Recall Notice, naming Cardinal Health as the manufacturer of the same product (product code MH00002T), indicated that the infant heel warmer was being recalled in order to add a caution statement reminding the user to activate the heel warmer away from the face and the infant based on "reports of pack rupture or leaking during activation." (Compl. at ¶ 18; Compl., Ex. 3.) This recall notice listed potential harms caused by contact with the liquid inside the heel warmer pouch as "rash, burn[,] and inflammation." (Compl. at ¶ 18; Compl., Ex. 3.) Consistent with the defect (exploding) and harms referenced in these FDA notices, Ms. Sattelmyer alleged in her complaint that, upon squeezing the heel warmer, its contents exploded in her face and, "[d]espite rinsing and flushing her eyes out at an eyewash station, her eyes became very irritated, painful, and red and she suffered

[2] According to the FDA website, "[a]n FDA product code describes a specific product and contains a combination of five to seven numbers and letters. The product code submitted with each FDA line item should match the actual product name and/or invoice description of the product. If the product has more than one name (e.g., a fish known under several regional names), the product code may have several different synonymous definitions associated with it. The easiest way to determine the product code is to become familiar with the product itself, including the label, the processing information, intended use of product, the container type, who will use or consume the product, etc." United States Food and Drug Administration, *Product Codes and Product Code Builder*, https://www.fda.gov/industry/import-program-tools/product-codes-and-product-code-builder (accessed Feb. 13, 2026) [https://perma.cc/3TRY-LJA7].

serious and permanent injuries to her eyes due to the exploding heel warmer package." (Compl. at ¶ 21-22.)

1. Manufacturing Defect–R.C. 2307.74

{¶ 31} Appellees argue that in order to establish a manufacturing defect claim, Ms. Sattelmyer must prove: (1) a defect in a product the defendant manufactured; (2) that the defect existed when the product left the defendant's control; and (3) that the defect proximately caused the plaintiff's injuries. (Appellees' Brief at 17-18, citing *Carroll v. Alliant Techsystems, Inc.*, 2006-Ohio-5521,¶ 9 (10th Dist.).) But, in actuality, these are the requirements a plaintiff must meet in order to survive summary judgment or prove her claim at trial—not to survive a motion to dismiss under Civ.R. 12(B)(6). *See, e.g.*, *Carroll* at ¶ 9-10 (finding no error in trial court's decision granting summary judgment). *See also Williams v. Boston Scientific Corp.*, 2023 U.S. Dist. LEXIS 220371, *4 (N.D.Ohio Dec. 11, 2023), citing *Jones v. Staübli Motor Sports Div. of Staübli Am. Corp.*, 897 F.Supp.2d 599, 607 (S.D.Ohio 2012), citing *Hickey v. Otis Elevator Co.*, 163 Ohio App.3d 765, 769-70 (10th Dist. 2005).

{¶ 32} In evaluating the sufficiency of Ms. Sattelmyer's defective manufacturing claim, the trial court found the complaint failed to include factual allegations "as to how the product deviated from its intended design specifications, formula, or performance standards" and failed to allege the defect "existed when the product left" the manufacturer's control under R.C. 2307.74. (Apr. 3, 2023 Decision and Entry at 9.) We disagree. The complaint alleged that Covidien manufactured the heel warmer, which was intended to warm when squeezed at the point of care—not to explode and splash chemicals onto medical providers and infants that could cause rash, burn, and inflammation, as happened in this case. (*See* Compl. at ¶ 12-27.) The complaint further alleged that, "[a]s described in the product recalls, the package design and/or selection was the defect that caused the package to rupture," causing injury to Ms. Sattelmyer. (*See* Compl. at ¶ 24.)

{¶ 33} These specific facts support Ms. Sattelmyer's allegation, under Ohio's notice-pleading standard, that the heel warmer deviated from its intended design specifications or performance standards. Furthermore, construing all factual allegations in the light most favorable to Ms. Sattelmyer, we find the complaint, in conjunction with the attached product recall notices, alleged sufficient facts from which we can reasonably infer—as we

must at the motion to dismiss stage—that the manufacturing defect in the heel warmer's packaging (bursting when squeezed) existed when it left the manufacturer's control. It bears repeating that, when determining whether dismissal is appropriate, the court "must presume all factual allegations contained in the complaint to be true and ***must make all reasonable inferences in favor of the plaintiff***." (Emphasis added.) *Bullard*, 2021-Ohio-1505, at ¶ 11 (10th Dist.). As such, we reject appellees' argument and find Ms. Sattelmyer's complaint pled sufficient facts satisfying the statutory elements of a defective-manufacture claim under the OPLA to survive the motion to dismiss.

{¶ 34} Of course, this determination does not mean Ms. Sattelmyer will succeed at proving her manufacturing defect claim. Rather, we find she has sufficiently pled her claim under Ohio's notice-pleading standard. Again, it bears repeating that information about a product's manufacturing process and the condition of a product when it left a manufacturing facility will not often be available to consumers before a product liability lawsuit is commenced. It is sound public policy to permit plaintiffs like Ms. Sattelmyer to engage in discovery where, as was the case here, a consumer is injured by a product while using the product in its intended manner.

2. Design Defect–R.C. 2307.75

{¶ 35} As to Ms. Sattelmyer's defective design claim, R.C. 2307.75(A) provides that a product is defective in design or formulation if, "at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of [this statute] exceeded the benefits associated with that design or formulation as determined pursuant to division (C)." For instance, courts are instructed to consider the nature and magnitude of the risks of harm associated with reasonably foreseeable uses of the product, the likely awareness of consumers of those risks based on warnings or general knowledge, and the likelihood that the design would cause harm. R.C. 2307.75(B). To determine the benefits associated with the design or formulation of a product, courts are instructed to consider the intended or actual utility of the product, including any performance or safety advantages associated thereto; the technical and economic feasibility, when the product left the control of the manufacturer, of using an alternative design or formulation; and the nature and magnitude of any foreseeable risks associated with an alternative design or formulation. R.C. 2307.75(C).

{¶ 36} With respect to her design defect claim, appellees argue Ms. Sattelmyer had to prove (1) the existence of a defect in the product at issue, (2) the defect existed at the time the product left the hands of the manufacturer, and (3) the defect was the direct and proximate cause of the plaintiff's injury. (Appellees' Brief at 13-14.) But "these are the requirements a plaintiff must meet in order to survive summary judgment, not a motion to dismiss." *Williams*, 2023 U.S. Dist. LEXIS 220371, at *4, citing *Jones*, 897 F.Supp.2d at 607, citing *Hickey*, 163 Ohio App.3d at 769-70. *See also Nationwide Mut. Ins. Co. v. ICON Health & Fitness, Inc.*, 2005-Ohio-2638, ¶ 3-5 (10th Dist.) (reviewing evidence relevant to ***jury's verdict*** on plaintiffs' design defect claims following ***trial***).

{¶ 37} In her complaint, Ms. Sattelmyer alleged "the package design and/or selection [of the heel warmer] was the defect that caused the package rupture that led to injuries of users and others, including Plaintiff in this incident." (Compl. at ¶ 24.) Furthermore, her allegation that the heel warmer packaging broke when activated in its intended manner (i.e., squeezing on the packaging) tenders more than a mere " 'naked allegation that a product failed, without more.' " *Compare Williams* at *4, quoting *O.M. Through McConnell v. KLS Martin LP*, 560 F.Supp.3d 1084, 1089-90 (N.D.Ohio 2021). It is true that Ms. Sattelmyer's complaint does not specifically allege that the non-exhaustive list of risk factors in R.C. 2307.75(B) exceeds the non-exhaustive list of benefits associated with the product's design in R.C. 2307.75(C). However, determining whether the risks outweighed the benefits of the heel warmer's design is an issue that ultimately lies with the finder of fact. That is to say, Ms. Sattelmyer has the burden of ***proving*** the risks of the product's design outweigh its benefits at a later date, not at the time she files her complaint.

{¶ 38} As notice pleading is not an onerous requirement, the trial court was obligated at this stage to draw all reasonable inferences in Ms. Sattelmyer's favor. On review, we find the complaint alleged sufficient facts from which we can reasonably infer—as we must—that the risks associated with a heel warmer used in the care of infants known, by at least 2015, to explode and spray harmful chemical liquid onto medical staff and infant children when used in its intended manner exceeds the benefits associated with the product design. This is particularly true given that the product was developed with the intended purpose of applying "the right amount of heat to an ***infant[']s*** heel for blood sampling." (Emphasis added.) (Compl., Ex. 2.) And, as stated above, we find the complaint, in

conjunction with the attached product recall notices, alleged sufficient facts from which we can reasonably infer the design defect in the heel warmer's packaging (bursting when squeezed) existed when it left the manufacturer's control. Consumers who, like Ms. Sattelmyer, are injured while using a product in its intended manner will often have a significantly limited ability to access information about a manufacturer's design process and standards before filing suit. Public policy supports applying the notice-pleading standard to such OPLA claims and allowing sufficiently-pled claims to proceed to discovery. *See York*, 60 Ohio St.3d at 144-45.

{¶ 39} Having determined that Ms. Sattelmyer's complaint provided appellees with the requisite notice to marshal their defense to this claim, we reject appellees' argument and find Ms. Sattelmyer's complaint pled sufficient facts satisfying the statutory elements of a defective-design claim under the OPLA to survive the motion to dismiss.

3. Nonconformance with Representations–R.C. 2307.77

{¶ 40} To succeed on a failure to conform claim under R.C. 2307.77, a plaintiff must show that: (1) the manufacturer made a representation as to a material fact relating to the character or quality of the product; (2) the product did not conform to that representation; (3) the plaintiff justifiably relied on that representation; and (4) the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries. *See, e.g.*, *Moshi v. Kia Am., Inc.*, 155 F.4th 652, 662-63 (6th Cir. 2025), citing *Gawloski v. Miller Brewing Co.*, 96 Ohio App.3d 160 (9th Dist. 1994). For purposes of the OPLA, "representation" refers to "an ***express*** representation of a material fact concerning the character, quality, or safety of a product." (Emphasis added.) R.C. 2307.71(A)(14). *See also Bleh v. Biro Mfg. Co.*, 142 Ohio App.3d 434, 440 (1st Dist. 2001) (express representation regarding machine operation).

{¶ 41} On review, we agree with the trial court's finding that Ms. Sattelmyer did not identify in her complaint any express representation(s) made by appellees about the heel warmer in her complaint. She merely alleged the product "did not conform to representations made about the product when it left the control of Defendant Covidien." (Compl. at ¶ 29.) But that allegation does little more than restate the requisite element of the OPLA claim and does not constitute an express representation.

{¶ 42} Because Ms. Sattelmyer did not attribute ***any*** express representation to Covidien, Cardinal Health, or John Doe Corporations 1-5 in her complaint—much less allege any specific representation of a material fact was expressly made by Covidien, Cardinal Health, or John Doe Corporations 1-5 concerning the character, quality, or safety of a product—her nonconformance claim was inadequately pled. As such, we find no error in the trial court's decision to dismiss the OPLA claim alleged under R.C. 2307.77 pursuant to Civ.R. 12(B)(6).

4. Inadequate Warning or Instructions–R.C. 2307.76

{¶ 43} As to the inadequate-warning claim, we note that Ms. Sattelmyer did not argue in her memorandum opposing dismissal that her complaint alleged an OPLA claim based on inadequate warning or instruction. But, on appeal, she cites to language in her complaint alleging "[t]he Argyle Infant Heel Warmer . . . failed to have proper warnings, which made it unsafe and dangerous to use" as support for her contention that she also alleged a claim for inadequate warning under R.C. 2307.76. (Appellant's Brief at 18-19, quoting Compl. at ¶ 23.) Thus, Ms. Sattelmyer contends it was error for the trial court to dismiss her product liability claims against appellees without addressing her "inadequate warning" claim. (Appellant's Brief at 18.) Although the complaint did not allege a claim for inadequate warning in the same manner as the others, we nonetheless address it.

{¶ 44} "Unless the danger posed by a product is generally known and recognized by a consumer, Ohio imposes on manufacturers two related duties to warn: a duty to warn of dangers known to the manufacturer at the time of sale of the product and a duty to warn of dangers that were not obvious at the time of sale but became known to the manufacturer after the product was sold to a consumer." *Linert v. Foutz*, 2016-Ohio-8445, ¶ 26. These duties are codified in R.C. 2307.76. A failure-to-warn claim has three elements: "(1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003), citing *Briney v. Sears, Roebuck & Co.*, 782 F.2d 585, 587 (6th Cir. 1986). "Ohio law presumes that an inadequate warning or instruction is the proximate cause of a plaintiff's injury." *Moshi*, 155 F.4th at 663, citing *Boyd v. Lincoln Elec. Co.*, 2008-Ohio-6143, ¶ 38 (8th Dist.), citing *Seley v. G. D. Searle & Co.*, 67 Ohio St.2d 192, 200-01 (1981). *See also Miles v. Kohli & Kaliher Assocs.*, 917 F.2d 235, 249 (6th Cir. 1990). "The

manufacturer has the burden of rebutting that presumption through evidence that a consumer would have disregarded a warning or instruction if it had been provided." *Moshi* at 663, citing *Miles* at 249.

{¶ 45} However, contrary to Ms. Sattelmyer's contention otherwise, she did not specifically allege any facts in her complaint to reasonably suggest that any actions by Covidien, Cardinal Health, or John Doe Corporations 1-5 resulted in an inadequate warning or instruction about the heel warmer. (*See* Compl. at ¶ 26-30.) Although Ms. Sattelmyer attached photographs depicting the packaging of the Argyle Infant Heel Warmer to her complaint (Compl., Ex. 1), the text on the packaging is mostly illegible. The complaint also lacked any factual statement about what, if any, warning or instructions had been issued about the product at the time of the incident or, for that matter, any allegation claiming Ms. Sattelmyer had no knowledge about the risk the heel warmer could explode when squeezed on December 23, 2020. Simply put, Ms. Sattelmyer did not allege facts explaining appellees' duty to warn or how she believes they breached such duty.

{¶ 46} For these reasons, we find Ms. Sattelmyer failed to clearly articulate facts that would provide appellees with the requisite notice to marshal their defense to an inadequate-warning claim. Thus, even if the trial court erred in failing to address this claim, we nonetheless find that dismissal of the inadequate-warning theory of Ms. Sattelmyer's product liability claim was warranted under Civ.R. 12(B)(6).

5. Dismissal of Claims Against Cardinal Health and John Doe Corporations 1-5

{¶ 47} While we find error with respect to dismissal of Ms. Sattelmyer's manufacturing defect and design defect claims as to Covidien, we are unable to find error in the trial court's decision to dismiss all OPLA claims against Cardinal Health and John Doe Corporations 1-5. Liberally construing the complaint, Ms. Sattelmyer also sought to raise manufacturing-defect, design-defect, and nonconformance with manufacturer's representations claims against Cardinal Health and John Doe Corporations 1-5. But her factual allegations lacked the detail necessary for the court to discern a viable cause of action against them under any legal theory. Indeed, Ms. Sattelmyer only alleged that ***Covidien*** "defectively manufactured or constructed" the heel warmer, ***Covidien*** "defectively designed" the heel warmer, and/or ***Covidien*** manufactured a heel warmer

that did not conform with its representations about that product. (*See* Compl. at ¶ 26-29.) Ms. Sattelmyer likewise only alleged that, "[a]s a direct and proximate result" of such conduct by ***Covidien***, she was injured. (Compl. at ¶ 30.) Ms. Sattelmyer did not, however, specifically allege that Cardinal Health or John Doe Corporations 1-5 are liable due to the manufacture or design of the defective product that caused her injury on December 23, 2020. (*See* Compl. at ¶ 26-30.)

{¶ 48} Put simply, Ms. Sattelmyer's complaint failed to give Cardinal Health and John Doe Corporations 1-5 fair notice of her OPLA claims against them and the grounds upon which they rest. Indeed, other than generally alleging that Covidien, Cardinal Health, and John Doe Corporations 1-5 all manufactured, made, or sold "the infant heel warmer product at issue in this case" (Compl. at ¶ 2-3), Ms. Sattelmyer failed to allege any specific facts about the actions taken by Cardinal Health or John Doe Corporations 1-5 that could have resulted in the damage to her eyes, and she failed to direct any legal claims against Cardinal Health or John Doe Corporations 1-5. In the absence of such allegations or legal claims directed at those defendants, we are unable to infer that Cardinal Health or John Doe Corporations 1-5 manufactured or designed the ***defective*** product that injured Ms. Sattelmyer on December 23, 2020. And, as already explained above, the complaint failed to sufficiently allege facts supporting a product liability claim based on inadequate warning and nonconformance with manufacturer's representations.

E. Disposition

{¶ 49} For these reasons, we find the trial court erred in granting appellees' joint motion to dismiss under Civ.R. 12(B)(6) as to Ms. Sattelmyer's claims under the OPLA for manufacturing defect (R.C. 2307.74) and defective design (R.C. 2307.75) against Covidien. However, we find the complaint failed to sufficiently allege product liability claims based on theories of inadequate warning (R.C. 2307.76) and nonconformance with manufacturer's representations (R.C. 2307.77). We also find that, even construing all facts and reasonable inferences in the light most favorable to Ms. Sattelmyer, the trial court did not err in dismissing her product liability claims against Cardinal Health and John Doe Corporations 1-5 for failure to state a claim upon which relief can be granted.

{¶ 50} Based on the foregoing, we sustain in part, and overrule in part, Ms. Sattelmyer's first assignment of error and overrule her second assignment of error. We

decline to grant Ms. Sattelmyer's request for leave to amend the complaint, as she did not seek leave to amend her complaint in the trial court. It is axiomatic that an appellate court will not address, in the first instance, an argument that falls outside the scope of an appellant's assignment of error or has not been properly preserved for appellate review. *See, e.g.*, *Zawahiri v. Alwattar*, 2008-Ohio-3473, ¶ 10-11 (10th Dist.). By not seeking leave to amend her complaint in the trial court, Ms. Sattelmyer has waived any argument supporting such relief from this court.

III. CONCLUSION

{¶ 51} Having sustained Ms. Sattelmyer's first assignment of error in part, and overruled her second assignment of error, we reverse in part, the judgment of the Franklin County Court of Common Pleas and remand this matter for further proceedings in accordance with law and consistent with this decision.

Judgment affirmed in part and reversed in part; *cause remanded*.

MENTEL, J., concurs.
BEATTY BLUNT, J., concurring in part and dissenting in part.

BEATTY BLUNT, J., concurring in part and dissenting in part.

{¶ 52} I do not believe the trial court committed reversible error when it granted the joint motion of appellees to dismiss filed pursuant to Civ.R. 12(B)(6). Accordingly, I would overrule appellant's first assignment of error in its entirety and affirm the judgment of the trial court. Because the majority decision does not, I respectfully dissent. Notwithstanding that disagreement, I agree with the majority's resolution of appellant's second assignment of error.

{¶ 53} The majority's conclusion that appellant's complaint states claims under the OPLA for manufacturing defect (R.C. 2307.74) and defective design (R.C 2307.75) against appellee Covidien sufficient to withstand the joint motion of appellees' to dismiss is premised on Civ.R. 8 and its provisions of notice-pleading. Specifically, the majority concludes that the trial court improperly applied a "heightened" federal pleading standard that is inapplicable to state law product liability claims filed in state court. Respectfully, I do not agree that the trial court applied any such heightened federal pleading standard in

this case. Instead, the trial court properly applied the requisite standard as set forth in Civ.R. 8 and appropriately found the standard was not met.

{¶ 54} As the majority acknowledges, there is a dearth of Ohio law discussing the application of the notice-pleading standard to claims filed under the OPLA. Nonetheless, Ohio case law is clear that Ohio "incorporated" the notice-pleading standard from the Federal Rules of Civil Procedure as its own. *York v. Ohio State Hwy. Patrol*, 60 Ohio St.3d 143, 144 (1991). Furthermore, "[b]ecause the Ohio Rules of Civil Procedure are modeled after the Federal Rules of Civil Procedure, federal law interpreting the federal rule is appropriate and persuasive authority in interpreting a similar Ohio rule." *Felix v. Ganley Chevrolet, Inc.*, 145 Ohio St.3d 329, 333 (2015), citing *Stammco, L.L.C. v. United Tel. Co. of Ohio*, 2013-Ohio-3019, ¶ 18, citing *Myers v. Toledo*, 2006-Ohio-4353, ¶ 18, and *Marks v. C.P. Chem. Co., Inc.*, 31 Ohio St.3d 200, 201 (1987). Thus, it is entirely appropriate for this court to look to and rely upon federal cases applying the federal rules of procedure pertaining to notice pleading and motions to dismiss in the context of claims brought under the OPLA.

{¶ 55} Therefore, I would apply the analysis applicable to product liability actions brought under the OPLA as prescribed by the authority set forth in the relevant federal case law, *e.g., Williams v. Boston Scientific Corp.*, 2023 U.S. Dist. LEXIS 220371, *4 (N.D.Ohio Dec. 11, 2023) (citation omitted) (explaining that the OPLA "requires more, even at the pleading stage," than a "naked allegation that a product failed, without more" and dismissing OPLA claims for failure to state a claim); *Frey v. Novartis Pharmaceuticals Corp.*, 642 F.Supp.2d 787, 795 (S.D.Ohio 2009) (dismissing design defect claim brought under OPLA because the plaintiffs "simply provided a formulaic recitation of the elements of a claim under the statute"); *Parker v. Medtronic Sofamor Danek USA, Inc.*, 2021 U.S. Dist. LEXIS 195681, *2 (N.D.Ohio Oct. 12, 2021) (merely alleging a product malfunction is insufficient to state a manufacturing defect claim; rather, plaintiff must identify a defect or deviation in the device). These cases establish that merely offering a rote recitation of statutory language asserting that a product was defectively manufactured, constructed or designed is simply not enough to sufficiently state a claim (or claims) under the OPLA.

{¶ 56} In the case before us, a review of appellant's complaint shows that appellant failed to set forth any facts in support of her claims for manufacturing defect (R.C. 2307.74)

and/or defective design (R.C 2307.75) against any of the appellees, including Covidien. More specifically, the complaint contains no allegations about the risks and benefits of the product's design or alternative designs, and it contains no factual allegations about how the product deviated from its intended design or from identical units. Instead, the allegations in the complaint are mere legal conclusions set forth as recitations of the pertinent statutes. Pursuant to the legal authorities discussed above, this is simply not enough. Therefore, her alleged claims for manufacturing defect and design defect under R.C. 2307.73 and 2307.74, respectively, fail as a matter of law.

{¶ 57} Thus, appellant's claims under the OPLA are not sufficient to withstand the joint motion of appellees' to dismiss filed pursuant to Civ.R. 12(B)(6) and I would find the trial court did not commit reversible error when it granted the motion. Because the majority does not so find, I respectfully dissent. Therefore, I would overrule the first assignment of error in its entirety.

{¶ 58} Notwithstanding the foregoing, I concur in the majority's finding that appellant's complaint failed to sufficiently allege product liability claims based on theories of inadequate warning (R.C. 2307.76) and nonconformance with manufacturer's representations (R.C. 2307.77) as to all appellees. I further concur in the majority's finding that as to appellees Cardinal Health and the John Doe Corporations 1-5, the trial court did not err in dismissing appellant's product liability claims for failure to state claims upon which relief may be granted. Thus, I would overrule both assignments of error.

{¶ 59} Accordingly, I respectfully concur in part, dissent in part, and dissent from the final judgment to reverse in part the judgment of the trial court and remand the matter for further proceedings.
