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IN THE
COURT OF APPEALS OF INDIANA

Bayer Corporation, et al.,
Appellants-Defendants,

v.

Rene Leach, et al.,
Appellees-Plaintiffs.

August 19, 2020

Court of Appeals Case No. 19A-CT-625

Interlocutory Appeal from the Marion Superior Court

The Honorable James B. Osborn, Judge

Trial Court Cause No. 49D14-1803-CT-12218

Bailey, Judge.

Case Summary

[1] Rene Leach and more than thirty other women (collectively, the "Women") claim that they were physically injured by a medical device called Essure, which was marketed as a form of permanent birth control. The Women sued Bayer Corporation and related entities—the alleged manufacturers of Essure. The nine-count complaint alleges liability under the Indiana Product Liability Act, the Uniform Commercial Code, and the Indiana Consumer Sales Act. Certain defendants (collectively, "Bayer") moved for judgment on the pleadings, asserting that (1) the claims are preempted and (2) aspects of the complaint are deficient. The trial court denied the motion. Bayer appeals.[1]

[2] We affirm in part, reverse in part, and remand for further proceedings.

Discussion and Decision

Standard of Review

[3] A Trial Rule 12(C) motion "tests the sufficiency of a claim or defense presented in the pleadings[.]" *KS&E Sports v. Runnels*, 72 N.E.3d 892, 898 (Ind. 2017). "In reviewing a motion under 12(C), a court must 'base [its] ruling solely on the

[1] The trial court certified its interlocutory order, and we accepted jurisdiction. *See* Ind. Appellate Rule 14(B). We subsequently held oral argument and issued an opinion, which was vacated on transfer. *See Bayer Corp. v. Leach*, 147 N.E.3d 313 (Ind. 2020). The case is now before us on remand from the Indiana Supreme Court with a directive to "consider the viability of each of the [Women's] claims." *Id.* at 316. As to the claims, Bayer asserts that the nine-count complaint contains "in substance . . . six theories of liability," which Bayer addresses in turn. Br. of Appellant at 19. However, we decline to follow Bayer's suggested consolidation of the allegations. Instead, we generally take a count-by-count approach, addressing claims under each count.

pleadings' and 'accept as true the material facts alleged in the complaint.'" *Bayer Corp. v. Leach*, 147 N.E.3d 313, 315 (Ind. 2020) (alteration in original) (quoting *KS&E Sports*, 72 N.E.3d at 898). "A court should grant the motion 'only when it is clear from the face of the pleadings that the plaintiff cannot in any way succeed under the operative facts and allegations made therein.'" *Id.* (quoting *Noblesville Redev. Comm'n v. Noblesville Assocs. Ltd. P'shp*, 674 N.E.2d 558, 562 (Ind. 1996)). "[W]e review a 12(C) ruling de novo." *KS&E Sports*, 72 N.E.3d at 898.

Regulatory Background

[4] The Food and Drug Administration (the "FDA") is a federal agency that enforces the Federal Food, Drug and Cosmetic Act (the "FDCA"), *see* 21 U.S.C. ch. 9, including the Medical Device Amendments of 1976 (the "MDA"), *see* Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. ch. 9). In passing the MDA, Congress established a "rigorous regime" of pre-market approval ("PMA") for Class III medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). The Women allege that Essure is a Class III medical device that went through the PMA process.

[5] To obtain PMA, a device manufacturer must submit a detailed application. *See* 21 U.S.C. § 360e(c). The FDA grants PMA if it finds "'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)(1)(A)). In making, selling, and distributing a device, the manufacturer must comply with all applicable federal requirements. *See* 21

U.S.C. §§ 351(h), 352(q). There are generally applicable requirements, including manufacturing standards. *See, e.g.*, 21 U.S.C. § 360j(f)(1)(A); 21 C.F.R. part 820. Moreover, the FDA may impose device-specific requirements as a condition to PMA—for example, the FDA could require warnings on the label. *See* 21 U.S.C. § 360e(d)(1)(B)(ii); 21 U.S.C. § 360j(e). If a manufacturer violates a generally applicable requirement, the device is deemed either adulterated or misbranded (depending on which requirement was violated). *See* 21 U.S.C. §§ 351, 352. Further, if a manufacturer violates a device-specific requirement, the device is deemed misbranded. *See* 21 U.S.C. § 352(q). Federal law prohibits selling adulterated or misbranded devices. 21 U.S.C. § 331(a).

[6] Notably, although PMA results in a series of federal requirements, the FDCA itself provides no mechanism for private litigants to sue for non-compliance. Indeed, the FDCA specifies that enforcement proceedings "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, although the federal government regulates medical devices, where—as here—a private litigant alleges injury from a device, the plaintiff must look to state law for a remedy. As to state law, there is a "historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). However, because of the Supremacy Clause in Article VI of the U.S. Constitution, courts "must not give effect to state laws that conflict with federal laws." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324 (2015). Put differently, where state law conflicts with federal law, state law is preempted. *See id.*

Express Preemption

[7] One type of preemption is express preemption—where Congress has included "explicit preemptive text[.]" *State v. Norfolk S. Ry. Co.*, 107 N.E.3d 468, 471 (Ind. 2018). When legislation contains such text, courts "do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the [text], which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Puerto Rico v. Franklin Cal. Tax-Free Tr,*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)); *see also Norfolk S. Ry. Co.*, 107 N.E.3d at 474 (applying no presumption and concluding that a claim was expressly preempted based on the preemptive text).

[8] In the MDA, Congress included the following explicit preemptive text:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use **any requirement** . . .
>
> > (1) which is **different from, or in addition to**, **any requirement applicable under this chapter** to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).[2] With this preemptive text, Congress established a uniform regulatory scheme. *See id.* That is, because different or additional state-law requirements are expressly preempted, manufacturers face only one standard of care—the federal standard of care. *See id.* In other words, Congress established both a regulatory floor and a regulatory ceiling. Through this centralized scheme, Congress prevented states from imposing burdensome regulations that could impede innovation or drive beneficial devices off the market. *See Riegel*, 552 U.S. at 326 (noting that the preemptive text suggests "the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States").

[9] For example, if the FDA requires monthly reporting and a state requires weekly reporting, the state law is unenforceable because it is expressly preempted. *Cf. Riegel*, 552 U.S. at 330 (noting that the explicit preemptive text precludes claims asserting a violation of state tort law "notwithstanding compliance with the relevant federal requirements"). It follows that a litigant could not predicate a claim on failing to make weekly reports; recovering would be tantamount to enforcing a requirement not found in federal law. *See* 21 U.S.C. § 360k(a).

[10] Thus, due to the explicit preemptive text in the MDA, federal law supplies all germane standards of care. A state may provide a cause of action. However,

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[2] This clause applies unless the FDA grants a specific exception. 21 U.S.C. § 360k(b). Here, there is no indication that a specific exception applies.

any viable state-law claim must be premised on the violation of federal law. Therefore, enforceable state requirements—*i.e.*, standards of care—must parallel federal requirements. *See Riegel*, 552 U.S. at 330 (recognizing the viability of parallel claims); *McGookin v. Guidant Corp.*, 942 N.E.2d 831, 838 (Ind. Ct. App. 2011) ("The MDA and *Riegel* could not be clearer that federal law broadly preempts any claim that would allow a jury to impose a standard of care different from or in addition to the FDA's specific federal requirements."); *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) (noting that where state and federal requirements are effectively the same, the state requirements are not expressly preempted).

Implied Preemption

[11] Even if a claim is not expressly preempted, however, the claim could be impliedly preempted. *See Norfolk*, 107 N.E.3d at 471. There are two types of implied preemption—field preemption and conflict preemption. *Id.*

Field Preemption

[12] Field preemption applies where Congress intended to exclusively occupy the field. *Id.* Here, the preemptive text leaves room for state-law claims premised on the violation of federal law. *See* 21 U.S.C. § 360k(a) (prohibiting different or additional state-law requirements). Thus, field preemption does not apply.

Conflict Preemption

[13] "Conflict preemption applies when it is 'physically impossible' to comply with both the state and federal laws" or "when state law does 'major damage' to the

federal law's purpose." *KS&E Sports*, 72 N.E.3d at 905 (quoting *Kennedy Tank & Mfg. Co., Inc. v. Emmert Indus. Corp.*, 67 N.E.3d 1025, 1029 (Ind. 2017)). The existence of preemptive text does not bar the "ordinary working" of conflict-preemption principles. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000).

[14] In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the United States Supreme Court considered whether principles of conflict preemption precluded claims that a device manufacturer defrauded the FDA. The Court examined congressional intent, looking to the statute specifying that proceedings to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). From the statute, the Court discerned "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352. The Court then disapproved of claims that "exist solely by virtue of the FDCA" while endorsing claims that rely on "traditional state tort law [that] had predated the federal enactments." *Id.* at 353. The Court determined that, where state-law claims exist solely because of the FDCA, allowing the litigation "would exert an extraneous pull on the scheme established by Congress." *Id.* The Court concluded that those types of state-law claims—where "the existence of th[e] federal enactments" supplies a "critical element"—are impliedly preempted. *Id.*

[15] Ultimately, to avoid both express and implied preemption, first, "the plaintiff must be suing for conduct that *violates* the FDCA (or else [the] claim is expressly preempted by [the explicit preemptive text])." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v.*

Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). In other words, the plaintiff must allege and prove that the defendant violated an applicable standard set forth in the FDCA. *See* 21 U.S.C. § 360k(a). Second, "the plaintiff must not be suing [solely] *because* the conduct [exclusively] violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Sprint Fidelis Leads*, 623 F.3d at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777). Rather, because only the United States can enforce the FDCA, state law must have recognized an independent duty that now parallels the standard set forth in the FDCA. *See Buckman*, 531 U.S. at 352-53 (interpreting and applying 21 U.S.C. § 337(a)). In short, the plaintiff's claim is not preempted when the plaintiff is enforcing a duty (1) derived from traditional state tort law (2) mirroring a standard imposed by the FDCA. *See id.*

Indiana Product Liability Act

[16] Turning to the instant case, the Indiana Product Liability Act ("IPLA") "governs all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought." I.C. § 34-20-1-1. Indeed, as our Supreme Court has explained, it is "clear" that the Indiana General Assembly intended that the IPLA govern "all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 975 (Ind. 2002) (quoting *Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (1981)); *see also*

Vaughn v. Daniels Co. (W. Va.), Inc., 841 N.E.2d 1133, 1144 (Ind. 2006). Whether the IPLA applies is a question of law. *Stegemoller*, 767 N.E.2d at 975.

[17] A medical device falls within the IPLA definition of a product. *See* I.C. § 34-6-2-114 (defining "product" as "any item or good that is personalty at the time it is conveyed by the seller to another party" in a transaction not "wholly or predominantly the sale of a service rather than a product"). Moreover, a device manufacturer is a manufacturer or seller under the IPLA. *See* I.C. § 34-6-2-77 (defining "manufacturer" as "a person or an entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product . . . before the sale of the product to a user or consumer"); I.C. § 34-6-2-136 (defining "seller" as "a person engaged in the business of selling or leasing a product for resale, use, or consumption"). Further, the Women allege that they each underwent implantation procedures that would make them users or consumers. *See* I.C. § 34-6-2-147 (giving "user" the same meaning as "consumer"); I.C. § 34-6-2-29 (defining "consumer" as "any individual who uses or consumes the product"). Finally, the Women allege that they were physically harmed by Essure devices.

[18] We conclude that the IPLA applies. Therefore, the only viable product-liability claims in the complaint are those recognized by the IPLA. *See* I.C. § 34-20-1-1. As to viable claims, the IPLA imposes liability on a manufacturer that

> puts into the stream of commerce any product **in a defective condition** unreasonably dangerous to any user or consumer . . . for physical harm caused by that product to the user or consumer . . . if:

> (1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;
>
> (2) the seller is engaged in the business of selling the product; and
>
> (3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under [the IPLA].

I.C. § 34-20-2-1 (emphasis added).

[19] The IPLA establishes when a product is in a defective condition. *Brewer v. PACCAR, Inc.*, 124 N.E.3d 616, 622 (Ind. 2019). Moreover, under the IPLA, there are only three ways a product can be in a defective condition: (1) if the product has a design defect, (2) if the product has a manufacturing defect, or (3) if the product has a defect because the manufacturer failed to give adequate information about the product, *e.g.*, inadequate warnings or inadequate instructions. *See* I.C. §§ 34-20-2-1, -4-1, 4-2; *see also Brewer*, 124 N.E.3d at 621.

[20] "[I]n an action based on an alleged design defect in the product or based on an alleged failure to provide adequate warnings or instructions regarding the use of the product," the plaintiff "must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions." I.C. § 34-20-2-2. Therefore, a negligence standard applies to those types of claims. *See id.* However, in an

action based on a manufacturing defect, the IPLA imposes liability "although . . . [the manufacturer] exercised all reasonable care in the manufacture and preparation of the product[.]" I.C. § 34-20-2-2. Therefore, a strict-liability standard applies to manufacturing-defect claims. *See id.*

Negligence *Per Se*

[21] Before addressing specific state-law claims under the IPLA, we note that the Women at times seek to import standards of care from the Indiana Uniform Food, Drug, and Cosmetic Act ("Indiana FDCA"), asserting liability under a theory of negligence *per se*. The Indiana FDCA imposes requirements on device manufacturers. *See* I.C. art. 16-42. Those requirements are "intended to be uniform with" the FDCA provisions that "outlaw the false advertisement of food, drugs, devices, and cosmetics"—"promot[ing] uniformity" in the enforcement of federal requirements. I.C. § 16-42-1-1. Because the Indiana FDCA is specifically designed to parallel federal requirements, we cannot say that the legislation is independent of the FDCA. Therefore, to the extent the Women premise liability on a standard imported from the Indiana FDCA, we conclude that the claim is impliedly preempted under the principles in *Buckman*.

Manufacturing Defect

[22] Indiana Code Section 34-20-4-1 provides the pertinent standard for whether a product is in a defective condition due to a manufacturing defect:

> A product is in a defective condition . . . if, at the time [the product] is conveyed by the seller to another party, it is in a condition: (1) not contemplated by reasonable persons among

> those considered expected users of the product; and (2) that will be unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption.[3]

[23] In Count 1 and Count 7, the Women allege manufacturing defects.[4] The Women specifically allege that Essure devices were "nonconforming products" in that they "failed to conform to the design and performance standards as described in the PMA and approved by the FDA." Appellant's App. Vol. 3 at 137. The Women allege that Essure was "promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder[.]" *Id.* at 137-38. The Women also allege that Essure devices "were defective in manufacture because they did not comply with [Bayer's] own design specifications[.]" *Id.* at 199. As to design specifications, the Women assert that "[v]iolating the conditions of [PMA] is another way of saying that the manufacturer violated the original design of the product and therefore creates a viable manufacturing defect claim." *Id.* at 198. The Women assert that approval "includes not only the physical components of

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[3] We observe that the parties have not anchored their arguments in the pertinent statutory standards for cognizable defects under the IPLA. Indeed, the parties do not cite Indiana Code Section 34-20-4-1 or -4-2.

[4] In Count 1, the Women do not use the phrase "manufacturing defect." Nevertheless, the allegations in Count 1 track language in the foregoing standard. *See* Appellant's App. Vol. 3 at 137 (alleging that Essure was "in a defective condition and unreasonably dangerous when put to a reasonably anticipated use"). Furthermore, the allegations focus on strict liability—and, as earlier discussed, the IPLA imposes strict liability only for manufacturing defects. *See* I.C. § 34-20-2-2. We therefore regard the allegations contained in Count 1 as allegations of manufacturing defects. As to Count 7, the Women separately allege "multiple manufacturing defects," Appellant's App. Vol. 3 at 197, under a heading of "IPLA - Negligent Manufacturing," *id.* at 198. Although strict liability, rather than negligence, applies to manufacturing-defect claims, *see* I.C. § 34-20-2-2, we regard the allegations in Count 7 as allegations of manufacturing defects.

the product, but the labeling and intended use of the product as well," and that violating a condition of PMA supports a manufacturing-defect claim. *Id.*

[24] In Count 1, the Women allege several violations of federal requirements: (1) making false or misleading statements in connection with Essure; (2) the failure to investigate and report adverse events; (3) the failure to submit a PMA supplement and proactively strengthen warnings on the Essure label; (4) the failure to report new clinical investigations and studies; (5) the failure to comply with quality control standards; (6) the failure to establish and maintain procedures for implementing corrective and preventive action; and (7) the failure to ensure that Essure was of merchantable quality. Moreover, the Women allege that they were injured "[a]s a direct and proximate result of [Bayer's] violations of one or more" of the federal requirements. *Id.* at 140.

[25] In Count 7, the Women focus on the assembly and construction of Essure, alleging that Bayer "used non-conforming material" and "deviated from otherwise identical units from the same product line, manufactured with the same specifications." *Id.* at 199. The Women allege ten ways in which the construction or assembly of individual Essure devices was defective, *e.g.*, that "the no lead solder could in fact have trace lead in it[.]" *Id.* at 198. The Women further allege that the defective Essure devices caused their injuries.

Adequacy of Pleading

[26] Bayer argues that the Women failed to adequately plead their manufacturing-defect claims. In so arguing, Bayer at times directs us to federal cases applying

a plausibility standard found in federal law. *Cf. Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (explaining that, under federal law, a claim must be facially plausible). However, Indiana is "a notice-pleading state, . . . requir[ing] that pleadings 'contain a short and plain statement of the claim showing that the pleader is entitled to relief, and a demand for relief.'" *KS&E Sports*, 72 N.E.3d at 901 (alteration in original) (quoting Ind. Trial Rule 8(A)). This "liberal" standard "merely requires that a 'complaint . . . put the defendant on notice concerning why it is potentially liable and what it stands to lose.'" *Id.* (alteration in original) (quoting *Noblesville Redev. Comm'n*, 674 N.E.2d at 564).

[27] According to Bayer, the Women failed to adequately plead a manufacturing-defect claim because the Women made "only a cursory effort to describe the manufacturing defects . . . [w]ithout any allegations to suggest that specific federal violations caused an identifiable defect that led to a particular injury[.]" Br. of Appellant at 52. Bayer also contends that "the Women's failure to allege in more than [a] conclusory fashion that Bayer's actions caused [the Women's] injuries also renders the claim inadequately pled under Indiana law." *Id.*

[28] Turning to the complaint, the Women alleged that Bayer violated federal requirements and that those violations caused their physical injuries. The Women cited specific federal regulations that they claim Bayer violated. *See id.* at 138-39. The Women also provided a list of ten alleged defects related to the assembly or construction of individual devices. Further, the Women alleged—plaintiff-by-plaintiff—specific physical injuries. *See, e.g.*, *id.* at 88 (noting that one plaintiff's "post-procedure course has been marked by menorrhagia,

extreme fatigue, abdominal pain, back pain, joint pain, and various skin rashes."). Moreover, the Women alleged that the purported "defects . . . were a foreseeable and substantial contributing cause of the injuries and damages . . . that would not have occurred but for" using Essure. *Id.* at 140.

[29] Having reviewed the matter, we conclude that Bayer has adequate notice of the manufacturing-defect claims under Indiana's liberal standard. *See KS&E Sports*, 72 N.E.3d at 901; *cf. Bausch*, 630 F.3d at 558 (noting that "courts must keep in mind that much of the product-specific information about manufacturing needed to investigate a [manufacturing-defect] claim fully is kept confidential by federal law" and "[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim").

Express Preemption

[30] As earlier discussed, a claim based on a failure to comply with a federal requirement is not expressly preempted. *See* 21 U.S.C. § 360k(a)(1) (prohibiting claims based on different or additional requirements). For the most part, Bayer does not dispute that federal law imposed the requirements alleged in support of Count 1 and Count 7. However, Bayer argues that federal law expressly preempts claims premising liability on (1) failing to proactively strengthen warnings and (2) making false or misleading statements regarding Essure. According to Bayer, the alleged conduct did not violate a federal requirement.

Strengthening Warnings

[31] In general, before a manufacturer may make a change "affecting the safety or effectiveness" of an approved device, the manufacturer "shall submit a PMA supplement for review and approval[.]" 21 C.F.R. § 814.39(a). Importantly, changing product labeling or packaging is the type of change that generally requires an approved PMA supplement. *See id.* Although an approved PMA supplement is generally required, a manufacturer **may** proactively make labeling changes that add or strengthen warnings. 21 C.F.R. § 814.39(d)(1), (d)(2). However, a manufacturer may instead decline to make proactive changes and continue making the device under the conditions the FDA set forth in issuing the PMA. *See* 21 U.S.C. § 360e(d)(5)(A)(i) (generally requiring a supplemental action "for any change to a device subject to an approved application . . . that affects safety or effectiveness"). A manufacturer may do so because "the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323.

[32] Of course, even if a device manufacturer declines to proactively make changes to the labeling, the manufacturer is subject to ongoing reporting requirements. *See* 21 U.S.C. § 360i(a); 21 C.F.R. § 803.50. For example, a manufacturer must timely report whenever it "become[s] aware of information, from any source, that reasonably suggests that a device . . . [m]ay have caused or contributed to a death or serious injury[.]" 21 C.F.R. § 803.50. Moreover, the FDA may withdraw PMA in light of the reported information—concluding that the device

is "unsafe . . . under the conditions of use prescribed, recommended, or suggested in the labeling[.]" 21 U.S.C. § 360e(e)(1).

[33] Throughout the complaint, the Women attempt to premise liability on Bayer's continued use of the approved Essure label. Indeed, the Women assert that, based on information known to it, Bayer should have proactively changed information on the label. Bayer focuses on these allegations in seeking judgment on the pleadings, asserting that federal law permitted—but did not require—proactively changing information on the approved label. Bayer maintains that any state-law claim premised on failing to take that permitted action is expressly preempted because federal law does not require the action.

[34] As the Seventh Circuit explained: "Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005). Applying the foregoing principle, this Court rejected a similar claim premising liability on a failure to proactively strengthen warnings on an approved label: "We cannot imagine a plainer example of an attempt to impose a standard of care in addition to the FDA's specific federal requirements." *McGookin*, 942 N.E.2d at 838.

[35] We conclude that federal law expressly preempts a manufacturing-defect claim based on failing to proactively strengthen warnings on the Essure label. *See id.* We therefore reverse the denial of the Trial Rule 12(C) motion as to that claim. Moreover, to the extent the Women predicate other tort claims on the alleged

failure to proactively strengthen warnings on the label, we reverse the denial of the Trial Rule 12(C) motion as to those expressly preempted claims as well.

False or Misleading Statements

[36] The Women also allege that Bayer violated federal requirements by making false or misleading statements. The Women quote several statements that they allege were false or misleading. For example, the Women allege that a patient brochure stated that Essure was "made from the same trusted, silicone free material used in heart stents," but that the device was "not made from the same material as heart stents" and was instead "made of PET fibers, which trigger inflammation and scar tissue growth." Appellant's App. Vol. 3 at 174. Bayer does not dispute that it was required to refrain from making false or misleading statements regarding Essure. However, Bayer argues that the claim is expressly preempted because the challenged statements were either approved by the FDA or substantially similar to approved statements. Bayer directs us to several exhibits attached to a memorandum supporting its 12(C) motion. According to Bayer, the exhibits establish that the FDA approved the challenged statements.

[37] Trial Rule 12(C) provides that "[i]f, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment[.]" Although Bayer directs us to matters outside the pleadings, Bayer expressly denies that this case is at the summary judgment stage—treating summary judgment as a future event at which it might assert choice-of-law issues. *See* Br. of Appellant at 37 n.7 ("Bayer does not concede that, at the summary judgment stage, Indiana law

rather than the law of other states would necessarily apply after an appropriate choice-of-law analysis."). Because Bayer does not concede that this case is at the summary judgment stage, we decline to consider the exhibits attached to Bayer's 12(C) motion.[5]

[38] Ultimately, the pleadings alone do not establish that Bayer made only approved statements regarding Essure. Thus, based on the pleadings, we cannot say that a tort claim premised on false or misleading statements is expressly preempted.

Implied Preemption

[39] We turn to whether the surviving manufacturing-defect claims are impliedly preempted. We find guidance in *Bausch*. There, the Seventh Circuit addressed whether a manufacturing-defect claim was impliedly preempted when premised on the violation of federal manufacturing requirements—conduct that would result in the device being "adulterated" under federal law. *Bausch*, 630 F.3d at 557. The Court determined that the claim was not impliedly preempted:

> The defendants argue that [the] claim that the medical device was "adulterated" must be impliedly preempted because there is simply no state tort duty to manufacture a product that is not adulterated. We disagree. The MDA defines an "adulterated" device as a device "not in conformity with applicable

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[5] In their appellate brief, the Women acknowledge that, "at one point, [the] FDA did approve many of the [challenged] statements . . . related to the original Essure professional labeling." Br. of Appellee at 40. Bayer directs us to this sentence, which it characterizes as a concession. Yet, assuming without deciding that the Women made a concession, Bayer nevertheless has not demonstrated its entitlement to judgment on the pleadings because the Women did not concede that all statements were approved—only some unspecified statements. Thus, this Court would have no way of identifying which claims are expressly preempted.

> requirements or conditions." 21 U.S.C. § 351(h). While there may not be a "traditional state tort law" claim for an "adulterated" product in so many words, the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law. The evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient.

Id. Although *Bausch* involved the condition of being "adulterated," we find the Seventh Circuit's reasoning equally applicable to the condition of being "misbranded," which arises from the violation of (a) certain general requirements or (b) device-specific requirements imposed through PMA. *Compare* 21 U.S.C. § 351(h) (concerning the condition of being adulterated) *with* 21 U.S.C. § 352(q) (concerning the condition of being misbranded); *see also* 21 U.S.C. § 331(a) (prohibiting the sale of an adulterated or misbranded device).

[40] Turning to Indiana tort law, a product has a manufacturing defect under the IPLA if "**it is in a condition**: (1) **not contemplated by reasonable persons** among those considered expected users of the product; and (2) that will be unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption." I.C. § 34-20-4-1 (emphasis added). Applying the Seventh Circuit's analytical framework in *Bausch*, here, a fact-finder could find that the alleged failure to comply with a federal requirement created an adulterated or misbranded product condition that rendered the device to be in a "condition . . . not contemplated by reasonable persons" that was "unreasonably dangerous to the expected user[.]"

Id. Put differently, a fact-finder could find that non-compliance with federal law constituted a manufacturing defect, in that a consumer would not anticipate being implanted with a misbranded or adulterated medical device. *See id.*

[41] Such a claim does not exist "solely by virtue of the FDCA[.]" *Buckman*, 531 U.S. at 353. Rather, this type of claim is derived from traditional Indiana tort law that requires products to comport with the reasonable expectations of consumers. *See* I.C. § 34-20-4-1 (setting forth the pertinent standard, which involves whether the device is in a "condition . . . not contemplated by reasonable persons"); *accord Bemis Co., Inc. v. Rubush*, 427 N.E.2d 1058, 1061-62 (Ind. 1981) (discussing common-law principles of strict liability that predated the IPLA and related to the expectations of an ordinary consumer), *superseded by the IPLA*; *Perfection Paint & Color Co. v. Konduris*, 258 N.E.2d 681, 685 (Ind. Ct. App. 1970) (noting that the justification for imposing common-law strict liability "rest[ed] upon the premise 'that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it'" (quoting Restatement (Second) of Torts § 402(A) cmt. c (Am. Law Inst. 1965))).

[42] Furthermore, we discern no way in which permitting the state-law claim would conflict with federal law or inflict major damage on a federal purpose. To be sure, the success of certain claims might involve a finding that, had Bayer complied with federal law, the FDA would have taken certain steps in response. For example, the Women allege that Bayer failed to report adverse events. If a fact-finder so finds, it could determine that Bayer is liable on a theory that, had

Bayer fulfilled its reporting duties, the FDA would have changed warnings on the label—deterring the Women from choosing Essure. Bayer suggests that allowing this type of claim would amount to impermissible second-guessing of the FDA, akin to a claim of fraud that would "'inevitably conflict with the FDA's responsibility to police' violations of its own rules." Br. of Appellant at 45 (quoting *Buckman*, 531 U.S. at 350). Bayer points out that sister courts have found similar claims impliedly preempted on that basis. *See, e.g.*, *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (noting that a theory of liability "based on a duty to file a report with the FDA . . . is very much like the 'fraud-on-the-FDA' claim the Supreme Court held was impliedly preempted"). Bayer also argues that allowing the claim would cause manufacturers, in an abundance of caution, to report a deluge of information that would burden the FDA. However, in the instant example, a manufacturer is already obligated to report, and it could be liable only by failing to report what the FDA requires.

[43] Although we acknowledge Bayer's reading of *Buckman*, we do not read the case so expansively as to preclude a fact-finder from deciding how the FDA would have responded to required reporting. Moreover, we are not persuaded that allowing such claims would interfere with the federal regulatory scheme. Ultimately, we regard the Seventh Circuit's approach as the most persuasive. As the Seventh Circuit noted, "[t]he idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive." *Bausch*, 630 F.3d at 549. Under the Seventh Circuit's approach, a claim based on "the breach of a

recognized state-law duty" is not impliedly preempted where the plaintiff "can show that she was harmed by a violation of applicable federal law." *Id.* at 558.

[44] We conclude that the manufacturing-defect claims are not impliedly preempted. Moreover, for the foregoing reasons, we ultimately conclude that, to the extent the Women allege that Bayer violated applicable federal requirements, the Women have stated viable claims of manufacturing defects under the IPLA.[6]

Inadequate Warnings or Instructions

Failure to Warn

[45] Indiana Code Section 34-20-4-2 provides the standard for whether a product is in a defective condition due to a failure to give adequate warnings: "A product is defective . . . if the seller fails to . . . properly package or label the product to give reasonable warnings of danger about the product . . . when the seller, by exercising reasonable diligence, could have made such warnings . . . available to the user or consumer."

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[6] In so concluding, we note that when Bayer addresses the claims of manufacturing defects, it focuses only on allegations in Count 7 involving the assembly and construction of specific Essure devices. Notably, the IPLA provides that a manufacturing defect arises not merely from product assembly and construction but more generally from the "condition" of a product. I.C. § 34-20-4-1; *cf.* I.C. § 34-6-2-77 (defining "[m]anufacturer" under the IPLA as "a person or an entity who designs, assembles, fabricates, produces, constructs, **or otherwise prepares a product** or a component part of a product before the sale of the product to a user or consumer" (emphasis added)). We also observe that, under common-law principles, there is a manufacturing defect if a product "departs from its intended design[.]" Restatement (Third) of Torts: Prod. Liab. § 2 (Am. Law. Inst. 1998). Were we tasked with applying common-law principles regarding manufacturing defects in this case, we could not say that a medical device is designed to be in an adulterated or misbranded condition.

[46] In Count 2, the Women allege that Bayer is liable for a failure to warn. In claiming a failure to warn, the Women allege that Bayer violated federal law by (1) failing to report or adequately respond to adverse events and (2) failing to report clinical investigations or studies.[7] The Women allege that, had Bayer complied with the federal reporting requirements, the reported information would have reached physicians—who would have informed the Women of the risks of using Essure. The Women also allege that the FDA would have required stronger warnings, which would have informed the Women of the risks of using Essure. The Women further allege that, had they been informed of those risks, "they would have declined to have the [Essure] device implanted and they would not have suffered injuries." Appellant's App. Vol. 3 at 156.

[47] Under the IPLA, a failure-to-warn claim is viable only if the packaging or labeling did not contain adequate warnings. *See* I.C. § 34-20-4-2 (providing that a product is defective "if the seller fails to . . . properly package or label the product to give reasonable warnings of danger about the product").[8] At bottom, then, the claim is that the manufacturer should have used different labeling or packaging. *See id.* However, as Bayer points out, the Women "do not allege that the warnings Bayer provided in any way deviated from the FDA-

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[7] The Women also predicate a claim on the failure to proactively strengthen the Essure label. As earlier discussed, that claim is expressly preempted because it is not premised on a violation of federal law.

[8] Our legislature has not defined "package" or "label" in this context. Under federal law, "'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). Moreover, "label" refers to "a display of written, printed, or graphic matter upon the immediate container of any article[.]" 21 U.S.C. § 321(k).

approved" labeling or packaging. Br. of Appellant at 26. Moreover, federal law does not require use of any labeling or packaging other than that which the FDA approved. *See* 21 C.F.R. § 814.39(a) (generally requiring the submission of "a PMA supplement for review and approval by [the] FDA before making a change affecting the safety or effectiveness of the device" subject to PMA, including before making "[l]abeling changes" or "[c]hanges in packaging"). As the Seventh Circuit explained when considering a similar failure-to-warn claim,

> [a] claim that a manufacturer failed to provide an adequate warning at the time of sale would be based on the assertion that the manufacturer should have provided a different warning than the one approved by the FDA. Such a state-law claim would impose a requirement that was different from, or in addition to, the applicable federal requirements and would be preempted.

McMullen, 421 F.3d at 488.

[48] The Women direct us to caselaw from other jurisdictions recognizing a viable state-law claim for a failure to report to the FDA. *See, e.g.*, *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc) (recognizing a viable claim under Arizona law, a type of claim the Arizona Supreme Court later rejected in *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 578-79 (Ariz. 2018)), *cert. denied*; *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769-71 (5th Cir. 2011). The Women also cite a federal case accepting at the pleading stage that Indiana law imposes a duty to warn the FDA. *See Fisk v. Medtronic, Inc.*, No: 3:17-CV-032, 2017 WL 4247983, at *6-7 (N.D. Ind. Sep. 25, 2017). However, the cited cases are distinguishable because they do not apply the pertinent definition of a defect under the IPLA.

That is, to prevail for a defect due to a failure to warn under the IPLA, a litigant must show that warnings on the labeling or packaging were inadequate. *See* I.C. § 34-20-4-2. Here, the Women claim that the approved labeling and packaging was rendered inadequate due to Bayer's omissions—*i.e.*, the failure to comply with federal reporting requirements. Yet, even assuming that Bayer failed to comply with federal reporting requirements, other federal law nevertheless required that Bayer use the approved labeling and packaging. *See* 21 C.F.R. § 814.39(a). Under the MDA, a state cannot impose a different or additional requirement. *See* 21 U.S.C. § 360k(a)(1). Thus, the claims that Bayer is liable for a failure to warn under the IPLA are expressly preempted, and we therefore reverse the denial of the 12(C) motion as to such claims.[9]

[49] In so concluding, we acknowledge the Women's point that a manufacturer cannot "sit back and do nothing" when it receives certain information regarding product safety. Br. of Appellee at 31 (emphasis removed). We agree, in that there is a federal duty to report. *See* 21 U.S.C. § 360i(a); 21 C.F.R. § 803.50. Thus, although we discern no viable claim for a failure to warn under the IPLA—a claim that involves the adequacy of labeling or packaging—we clarify that the alleged violation of reporting requirements is potentially actionable as a manufacturing defect under the IPLA. As earlier discussed, such a violation

[9] Having concluded that the Women have not identified a violation of federal labeling or packaging requirements, we need not address the parties' arguments regarding whether a manufacturer's duty to warn extends to a patient or only to a physician. *See generally Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 162 n.10 (Ind. Ct. App. 1997) (discussing the "learned intermediary" exception to the duty to warn), *trans. denied*.

would render the product to be in the condition of being adulterated or misbranded.

Failure to Instruct

[50] Indiana Code Section 34-20-4-2 provides the standard for whether a product is in a defective condition due to a failure to give adequate instructions: "A product is defective . . . if the seller fails to . . . give reasonably complete instructions on proper use of the product . . . when the seller, by exercising reasonable diligence, could have made such . . . instructions available to the user or consumer."

[51] In Count 5, the Women allege that Bayer is liable for failing to give adequate instructions regarding the use of Essure. The Women allege that, in issuing the PMA, the FDA imposed a "duty to train physicians" to safely use Essure, requiring Bayer to "use reasonable care" in the training. Appellant's App. Vol. 3 at 191. The Women allege that Bayer breached the applicable standard of care, causing injuries due to the improper implantation of Essure devices.

[52] In addition to alleging that Bayer failed to comply with the federal training requirements, the Women allege that Bayer "independently undertook a duty of training physicians"—assuming duties beyond that which the FDA imposed. *Id.* at 190. The Women allege that Bayer negligently performed those self-imposed duties and is therefore liable for the failure to adequately instruct.

Express Preemption

[53] As to express preemption, Bayer disputes the scope of the FDA-imposed training requirements, directing us to an exhibit purportedly containing those requirements. Yet, for the reasons earlier discussed, we decline to consider matters outside the pleadings.[10] We will therefore assume that the FDA imposed the training requirements alleged in the complaint. As to those alleged training requirements, Bayer asserts that the Women are essentially "challeng[ing] Bayer's training program in general, claiming that the FDA-approved training program as a whole was deficient[.]" Br. of Appellant at 48. However, we do not read the complaint as challenging the adequacy of the FDA-imposed training requirements. Rather, the Women allege that Bayer negligently performed the required training. *See* Appellant's App. Vol. 3 at 191 (alleging that Bayer "breached [its] duties under the PMA and federal law to train physicians on the safe and proper use of Essure"). We conclude that the claim that Bayer is liable for negligently performing the FDA-required training is not expressly preempted because it is premised on the violation of purported federal requirements. *See Bausch*, 630 F.3d at 552 (noting that "state law claims based on violations of federal law are not expressly preempted" by the MDA).

[54] To the extent the Women premise liability on allegedly negligent training that Bayer voluntarily undertook beyond the FDA-imposed requirements, the claim

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[10] We also observe that Bayer's arguments regarding claims specific to Leach rely on matters outside the pleadings. Apart from acknowledging those arguments in this footnote, we otherwise do not address them.

is similar to a claim addressed in *Medtronic, Inc. v. Malander*, 996 N.E.2d 412 (Ind. Ct. App. 2013). There, the plaintiff premised liability on allegedly deficient technical support that a device manufacturer's representative gave to a physician during surgery. *See id.* at 414-15. The *Malander* Court noted that the technical support did not "involve the mere restatement of information given in the labeling," *i.e.*, information that the FDA approved. *Id.* at 419. Looking to persuasive caselaw, the *Malander* Court ultimately determined that the conduct at issue—a specific post-approval interaction with a physician—was extra-regulatory and not expressly preempted by the MDA. *See id.*

[55] Bayer asserts that the instant case is distinguishable in that, in *Malander*, there was no indication that the FDA required any physician training whereas, here, the FDA required at least some degree of training "as part of Essure's labeling." Br. of Appellant at 48. Bayer appears to suggest that, because the FDA imposed a training requirement regarding Essure, the Women cannot premise a claim on the alleged negligent performance of additional training services. According to Bayer, that type of claim would be improperly premised on requirements not found in federal law, *i.e.*, different or additional duties.

[56] However, we conclude that, to the extent the Women premise liability on actions Bayer voluntarily undertook beyond federal requirements, those claims either: (1) do not implicate the explicit preemptive text of the MDA for the reasons identified in *Malander*; or (2) assert a violation of a federal requirement, in that the FDA allegedly imposed training requirements regarding Essure, and federal law generally requires a manufacturer to submit a PMA supplement

before making any change that affects the safety or effectiveness of a device. *See* 21 C.F.R. § 814.39. In either case, the claim would not be expressly preempted.

Implied Preemption

[57] As to implied preemption, a product is defective under the IPLA if the seller negligently failed to give reasonably complete instructions on proper use. *See* I.C. § 34-20-4-2. Applying the Seventh Circuit's analytical framework in *Bausch*, a reasonable fact-finder could conclude that Bayer breached a state-law duty—*i.e.*, failed to exercise reasonable care under the circumstances—by failing to comply with federal training requirements. We discern no way in which enforcing the state-law duty would implicate *Buckman* concerns or interfere with the federal regulation of medical devices. *See Bausch*, 630 F.3d at 558 (determining that a plaintiff may pursue a claim based on a "breach of a well-recognized duty owed to her under state law . . . so long as she can show that she was harmed by a violation of applicable federal law"). Similarly, to the extent the Women allege liability in connection with the self-assumed duties, we discern no conflict with the federal regulatory scheme. *See id.* We therefore conclude that the failure-to-instruct claims are not impliedly preempted.

[58] The Women have stated a cognizable claim for a failure to adequately instruct.

Remaining Tort Claims

[59] In addition to claims of manufacturing defects in Counts 1 and 7 and claims of a failure to warn or instruct in Counts 2 and 5, the complaint involves several other tort claims. That is, the Women allege that they were physically injured

by Essure as a result of (a) fraudulent misrepresentation and fraud in the inducement in Count 3; (b) fraudulent concealment and fraudulent omissions in Count 4; and (c) negligent failure to test in Count 6. At bottom, these are product-liability claims governed by the IPLA. *See* I.C. § 34-20-1-1; *cf. Cavender v. Medtronic, Inc.*, No. 3:16-CV-232, 2017 WL 1365354, at *13 (N.D. Ind. Apr. 14, 2017) (noting that, "[n]otwithstanding the many ways [the plaintiff] dresses her claims, they all boil down to a claim for personal injuries allegedly caused by a . . . medical device" and the IPLA "affords the only avenue" for bringing such claims). Indeed, in the complaint, the Women state that the IPLA forms the basis for these claims. *See* Appellant's App. Vol. 3 at 136 (stating that "Counts 1-7 fall under the Indiana Product[] Liability Act"). Moreover, on appeal, the Women confirm that the IPLA forms the basis for these claims. *See* Br. of Appellee at 16 ("All the [Women's] claims are based on the [IPLA] and the multiple theories that a product can be defined 'defective' under that Act").

[60] We reiterate that the IPLA permits only three types of product-liability claims: (1) a design defect, (2) a manufacturing defect, and (3) a defect due to failing to adequately warn or instruct. The Women have not alleged a design defect and we have already addressed whether the Women stated viable claims for a manufacturing defect and a defect due to failing to adequately warn or instruct. To the extent the Women argue that Indiana law recognizes additional types of

defects, we disagree.[11] Therefore, having addressed the cognizable grounds for tort liability under Indiana law, we reverse the denial of judgment on the pleadings as to the remaining tort claims. *See* I.C. § 34-20-1-1 (stating that the IPLA governs when it applies, "regardless of the substantive legal theory or theories upon which the action is brought").[12]

[61] For the foregoing reasons, we reverse the denial of judgment on the pleadings as to the tort claims set forth in Count 3, Count 4, and Count 6.[13]

Uniform Commercial Code

[62] Turning to Count 8, the Women allege that Bayer is liable under the Uniform Commercial Code ("UCC") for the breach of an express warranty—allegations that sound in contract law rather than tort law. Decades ago, this Court concluded that the adoption of the IPLA "did not vitiate the provisions of the UCC" and that a litigant could proceed on both tort-based and contract-based theories. *Hitachi Const. Mach. Co., Ltd. v. AMAX Coal Co.*, 737 N.E.2d 460, 465 (Ind. Ct. App. 2000) (quoting *B & B Paint Corp. v. Shrock Mfg., Inc.*, 568 N.E.2d 1017, 1020 (Ind. Ct. App. 1991), *trans. denied*), *trans. denied*. However, in the

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[11] Even though the IPLA does not recognize additional types of defects—such as a defect for a failure to test, which forms the basis for the Women's allegations in Count 6—we again note that any allegation of a violation of a federal requirement may support a claim of a manufacturing defect under the IPLA.

[12] On appeal, the Women assert duties regarding post-market safety surveillance and risk management. As Bayer notes, it does not seem that the complaint contains corresponding allegations. Regardless, even if those tort claims are contained in the complaint, we would reverse as to those claims for the same reasons.

[13] Having concluded that the claims set forth in these counts are not cognizable, we do not address other arguments regarding the claims.

ensuing years, our Supreme Court has "never addressed whether the [IPLA] preempts warranty-based theories of recovery for physical harm." *Kovach v. Caligor Mw.*, 913 N.E.2d 193, 197 (Ind. 2009). In any case, we follow this Court's long-standing precedent that express-warranty claims are not subsumed by the IPLA, particularly in light of the legislative inaction as to the relationship between the UCC and the IPLA. *See, e.g.*, *DePuy, Inc. v. Farmer*, 847 N.E.2d 160, 168 (Ind. 2006) (discussing the doctrine of legislative acquiescence).

[63] Pursuant to the UCC as set forth in Indiana Code Section 26-1-2-313(1),

> Express warranties by the seller are created as follows:
>
> (a) any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Moreover, "[i]t is not necessary to the creation of an express warranty that the seller use formal words such as 'warrant' or 'guarantee' or that he have a specific intention to make a warranty," however, "an affirmation merely of the

value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." I.C. § 26-1-2-313(2).

Adequacy of the Pleading

Causation

[64] As an initial matter, Bayer argues that the Women failed to adequately plead a claim of breach of warranty. Bayer asserts that the Women "simply assert a laundry list of alleged misrepresentations without describing a 'causal link' . . . [to] any injuries." Br. of Appellant at 35-36. Bayer contends that the allegations are impermissibly conclusory, arguing that the complaint "includes no allegations as to which of the multitude of supposed misrepresentations were actually reviewed by each [p]laintiff, much less how they influenced each [p]laintiff's decisions." *Id.* at 35. Yet, in alleging a breach of warranty, the Women quote statements purportedly made when advertising Essure. *See, e.g.*, Appellant's App. Vol. 3 at 201 (cross-referencing statements quoted at 168-78). The Women also focus on statements on the Essure label. *See, e.g.*, *id.* (cross-referencing statements quoted at 167-68). The Women allege that the representations "became part of the basis of the bargain," *id.* at 202, and that "[t]he breach of the warranty was a substantial factor in bringing about [the Women's] injuries," *id.* at 203. The Women further allege that the Women "were justified in their reliance on . . . representations and marketing." *Id.*

[65] Having reviewed the matter, we conclude that the allegations regarding a breach of a warranty are sufficient to satisfy the notice-pleading standard.

Indeed, regardless of the number of alleged misrepresentations set forth in the complaint, Bayer nevertheless has notice of specific statements the Women allege support a claim of breach of warranty. Ultimately, Bayer is "on notice concerning why it is potentially liable and what it stands to lose." *KS&E Sports*, 72 N.E.3d at 901 (quoting *Noblesville Redev. Comm'n*, 674 N.E.2d at 564).

Vertical Privity

[66] Next, Bayer contends that the Women "fail to allege a crucial element of their claims for breach of express warranty—vertical privity." Br. of Appellant at 36. "[V]ertical privity exists only between immediate links in a distribution chain." *Hyundai Motor Am., Inc. v. Goodin*, 822 N.E.2d 947, 952 (Ind. 2005). "A buyer in the same chain who did not purchase directly from a seller is 'remote' as to that seller"—*i.e.*, the buyer lacks vertical privity as to that seller. *Id.*[14]

[67] Here, the Women have not alleged that they acquired Essure directly from Bayer. Therefore, the Women have not alleged vertical privity. According to Bayer, the complaint is inadequate because vertical privity is required. In arguing that vertical privity is required, Bayer directs us to two federal court cases. In one of those cases, the federal court indeed concluded that "vertical privity is required for claims of breach of express warranty" under Indiana law. *Atkinson v. P & G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1026 (N.D. Ind. 2011).

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[14] Our Supreme Court's *Goodin* decision extensively discusses privity. *See id.* at 951-59. However, the case ultimately addresses whether vertical privity is required for claims involving an implied warranty. *See id.* at 959. The case does not address vertical privity as to claims involving an express warranty under the UCC.

However, in the other case, the federal court recognized an exception to that general requirement. *See Ryden v. Tomberlin Auto. Grp.*, No. 1:11-cv-1215, 2012 WL 4470266, at *2 (S.D. Ind. Sep. 27, 2012). The exception is outlined in *Prairie Prod., Inc. v. Agchem Div.-Pennwalt Corp.*, wherein this Court noted that "the authority in favor of discarding the privity requirement in express warranty cases is overwhelming." 514 N.E.2d 1299, 1302 (Ind. 1987), *reh'g denied*. This Court ultimately held that a remote purchaser was "not precluded from suing [a manufacturer] because of lack of privity of contract, where [the manufacturer] allegedly made express warranties" directly to the remote purchaser. *Id.*

[68] Here, the Women allege that Bayer made express warranties directly to them. *See* Appellant's App. Vol. 3 at 202-03 (alleging that affirmations of fact became express warranties and the Women relied on those warranties in using Essure). Adhering to *Prairie Prod., Inc.*, we conclude that vertical privity is not required to pursue a claim based on those alleged express warranties. Thus, Bayer is not entitled to judgment on the pleadings due to a failure to allege vertical privity.[15]

Express Preemption

[69] We now turn to whether federal law expressly preempts a claim that Bayer breached an express warranty. An express warranty arises when a person voluntarily enters a private contract. *See generally State v. Int'l Bus. Machs. Corp.*,

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[15] The Women also allege liability under the Uniform Commercial Code due to express warranties made to physicians. In raising the issue of privity on appeal, Bayer does not challenge the physician-related claims.

51 N.E.3d 150, 160 (Ind. 2016) (discussing principles of freedom to contract). Moreover, when the United States Supreme Court has considered preemption in other contexts, the Court has distinguished "state-imposed obligations" from "self-imposed undertakings," *Am. Airlines, Inc. v. Wolens*, 513 U.S. 219, 228 (1995), determining that "a common-law remedy for a contractual commitment voluntarily undertaken" should not be regarded as a requirement imposed under state law, *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 526 (1992).

[70] Here, the preemptive text in the MDA prohibits only the enforcement of a different or additional **state-imposed** requirement. *See* 21 U.S.C. § 360k(a) ("[N]o State or political subdivision of a State may establish or continue in effect with respect to a device . . . any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device[.]"). We therefore conclude that the MDA does not expressly preempt a claim predicated upon the breach of an express warranty, which arises from a **self-imposed** undertaking.[16] *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997) (concluding that "[a] state judgment based on the breach of an express representation" is not preempted under the MDA); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1325-26 (3rd Cir. 1995) (determining that express warranty claims were not expressly preempted under the MDA, noting that "[t]he parties to a contract, not the state, define the substantive obligations of the contract and

[16] In arguing that the warranty claims are expressly preempted, Bayer argues that the FDA approved the factual assertions embodied in the warranties. However, because the MDA does not restrict the enforceability of self-imposed requirements, it is of no moment whether the FDA approved the assertions.

hence any express warranties"), *rejected on other grounds*. Thus, the Women's claim that Bayer breached an express warranty is not expressly preempted.

Implied Preemption

[71] In *Buckman*, the United States Supreme Court expressed concern about claims that "exist solely by virtue of the FDCA," noting that such claims "exert an extraneous pull on the scheme established by Congress[.]" 531 U.S. at 353. Here, a claim that Bayer breached an express warranty does not involve federal law. Rather, the pertinent inquiry is whether Bayer broke a promise. *See* I.C. § 26-1-2-313(1) (providing that an express warranty is a promise that goods will conform to a particular description or affirmation). Because the *Buckman* concerns are not present here, we conclude that the express-warranty claims are not impliedly preempted. *See Mitchell*, 126 F.3d at 915 (concluding, prior to *Buckman*, that "[a] state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA").

[72] Ultimately, Bayer has not demonstrated its entitlement to judgment on the pleadings on the Women's claims that Bayer breached an express warranty.

Consumer Sales Act

[73] In Count 9, the final count of the complaint, the Women allege that Bayer is liable under provisions of the Indiana Consumer Sales Act. In its Brief of Appellant, Bayer mentions the Indiana Consumer Sales Act just once, baldly asserting that the "claims for . . . violations of the Indiana Consumer Sales Act

are not pleaded with the specificity required under Trial Rule 9(B)." Br. of Appellant at 36. Bayer does not cite to the portion of the complaint that contains allegations under the Indiana Consumer Sales Act. Moreover, Bayer does not quote from Rule 9(B) or the Indiana Consumer Sales Act, and Bayer does not specifically explain why Rule 9(B) applies to claims arising under the Act. We conclude that Bayer waived its appellate argument that Bayer is entitled to judgment on the pleadings for claims under the Indiana Consumer Sales Act. Ind. Appellate Rule 46(A)(8)(a) ("The argument must contain the contentions of the appellant on the issues presented, supported by "cogent reasoning" and citations to the "Appendix or parts of the Record on Appeal relied on"); *see Robinson v. State*, 5 N.E.3d 362, 365 n.6 (Ind. 2014) (identifying appellate waiver where a party did not adequately develop an argument).

Conclusion

[74] Bayer is entitled to judgment on the pleadings on all tort claims premised on the failure to strengthen label warnings because federal law did not require Bayer to do so. Next, Bayer is entitled to judgment on the pleadings on all tort claims that do not involve a defect recognized by the IPLA. Further, as to the claim that Bayer is liable for a failure to warn, because the IPLA contemplates a defect only where labeling or packaging is inadequate—and because the Women have not alleged that Bayer deviated from the FDA-approved labeling or packaging—Bayer is entitled to judgment on the pleadings on that claim. We therefore reverse the denial of the 12(C) motion as to the foregoing claims.

However, because Bayer has otherwise not demonstrated its entitlement to judgment on the pleadings, we affirm the judgment in all other respects.

[75] Affirmed in part, reversed in part, and remanded for further proceedings.

Najam, J., and Baker, S.J., concur.