



INDIANA PRODUCTS LIABILITY LAW

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November 2014

INTRODUCTION

In Indiana, negligence and strict products liability actions for defective products are governed by the Indiana Products Liability Act (“the IPLA”). IND. CODE 34-20-1-1, *et seq.*¹ The IPLA governs all products liability actions that are brought by a *user* or *consumer*, against a *manufacturer* or *seller*, for *physical harm* caused by a *product*, regardless of the substantive legal theory or theories upon which the action has been brought. *Id.* at § 34-20-1-1 (emphasis added).

The IPLA defines a user or consumer as “a purchaser[,]” or “any individual who uses or consumes the product[,]” or “any other person who, while acting for or on behalf of the injured party, was in possession and control of the product in question[,]” or “any bystander injured by the product who would reasonably be expected to be in the vicinity of the product during its reasonably expected use.” IND. CODE § 34-6-2-29.

A manufacturer is defined 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.” *Id.* at § 34-6-2-77. The definition of a manufacturer includes a seller who: (1) has actual knowledge of a defect in the product; (2) creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant control over all or a portion of the manufacturing process; (3) alters or modifies the product in any significant manner after the product comes into the seller’s possession and before it is sold to the ultimate user or consumer; (4) is owned in whole or significant part by the manufacturer; or (5) owns in whole or significant part the manufacturer. *Id.* at § 34-6-2-77(a).

A seller is defined as “a person engaged in the business of selling or leasing a product for resale, use, or consumption.” *Id.* at § 34-6-2-136.

Physical harm means “bodily injury, death, loss of services, and rights arising from any such injuries, as well as sudden, major damage to property.” *Id.* at § 34-6-2-105(a). Physical harm for the purposes of the IPLA does not include gradually evolving damage to property or economic losses from such damage. *Id.* at § 34-6-2-105(b).

A product is any “item or good that is personalty at the time it is conveyed by the seller to another party.” *Id.* at § 34-6-2-114(a). A product for the purposes of the IPLA does not include

¹The Indiana Products liability Act (“the IPLA”) was amended in 1998 by P.L. 1-1998, § 15. The IPLA applies to causes of action accruing after June 1, 1978. The amendments apply to causes of action accruing after July 1, 1998.

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a transaction that, by its nature, involves wholly or predominantly the sale of a service rather than a product. *Id.* at § 34-6-2-114(b).

GROUND FOR ACTION – WHEN IS A PRODUCT DEFECTIVE?

The IPLA codifies the elements that must be alleged and proved in a products liability action.

A product is in a defective condition if, at the time it is conveyed by the seller to another party, it is in a condition “not contemplated by reasonable persons among those considered expected users or consumers of the product;” **and**, it is in a condition that will be “unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption.” IND. CODE § 34-20-4-1. “Unreasonably dangerous” refers to “any situation in which the use of a product exposes the user or consumer to a risk of physical harm to an extent beyond that contemplated by the ordinary consumer who purchases the product with the ordinary knowledge about the product’s characteristics common to the community of consumers.” *Id.* at § 34-6-2-146.

To establish a *prima facie* case of liability under the IPLA, the plaintiff must show that: (1) the product is defective and unreasonably dangerous; (2) the defective condition existed at the time the product left the defendant’s control; and, (3) the defective condition was a proximate cause of the plaintiff’s injuries. *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 160 (Ind. Ct. App. 1997), *trans. denied* (1998). The product may be defective within the meaning of the IPLA because of a manufacturing flaw, defective design, or the failure to warn of the dangers in the product’s use. *Id.* at 161 (citing *Hoffman v. E.W. Bliss Co.*, 448 N.E.2d 277, 281) (Ind. 1983)).

A product is defective if the seller fails to “properly package or label the product to give reasonable warnings of danger about the product” or 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 warnings or instructions available to the user or consumer. IND. CODE § 34-20-4-2.

A product is **not** defective if it is safe for reasonably expectable handling and consumption. If an injury results from handling, preparation for use, or consumption that is not reasonably expectable, then the seller is not liable. IND. CODE § 34-20-4-3. Also, a product is **not** defective if the product is incapable of being made safe for its reasonably expectable use when it is manufactured, sold, handled, and packaged properly. *Id.* at § 34-20-4-4.

STRICT LIABILITY FOR MANUFACTURING DEFECTS; NEGLIGENCE STANDARDS APPLIES TO DESIGN DEFECT AND FAILURE TO WARN CASES

“[A] person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user’s or consumer’s property is subject to liability for physical harm caused by that product . . . if (1) that

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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[.]” IND. CODE § 34-20-2-1.

This rule applies even if: (1) the seller has exercised all reasonable care in the manufacturer and preparation of the product; and, (2) the user or consumer has not bought the product from or entered into any contractual relation with the seller. IND. CODE § 34-20-2-2.

However, in a lawsuit 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 party making the claim 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. IND. CODE § 34-20-2-2; *TRW Vehicle Safety Sys. v. Moore*, 936 N.E.2d 201, 214-16 (Ind. 2010) (citing the IPLA and vacating judgment against defendant manufacturer as to liability under the IPLA in light of insufficient evidence to establish that manufacturer failed to exercise reasonable care under the circumstances).

STRICT LIABILITY APPLIES TO MANUFACTURERS

Strict liability applies only against a seller who was the manufacturer of the product or its defective component. IND. CODE §34-20-2-3. A products liability action based on the doctrine of strict liability in tort may not be commenced or maintained against a seller of a product that is alleged to contain or possess a defective condition unreasonably dangerous to the user or consumer unless the seller is a manufacturer of the product or of the part of the product alleged to be defective.² *Id.*

If a court is unable to hold jurisdiction over a particular manufacturer of a product or part of a product alleged to be defective, then that manufacturer’s principal distributor or seller over whom a court may hold jurisdiction is considered the manufacturer of the product. IND. CODE § 34-20-2-4.

The purpose of the strict liability doctrine is to deter manufacturers from producing products that are unreasonably dangerous to the foreseeable users of those products. *Guerrero v. Allison Engine Co.*, 725 N.E.2d 479, 482 (Ind. Ct. App. 2000) (citing *Maxon Corp. v. Tyler Pipe Indus., Inc.*, 479 N.E.2d 570, 578 (Ind. Ct. App. 1986)).

²Prior to 1995, sellers could be held strictly liable for product defects. Sellers may now only be held strictly liable if they are considered a manufacturer of the product. The 1995 amendment abolished strict liability for all claims of defective design or of inadequate warning or instruction and substituted a negligence standard.

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While a manufacturer has no duty to produce accident-proof products, it is legally bound to design and build products which are reasonably fit and safe for the purpose for which they are intended. *Liberty Mut. Ins. Co. v. Rich Ladder Co.*, 441 N.E.2d 996, 999 (Ind. Ct. App. 1982) (citing *Zahora v. Harnischfeger Corp.*, 404 F.2d 172 (7th Cir. 1968)); see *Kostidis v. Gen. Cinema Corp.*, 754 N.E.2d 563, 572 (Ind. Ct. App. 2001) (noting Indiana law places no duty on manufacturers to produce accident-proof goods).

Strict liability in tort is inapplicable to claims of damage to the product itself; the proper remedy is warranty. *Interstate Cold Storage Inc. v. Gen. Motors Corp.*, 720 N.E.2d 727, 731 (Ind. Ct. App. 1999).

In products liability claims alleging a design defect, the IPLA substitutes a negligence standard for strict liability and prescribes the applicable standard of care. *TRW Vehicle Safety Sys., Inc. v. Moore*, 936 N.E.2d 201, 214 (Ind. 2010). To recover damages, a plaintiff asserting a claim of defective product design “must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product.” *Id.* (citing Ind. Code § 34-20-2-2).

FAILURE TO WARN CLAIMS

Under IND. CODE § 34-20-4-2, a product is defective if the seller fails to (1) properly package or label the product to give reasonable warnings of danger about the product or (2) give reasonably complete instructions on proper use of the product when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer.

The duty to warn stems from the view that a manufacturer should have superior knowledge of its products. *Smock Materials Handling Co. v. Kerr*, 719 N.E.2d 396, 403 (Ind. Ct. App. 1999) (citing *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 163 (Ind. Ct. App. 1997)). The determination of whether a duty to warn exists is generally a question of law for the court to decide. *Natural Gas Odorizing, Inc.*, 685 N.E.2d at 161. A manufacturer has a duty to warn with respect to latent dangerous characteristics of the product, even though there is no “defect” in the product itself. *Id.*

A manufacturer may be found liable if it puts a product into the stream of commerce without adequate warnings that could reasonably have been given, if the lack of such warnings rendered the product unreasonably dangerous for its expected use. *Downs v. Panhandle E. Pipeline Co.*, 694 N.E.2d 1198, 1211 (Ind. Ct. App. 1998) (citing *Jarrell v. Monsanto Co.*, 528 N.E.2d 1158, 1166 (Ind. Ct. App. 1988)). A manufacturer, seller, or distributor of a product has a duty to warn those persons who would reasonably be likely to use its product or who are likely to come into contact with the danger inherent in the product’s use. *Ford Motor Co. v. Rushford*, 868 N.E.2d 806, 810-11 (Ind. 2007). The manufacturer has a duty to warn the ultimate user of a product when the ultimate user is a party the manufacturer should expect to use the product. *Downs v.*

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Panhandle E. Pipeline Co., 694 N.E.2d 1198, 1208-09 (Ind. Ct. App. 1998) (citing *Jones v. Hittle Serv., Inc.*, 549 P.2d 1383, 1392-94 (Kan. 1976)).

A seller has a duty to warn only when the seller knew or had reason to know that the product was likely to be dangerous when used in a foreseeable manner. *Morgen v. Ford Motor Co.*, 797 N.E.2d 1146, 1150 (Ind. 2003) (citing *Underly v. Advance Mach. Co.*, 605 N.E.2d 1186, 1189 (Ind. Ct. App. 1993)).

Failure to warn is a theory of recovery that is separate from a claim alleging defective design. *Minisan v. Danek Med., Inc.*, 79 F.Supp. 2d 970 (N.D. Ind. 1999) (citing *Gorton v. Am. Cyanamid Co.*, 533 N.W.2d 746 (Wis. 1995)); see also *Kovach v. Midwest*, 913 N.E.2d 193 (Ind. 2009) (holding that manufacturer's failure to warn against medicine cup's use for precision measurement was not proximate cause of patient's death). In a failure-to-warn case, the plaintiff is not required to establish that he would have read the warning and taken the steps to avoid injury. *Kovach*, 913 N.E.2d at 199. However, the "read-and heed" presumption does not completely dispose of the causation issue in a failure-to-warn case. The plaintiff invoking the presumption must still show that the danger that would have been prevented by an appropriate warning was the danger that materialized in the plaintiff's case. *Id.*

DEFENSES

Comparative Fault Applies/No Joint & Several Liability

In products liability actions, the fault of the person suffering the physical harm, as well as the fault of all others who caused or contributed to cause the harm, shall be compared by the trier of fact in accordance with Indiana's Comparative Fault Act (IND. CODE § 34-51-2-7; IND. CODE § 34-51-2-8; IND. CODE § 34-51-2-9). "Fault" means an act or omission that is negligent, willful, wanton, reckless, or intentional toward the person or property of others. *Id.* at § 34-6-2-45(a). "Fault" also includes an "unreasonable failure to avoid an injury or to mitigate damages." *Id.* at § 34-6-2-45(a)(1). Furthermore, the term "fault" includes a finding that a person is subject to liability for physical harm caused by a product, notwithstanding the lack of negligence or willful, wanton, or reckless conduct by the manufacturer or seller. *Id.* at § 34-6-2-45(b). In assessing the percentage of fault, the jury shall consider the fault of all persons who contributed to the physical harm, regardless of whether the person was or could have been named as a party, as long as the nonparty was alleged to have caused or contributed to cause the physical harm.³ *Id.* at § 34-20-8-1.

³Prior to the 1995 amendments, only the fault of those persons or entities that were subject to liability to the plaintiff could be named as nonparties. Thus, fault could not be allocated to persons and entities immune from suit by the plaintiff. Now, the trier of fact may apportion fault to employers, co-employees, immune governmental agencies, spouses, children, and other similar entities.

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Where liability is assessed against more than one defendant, a defendant is not liable for more than the amount of fault directly attributable to that defendant, as determined by IND. CODE § 34-20-8-1.⁴ IND. CODE § 34-20-7-1. A defendant in a products liability action may not be held jointly liable for damages attributable to the fault of another defendant. *Id.*; see *Owens Corning Fiberglass Corp. v. Cobb*, 754 N.E.2d 905, 906 (Ind. Ct. App. 2001) (reversing summary judgment for plaintiff as to liability for damages where defendant manufacturer asserted non-party defense and attributed fault to nonparty).

Use of Product with Knowledge of Defect – Assumption of Risk

It is a defense that the user or consumer bringing the action (1) knew of the defect, (2) was aware of the danger in the product, and (3) nevertheless proceeded to make use of the product and was injured. IND. CODE § 34-20-6-3. A user or consumer incurs or assumes the risk of injury by continuing to use a product after discovering a defect. *DeVoe Chevrolet-Cadillac, Inc. v. Cartwright*, 526 N.E.2d 1237, 1239 (Ind. Ct. App. 1988).

Unreasonable use of a product by a consumer who is aware of a defect is a defense to a strict products liability claim. A person who knows of a danger, understands the risk involved, and voluntarily exposes himself to such danger, is said to have incurred the risk of injury; consequently, and a jury could properly find for the defendant manufacturer in such a situation. *Rogers v. R.J. Reynolds Tobacco Co.*, 731 N.E.2d 36, 53 (Ind. Ct. App. 2000); *vacated in part, aff'd in part, Rogers v. R.J. Reynolds Tobacco Co.*, 745 N.E.2d 793 (Ind. 2001).

Even if a product is sold in a defective condition such that it is unreasonably dangerous, recovery will be denied to an injured plaintiff who has actual knowledge and appreciation of the specific danger and voluntarily accepts or incurs the risk. *Hooper v. Carey*, 716 N.E.2d 566, 576 (Ind. Ct. App. 1999) (citing *Koske v. Townsend Eng'g Co.*, 551 N.E.2d 437, 441 (Ind. 1990)).

Misuse of Product

When a defendant can show that physical harm was caused by the misuse of the product by the claimant or any other person not reasonably expected by the seller at the time the seller sold or otherwise conveyed the product to another party, the defense of misuse is available. IND. CODE § 34-20-6-4. A manufacturer is not liable if a product becomes dangerous because of “misuse” by a consumer whether a claim of liability is based on strict liability, implied warranty, or negligence. *Jarrell v. Monsanto Co.*, 528 N.E.2d 1158, 1168 (Ind. Ct. App. 1988). In Indiana, the term “misuse” refers to the use of a product for a purpose or in a manner not unreasonably foreseeable. *Id.* (citing *Perfection Paint & Color Co. v. Konduris*, 258 N.E.2d 681 (Ind. Ct. App. 1970)).

⁴Joint liability applied to products liability actions before the 1995 amendments.

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Under the IPLA, “misuse” is a defense which completely bars recovery if the seller can prove that the misuse, from the seller’s perspective, was not reasonably foreseeable. The foreseeability of an intervening misuse is a question for the jury. *Underly v. Advance Mach. Co.*, 605 N.E.2d 1186, 1189 (Ind. Ct. App. 1993); *Morgen v. Ford Motor Co.*, 797 N.E.2d 1146, 1149 (Ind. 2003). In order to determine if a product has been misused, courts look at the “reasonably expectable use” of a product, which centers on the manner of use of the product by an ordinary prudent consumer under the same or similar circumstances, not on what the individual fact finder or jury collective would have done. *Short by Southerland v. Estwing Mfg. Corp.*, 634 N.E.2d 798, 801 (Ind. Ct. App. 1994) (citing *Lovely v. Keele*, 333 N.E.2d 866 (Ind. Ct. App. 1975)).

For purposes of the misuse defense in products liability cases, when a manufacturer does not reasonably expect a particular use, the plaintiff’s failure to use available safety devices can constitute misuse. *Morgen*, 797 N.E.2d at 1149.

Breach of Warranty

Indiana courts have noted that breach of implied warranty claims sounding in tort are redundant with strict liability claims under the IPLA, but a plaintiff may raise claims arising under the UCC and claims arising under the IPLA simultaneously. *Kovach v. Midwest*, 913 N.E.2d 193, 197 (Ind. 2009); *Hitachi Constr. Mach. Co. Ltd. v. AMAX Coal Co.*, 737 N.E.2d 460 (Ind. Ct. App. 2000) (stating the UCC and the IPLA represent two different causes of action and provide alternative remedies). However, federal courts interpreting claims under the UCC and the IPLA have found that the IPLA supplants certain UCC claims, such as breach of implied warranty claims. *See Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1024-25 (N.D. Ind. 2001) (citing federal and Indiana case law). Moreover, courts have held that strict liability in tort is inapplicable to claims of damage to the product itself, as the proper remedy is warranty. *Gunkel v. Renovations, Inc.*, 822 N.E.2d 150, 152-53 (Ind. 2005); *Interstate Cold Storage, Inc. v. Gen. Motors Corp.*, 720 N.E.2d 727 (Ind. Ct. App. 1999) (affirming summary judgment as to strict liability and negligence claims under the IPLA).

Modification or Alteration of Product

A products liability claim is also defensible when the cause of the physical harm is a modification or alteration of the product made by any person after the product’s delivery to the initial user or consumer, if the modification or alteration is the proximate cause of physical harm and where the modification or alteration is not reasonably expected by the seller. IND. CODE § 34-20-6-5.

In order for the modification or alteration defense to apply, the modification or alteration of the product must be independent of the expected and intended use of the product. *Smock Materials Handling Co., Inc. v. Kerr*, 719 N.E.2d 396, 404 (Ind. Ct. App. 1999). It is only when a change or modification could be reasonably foreseen by the manufacturer to be a safety hazard and

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would not be apparent to the consumer or user that the manufacturer could be liable. *Conder v. Hull Lift Truck, Inc.*, 435 N.E.2d 10, 17 (Ind. 1982) (citations omitted).

State of the Art/Compliance with Laws

In a products liability action, there is a rebuttable presumption that the product that caused the physical harm was not defective and that the manufacturer or seller of the product was not negligent if, before the sale by the manufacturer, the product (1) was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, and labeled; or, (2) complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana. IND. CODE § 34-20-5-1.

The term “state of the art” is defined as the best technology reasonably feasible at the time the product was manufactured. Indiana courts have adopted the plain meaning of this non-legal term. *See Montgomery Ward & Co. v. Gregg*, 554 N.E.2d 1145, 1155-56 (Ind. Ct. App. 1990) (determining that “state of the art” is not a legal term of art). The term refers to the generally recognized technological environment at the time of manufacture including the available scientific knowledge, economic feasibility, and the practicalities of implementation when the product was manufactured. *See Weller v. Mack Trucks, Inc.*, 570 N.E.2d 1341, 1342 (Ind. Ct. App. 1991) (affirming jury instruction as to definition of “state of the art”). When considering a product manufacturer’s conformance with the generally recognized “state of the art,” the court will consider evidence of the existing level of technology, industry standards, the lack of other advanced technology, and the product’s safety record the time the product was manufactured. *Indianapolis Athletic Club v. Alco Standard Corp.*, 709 N.E.2d 1070, 1074 (Ind. Ct. App. 1999), *superseded on other grounds as stated in Barnard v. Saturn Corp.*, 790 N.E.2d 1023, 1030 (Ind. Ct. App. 2003).

The “state of the art” defense is a statutory affirmative defense. As such, a defendant is required to plead it or have it litigated by consent of the parties; failing to do either effectively waives the issue. *FMC Corp. v. Brown*, 526 N.E.2d 719 (Ind. Ct. App. 1988) (providing general rule on raising statutory affirmative defenses so as to avoid waiver of “state of the art” defense). The “state of the art” defense may be asserted against a manufacturing defect claim; it is not restricted to design defect matters. *Indianapolis Athletic Club*, 709 N.E.2d at 1075.

Statute of Limitation & Repose

A products liability action must be commenced within two years after the cause of action accrues or within 10 years after the delivery of the product to the initial user or consumer. IND. CODE § 34-20-3-1(b). However, if the cause of action accrues at least eight years but less than 10 years after that initial delivery, the action may be commenced at any time within two years after the cause of action accrues. *Id.* For purposes of this statute of limitations, the term “user or

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consumer” means the first consuming entity and does not include the retailer or distributor of the product who may have held the product in inventory. *Whittaker v. Fed. Cartridge Corp.*, 466 N.E.2d 480, 482 (Ind. Ct. App. 1984).

Additionally, the IPLA has a specific section pertaining to asbestos-related actions. A products liability action based on property damage resulting from asbestos or personal injury, disability, disease, or death resulting from exposure to asbestos must be brought within two years after the cause of action accrues. IND. CODE § 34-20-3-2(a). The cause of action for personal injury or property damage resulting from asbestos exposure accrues when the person knows that he has an asbestos related disease or injury or that the property damage resulted from asbestos. *Id.* at § 34-20-3-2. This section of the IPLA only applies to actions against the following entities: “(1) persons who mined and sold commercial asbestos; and (2) funds that have, as a result of bankruptcy proceedings or to avoid bankruptcy proceedings, been created for the payment of asbestos related disease claims or asbestos related property damage claims.” *Id.* at § 34-20-3-2(d).

Sophisticated Intermediary Doctrine

The sophisticated intermediary doctrine is a recognized defense in Indiana. See *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 162-64 (Ind. Ct. App. 1997) (providing overview of the sophisticated intermediary doctrine); *Smock Materials Handling Co. v. Kerr*, 719 N.E.2d 396, 403-4 (Ind. Ct. App. 1999) (discussing the sophisticated user defense). Under the sophisticated intermediary doctrine, the manufacturer may be considered to have satisfied its duty to warn by relying upon an intermediary to inform the ultimate users or consumers of the product’s dangers. In determining whether a manufacturer has satisfied its duty to warn by relying on a sophisticated intermediary, several factors are considered; namely:

- (1) the likelihood or unlikelihood that harm will occur if the intermediary does not pass on the warning to the ultimate user;
- (2) the trivial nature of the probable harm;
- (3) the probability or improbability that the particular intermediary will not pass on the warning; and,
- (4) the ease or burden the giving of the warning by the manufacturer to the ultimate user.

Natural Gas Odorizing, Inc., 685 N.E.2d at 164. Furthermore, the intermediary must have knowledge or sophistication equal to that of the manufacturer or supplier; and, the manufacturer must be able to reasonably rely on the intermediary to warn the ultimate consumer. Reliance is only reasonable if the intermediary knows or should know of the product’s dangers. Actual or constructive knowledge may arise where the supplier has provided an adequate explicit warning of the product’s dangers, or where information of the product’s dangers is available in the public domain. The question of whether a manufacturer has discharged its duty under the sophisticated intermediary doctrine is almost always a question for the trier of fact. *Kerr*, 719 N.E.2d at 403.

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Similarly, under the sophisticated user exception, there is no duty to warn when the dangers posed by the product are already known to the user. *Id.*

Learned Intermediary Doctrine

Indiana has adopted the learned intermediary doctrine for prescription products. *See Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 548-49 (Ind. Ct. App. 1979) (“Since such drugs are available only by prescription, a manufacturer’s duty to warn extends only to the medical profession, and not the ultimate users.”) (citations omitted); *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 303 (7th Cir. 1987) (finding “no principled basis” to distinguish prescription medical devices (e.g., heart catheters) from drugs); *Koehler v. Wyeth Lab. Div. of Am. Home Prods. Corp.*, 1987 U.S. Dist. LEXIS 16861, at *13-14 (S.D. Ind. Sept. 8, 1997) (applying learned intermediary doctrine to vaccines).

This doctrine, unlike the sophisticated intermediary doctrine which could conceivably insulate a manufacturer when there are multiple intermediaries between the manufacturer and the end user, contemplates only one intermediary – for example, a doctor – between a manufacturer and an end user. *See Tucker v. SmithKline Beecham Corp.*, 701 F. Supp. 2d 1040 (S.D. Ind. 2010) (discussing application of learned intermediary doctrine). “[U]nder the Learned Intermediary Doctrine, manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product.” *Menges v. DePuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (citations omitted). “The patient is expected to and, it can be presumed, does place primary reliance upon [the doctor’s independent] judgment. The physician decides what facts should be told to the patient.” *Ortho Pharm. Corp.*, 388 N.E.2d at 549 (citing *Terhune v. A.H., Robins Co.*, 577 P.2d 975 (Wash. 1978)). Moreover, “even where the warning to the physician may be inadequate, the learned intermediary rule is not suspended and a duty to warn the patient imposed.” *Koehler v. Wyeth Lab. Div. of Am. Home Prods. Corp.*, 1987 U.S. Dist. LEXIS 16861, at *13 (S.D. Ind. Sept. 8, 1997) (citing *Ortho Pharm. Corp.*, 388 N.E.2d at 548, 552, 557)).

[E]ven if the manufacturer provides inadequate information, however, the manufacturer will not be liable if the plaintiff’s physician independently knew of the risks and failed to advise the plaintiff. Hence, a plaintiff must not only show that a manufacturer’s warning was inadequate, but that such inadequacy affected the prescribing physician’s use of the product and thereby injured the plaintiff.

Menges, 61 F. Supp. 2d at 830 (internal citations omitted); *see also Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970 (N.D. Ind. 1999) (applying learned intermediary doctrine). The intended user in a case involving a prescription drug or device is the prescribing physician. *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 302-3 (7th Cir. 1987) (stating surgeon is both a “user” and a “consumer” of the medical device). As the Indiana Court of Appeals in *Ortho Pharm. Corp. v. Chapman* stated:

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Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. . . . It is his duty to inform himself of the qualities and characteristics of those products which he prescribes[,] . . . and to exercise an independent judgment

The patient is expected to and . . . does place primary reliance upon that judgment. . . . It has also been suggested that the rule is made necessary by the fact that it is ordinarily difficult for the manufacturer to communicate directly with the consumer.

388 N.E.2d at 549 (internal citations and quotations omitted). Therefore, the relevant inquiry is whether the plaintiff’s medical care providers – learned intermediaries – were aware of the potential risks and complications attendant to use of the defendant’s product. If the manufacturer properly and adequately warned the plaintiff’s physicians of the risks of the product, by way of package insert or otherwise, the defendant may be considered to have fulfilled its obligation to warn the user of the product under the learned intermediary doctrine. Moreover, a plaintiff must establish that, had the manufacturer provided more or different information (whether by labeling or promotion), the plaintiff’s physicians would have acted differently in a way that would have prevented the plaintiff’s injuries. Where there is no evidence that the physicians’ choice of treatment for the plaintiff was in any way determined by any oral or written information by the manufacturer, the plaintiff’s failure to warn claim must fail. If the physician was well aware of the risks and benefits of the product before using it in treating the plaintiff, then the plaintiff’s failure to warn claim may fail as a matter of law because the physician cannot be said to have relied upon information from the manufacturer.

Sophisticated Bulk Purchaser

The sophisticated bulk purchaser defense to failure to warn claims is arguably recognized in Indiana. See *Baker v. Monsanto Co.*, 962 F. Supp. 1143, 1151-52 (S.D. Ind. 1997) (stating sophisticated bulk purchaser defense is viable in Indiana, but various factors must be balanced to determine application of defense; declining to hold that, where manufacturer relies on sophisticated bulk purchaser to warn ultimate users of product dangers, such manufacturer is automatically insulated from liability).

In *Baker*, the court stated that “an Indiana court would likely apply the factors that animate the knowledgeable, sophisticated bulk purchaser defense in cases of negligence and strict liability duty to warn, thereby permitting a manufacturer reasonably to rely on an intermediary purchaser to warn ultimate users of dangers associated with the use of a product.” *Id.* at 1151. However, it is unclear “whether the doctrine would be adopted as an absolute bar to liability under all

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circumstances.” *Id.* “[T]he mere fact of a knowledgeable, sophisticated bulk purchaser does not automatically relieve a manufacturer of its duty to warn.” *Id.* (citing *York v. Union Carbide Corp.*, 586 N.E.2d 861 (Ind. Ct. App. 1992)).

Open and Obvious Danger

Technically, the open and obvious rule does not apply to strict liability claims under the IPLA. However, in order to be unreasonably dangerous (as required by IND. CODE § 34-20-4-1), a defective condition must be hidden or concealed. *FMC Corp. v. Brown*, 526 N.E.2d 719, 728 (Ind. Ct. App. 1988); *see also Johnson v. Kempler Indus., Inc.*, 677 N.E.2d 531, 538 (Ind. Ct. App. 1997) (stating manufacturer of product is liable only for defects which are hidden and not normally observable); *Welch v. Scripto-Tokai Corp.*, 651 N.E.2d 810, 815 (Ind. Ct. App. 1995) (same). In other words, “whether a danger is open and obvious and whether the danger is hidden are two sides of the same coin.” *Cole v. Lantis Corp.*, 714 N.E.2d 194 (Ind. Ct. App. 1999) (citing *McDonald v. Sandvik Process Sys., Inc.*, 870 F.2d 389, 393 (7th Cir. 1989)). Evidence of the open and obvious nature of the danger serves to negate a necessary element of the plaintiff’s *prima facie* case; namely, that the defect was hidden. *Brown*, 526 N.E.2d at 728. However, the open and obvious nature of the danger is not an affirmative defense; moreover, the burden of proof is not on the defendant. *Id.* at 729.

Whether the open and obvious rule applies may be, but is not always, a question of law for the court. *Schooley v. Ingersoll Rand, Inc.*, 631 N.E.2d 932, 939 (Ind. Ct. App. 1994). When the facts or the reasonable inferences to be drawn from those facts are in conflict, the open and obvious nature of the danger is a question of fact for the jury. *Brown*, 526 N.E.2d at 724.

In examining whether a given danger is open and obvious, courts employ an objective test based on what the reasonable consumer would have known. Whether a danger is open and obvious depends not only on what people can see with their eyes but also on what they know and believe about what they see. Mainly, if people generally believe that there is a danger associated with the use of a product, but that there is a safe way to use it, any danger there may be in using the product in the way generally believed to be safe is not considered “open and obvious.” *Cole v. Lantis Corp.*, 714 N.E.2d 194, 199 (Ind. Ct. App. 1999) (citing *Kroger Co. Sav-On Store v. Presnell*, 515 N.E.2d 538, 544 (Ind. Ct. App. 1987)).

Adequacy of Warning

A product may be defective and unreasonably dangerous because of deficiencies or inadequacies in warnings. A product may be defective because of a failure to supply adequate warnings with regard to potential dangers in use of the product, although the product is essentially faultless in design, material, and workmanship if reasonable prudence would require such a warning. *Montgomery Ward & Co. v. Gregg*, 554 N.E.2d 1145, 1162 (Ind. Ct. App. 1990).

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A manufacturer is not required to furnish additional warnings where such warnings “would not add to the user’s understanding of the characteristics of the product.” *Downs v. Panhandle E. Pipeline Co.*, 694 N.E.2d 1198, 1211 (Ind. Ct. App. 1998) (citing *Shanks v. A.F.E.Indus.*, 416 N.E.2d 833, 837 (Ind. 1981)); *see also Ford Motor Co. v. Rushford*, 868 N.E.2d 806 (Ind. 2007) (holding seller was under no duty to give additional warnings to buyer where all relevant information concerning product at issue was contained within that product’s owner’s manual); *Dias v. Daisy-Heddon*, 390 N.E.2d 222 (Ind. Ct. App. 1979) (“Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous”) (citation omitted).

Not a “Seller”

A “seller” means a person engaged in the business of selling or leasing a product for resale, use, or consumption. IND. CODE § 34-6-2-136. However, an occasional seller who is not engaged in that activity as part of his business is not liable in a products liability action. *Lucas v. Dorsey Corp.*, 609 N.E.2d 1191, 1202 (Ind. Ct. App. 1993) (citing, *Perfection Paint v. Konduris*, 258 N.E.2d 681, 686 (Ind. Ct. App. 1971)). Additionally, sporadic and isolated dealings do not constitute the type of regular business activity necessary to classify an entity as a “seller”. *Crist v. K-Mart Corp.*, 653 N.E.2d 140, 144 (Ind. Ct. App. 1995).



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