SURVEY OF RECENT DEVELOPMENTS IN INDIANA PRODUCT LIABILITY LAW

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INTRODUCTION

This survey provides analyses and commentary on product liability cases that have been decided by Indiana courts—both state and federal—between October 1, 2017 and November 1, 2018 (the "Survey Period"). The cases are governed by the Indiana Product Liability Act ("IPLA"),[1] and this survey is organized according to the structure of the IPLA. While a significant number of product liability cases were decided by Indiana courts within the Survey Period, this survey does not address them all. Instead, it focuses on cases that are of consequence to the development and growth of Indiana product liability law. Moreover, although the core period of time addressed in this survey is October 2017 through November 2018, this survey also addresses cases and commentary that may pre- or post-date the Survey Period because of their significance to product liability law in Indiana today.

The cases within the Survey Period continue to interpret and apply various aspects of the IPLA, such as definitions within the IPLA, evidence necessary to prove a defect claim, and defenses available under the IPLA. The cases within this survey also address a few more nuanced issues, including the extent to which a plaintiff must establish a reasonable alternative design to prove a design defect claim and a court's ability to dismiss a case at the motion to dismiss stage based on a statute of limitations defense. These cases build on prior years of product liability development in Indiana and shed new light on common issues facing product liability practitioners today.

I. THE SCOPE OF THE IPLA

The IPLA governs actions (1) brought by a user or consumer (2) against a

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1. IND. CODE §§ 34-20-1-1 to -9-1 (2017). Representative Matt Lehman introduced a bill in the 2018 Indiana General Assembly to amend the IND. CODE §§ 34-20-3, 34-61, and 34-62. *See* House Bill No. 1061 (2018). Specifically, the proposed amendments would repeal sections of the IPLA pertaining to product liability actions based on damage or injury resulting from asbestos. *Id*. The legislation did not pass; therefore, no material modifications were made to the IPLA from 2017 to 2018. Notably, the same 2018 amendments were proposed again in the 2019 General Assembly and are currently pending.

manufacturer or seller (3) for physical harm caused by a product.[2] The IPLA defines each of these terms, and case law helps interpret those definitions. Specifically, §§ 34-20-1-1 and 34-20-2-1 provide for liability in cases brought by a "user or consumer," which is defined as someone in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition of a product.[3] A user or consumer may bring a claim against a seller or manufacturer for physical harm caused by a product when that product is in a defective condition unreasonably dangerous and reached the user or consumer without substantial alteration of its condition.[4] The IPLA governs all cases that fall under these definitions regardless of the substantive legal theories upon which the action is brought.[5]

A. User or Consumer

Indiana courts have interpreted and applied the definition of "user" and "consumer" in an abundance of cases. In 2018, the Indiana Court of Appeals interpreted these definitions as they apply to workers who install component parts onto a product. In *Davis v. Lippert Components Manufacturing, Inc.*, the plaintiff worked for Evergreen Recreational Vehicles, L.L.C. ("Evergreen") in its "slide-out department" as a "box installer," where his job was to install slidable boxes on towable travel trailers.[6] The defendant, Lippert, manufactured the Schwintek System In–Wall Slide Out ("Schwintek System"), which is a mechanism attached to the slide-out box during the manufacturing process that allows the box to slide in and out of the trailer or recreational vehicle at the direction of its owner.[7] After the plaintiff installed the boxes on the trailers, the trailers went through three more manufacturing departments at Evergreen before they were complete and ready for sale to dealers.[8] While the plaintiff was working, a box from the trailer fell on his lower back, causing the plaintiff significant injuries, including paralysis from the waist down.[9] The trial court granted the defendant's motion for summary judgment on plaintiff's IPLA claims after it determined that the plaintiff was not a "user" or "consumer" as those terms are defined in the IPLA.[10] Thus, the question before the Court of Appeals was who qualifies as a "user" or "consumer" under the IPLA.

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2. *Id.* § 34-20-1-1.
3. *Id.* §§ 34-20-1-1 to -2.
4. *Id.*
5. *Id.* § 34-20-1-1.
6. 95 N.E.3d 200, 201 (Ind. Ct. App. 2018). For further discussion of *Davis* and *Campbell Hausfield/Scott Feltzer, Co. v. Johnson*, 109 N.E.3d 953 (Ind. 2018), as well as other areas of tort law, see Paul S. Kruse et al., *Recent Developments in Indiana Tort Law*, 52 IND. L. REV. 817 (2019).
7. *Id.*
8. *Id.*
9. *Id.*
10. *Id.*

The court started its analysis by reiterating the definition of "consumer" in the IPLA, which is any one of the following: (1) a purchaser; (2) any individual who uses or consumes the product; (3) 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 (4) any bystander injured by the product who would reasonably be expected to be in the vicinity of the product during its reasonably expected use.[11] The plaintiff argued that he qualified as an "individual who uses or consumes the product" because Lippert manufactured and sold the Schwintek System in its uninstalled and unassembled form, and the plaintiff used it while assembling the box for the towable trailer.[12] He also maintained that he fell within the "bystander" definition because Lippert should reasonably expect that the Schwintek System would be assembled and installed onto a trailer.[13] The court disagreed. Specifically, the court held that Schwintek System at issue was never intended or expected to reach the ultimate user or consumer in an unassembled or uninstalled form.[14] The court noted that the "user or consumer" is "the first consuming entity to obtain possession of the *completed* product."[15] The court further stated, "[Plaintiff's] installation of the box and the Schwintek System was part of the assembly and manufacture of the trailer before being released into the stream of commerce for public consumption. As a result, we cannot say that Davis was a "consumer" or "user" under Indiana Code section 34-6-2-29."[16]

Note, however, that in *Vaughn v. Daniels Co.*, the Supreme Court of Indiana held that a user or consumer may include an individual that assembles and installs a product, but only if the product is expected to reach the ultimate user or consumer in an unassembled or uninstalled form.[17] The *Vaughn* court's interpretation is consistent with another seminal Indiana case on this issue—*Butler v. City of Peru*—in which the Supreme Court of Indiana held that "the legislature intended 'user or consumer' to characterize those who might foreseeably be harmed by a product at or after the point of its retail sale or equivalent transaction with a member of the consuming public."[18] The court in *Butler* held that "user or consumer" includes any member of the *consuming public* that may be injured by a product, including family members of a purchaser, an employee of a purchaser, a guest at the purchaser's dinner table, or a donee to the purchaser.[19]

Thus, while the definition of "user or consumer" extends broadly, it only applies to individuals who use the product in the condition intended for the

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11. IND. CODE § 34-6-2-29.

12. *Davis*, 95 N.E.3d at 202.

13. *Id.* at 203.

14. *Id.*

15. *Id.* (emphasis added).

16. *Id.*

17. 841 N.E.2d 1133, 1124 (Ind. 2006).

18. Butler v. City of Peru, 733 N.E.2d 912, 919 (Ind. 2000) (quoting Thiele v. Faygo Beverage, Inc., 489 N.E.2d 562, 586 (Ind. Ct. App. 1986)).

19. *Id.* (emphasis added).

consuming public. While the *Davis* ruling may seem unfair at first blush, it ensures that manufacturers will not be held liable for alleged "defects" in their products that exist before the final product is created. It should not be surprising that unique risks exist when products are not in final form for release to the public, and therefore, the IPLA does not provide a cause of action against manufacturers for products they have not finalized and provided to the consuming public.

B. Manufacturer or Seller

The Survey Period did not generate any new cases that further developed or expanded this aspect of the IPLA. The IPLA defines "manufacturer" 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."[20] A "manufacturer" also includes a seller who: (1) has actual knowledge of a defect in a product; (2) creates and furnished a manufacturer with specifications relevant to the alleged defect for producing the product, or who otherwise exercises significant control over all or part of the manufacturing process; (3) alters or modifies the product in a significant manner; (4) is owned in whole or in part by the manufacturer; or (5) owns in whole or in part the manufacturer.[21]

C. Physical Harm Caused By A Product

The IPLA only provides a remedy for *physical harm* caused by a *product*.[22] The Survey Period did not generate any new cases that further developed or expanded this aspect of the IPLA. Accordingly, we must continue to rely on the IPLA language and interpretations of cases from prior survey periods. Under the IPLA, "physical harm" means "bodily injury, death, loss of services, and rights arising from any such injuries, as well as sudden, major damage to property."[23] A "product" is "any item or good that is personalty at the time it is conveyed by the seller to another party."[24] The term "product" does "not apply to a transaction that, by its nature, involves wholly or predominantly the sale of a service rather than a product."[25] Accordingly, damages from physical harm from services, as opposed to products, are not recoverable under the IPLA.

Similarly, economic loss is not "physical harm" and therefore, is not recoverable. Specifically, "Pure Economic Loss" is defined as pecuniary harm not resulting from an injury to the plaintiff's person or property,[26] and under Indiana

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20. IND. CODE § 34-6-2-77(a).
21. *Id.* § 34-6-2-77.
22. *Id.* § 34-20-1-1.
23. *Id.* § 34-6-2-105(a).
24. *Id*. § 34-6-2-114(a).
25. *Id*. § 34-6-2-114(b).
26. *Id*.

law, a plaintiff cannot recover in tort for "pure economic loss."[27] Likewise the IPLA does not recognize damages for purely mental or emotional distress because mental and emotional distress, standing alone, do not fall within the definition of "physical harm."[28] However, a plaintiff can recover under the IPLA for mental or emotional distress if he or she can prove a physical manifestation of such distress, which arose out of an injury caused by a defective product.[29] In sum, a number of Indiana courts during the past two decades have interpreted and applied the concept of physical harm caused by a product, and during that time, the courts have strictly adhered to the language of the IPLA and its requirements of actual physical harm.[30]

D. Defective and Unreasonably Dangerous

Liability under the IPLA extends only to products in a "defective condition" at the time it is conveyed by the seller to another party.[31] That is a product in a condition "(1) not contemplated by reasonable persons among those considered expected users or consumers 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."[32] The IPLA further clarifies "unreasonably dangerous" as a situation that "exposes the user or consumer to a risk of physical harm to an extent beyond that contemplated by the ordinary consumer who purchases [it] with the ordinary knowledge about the product's characteristics common to the community of consumers."[33] Accordingly, a plaintiff must prove the product is in a condition not contemplated by a reasonably experienced user, and in a condition that exposes the consumer to physical harm not reasonably contemplated by a consumer using the product in an expected way.

E. Decisions Involving Specific Defect Theories

In Indiana, a plaintiff may establish a "defective condition" by proving a

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27. Indianapolis-Marion Cty. Pub. Library v. Charlier Clark & Linard, P.C., 929 N.E.2d 722, 731 (Ind. 2010).

28. Doerner v. Swisher Int'l, Inc., 272 F.3d 928, 932 (7th Cir. 2001).

29. *Id.*

30. *See* Joseph R. Alberts et al., *Survey of Recent Developments in Indiana Product Liability Law*, 51 IND. L. REV. 1149 (2018) (citing Bell v. Par Pharm. Cos., No. 1: 1 l-cv-01454-TWP-MJD, 2013 WL 2244345 (S.D. Ind. May 21, 2013); Barker v. CareFusion 303, Inc., No. I :l 1-cv-00938-TWP-DKL, 2012 WL 5997494 (S.D. Ind. Nov. 30, 2012); Hathaway v. Cintas Corp. Servs., Inc., 903 F. Supp. 2d 669 (N.D. Ind. 2012); Pentony v. Valparaiso Dep't of Parks & Recreation, 866 F. Supp. 2d 1002 (N.D. Ind. 2012); GuideOne Ins. Co. v. U.S. Water Sys., Inc., 950 N.E.2d 1236, 1244 (Ind. Ct. App 2011); Fleetwood Enters., Inc. v. Progressive N. Ins. Co., 749 N.E.2d 492, 493-94 (Ind. 2001); Miceli v. Ansell, Inc., 23 F. Supp. 2d 929, 932 (N.D. Ind. 1998)).

31. IND. CODE § 34-20-2-1 (2019).

32. *Id.* § 34-20-4-1 (emphasis added).

33. *Id.* § 34-6-2-146.

design defect, a manufacturing defect or inadequate warnings.[34] Indiana Courts have addressed each of these theories, including design defect,[35] manufacturing defect,[36] and warning defect over the past decade.[37]

In *Timm v. Goodyear Dunlop Tires North America Ltd.*, a case within the Survey Period, the Northern District of Indiana considered whether the failure to include additional available safety features renders a product "unreasonably dangerous" under the IPLA.[38] Specifically, this case was brought by two plaintiffs who were injured in a motorcycle accident against the motorcycle manufacturer and tire manufacturer.[39] The opinion largely focused on the exclusion of plaintiffs' expert witnesses, but the court also addressed the effect of evidence regarding safety features of a product. The plaintiffs argued that the tires at issue should have been equipped with a tire pressure monitoring system ("TPMS"), and that the defendants' failure to equip the tires with a TPMS was evidence of a defective design.[40] But the court disagreed, stating that just because the inclusion of TPMS would have made the tires *safer*, its absence did not mean that the motorcycle was unreasonably dangerous or defectively designed.[41] "A manufacturer is under no duty to produce accident-proof products."[42] Instead, a manufacturer's duty is to make products that are *reasonably* fit for their intended use.[43] Thus, a lack of additional safety features does not equate to a defect. This case is instructive because plaintiffs often assert that because a product could be

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34. *See* Alberts et al., *supra* note 30 (citing Westchester Fire Ins. Co. v. Am. Wood Fibers, Inc., No. 2:03-CV-178-TS, 2006 WL 752584, at *5 (N.D. Ind. Mar. 31, 2006); First Nat'l Bank & Trust Corp. v. Am. Eurocopter Corp. (Inlow II), 378 F.3d 682, 689 (7th Cir. 2004); Baker v. Heye-Am., 799 N.E.2d 1135, 1140 (Ind. Ct. App. 2003)).

35. *See* Alberts et al., *supra* note 30 (citing Terex-Telelect, Inc. v. Wade, 59 N.E.3d 289 (Ind. Ct. App. 2016); Piltch v. Ford Motor Co., 778 F.3d 628 (7th Cir. 2015); Simmons v. Philips Elecs. N.A. Corp., No. 2:12-CV-39-TLS, 2015 WL 1418772 (N.D. Ind. Mar. 27, 2015); Weigle v. SPX Corp., 729 F.3d 724 (7th Cir. 2013); Lapsley v. Xtek, Inc., 689 F.3d 802 (7th Cir. 2012); *Hathaway*, 903 F. Supp. 2d 669 (discussing design defects and products liability); Green v. Ford Motor Co., 942 N.E.2d 791 (Ind. 2011); TRW Vehicle Safety Sys., Inc. v. Moore, 936 N.E.2d 201 (Ind. 2010)).

36. *See Piltch*, 778 F.3d at 632-33; *Hathaway*, 903 F. Supp. 2d 669.

37. *See* Alberts et al., *supra* note 30 (citing *Simmons*, 2015 WL 1418772; Shelter Ins. Cos. v. Big Lots Stores, Inc., No. 3:12-CV-433- JVB, 2014 WL 4494382 (N.D. Ind. Sept. 10, 2014); *Weigle*, 729 F.3d 724; Hartman v. Ebsco Indus., Inc., No. 3:10-CV-528-TLS, 2013 WL 5460296 (N.D. Ind. Sept. 30, 2013); Stuhlmacher v. Home Depot U.S.A., Inc., No. 2:10-CV-00467-JTM-APR, 2013 WL 3201572 (N.D. Ind. June 21, 2013); Tague v. Wright Med. Tech., Inc., No. 4: 12-CV-13-TLS, 2012 WL 1655760 (N.D. Ind. May 10, 2012); *Hathaway*, 903 F. Supp. 2d 669).

38. Timm v. Goodyear Dunlop Tires N. Am. Ltd., No. 2:14CV232-PPS, 2018 WL 1566827, *11 (N.D. Ind. March 29, 2018).

39. *Id*.

40. *Id*. at *11.

41. *Id*.

42. *Id.* (citing Short *ex rel* Southerland v. Estwing Mfg. Corp., 634 N.E.2d 798, 802 (Ind. Ct. App. 1994); Guerrero v. Allison Engine Co., 725 N.E.2d 479, 482 (Ind. Ct. App. 2000)).

43. *Id*.

made in a way that reduces risk to the user (or "safer" as the *Timm* court says) then it must be defective. Not so. As *Timm* shows, such a conclusion would leap over the bedrock principle that a plaintiff in a product liability case must first prove the product is defective, irrespective of whether it could have been made safer or with less risk.

Another case during the Survey Period confronted a sister question of whether a plaintiff must also prove the existence of a safer alternative design as an element of their claim. In *Kaiser v. Johnson & Johnson*,[44] the Northern District of Indiana commented on *TRW Vehicle Safety Systems, Inc. v. Moore*, in which the Indiana Supreme Court declined to require proof of reasonable alternative design as an element of a strict liability design defect claim because such proof was not required by statute.[45] The court in *Kaiser* noted that "[o]ne would think that *TRW* put to bed the question of whether, under Indiana law, a safer alternative design is a necessary element of a design defect claim."[46] However, the court also noted that "in the eight years that followed [*TRW*], many state and federal courts in Indiana continued to find that proof of alternative design is required for a design defect claim."[47]

In an attempt to clarify confusion among Indiana courts, the *Kaiser* court held that "the Indiana Supreme Court could not have been any clearer in *TRW* in holding that proof of a safer alternative design is not required under the IPLA."[48] The court's reasoning was two-fold. First, the Indiana Legislature could have adopted the standard set forth in the Restatement (Third) of Torts: Products Liability § 2(b)(1997), which requires proof of an alternative design, but chose not to.[49] Second, the Indiana Model Civil Jury Instructions[50] are void of any requirement to prove a safer alternative design in a design defect case. Indeed, the court noted that the jury instructions "don't say boo about it."[51]

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44. Kaiser v. Johnson & Johnson, No. 2:17-CV-114-PPS, 2018 WL 739871 (N.D. Ind. Feb. 7, 2018).

45. TRW Vehicle Safety Sys., Inc. v. Moore, 926 N.E.2d 201 (Ind. 2010).

46. *Kaiser*, 2018 WL 739871, at *5.

47. *Id.* Several courts have held that prove of a safer alternative design is a prerequisite to finding a defect. *See* e.g. Piltch v. Ford Motor Co., 778 F.3d 628, 632-33 (7th Cir. 2015) (quoting Pries v. Honda Motor Co., 31 F.3d 543, 545-46 (7th Cir. 1994) (plaintiff must "show that another design not only could have prevented the injury but also was cost effective under general negligence principles")).

48. *Kaiser*, 2018 WL 739871, at *5.

49. *Id.*

50. The Indiana Model Jury Instructions are drafted and published by the Civil Instructions Committee. The Civil Instructions Committee consists of various judges throughout Indiana. The Indiana Model Jury Instructions are not reviewed or approved by the Indiana Supreme Court and use of the instructions is purely discretionary. *See* Keith Hays & B.J. Brinkerhoff, *DTCI: Indiana's New Pattern Jury Instructions in Products Liability Cases*, IND. LAW. 11 (Nov. 10, 2010). However, many judges encourage or even require use of the model instructions as a baseline for the instructions used in their court. *Id*.

51. *Kaiser*, 2018 WL 739871, at *6.

But *Kaiser* is not the last word on this topic. Approximately six months after the *Kaiser* ruling, the Northern District of Indiana handed down a ruling that says nearly the exact opposite. Specifically, the court in *Jeffords v. BP Products North America, Inc.*—decided after *Kaiser*—held that a reasonable alternative design *is* an additional requirement to prove a product design defect under Indiana law: "Indiana requires the plaintiff to show that another design not only could have prevented the injury, but also was cost-effective under general negligence principals."[52] Notably, the *Jeffords* court cited to the Indiana Supreme Court in *Whitted v. General Motors Corp.*, in support of this proposition, which the court in *Kaiser* described as "outdated common law."[53] Nevertheless, the *Jeffords* court relied on this precedent—outdated or not—in holding that the plaintiff had not presented sufficient evidence to maintain its design defect claim:

> In this design defect scenario, a jury must compare costs and benefits between the Model 110 and a crane with the Plaintiff's alternative designs. Such testimony would allow the jury to ultimately decide whether Link-Belt was negligent in failing to adopt a cost-efficient alternative design that increased the safety of potential end users of its product.[54]

The plaintiff in *Jeffords* filed a Notice of Appeal to the Seventh Circuit on March 25, 2019.[55]

It should be noted that statutory language within the IPLA supports the court's conclusion in *Jeffords*. Section 34-20-5-1 provides a product is presumed not defective and the manufacturer is presumed not negligent, if the product, before its sale, was "in conformity with the generally recognized state of the art" at the time. Likewise, IPLA claims regarding the design of a product require proof that the manufacturer was negligent in failing to design something better.[56] Finally, this theme is found in § 34-20-4-4, declaring that a product is not defective if incapable of being made safe.[57] These IPLA provisions support the court's conclusions that a plaintiff must prove another design was safer at the time.[58]

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52. Jeffords v. BP Prods. N. Am., Inc., No. 2:15-CV-55-TLS, 2018 WL 3819251, at *7 (N.D. Ind. Aug. 10, 2018) (quoting Whitted v. Gen. Motors Corp., 58 F.3d 1200, 1206 (7th Cir. 1995)).

53. *Kaiser*, 2018 WL 739871, at *5.

54. *Jeffords*, 2018 WL 3819251, at *8.

55. Jeffords v. BP Corp. N. Am., No. 2:15-CV-00055-TLS (7th Cir. March 25, 2019).

56. *See* IND. CODE § 34-20-5-1 (stating that there is a rebuttable presumption that a product was not defective if, before sale to the consumer, the product conformed to the generally recognized state of the art applicable to the safety of the product). Thus, if the defendant proves that the product conformed to the generally recognized state of the art, then the presumption of no defect arises and the plaintiff must present evidence to rebut this presumption. If the defendant does not affirmatively show that the product conforms to the state of the art, however, then the presumption does not arise and the plaintiff therefore does not need to present evidence to rebut the presumption.

57. *Id.* § 34-20-4-4.

58. *Jeffords*, 2018 WL 3819251, at *7.

Similarly, in *Aregood v. Givaudan Flavors Corp.*, another Survey Period case, the Northern District of Indiana considered claims brought by various claimants who alleged that they developed "popcorn lung," a respiratory injury caused by exposure to butter flavors that contained diacetyl, while working at a popcorn packaging facility.[59] The plaintiffs' expert testified that diacetyl-free butter flavors were available in the time period in question.[60] The court noted that to show a defective design in Indiana, plaintiffs must compare the costs and benefits of alternative designs and "show that another design not only could have prevented the injury but was also cost-effective under general negligence principles."[61] Plaintiffs provided no expert testimony that the butter alternatives were cost-effective, and the court held that expert testimony was required, as such information was not within the common knowledge of the jurors.[62] "Further, the fact that the diacetyl-free alternative existed is not enough; Plaintiffs must present evidence that the diacetyl-free butter flavors' risks, benefits, and costs were favorable."[63] The court held that in the absence of such expert evidence, the plaintiffs could not prove that the defendant failed to exercise reasonable care as required by the IPLA and granted summary judgment on plaintiffs' design defect claim.[64]

These cases within the Survey Period demonstrate some confusion among Indiana Courts regarding the requirement to prove a safer alternative design in support of a design defect claim. On the one hand, the Northern District of Indiana has held that Indiana law does not require proof of a safer alternative design in support of a design defect claim.[65] On the other hand, the same court held six months later that without evidence of a reasonable alternative design, a plaintiff has not presented sufficient evidence to maintain a design defect claim.[66] The appeal filed by the plaintiff in *Jeffords* could help resolve the apparent conflict.

F. Defenses

The IPLA provides statutory defenses to a product liability claim, including: (1) incurred risk; (2) product misuse; and (3) product alteration.[67] The Supreme Court of Indiana handed down a significant ruling in November 2018 regarding the statutory defense of misuse in *Campbell Hausfeld/Scott Fetzer Co. v.*

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59. 2017 WL 4699275, at *2 (N.D. Ind. Oct. 18, 2017).

60. *Id.*

61. *Id.* (quoting Piltch v. Ford Motor Co., 778 F.3d 628, 632 (7th Cir. 2015)).

62. *Id.*

63. *Id.*

64. *Id.*

65. *See* Kaiser v. Johnson & Johnson, 2018 WL 739871, at *6 (S.D. Ind. Feb. 7, 2018); *see also* TRW Vehicle Safety Sys., Inc. v. Moore, 926 N.E.2d 201 (Ind. 2010).

66. *See* Jeffords v. BP Prods. N. Am., Inc., 2018 WL 3819251, at *4; *see also Aregood*, 2017 WL 4699275, at *2.

67. IND. CODE §§ 34-20-6-3 to -5 (2018).

Johnson.[68] Specifically, the court addressed for the first time whether the affirmative defense of misuse serves as a complete bar to recovery in a product liability action.[69]

In *Johnson,* the plaintiff brought claims against the manufacturer of a mini air die grinder ("the Grinder"), which is a hand-held power tool intended for grinding, polishing, deburring, and smoothing sharp surfaces.[70] The Grinder included various instructions and warnings, including warnings that safety glasses must be worn during operation of the Grinder and that users should not use a cut-off disc mandrel on the grinder unless a safety guard is in place.[71] The plaintiff used the Grinder to work on the headlights of his friend's truck.[72] The plaintiff wore only his prescription glasses, rather than safety glasses, as he believed those were sufficient to serve as safety glasses.[73] Moreover, in direct violation of the warnings and instructions, the plaintiff attached a cut-off disc to the grinder.[74] Not surprisingly, when using the Grinder, the cut-off disc came apart and a piece struck the plaintiff on the left side of his face, ultimately causing him to lose his left eye.[75]

The plaintiff asserted claims for failure to warn and design defect under the IPLA.[76] The defendants asserted the affirmative defense of "misuse" and argued that misuse should be a complete bar to plaintiff's recovery.[77] In reply, the plaintiff argued that misuse should not be a complete defense but instead should be considered with all other fault in the case under the comparative fault scheme.[78] Ultimately, the court followed the majority of jurisdictions in holding that "misuse operates as a complete bar to recovery, and that misuse of a product, irrespective of the existence of a product defect, will preclude the manufacturer's or seller's liability for injury or death resulting from use of the product."[79] The court also held that misuse must be proven by the defendant. Specifically, the defendant must prove that misuse of the product was (1) the cause of the harm, and (2) not reasonably expected by the seller.[80]

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68. 109 N.E.3d 953 (Ind. 2018).

69. This question was left open by the Indiana Supreme Court in *Morgen v. Ford Motor Co*., 797 N.E.2d 1146, 1148 n. 3 (Ind. 2003) ("At least two recent decisions have held that under Indiana products liability law, the defense of misuse is not a complete defense, but instead an element of comparative fault . . . . The parties [ ] make no argument along these lines and we express no opinion on it.").

70. *Campbell Hausfeld*, 109 N.E.3d at 955.

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.* at 959.

75. *Id*. at 955.

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.* at 958.

80. *Id.*

II. PLEADING REQUIREMENTS

An initial question asked at the outset of a case typically is whether the statute of limitations has run on the allegations set forth in the complaint. Often times, a pleading does not set forth the dates that are pertinent to answering this question, and the Southern District of Indiana recently held that it does not have to. In *Frazier Industrial Co. v. Mike's Five Star Truck Wash, Inc.*,[81] the court considered a motion to dismiss claims for strict liability and negligence under the IPLA on the grounds that such claims were time barred by the applicable statute of limitations.[82] The significance of this case lies in the court's statements regarding the ability to rule on a motion to dismiss based on the statute of limitations. Specifically, the court noted at the outset of its opinion that "generally, at the motion to dismiss stage, consideration of a statute-of-limitations affirmative defense is inappropriate."[83] The court reasoned that statute of limitations is an affirmative defense, and "a plaintiff need not anticipate or allege facts that would defeat affirmative defenses" in its pleading.[84] The court went so far as to say that a court cannot typically dismiss a complaint for failure to comply with the applicable statute of limitations until summary judgment. However, the court also noted that where the complaint pleads the relevant dates, which show that the statute of limitations period has expired, a court may consider a statute of limitations argument on a motion to dismiss.[85] Thus, a plaintiff may plead its way to dismissal by setting forth facts that establish a violation of the statute of limitations period. Ultimately, the court held that the particular plaintiff in that case had not pled itself out of court via the statute of limitations period, and therefore dismissal was not appropriate at the motion to dismiss stage.[86]

A similar case within the Survey Period addressed a plaintiff's attempt to get out ahead of an affirmative defense by addressing it in the complaint. In *Leach v. Bayer Corp.*, the plaintiffs filed a product liability case regarding Essure, a permanent contraceptive device.[87] Because the device was regulated by the FDA and the plaintiffs anticipated that the defendants would assert a preemption affirmative defense, the complaint explicitly stated that plaintiff "plead[ed] to avoid [the Defendants'] *affirmative defense* of 'express' preemption under the Medical Device Amendments."[88] The defendants tried to use this statement to

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81. 2018 WL 953077 (S.D. Ind. 2018).

82. *Id.* at *2.

83. *Id.* at *3.

84. *Id.* (citing Barry Aviation Inc. v. Land O'Lakes Mun. Airport Comm'n, 377 F.3d 682, 688 (7th Cir. 2004)).

85. *Id.* (citing Brooks v. Ross, 578 F.3d 574, 579 (7th Cir. 2009)).

86. *Id.* at *4.

87. 2018 WL 3454705, at *1 (S.D. Ind. July 18, 2018).

88. *Id.*

assert federal question jurisdiction, but the court denied their attempt.[89] The court specifically noted that following the Supreme Court's ruling in *Gully*,[90] "the Plaintiffs are allowed to plead in anticipation of the defense being raised," and such pleading does not create federal question jurisdiction.[91]

Although more recent than the Survey Period, federal courts have since echoed the court's decision in *Leach* in finding that defenses and anticipatory claims that refer to federal law do not necessarily give rise to federal question jurisdiction. Specifically, in *Burrell v. Bayer Corp.*,[92] the Fourth Circuit Court of Appeals considered a remand order in a product liability case against the manufacturer of a birth control medical device.[93] The plaintiffs brought state law claim for negligence, strict liability, breach of warranties, fraud, and deceptive trade practices against Bayer Corp., and alleged that Bayer Corp. (1) failed to disclose numerous adverse events to the FDA and the public, (2) failed to update its labeling and marketing materials regarding risks, (3) sold their birth control product with manufacturing defects, and (4) did not adequately train doctors on the implantation procedure.[94] Bayer removed the case to federal court, arguing that plaintiffs' state-law claims necessarily raise substantial questions of federal law.[95] Specifically, Bayer argued that plaintiffs' complaint included multiple references to federal regulatory requirements allegedly violated by Bayer and that plaintiffs' claims could be preempted by federal law.[96] The district court agreed with Bayer, but the Fourth Circuit reversed. The court referred to the Supreme Court's four-prong test, which analyzes whether federal jurisdiction exists: the case must (1) necessarily raise a federal issue, which must be (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.[97] Applying those factors, the Fourth Circuit held that "a substantial majority of district courts to consider the issue have held that state-law tort and products liability claims regarding medical devices regulated by the FDA—including Bayer's Essure—do not give rise to federal question jurisdiction."[98] The court reasoned that such claims either do not "necessarily raise" federal law questions, or any issues that may be "necessarily raised" are not substantial or cannot be heard in federal court without disrupting the federal-state balance.[99]

Thus, federal courts both inside and outside of Indiana appear to strictly apply the Supreme Court's four-prong analysis from *Grable.* The federal question at

89. *Id.* at *2.
90. Gully v. First Nat'l Bank, 299 U.S. 109, 112 (1936).
91. *Leach*, 2018 WL 3454705, at *1.
92. Burrell v. Bayer Corp., 2019 WL 1186722 (4th Cir. Mar. 14, 2019).
93. *Id.* at *1.
94. *Id.* at *2.
95. *Id.* at *3.
96. *Id.*
97. Grable & Sons Metal Prods. v. Darue Eng'g & Mfg., 545 U.S. 308, 314 (2005).
98. *Burrell*, 2019 WL 1186722, at *4.
99. *Id.* (internal citations omitted).

issue must truly be substantial and central to the case, otherwise, remand is likely.

III. EVIDENTIARY REQUIREMENTS

A. Expert Testimony

Under the IPLA, it is not enough for a plaintiff to merely assert a defect exists and that his or her injuries were proximately caused by the alleged defect. The IPLA requires expert testimony proving the defect and causation when the issues are not within the understanding of a lay person. Whether issues are "within the understanding of a lay person" has been a constant question before Indiana courts, and 2018 was no exception.

In *Dalton v. Teva North America*, the plaintiff brought a claim against the manufacturer of an Intrauterine Device ("IUD") after a piece of the IUD broke off during its removal and lodged in her uterus.[100] The doctors advised the plaintiff that removing the piece of the IUD would require a hysterectomy.[101] The district court dismissed plaintiff's claims because she did not provide expert evidence on the issue of causation.[102] On appeal to the Seventh Circuit, the plaintiff argued that proximate cause was obvious because the case involved uncomplicated facts that led to only one conclusion.[103] More specifically, plaintiff asserted that the jury could look at a broken IUD and plainly see that the product was defective.[104] The Seventh Circuit disagreed: "that is exactly the sort of speculation that is insufficient to sustain a products liability action under the Indiana law."[105] The court noted that while there are cases in which causation is so obvious that a plaintiff could forego expert testimony, this was not one of them.[106]

In *Timm* discussed above, the Northern District of Indiana applied the requirement for expert testimony to allegations of "enhanced injuries."[107] Claims of "enhanced injuries" fall within the Crashworthiness Doctrine, which the Indiana Supreme Court expressly recognized in 1990.[108] The Crashworthiness Doctrine states that "the manufacturer should be liable for that portion of damage or injury caused by the defective design over and above the damage or injury that probably would have occurred as a result of the impact or collision absent the

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100. 891 F.3d 687 (7th Cir. 2018).

101. *Id.*

102. *Id.* at 689.

103. *Id.* at 691.

104. *Id.*

105. *Id.*

106. *See, e.g.,* Higgins v. Koch Dev. Corp., 794 F.3d 697, 702 (7th Cir. 2015) ("[W]hen a plaintiff suffers from a broken leg or a gash when hit by a vehicle, he doesn't need to produce expert testimony." (quoting Myers v. Ill. Cent. R.R. Co., 629 F.3d 639, 643 (7th Cir. 2010)).

107. Timm v. Goodyear Dunlop Tires N. Am. Ltd., 309 F. Supp. 3d 595, 597 (N.D. Ind. 2018).

108. Miller v. Todd, 551 N.E.2d 1139, 1142 (Ind. 1990) ("[T]he doctrine of crashworthiness merely expands the proximate cause requirement to include enhanced injuries.").

defective design."[109] This doctrine has been widely recognized by Indiana courts since it was first recognized by *Miller*.[110]

In *Timm*, the plaintiffs were seriously injured after losing control of their motorcycle and crashing into a highway barricade.[111] Plaintiffs sued several parties, including the manufacturer of the helmets they wore at the time of the accident.[112] Plaintiffs alleged that a defect in the helmets caused their injuries to be worse than they would have been had they not been wearing a defective helmet—a classic iteration of the Crashworthiness Doctrine.[113] In *Timm*, the only evidence plaintiffs presented regarding their enhanced injuries were medical records showing the extent of their injuries.[114] As the court noted, "the question is not how bad their injuries were—it's what injuries were the result of the motorcycle crash and what injuries were the enhanced injuries caused by the allegedly defective helmets."[115] The court found that the answers to these enhanced injury causation questions were outside the purview of a layperson, and thus, the court dismissed plaintiffs' claims upon finding that they lacked the required expert testimony to support their claims of enhanced injuries.[116]

These two decisions demonstrate that courts will almost always require expert testimony in complex product liability cases. Whether the question concerns the existence of a defect, causation, or the nature and extent of injuries, courts have repeatedly refused to allow juries to make determinations without the assistance of expert witnesses.

B. FDA Approval and Clearance for Medical Devices

Medical device litigation is presently at the forefront of product liability litigation. In these cases, the admissibility of evidence regarding how a medical device came to market is a frequently visited battleground for parties, whether the fight is about the admissibility of the evidence altogether or the ability to say the Food and Drug Administration ("FDA") found a particular device to be "safe and effective." As a brief background, the FDA provides two avenues for most medical devices to make their way onto the market: (1) Pre-Market Approval

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109. Green v. Ford Motor Co., 942 N.E.2d 791, 793 (Ind. 2011) (citing Larsen v. Gen. Motors Corp., 391 F.2d 495, 502 (8th Cir. 1968)).

110. *See, e.g.,* Barnard v. Saturn Corp., 790 N.E.2d 1023, 1032 (Ind. Ct. App. 2003) (explaining that the doctrine "is merely a variation of the strict liability theory, extending a manufacturer's liability to situations in which the defect did not cause the accident or initial impact, but rather increased the severity of the injury"); Montgomery Ward & Co. v. Gregg, 554 N.E.2d 1145, 1154 (Ind. Ct. App. 1990) (noting that a vehicle manufacturer may be strictly liable for injuries "when a design defect, though not the cause of the accident, causes or enhances injuries").

111. *Id.*

112. *Id.*

113. *Id.* at 600.

114. *Id.* at 601.

115. *Id.*

116. *Id.*

("PMA") and (2) 510(k) clearance. The avenue that a device must follow depends on its classification—Class I devices are simpler, lower risk devices; Class II devices are moderate-risk devices; and Class III devices are higher risk devices.[117] A Class III device typically requires the PMA process because of its high-risk nature. The PMA process is the most stringent type of device marketing application required by FDA, and it requires the applicant to prove that the device is safe and effective for its intended use.[118] A 510(k) application requires the device manufacturer to demonstrate that the device is "substantially equivalent" to a device already on the market (the "predicate device").[119]

The Supreme Court addressed these two processes in two seminal cases: *Medtronic, Inc. v. Lohr*[120] and *Riegel v. Medtronic, Inc.*[121] In *Lohr*, the Supreme Court considered whether the Medical Device Amendments of 1976 preempt common law negligence and strict liability actions against the manufacturer of a medical device.[122] The device at issue in *Lohr* had gone through the 510(k) clearance process, which demonstrated the device's substantial equivalence to a device already on the market.[123] The Court held that the particular claims at issue were not preempted by the Medical Device Amendments because the "substantially equivalent" requirement does not amount to a federally enforceable design requirement with which state law conflicts.[124] The Court specifically distinguished the 510(k) process from the PMA process, noting that the PMA process focused on safety, while the 510(k) process is focused on equivalence.[125]

However, the device at issue in *Lohr* (a Medtronic pacemaker), received 510(k) clearance in 1982, when the Medical Device Amendments of 1976 were in place.[126] In 1990, Congress passed the Safe Medical Device Amendments ("SMDA"), which added key language to 21 U.S.C. § 360c regarding the 510(k) process. Specifically, the SMDA requires that manufacturers, in their 510(k) applications, provide a "a summary of and a citation to all adverse safety and effectiveness data respecting [the predicate] device and respecting the device for which the section 360(k) report is being made."[127] Further, the SMDA provides that "[t]he Secretary may require the manufacturer to submit the adverse safety

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117. 21 U.S.C. § 360c(a) (2019); 21 C.F.R. § 860.3 (2018).

118. *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/ [https://perma.cc/9L5D-64X3].

119. *510(k) Clearances*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm [https://perma.cc/NS4S-VJHQ].

120. 518 U.S. 470 (1996).

121. 552 U.S. 312 (2008).

122. *Lohr*, 518 U.S. at 471.

123. *Id.*

124. *Id.*

125. *Id.* at 493.

126. *Id.* at 480.

127. 21 U.S.C. § 360c(f)(4)(C) (2019).

and effectiveness data described in the report."[128] Thus, the SMDA requires substantial safety and effectiveness data as part of the 510(k) process, and the SMDA implies that in the substantial equivalence inquiry, safety and effectiveness are considered to a greater extent now than they were in 1976. Moreover, 21 CFR § 807.92 lays out the content and format of a 510(k) summary. Subparagraphs (b)(2) and (3) state that the 510(k) summaries must include "a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications," and "[t]he conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective."[129]

Moreover, various FDA publications and guidance documents have reiterated that safety and effectiveness is a central focus of the 510(k) process. Specifically, a 2014 FDA Guidance document regarding the 510(k) process states that "classification of a new device through the 510(k) process requires FDA to determine the issues of safety and effectiveness presented by the new device.[130] The FDA even addressed the differences between the PMA process and the 510(k) process in this guidance document and reaffirmed the focus on safety and effectiveness:

> The 510(k) review standard (substantial equivalence of a new device to a legally marketed (predicate) device) differs from the PMA review standard (reasonable assurance of safety and effectiveness). The 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness. Nonetheless, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review.[131]

Thus, the FDA has clarified and emphasized the importance of the safety and effectiveness analysis in the 510(k) process. Notably, the *Lohr* decision was limited several years later by another Supreme Court decision in *Riegel*. Unlike the device in *Lohr*, the device in *Riegel* had gone through the PMA process.[132] After discussing the details of its decision in *Lohr*, the Court compared the PMA and 510(k) processes. The Court noted that the PMA process imposes "requirements" under the Medical Device Amendments and is specific to individual devices.[133] The Court also held that PMA approval is focused on safety, not equivalence—that is, "the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and

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128. *Id.*

129. 21 C.F.R. § 807.92.

130. *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, U.S. FOOD & DRUG ADMIN. (July 28, 2014), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k [https://perma.cc/FF39-6JVN].

131. *Id.*

132. Riegel v. Medtronic, Inc., 552 U.S. 312, 320 (2008).

133. *Id.* at 322.

effectiveness."[134] The Court ultimately held that common law claims for negligence and strict liability relating to a PMA-approved device are preempted by the Medical Device Amendments.[135]

As stated above, irrespective of the decisions in *Lohr* and *Riegel*, the FDA's own statements demonstrate that the 510(k) process intends to address the safety and effectiveness of 510(k) devices. At least one court in California agreed during the Survey Period. Specifically, the Court in *Otero v. Zeltig Aesthetics, Inc.*, held that:

> Although *Medtronic* [a/k/a *Riegel*] observed that obtaining Section 510(k) clearance is not as onerous as the "rigorous" PMA process, the Supreme Court did not find that the former has no bearing on a device's safety and effectiveness. . . In fact, *Medtronic* acknowledged that "the FDA may well examine § 510(k) applications . . . with a concern for the safety and effectiveness of the device."[136]

While *Lohr* and *Riegel* addressed the extent to which common law claims against medical device manufacturers are preempted, they did not address the admissibility of PMA or 510(k) evidence in medical device cases. This is a common dispute between parties, the result of which varies among and even within states. In many states, the battle over the admissibility of PMA and 510(k) evidence is heightened because of statutes like Indiana Code § 34-20-5-1, which provides rebuttable presumption that a product is not defective, and the manufacturer is therefore not negligent, where a product complies with applicable codes, standards, regulations, or specifications.[137] Medical device manufacturers often point to these types of statutes to argue for the admissibility of PMA or 510(k) evidence, stating that such evidence is relevant because of this rebuttable presumption.[138]

In *Kaiser v. Johnson & Johnson*, a case within the Survey Period and discussed above, the court considered the admissibility of 510(k) evidence in a product liability case involving a mesh product manufactured by Ethicon.[139] As an initial matter, the court noted that while the Medical Device Amendments of 1976 provided the initial framework for the FDA's oversight process, the Safe Medical Devices Act of 1990 provided "firmer footing for this loosely designed process" by codifying "the definition of substantial equivalence that the FDA has developed administratively through the experience of clearing devices for the 14 years since the enactment of the MDA."[140]

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134. *Id.* at 323.

135. *Id.*

136. Otero v. Zeltig Aesthetics, Inc., 2018 WL 3012942, at *3 (C.D. Cal. June 11, 2018) (quoting *Riegel*, 552 U.S. at 478-79, 493).

137. IND. CODE § 34-20-5-1 (2019); *see also* Kaiser v. Johnson & Johnson, 2018 WL 1358407, at *1 (N.D. Ind. March 16, 2018).

138. *See, e.g., Kaiser*, 2018 WL 1358407, at *1.

139. *Id.* at *2.

140. *Id.*

The product had been cleared for marketing through the 510(k) process, and Ethicon sought to admit evidence of the clearance on the grounds that it would entitle Ethicon to the rebuttable presumption found in Indiana Code § 34-20-1.[141] The court, however, disagreed. Specifically, the court held that while the wording of the presumption relates to the safety of the product, "the Indiana Court of Appeals has explicitly found that in order 'for evidence of compliance with governmental standards to be relevant, the standard itself must relate to the risk or product defect at issue.'"[142] Accordingly, the court held that for the presumption to apply, Ethicon would have to show that the standard with which it complied spoke to safety.[143] The court held that Ethicon could *not* show that the 510(k) process spoke to safety because the 510(k) process speaks to equivalence.[144] The court specifically addressed *Lohr* and *Riegel* in support of its decision to exclude all evidence of 510(k) clearance: "the § 510(k) evidence does not speak directly to safety and efficacy and, therefore, is of very little probative value."[145] The court went one step further to note that the trial would have been "completely sidetracked" with the introduction of 510(k) evidence, which would have required the introduction of additional evidence and testimony from regulatory experts and Ethicon employees.[146] This ruling should not discourage defendants from continuing to fight for the application of Indiana Code § 34-20-5-1 to 510(k) devices. Indeed, the language of the SMDA and the FDA's statements provide compelling evidence in support.

IV. PREEMPTION

An Indiana federal court decision within the Survey Period addressed whether the assertion of a federal preemption defense established federal question jurisdiction under 28 U.S.C. § 1441. In *Leach v. Bayer Corp.*,[147] which was addressed briefly above, the plaintiff filed their product liability case regarding Essure, a permanent contraceptive device, in a Marion County, Indiana, state court.[148] The defendant removed the case to federal court, asserting that "because Plaintiffs' claims relate to a medical device with premarket approval that is heavily regulated by FDA and Plaintiffs' claims turn on the interpretation of federal law . . . this case arises from and turns on a question of federal law."[149] Essentially, the defendants asserted that the plaintiffs' claims would be dependent on their ability to show violations of federal law.[150] However, the court disagreed,

141. *Id.*
142. *Id.* (citing Wade v. Terex-Telect, Inc., 966 N.E.2d 186, 194 (Ind. Ct. App. 2012)).
143. *Id.*
144. *Id.*
145. *Id.* at *4.
146. *Id.*
147. Leach v. Bayer Corp., 2018 WL 3454705, at *1 (S.D. Ind. July 18, 2018).
148. *Id.*
149. *Id.*
150. *Id*. at *2.

finding that it was not *plaintiffs' claims* that depended on federal law, but rather *defendants' affirmative defense of preemption.*[151] While the affirmative defense of federal preemption might make it very likely that a question under the Constitution would arise, it did not show that the plaintiffs' original cause of action *arose under the Constitution.*[152] Thus, neither the affirmative defense of federal preemption nor the anticipation of such defense in a plaintiff's complaint established federal question jurisdiction.

V. STATUTES OF LIMITATION AND REPOSE

The IPLA contains a two-year statute of limitation and a statute of repose of ten years from the date the product at issue was first delivered to the initial user or consumer.[153]

As discussed above, the court in *Frazier Industrial Co.*[154] considered a motion to dismiss product liability claims under the IPLA on the grounds that such claims were time barred by the statute of limitations.[155] The court reiterated that the two-year limitation period begins when a cause of action accrues,[156] and a cause of action "accrues" when the plaintiff knew or should have known of the damage and that it was caused by another.[157] As explained above, the court explained that "generally, at the motion to dismiss stage, consideration of a statute-of-limitations affirmative defense is inappropriate."[158] However, where the complaint pleads the relevant dates that illustrate that the statute of limitations period has expired, a court may consider a statute of limitations argument on a motion to dismiss.[159] Thus, a statute of limitations bar may be raised in a motion to dismiss a motion for summary judgment depends on the language of the

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151. *Id.* (citing Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010) (recognizing that preemption "protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law").

152. *Id.* (citing Franchise Tax Bd. v. Constr. Laborers Vacation Tr., 463 U.S. 1, 10 (1983)).

153. IND. CODE § 34-20-3-1 (2019). A statute of limitations dictates the amount of time after an event occurs within which a legal claim related to that event can be filed, whereas a statute of repose dictates the amount of time after a product has been delivered to the initial user or consumer within which a legal claim related to that product can be filed. For example, imagine a claimant is mowing his lawn with an 11-year-old lawn mower when he becomes injured by the lawn mower. Pursuant to the statute of limitations, the claimant may file a lawsuit within two years of this injury. However, the statute of repose will preclude him from filing a lawsuit because the ten-year period following his initial purchase (i.e., receipt) of the lawn mower has expired.

154. Frazier Indus. Co. v. Mike's Five Star Truck Wash, Inc., 2018 WL 953077 (S.D. Ind. 2018).

155. *Id.* at *2.

156. *Id.* at *3 (citing IND. CODE § 34-20-3-1).

157. *Id.* at *2.

158. *Id.* at *3.

159. *Id.* (citing Brooks v. Ross, 578 F.3d 574, 579 (7th Cir. 2009)).

pleading and whether it establishes a prima facie violation.

VI. PRODUCT LIABILITY TRENDS

The Southern District of Indiana has been addressing key issues and trends in product liability law over the past few years. For example, the *Cook IVC Filter* Multi District Litigation ("MDL"), which is venued in the Southern District of Indiana, has brought many of these issues and trends to the forefront, such as the scope of the learned intermediary doctrine,[160] the boundaries of expert testimony in a complex product liability cases,[161] bifurcation,[162] and consolidation.[163] The last two in particular—bifurcation and consolidation—are worthy of more discussion.

A. Bifurcation

In a product liability trial against a manufacturer or seller of an allegedly defective product, the jury must always answer whether the manufacturer or seller is liable for the harm allegedly caused to the plaintiff, and if so, what amount of damages will compensate the plaintiff for the harm. Where the plaintiff seeks punitive damages, an additional and quite different question is put to a jury—the extent to which it wants to punish the manufacturer for its conduct.

Unlike compensatory damages, which are intended to *compensate* an injured plaintiff for physical harm, punitive damages are intended to *punish* a tortfeasor

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160. *In re* Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig., (Tonya Brand), 2018 WL 6415585 (S.D. Ind. Dec. 5, 2018) (finding that, under Georgia law, a plaintiff can prevail on a failure to warn claim only by proving that the warnings were inadequate and that those inadequate warnings proximately caused her injuries).

161. *In re* Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig., (Tonya Brand), 2018 WL 5830711 (S.D. Ind. Nov. 7, 2018) (finding that a biomedical engineer could testify about the IVC filter's ability to catch blood clots from a biomedical design and engineering perspective); *In re* Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig., (Tonya Brand), 2018 WL 5926510 (S.D. Ind. Nov. 13, 2018) (limiting a non-retained expert treating physician's opinions to the opinions that were formed during the course of care and treatment to the plaintiff, pursuant to Rule 26(a)(2)(C)); *In re* Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig., (Tonya Brand), 2018 WL 6047018 (S.D. Ind. Nov. 19, 2018) (finding that a plaintiff cannot move to exclude an expert for not examining the plaintiff when the expert was not given an opportunity for an exam).

162. Order On The Cook Defendants' Motion to Bifurcate, *In re* Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig., (Tonya Brand), No. 1:14-cv-6016-RLY-TAB, Doc. 6944 (S.D. Ind. Oct. 20, 2017) [hereinafter Cook Bifurcation Order] (granting Cook Defendants' Motion to Bifurcate); Entry For January 8-9, 2019, No. 1:14-cv-06018, Doc. 9892 (S.D. Ind. Jan. 11, 2019) (granting Defendants' Motion to Bifurcate).

163. Order On The Cook Defendants Motion For Screening Order And Bellwether Selection Plan, *In re* Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig., No. 1:14-ml-02570-RLY-TAB, Doc. 9322, at 4 n.2 (S.D. Ind. Oct. 2, 2018) [hereinafter Cook Bellwether Plan].

for willful and wanton misconduct.[164] Consequently, evidence that is relevant to punitive damages differs substantially from the evidence relevant to liability and compensatory damages. For example, the evidence relevant to liability will focus on the product, including the design, manufacture, and/or warnings for the product. It will also focus on the plaintiff's injury, the plaintiff's conduct, and whether a defect caused the plaintiff's injury. In contrast, the evidence relevant to the punitive damages inquiry will focus almost entirely on the defendant, including its allegedly reprehensible conduct and its financial condition.

Recognizing the risks of unfair prejudice to defendants arising from the different foci of evidence and argument when punitive damages are sought, many state legislatures and state courts have enacted rules or procedures allowing bifurcation—that is, the division of a trial into two phases: (1) Trying liability for the underlying tort and compensatory damages; and (2), if necessary, the issue of punitive damages. Although Indiana is not one of the states that has adopted a rule requiring bifurcation, both the Federal Rules of Civil Procedure and the Indiana Rules of Trial Procedure permit a defendant manufacturer to request bifurcation, which is then granted or denied at the trial court's discretion.

The basis for moving for bifurcation can be found in Indiana Trial Rule 42. Under Indiana Trial Rule 42(B), a trial court may order separate trials on the issues of liability and damages:

> The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues, always preserving inviolate the right of trial by jury.[165]

Moreover, Indiana Trial Rule 42(C) provides: "The Court upon its own motion or the motion of any party for good cause shown may allow the case to be tried and submitted to the jury in stages or segments including, but not limited to, bifurcation of claims or issues of compensatory and punitive damages."[166]

In applying Trial Rule 42(B) and (C), the Court of Appeals of Indiana has offered the following guidance for trial courts considering the issue of bifurcation:

> The avoidance of prejudice is more than sufficient reason for a separate trial. However, a separate trial should not be granted solely upon the movant's speculation that it might be prejudiced by certain testimony. If

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164. Witham v. Norfolk & W. Ry. Co., 561 N.E.2d 484, 486 (Ind. 1990). Indiana law defines "wanton or willful conduct" as either: "1) an intentional act done with reckless disregard of the natural and probable consequence of injury to a known person under the circumstances known to the actor at the time; or 2) an omission or failure to act when the actor has actual knowledge of the natural and probable consequence of injury and his opportunity to avoid the risk." *Id.*

165. IND. R. TRIAL P. 42(B).

166. IND. R. TRIAL P. 42(C).

> an issue can be conveniently and expeditiously resolved, a separate trial may be ordered in the interest of judicial economy. If the proof of damages will be complicated and costly the issue of liability could first be separately tried. This was the specific purpose in adding subdivision (C) to T.R. 42. However, a federal court has observed that while the separation of trials can result in judicial economy when the defendant prevails on the issue of liability (by obviating the need for a trial on damages), the defendant must first convince the court that it has a persuasive argument on the question of liability in order to justify the potential risk and expense of two trials.[167]

Likewise, Federal Rule of Civil Procedure 42(b) permits a district court to order a separate trial of one or more separate issues, claims, cross-claims, counter-claims, or third-party claims "for convenience, to avoid prejudice, or to expedite and economize."[168] If just one of these criteria is met, the district court may order bifurcation so long as it will not prejudice the nonmoving party and it will not violate the Seventh Amendment.[169] A district court's decision to bifurcate will be overturned "only upon a clear showing of abuse."[170]

As mentioned above, the Southern District of Indiana recently addressed bifurcation in product liability actions on multiple occasions. In the *Cook IVC Filter* MDL, for example, the court has twice granted the defendants' motion to bifurcate the liability and compensatory damages phase of the trial from the punitive damages phase of the trial.[171] There, the court found that bifurcation would conserve judicial resources and protect the defendants from unfair prejudice,[172] consistent with the language of Federal Rule of Civil Procedure

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167. Frito-Lay, Inc. v. Cloud, 569 N.E.2d 983, 990 (Ind. Ct. App. 1991) (reversing the trial court's decision to deny the defendant's motion to bifurcate liability and compensatory damages under Indiana Trial Rule 42(B) because the jury was inundated at trial with evidence that intertwined liability and damages, which could have evoked the jury's sympathy for the sixteen-year-old victim and prejudiced the jury's ability to render a fair verdict on the issue of liability) (citations omitted). *But see* Shafer & Freeman Lakes Envtl. Conservation Corp. v. Stichnoth, 877 N.E.2d 475, 483 (Ind. Ct. App. 2007) (reversing trial court's decision to deny the defendant's motion to bifurcate because "[defendant] cannot show more than the potential for prejudice, which is insufficient to justify a new trial on this issue").

168. Note that bifurcation of a trial is a procedural issue. Therefore, federal courts will apply the forum's law to the issue, and any briefing submitted on the issue should reflect the law of the forum court.

169. Chlopek v. Fed. Ins. Co., 499 F.3d 692, 700 (7th Cir. 2007) (in a product liability case involving a prescription medical device, holding that plaintiff was not prejudiced by bifurcation of trial and that the full extent of the plaintiff's alleged injuries was irrelevant to the first phase of trial where the only question was whether the product at issue was defective because of inadequate warnings); *see also* Houseman v. U.S. Aviation Underwriters, 171 F.3d 1117, 1121 (7th Cir. 1999).

170. *Houseman*, 171 F.3d at 1121.

171. Cook Bifurcation Order, *supra* note 162.

172. *Id.*

42(b) and *Chlopek*.[173]

B. Consolidation

Another recent trend in product liability cases is found in plaintiffs' attempts to consolidate recent cases, either for discovery and pretrial proceedings only, or for all purposes, including trial. Indiana Trial Rule 42(D) permits consolidation of actions pending in different courts for purposes of discovery and pretrial proceedings when the actions involve "a common question of law or fact" and requires that any such consolidation take place with the case that has the earliest filing date.[174] Notably, the standard for consolidation under Rule 42(D) does not require that the harm occur in the same transaction or occurrence, as is found in the rule governing joinder of defendants.[175] Thus, cases involving injuries that occurred on separate occasions may be consolidated, so long as they involve common questions of law or fact.

As product liability and mass tort litigation have increased in recent years, the trend toward seeking consolidation also has increased. Consolidation for discovery and pre-trial purposes can have benefits for parties, who may conduct "common issue" discovery, such as expert and company case discovery that may apply equally to all cases. Thus, rather than deposing the same expert or company witness ten different times in ten different cases, the parties can conduct a single deposition to be used in all of the consolidated cases.

Often times, plaintiffs try to take consolidation one step further by seeking to consolidate cases for trial such that one trial is held for multiple plaintiffs. This can create confusion of the issues and facts for jurors. For example, in a medical device case, the jury might find it difficult to parse and independently consider different medical procedures at different times and separate the medical histories and patient experiences for the individual plaintiffs. Moreover, jurors may hear "spill over" evidence related to one plaintiff and subconsciously apply that evidence to a different plaintiff to which the evidence does not apply. The Southern District of Indiana recently recognized this potential issue after MDL plaintiffs sought to consolidate multiple bellwether cases for trial. Specifically, the court denied the request, "[a]fter further reflection, the court finds multi-Plaintiff bellwethers run the risk of confusing the jury and of significantly increasing the length of trials."[176] Accordingly, the court recognized the potential for harm when consolidating product liability cases.

CONCLUSION

The cases addressed within this survey demonstrate that product liability law continues to grow and develop both inside and outside of Indiana. Further, the

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173. *Chlopek*, 499 F.3d at 700 (7th Cir. 2007).

174. *See* IND. R. TR. P. 42(D); *see also* Boden v. Bancroft, 825 N.E.2d 380, 383 (Ind. Ct. App. 2005).

175. *Boden*, 825 N.E.2d at 383.

176. Cook Bellwether Plan, *supra* note 163.

decisions of Indiana courts involve many of the same issues and trends that federal and state courts across the United States are contemplating. Thus, Indiana courts remain on the forefront of mass tort litigation and have the potential to influence other courts across the country as they analyze and interpret the future of product liability law.