

# SURVEY OF RECENT DEVELOPMENTS IN INDIANA PRODUCT LIABILITY LAW

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## INTRODUCTION

This Survey reviews the significant product liability cases decided during the survey period.<sup>1</sup> It offers select commentary and context and organizes its treatment of the relevant cases into a basic structure that mirrors the Indiana Product Liability Act (“IPLA”).<sup>2</sup> This Survey does not attempt to address all product liability cases decided during the survey period in detail. Rather, it focuses on cases involving important substantive product liability concepts arising under Indiana law and offers appropriate background information about the IPLA.

The 2017 cases addressed many issues that courts have tackled in the recent past, such as warning and design defects, the “merger” of negligence and tort-based warranty claims into IPLA claims, the use of expert witnesses in product liability cases, and federal preemption. The 2017 decisions also focused on a couple issues that have not been as widely reviewed in recent years, including the specific pleading requirements necessary to sustain a product liability action and what constitutes “physical harm,” a specific and necessary element of a product liability claim.

## I. THE SCOPE OF THE IPLA

The IPLA governs actions brought by “users” or “consumers” against “manufacturers” or “sellers” when a product causes “physical harm.”<sup>3</sup> The IPLA defines each of those quoted terms, and case law has helped to clarify those definitions. When read together, Indiana Code sections 34-20-1-1 and 34-20-2-1 establish five unmistakable threshold requirements for IPLA liability: (1) a

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1. The survey period is October 1, 2016 to September 30, 2017.

2. IND. CODE §§ 34-20-1-1 to -9-1 (2017). This Survey follows the lead of the Indiana General Assembly and employs the term “product liability” (not “products liability”) when referring to actions governed by the IPLA.

3. *Id.*

claimant who is a user or consumer and is also “in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;”<sup>4</sup> (2) a defendant that is a manufacturer or a “seller . . . engaged in the business of selling [a] product;”<sup>5</sup> (3) “physical harm caused by a product;”<sup>6</sup> (4) a “product in a defective condition unreasonably dangerous to [a] user or consumer” or to his or her property;<sup>7</sup> and (5) a product that “reach[ed] the user or consumer without substantial alteration in [its] condition . . . .”<sup>8</sup> Indiana Code section 34-20-1-1 further establishes the IPLA governs every claim that satisfies those threshold requirements, “regardless of the substantive legal theory or theories upon which the action is brought.”<sup>9</sup>

#### *A. User/Consumer and Manufacturer/Seller*

Over the last decade, there have been a number of cases addressing the scope and reach of the IPLA. Several of those cases addressed who may file suit in Indiana as product liability plaintiffs because they are “users”<sup>10</sup> or “consumers.”<sup>11</sup> By the same token, there is now a fairly robust body of case law in Indiana identifying people and entities that are “manufacturers”<sup>12</sup> or “sellers”<sup>13</sup> and,

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4. *Id.* § 34-20-2-1(1).

5. *Id.* § 34-20-2-1(2). For example, corner lemonade stand operators and garage sale sponsors are excluded from IPLA liability, according to the latter section.

6. *Id.* § 34-20-1-1(3).

7. *Id.* § 34-20-2-1.

8. *Id.* § 34-20-2-1(3).

9. *Id.* § 34-20-1-1.

10. *Id.* § 34-6-2-147.

11. *Id.* § 34-20-1-1. A literal interpretation of the IPLA demonstrates even if a claimant qualifies as a statutorily-defined “user” or “consumer,” before proceeding with a claim under the IPLA, he or she also must satisfy another statutorily-defined threshold. *Id.* § 34-20-2-1(1). That additional threshold is found in Indiana Code section 34-20-2-1(1), which requires the “user” or “consumer” also be “in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition.” *Id.* Thus, the plain language of the statute assumes a person or entity must already qualify as a “user” or a “consumer” *before* a separate “reasonable foreseeability” analysis is undertaken. In that regard, it does not appear the IPLA provides a remedy to a claimant whom a seller might reasonably foresee as being subject to the harm caused by a product’s defective condition if that claimant does not fall within the IPLA’s definition of “user” or “consumer.” Two of the leading recent cases addressing “users” and “consumers” include *Vaughn v. Daniels Co.*, 841 N.E.2d 1133 (Ind. 2006), and *Butler v. City of Peru*, 733 N.E.2d 912 (Ind. 2000).

12. IND. CODE § 34-6-2-77. For purposes of the IPLA, a manufacturer is “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.* § 34-6-2-77(a). A few of the more recent influential cases that evaluated whether an entity qualifies as a “manufacturer” under the IPLA include *Mesman v. Crane Pro Services*, 512 F.3d 352 (7th Cir. 2008), *Pentony v. Valparaiso Department of Parks & Recreation*, 866 F. Supp. 2d 1002 (N.D. Ind.

therefore, proper defendants in Indiana product liability cases. Several of those cases address the specific circumstances under which retail sellers and distributors may be deemed to be manufacturers under the IPLA, including *Parks v. Freud America, Inc.*,<sup>14</sup> *Shelter Insurance Cos. v. Big Lots Stores, Inc.*,<sup>15</sup> and *Heritage Operating LP v. Mauck*.<sup>16</sup>

### B. Physical Harm Caused by a Product

For purposes of the IPLA, “[p]hysical harm” . . . means bodily injury, death, loss of services, and rights arising from any such injuries, as well as sudden, major damage to property.<sup>17</sup> It “does not include gradually evolving damage to property or economic losses from such damage.”<sup>18</sup> A “product” is “any item or good that is personalty at the time it is conveyed by the seller to another party,” but not a “transaction that, by its nature, involves wholly or predominantly the sale of a service rather than a product.”<sup>19</sup> A number of notable Indiana decisions over the past twenty years or so have helped to refine the concept of “physical harm caused by a product.”<sup>20</sup> The 2017 survey period produced three more.

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2012), and *Warriner v. DC Marshall Jeep*, 962 N.E.2d 1263 (Ind. Ct. App. 2012).

13. IND. CODE § 34-6-2-136. The IPLA defines a seller as “a person engaged in the business of selling or leasing a product for resale, use, or consumption.” *Id.* Indiana Code section 34-20-2-1 adds three additional and clarifying requirements as it relates to “sellers.” First, an IPLA defendant must have sold, leased, or otherwise placed an allegedly defective product in the stream of commerce. *Id.* Second, the seller must be in the business of selling the product. *Id.* And, third, the seller expects the product to reach and, in fact, it did reach the user or consumer without substantial alteration. *Id.*; see also *Williams v. REP Corp.*, 302 F.3d 660, 662-64 (7th Cir. 2002). Sellers can also be held liable as manufacturers in two ways. First, a seller may be held liable as a manufacturer if the seller fits within the definition of “manufacturer” found in Indiana Code section 34-6-2-77(a). Second, a seller may be held liable as a manufacturer “[i]f a court is unable to hold jurisdiction over a particular manufacturer” and if the seller is the “manufacturer’s principal distributor or seller.” *Kennedy v. Guess, Inc.*, 806 N.E.2d 776, 781 (Ind. 2004) (quoting IND. CODE § 34-20-2-4 (1999)). When the theory of liability is based upon “strict liability in tort,” Indiana Code section 34-20-2-3 makes clear a “seller” that cannot otherwise be deemed a “manufacturer” is not liable and is not a proper IPLA defendant.

14. No. 2:14-cv-00036-LJM-WGH, 2016 U.S. Dist. LEXIS 7525, at \*1-2 (S.D. Ind. Jan. 22, 2016).

15. No. 3:12-cv-433 JVB, 2014 WL 4494382 (N.D. Ind. Sept. 10, 2014).

16. 37 N.E.3d 514 (Ind. Ct. App. 2015), *trans. denied*, 43 N.E.3d 1278 (Ind. 2016).

17. IND. CODE § 34-6-2-105(a) (2017).

18. *Id.* § 36-6-2-105(b).

19. *Id.* § 34-6-2-114(a)-(b).

20. See, e.g., *Bell v. Par Pharm. Cos.*, No. 1:11-cv-01454-TWP-MJD, 2013 WL 2244345 (S.D. Ind. May 21, 2013); *Barker v. CareFusion 303, Inc.*, No. 1:11-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.

In *Watts Water Technologies, Inc. v. State Farm Fire & Casualty Co.*,<sup>21</sup> the court addressed the issue of property damage as the “physical harm” necessary to form the basis of a product liability claim. In this subrogation case, an insurer sued the manufacturer of a water heater component, alleging that the component failed and caused water damage to the insured’s property.<sup>22</sup> The insurer and the manufacturer were parties to an arbitration agreement, which expressly excluded product liability actions from arbitration.<sup>23</sup> The question before the court was whether the dispute was subject to arbitration.<sup>24</sup> The manufacturer argued, in part, that the insurer’s allegations were insufficient to meet the “physical harm” requirement of the IPLA because the complaint did not allege “sudden, major damage” to property; thus, the case did not fall under the arbitration clause’s product liability exclusion.<sup>25</sup> The court began by noting that “physical harm” covers “sudden, major damage to property,” and that “physical harm” does not encompass “gradually evolving damage to property.”<sup>26</sup> The complaint alleged that the failure occurred “on or about” November 30, 2014.<sup>27</sup> The manufacturer argued that this language did not suggest “sudden, major damage;” rather, it suggested “gradually evolving damage.”<sup>28</sup> The court concluded that the complaint sufficiently alleged water damage to the insured’s property; thus it was possible that the claim fell within the arbitration agreement’s product liability exclusion.<sup>29</sup> The court affirmed the trial court’s order denying the manufacturer’s motion to compel arbitration.<sup>30</sup>

In *Constructora Mi Casita v. Nibco, Inc.*, a condominium developer sued the manufacturer of various plumbing fixtures used throughout its condominium project.<sup>31</sup> The developer alleged that the fixtures failed, which caused the condominiums to sustain water damage, which in turn led to mold growth.<sup>32</sup> The developer brought an IPLA claim to recover for the water damage to the condominium units, as well as mold remediation.<sup>33</sup> In its motion to dismiss, the manufacturer argued that these claims were barred by the economic loss doctrine, which prohibits the recovery in tort for damage to the product itself and other

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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).

21. 66 N.E.3d 983, 991-92 (Ind. Ct. App. 2016).

22. *Id.* at 986.

23. *Id.*

24. *Id.* at 990.

25. *Id.* at 991-92.

26. *Id.*

27. *Id.* at 992.

28. *Id.*

29. *Id.* at 993.

30. *Id.*

31. No. 3:16-cv-565-PPS-MGG, 2017 WL 3438182, at \*1 (N.D. Ind. Aug. 9, 2017).

32. *Id.* at \*6.

33. *Id.*

economic losses, but allows recovery in tort for damage to other property.<sup>34</sup> The court ruled that the developer could recover for damage to the condominium units and common areas, as these were “other property,” but the developer could not recover in tort for the cost of the defective plumbing fixtures or “other purely economic loss, including the costs associated with relocating residents and lost profits.”<sup>35</sup> The manufacturer also argued that the developer could not recover the cost of mold remediation because mold is not “sudden, major” property damage.<sup>36</sup> Rather, mold occurs gradually and therefore is not the type of property damage that is covered by the IPLA.<sup>37</sup> The court noted that additional facts were needed to determine whether the mold could be considered “sudden” property damage under the IPLA.<sup>38</sup> The court concluded that for the purposes of surviving a motion to dismiss, the developer had sufficiently pleaded the mold remediation claim under the IPLA.<sup>39</sup>

The third of the three cases, *Direct Enterprises, Inc. v. Sensient Colors LLC*<sup>40</sup> involved a dispute between a seed treatment distributor and a seller of seed colorants.<sup>41</sup> The distributor purchased the seed colorants, which it then incorporated into its seed treatment blends.<sup>42</sup> The seed treatment distributor then sold the treatment blends to its customers, who reported that the containers holding the treatment blends developed a “sludge” at the bottom.<sup>43</sup> The seed treatment distributor alleged that the colorant caused the sludge, and it sued the colorant seller under various theories, including the IPLA.<sup>44</sup> The defendant seller moved to dismiss the IPLA claim under the economic loss doctrine.<sup>45</sup> In essence, the seller argued that the colorant was part of the plaintiff’s seed treatment blend; therefore, the plaintiff was seeking to recover for damage to the “product itself” instead of “other property.”<sup>46</sup> The court relied on *Gunkel v. Renovations, Inc.*<sup>47</sup> in noting that the economic loss doctrine precludes recovery in tort for damages sustained to the product itself, and only damage to “other property” is recoverable under the IPLA.<sup>48</sup> Thus, the question was whether the seed treatment blend, which contained the colorant, was “other property,” or whether it was “the product

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34. *Id.* (citing *Gunkel v. Renovations, Inc.*, 822 N.E.2d 150, 153 (Ind. 2005)).

35. *Id.* at \*6. Note however, that the court found that the developer could potentially recover these economic losses under a breach of warranty theory. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. No. 1:15-cv-01333-JMS-TAB, 2017 WL 3314793, at \*1 (S.D. Ind. Aug. 3, 2017).

41. *Id.*

42. *Id.* at \*2-4.

43. *Id.* at \*3.

44. *Id.*

45. *Id.* at \*9.

46. *Id.*

47. 822 N.E.2d 150 (Ind. 2005).

48. *Direct Enters., Inc.*, 2017 WL 3314793, at \*9.

itself.”<sup>49</sup> The court found guidance on this point in *Gunkel*: “‘property acquired separately [is] ‘other property’ for purposes of the economic loss doctrine even if the defective product is to be incorporated into a completed product for use or resale.’”<sup>50</sup> The court concluded that the colorants were purchased separately from the other components of the finished seed blends.<sup>51</sup> To the extent the colorants damaged the other components and the finished seed blend, the damage was to “other property.”<sup>52</sup> Accordingly, the economic loss doctrine did not bar the IPLA claim.<sup>53</sup> The defendant also argued that the IPLA claim failed because the plaintiff did not plead “sudden, major” property damage; instead, the plaintiff claimed that “the treatments ‘began to show a thick sludge,’” which suggested that the damage arose gradually.<sup>54</sup> The court rejected this argument because the court did not read the complaint “as alleging that the sludge developed slowly, but instead as alleging that the Plaintiffs and their customers *discovered* the sludge in spring of 2013, when they began to treat seeds for planting.”<sup>55</sup>

### *C. Defective and Unreasonably Dangerous*

IPLA liability only extends to products that are in “defective condition,”<sup>56</sup> which exists if the product, at the time it is conveyed by the seller to another party, is: “(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.”<sup>57</sup> Both are threshold proof requirements.<sup>58</sup>

Indiana claimants may prove a product is in a “defective condition” by asserting one or any combination of the following three theories: (1) the product has a defect in its design (“design defect”); (2) the product lacks adequate or appropriate warnings (“warning defect”); or (3) the product has a defect that is the result of a problem in the manufacturing process (“manufacturing defect”).<sup>59</sup>

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49. *Id.*

50. *Id.* (quoting *Gunkel*, 822 N.E.2d at 156).

51. *Id.* at \*10.

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.* (Emphasis original).

56. IND. CODE § 34-20-2-1 (2017).

57. *Id.* § 34-20-4-1.

58. *See Baker v. Heye-Am.*, 799 N.E.2d 1135, 1140 (Ind. Ct. App. 2003), *trans. denied*, 812 N.E.2d 799 (Ind. 2004) (“[U]nder the IPLA, the plaintiff must prove that the product was in a defective condition that rendered it unreasonably dangerous.”).

59. *See 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*, 799 N.E.2d at 1140.

Although claimants are free to assert any of the three theories, or a combination, for proving that a product is in a ‘defective condition,’ the IPLA provides explicit statutory

An unreasonably dangerous product under the IPLA is one that “exposes the user or consumer to a risk of physical harm . . . 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.”<sup>60</sup> If a product injures, in a fashion that is objectively known to the community of product consumers, it is not unreasonably dangerous as a matter of law.<sup>61</sup> Courts in Indiana have been fairly active in recent years when it comes to dealing with concepts of unreasonable danger and causation in Indiana product liability actions.<sup>62</sup>

The IPLA, specifically Indiana Code section 34-20-2-2, imposes a negligence standard in all product liability claims relying upon a design or warning theory to prove a product is in a defective condition:

[I]n an action based on an alleged design defect in the product or based on an alleged failure to provide adequate warnings or instructions regarding the use of the product, the 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.<sup>63</sup>

Accordingly, the term “strict” liability is no longer applicable in design and warning cases to the extent the term “strict” connotes the imposition of liability

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guidelines for identifying when products are not defective as a matter of law. Indiana Code section 34-20-4-3 provides that ‘[a] product is not defective under [the IPLA] 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, the seller is not liable under [the IPLA].’ IND. CODE § 34-20-4-3 (2013). In addition, ‘[a] product is not defective under [the IPLA] if the product is incapable of being made safe for its reasonably expectable use, when manufactured, sold, handled, and packaged properly.’ *Id.* § 34-20-4-4.

Joseph R. Alberts et al., *Survey of Recent Developments in Indiana Product Liability Law*, 47 Ind. L. Rev. 1129, 1133-34 n.45 (2014).

60. IND. CODE § 34-6-2-146; *see also Baker*, 799 N.E.2d at 1140.

61. *Baker*, 799 N.E.2d at 1140; *see also Moss v. Crosman Corp.*, 136 F.3d 1169, 1174-75 (7th Cir. 1998).

62. *See* Joseph R. Alberts et al., *Survey of Recent Developments in Indiana Product Liability Law*, 49 Ind. L. Rev. 1125, 1130 (2016); *see also Pilch v. Ford Motor Co.*, 778 F.3d 628 (7th Cir. 2015), *Stuhlmacher v. Home Depot U.S.A., Inc.*, No. 2:10-CV-00467-JTM-APR, 2013 WL 3201572 (N.D. Ind. June 21, 2013); *Bell v. Par Pharm. Cos.*, No. 1:11-cv-01454-TWP-MJD, 2013 WL 2244345, at \*1 (S.D. Ind. May 21, 2013); *Beasley v. Thompson/Center Arms Co.*, No. 2:11-cv-3-WTL-WGH, 2013 WL 968234 (S.D. Ind. Mar. 12, 2013); *Hathaway v. Cintas Corp. Servs., Inc.*, 903 F. Supp. 2d 669 (N.D. Ind. 2012); *Roberts v. Menard, Inc.*, No. 4:09-CV-59-PRC, 2011 WL 1576896 (N.D. Ind. Apr. 25, 2011); *Price v. Kuchaes*, 950 N.E.2d 1218, 1232-33 (Ind. Ct. App. 2011).

63. IND. CODE § 34-20-2-2.

without regard to fault or the exercise of reasonable care.<sup>64</sup> The IPLA contemplates the traditional type of “strict” liability (without fault or proof of negligence) only for so-called “manufacturing” defects—those that arise “in the manufacture and preparation of the product.”<sup>65</sup> For manufacturing defects, liability can be established even if the seller has “exercised all reasonable care.”<sup>66</sup>

The IPLA has, for nearly twenty years, made clear “strict” liability applies only in cases involving alleged manufacturing defects.<sup>67</sup> Several decisions have recognized that point, including a 2017 survey period case, *Aregood v. Givaudan Flavors Corp.*<sup>68</sup> Other decisions have been slow to recognize that concept.<sup>69</sup> Indeed, at least one recent decision recognized that there has been some confusion about the proper use of the term “strict” liability in the context of the current IPLA.<sup>70</sup> Another recent decision illustrates how a court’s understanding and

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64. IND. CODE § 34-6-2-2(1).

65. *Id.*; see also *Mesman v. Crane Pro Servs.*, 409 F.3d 846, 849 (7th Cir. 2008), *reh’g and petition for reh’g en banc denied*, (July 26, 2005), *appeal after new trial*, 512 F.3d 352 (7th Cir. 2008); *Conley v. Lift-All Co.*, No. 1:03-CV-1200-DFH-TAB, 2005 WL 1799505, at \*6 (S.D. Ind. July 25, 2005); *Bourne v. Marty Gilman, Inc.*, No. 1:03-CV-1375-DFH-VSS, 2005 WL 1703201, at \*3 (S.D. Ind. July 20, 2005); *First Nat’l Bank & Tr. Corp. v. Am. Eurocopter Corp. (Inlow II)*, 378 F.3d 682, 689 n.4 (7th Cir. 2004).

66. IND. CODE § 34-6-2-2(1). “Strict” liability for defects “in manufacturing and preparation” is also subject to the additional requirement that the “user or consumer has not bought the product from or entered into any contractual relation with the seller.” *Id.* § 34-6-2-2(2).

67. See generally *Warriner v. DC Marshall Jeep*, 962 N.E.2d 1263 (Ind. Ct. App. 2012); see also *Vaughn v. Daniels Co.*, 841 N.E.2d 1133, 1138-39 (Ind. 2006); *Whitted v. Gen. Motors Corp.*, 58 F.3d 1200, 1206 (7th Cir. 1995).

68. No. 1:14-cv-00274-LJM-TAB, 2017 WL 2378258, at \*9 (S.D. Ind. June 1, 2016).

69. See generally *Warriner*, 962 N.E.2d at 1263; see also *Vaughn*, 841 N.E.2d at 1138-39; *Whitted*, 58 F.3d at 1206.

70. *Jones v. Horseshoe Casino*, No. 2:15-cv-00014-PPS-PRC, 2015 WL 3407872, at \*2 (N.D. Ind. May 27, 2015). See Joseph R. Alberts et al., *Survey of Recent Developments in Indiana Product Liability Law*, 50 Ind. L. Rev. 1305, 1310-12 (2017); Alberts et al., *supra* note 62, at 1132-33. A misleading short title in the *Burns Indiana Statutes Annotated* compendium may be contributing to some of the confusion in this area. IND. CODE § 34-20-2-2. In the 1998 Replacement Volume, the *Burns* editors inserted a short title for Indiana Code section 34-20-2-2, entitled, “Strict liability – Design defect.” *Id.* That short title unfortunately makes it appear to some readers as though strict liability applies either to the entire section (and thereby all three theories for proving defectiveness) or, at the very least, to design defect claims. See, e.g., *Whitted*, 58 F.3d at 1206; *Vaughn*, 841 N.E.2d at 1138-39; *Warriner*, 962 N.E.2d 1263. Neither is accurate because, as noted above, a close reading of the statute reveals “strict” liability (liability without fault or proof of negligence) applies only to cases involving manufacturing defect theories and not to cases alleging either design or warning theories. IND. CODE § 34-6-2-2(1). Incidentally, the *West* editors did not use the same short title in the *West’s Annotated Indiana Code*, choosing instead to use a more accurate short title styled, “Exercise of reasonable care; privity.” IND. CODE § 34-20-2-2. The Indiana General Assembly originally codified in 1995 the language now found in Indiana Code section 34-20-2-2. That language was subsequently re-numbered in 1998 as part of a reorganization

application of the “strict” liability concept can profoundly affect the outcome of a case.<sup>71</sup>

And just like a claimant advancing any other type of negligence theory, a claimant advancing a product liability design or warning defect theory must meet the traditional negligence elements: duty, breach, injury, and causation.<sup>72</sup> As it relates to causation, such a claimant must demonstrate with sufficient admissible evidence that the product’s defective and unreasonably dangerous condition was both the cause-in-fact and the legal or “proximate” cause of the damages alleged.<sup>73</sup>

#### *D. Decisions Involving Specific Defect Theories*

*1. Design Defect Theory.*—State and federal courts in Indiana have issued several recent decisions addressing design defect theories and the proof required

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of Title 34. Neither the 1995 enactment nor the 1998 recodification, as published by the Indiana General Assembly, included any section short title for the particular section involved here.

71. In *Heritage Operating LP v. Mauck*, 37 N.E.3d 514 (Ind. Ct. App. 2015), *trans. denied*, 43 N.E.3d 1278 (Ind. 2016), the court initially resolved a manufacturer/seller issue as a matter of law, but in doing so, it presumed there was an operative IPLA-based “strict liability” claim. *Id.* at 522-25. A close reading of the decision reveals the plaintiffs’ only real IPLA-based defect theory alleged an inadequate warning. *Id.* at 520. The decision does not indicate plaintiffs were pursuing any design defect claims, nor did the plaintiffs appear to have asserted a “manufacturing defect” claim by contending the natural gas product itself suffered from some kind of problem or glitch in the manufacturing process. *Id.* at 519. The plaintiffs appeared to have recognized natural gas is what it is, and they did not appear to have taken any issue with the process of refining or producing it. *Id.* Accordingly, there was no “strict” liability theory Indiana Code section 34-20-2-2(1) would allow in the *Mauck* case. To the extent “strict” liability is a term associated with the concept of liability without regard to fault or proof of negligence, it is not a doctrine the IPLA recognizes as applicable to inadequate warning theories. *Id.* at 519. It is, therefore, peculiar that the *Mauck* court took such great pains to reject the Indiana Supreme Court’s venerable *Webb v. Jarvis* three-part duty analysis applicable to negligence cases in favor of a separate duty analysis arising out of an older line of non-IPLA cases that treated natural gas as “a dangerous instrumentality.” *Id.* at 521 (quoting *Palmer & Sons Paving, Inc. v. N. Ind. Pub. Serv. Co.*, 758 N.E.2d 550, 554 (Ind. Ct. App. 2001)). Perhaps the fact that the *Mauck* court was under the impression an IPLA-based warnings defect negligence case is functionally the same as a traditional “strict” liability case might help explain why it rejected the *Webb* test in favor of a special rule when natural gas is the “product” at issue. *Id.* at 522-25.

72. *See, e.g., Kovach v. Caligor Midwest*, 913 N.E.2d 193, 197-99 (Ind. 2009).

73. *See Costanza v. Vulcan Ladder Co.*, No. 1:13-CV-260-TLS, 2016 WL 7048799, at \*9 (N.D. Ind. Dec. 5, 2016) (causation and its necessary evidentiary support is a required element in sustaining a product liability claim); *see also Bowersock v. Davol, Inc.*, 236 F. Supp. 3d 1074, 1089 (S.D. Ind. 2017) (causation and its necessary evidentiary support is a required element in sustaining a product liability claim); *Lyons v. Leatt Corp.*, No. 4:15-CV-17-PRC, 2017 WL 4117775 (N.D. Ind. Sep. 14, 2017) (product liability cases often require expert opinion testimony to establish a legal causal connection). *See also infra* Part III.B.

to sustain that theory.<sup>74</sup> The 2017 survey period contributed another such decision, *Aregood v. Givaudan Flavors Corp.*<sup>75</sup> In that case, several popcorn factory workers alleged that their exposure to butter flavors containing diacetyl caused them respiratory problems.<sup>76</sup> Among other things, the plaintiffs claimed that the design of the butter flavoring was defective because it was more dangerous than an ordinary consumer would expect when it was used as intended.<sup>77</sup> Relying upon much of the same evidence used to successfully establish a learned intermediary defense<sup>78</sup> to the plaintiffs' defective warning claims, the flavoring supplier argued that the plaintiffs' employer's knowledge of an association between diacetyl in butter flavors and lung disease coupled with its complete control over workplace safety, broke the causal chain between the plaintiffs' alleged injuries and the defective design of the butter flavoring.<sup>79</sup> The court did not agree.<sup>80</sup> It reasoned the doctrine of intervening or superseding causation had not been adequately addressed by the parties.<sup>81</sup> The doctrine focuses upon whether the harm resulting from the intervening act was reasonably foreseeable by the manufacturer.<sup>82</sup> If the harm is the natural, probable or foreseeable result of the original negligent act, the original negligent actor can still be liable even though "independent agencies" intervene.<sup>83</sup> If, however, the intervening act is not foreseeable, then the original negligent actor is not liable for the harm that results.<sup>84</sup> The court could not conclude, based on the evidence before it, that the worker's employer's safety program was an unforeseeable intervening cause.<sup>85</sup>

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74. See Alberts et al., *supra* note 70, at 1312-14; Alberts et al., *supra* note 62, at 1137-38. See also *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 v. Cintas Corp. Servs., Inc.*, 903 F. Supp. 2d 669 (N.D. Ind. 2012) (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); *Mesman v. Crane Pro Servs., Inc.*, 409 F.3d 846 (7th Cir. 2005), *reh'g and petition for reh'g en banc denied*, (July 26, 2005), *appeal after new trial*, 512 F.3d 352 (7th Cir. 2008).

75. No. 1:14-cv-274-LJM-TAB, 2017 WL 2378258 (S.D. Ind. June 1, 2016).

76. *Id.* at \*4.

77. *Id.* at \*9.

78. See discussion *infra* Part D.2.

79. *Aregood*, 2017 WL 2378258, at \*12.

80. *Id.*

81. *Id.*

82. *Id.* (quoting *Hooks SuperX, Inc. v. McLaughlin*, 642 N.E.2d 514, 520 (Ind. 1994)).

83. *Id.* at \*12.

84. *Id.*

85. *Id.* The plaintiffs' victory was relatively short-lived, however. After additional discovery, summary judgment was later granted against the plaintiffs' design defect claim because the plaintiffs had not established that the use of a diacetyl-free butter flavoring was a feasible, cost-effective alternative design. See No. 1:14-cv-00274-SEB-TAB, 2017 WL 4699275 (S.D. Ind. Oct.

2. *Warning Defect Theory*.—The IPLA contains a specific statutory provision covering the warning defect theory:

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.<sup>86</sup>

For a cause of action to attach in failure to warn cases, the “unreasonably dangerous” inquiry is similar to the requirement that the danger or alleged defect be latent or hidden.<sup>87</sup>

There are several relatively recent decisions that have helped define the contours of the IPLA’s warnings defect theory and what proof is required to sustain such a theory.<sup>88</sup> The 2017 survey period produced three more notable cases in this area, *Costanza v. Vulcan Ladder Co.*,<sup>89</sup> *Aregood v. Givudan Flavors Corp.*,<sup>90</sup> and *Fisk v. Medtronic, Inc.*<sup>91</sup>

In the first case, *Costanza v. Vulcan Ladder Co.*, the plaintiff was injured when he claimed that a multi-positional, extendable articulating ladder collapsed, causing him to suffer serious leg injuries.<sup>92</sup> The court addressed two issues of note for this survey: (1) the admissibility of plaintiff’s expert witness’s testimony, which is discussed in section III.B.; and (2) whether the warnings and instructions that accompanied the ladder were adequate, which is discussed here.<sup>93</sup>

Costanza purchased the ladder at a local retail store.<sup>94</sup> The ladder could be used in a position as an “A-frame” stepladder or fully-extended as a straight extension ladder.<sup>95</sup> The ladder was hinged and had two lock positions on its

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18, 2017).

86. IND. CODE § 34-20-4-2 (2017).

87. See *First Nat’l Bank & Trust Corp. v. Am. Eurocopter Corp. (Inlow II)*, 378 F.3d 682, 690 n.5 (7th Cir. 2004).

88. See generally *Simmons v. Philips Elecs. N.A. Corp.*, No. 2:12-CV-39-TLS, 2015 WL 1418772 (N.D. Ind. Mar. 27, 2015); *Shelter Ins. Cos. v. Big Lots Stores, Inc.*, No. 3:12-CV-433-JVB, 2014 WL 4494382 (N.D. Ind. Sept. 10, 2014); *Weigle v. SPX Corp.*, 729 F.3d 724 (7th Cir. 2013); *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 v. Cintas Corp. Servs., Inc.*, 903 F. Supp. 2d 669 (N.D. Ind. 2012). See also *Alberts et al.*, *supra* note 62, at 1134-37.

89. No. 1:13-CV-260-TLS, 2016 WL 7048799 (N.D. Ind. Dec. 5, 2016).

90. *Aregood*, 2017 WL 2378258.

91. No. 3:17-CV-032-JD, 2017 WL 4247983 (N.D. Ind. Sept. 25, 2017).

92. *Costanza*, 2016 WL 7048799 at \*1.

93. *Id.* at \*7.

94. *Id.* at \*1.

95. *Id.*

hinges.<sup>96</sup> The first locked the ladder into an “A-frame” configuration as a traditional stepladder.<sup>97</sup> A user could then depress a knob on the hinge and the ladder would rotate into a straight, extension ladder position.<sup>98</sup> Costanza positioned the ladder into the straight position and used it to attempt to climb to his roof.<sup>99</sup> As he stepped onto the roof, he fell.<sup>100</sup> He was later discovered tangled in the ladder and the ladder was in an “A-frame” position.<sup>101</sup> Plaintiff contended that even though he positioned the ladder in a straight position, the hinge locks did not engage and the instructions on the ladder made him believe that if he heard one click, instead of two, the hinge lock was engaged.<sup>102</sup>

The ladder manufacturer moved for summary judgment, contending that the plaintiff’s expert’s opinions were inadmissible and arguing that the plaintiff’s description of the accident simply couldn’t have happened in the manner alleged.<sup>103</sup> Plaintiff’s expert contended that the instructions were inadequate because the manufacturer failed to provide visual warnings that the hinges on the ladder were not locked and failed to provide instructions explaining how to verify the hinge locks were engaged.<sup>104</sup> Interestingly, during the hearing the plaintiff was able to demonstrate how the ladder could be placed into a position where the hinge did not lock and the ladder could collapse.<sup>105</sup> The court opined that historically questions of the adequacy of warnings and instructions were questions for the trier of fact and inappropriate for summary judgment.<sup>106</sup> The court held that a question of fact existed because the plaintiff and the manufacturer offered competing testimony about whether the ladder could be climbed in a straight position without the hinge lock engaging and both experts disagreed about the adequacy and clarity of the instructions and warnings on the ladder itself and available at the point of its sale.<sup>107</sup> The court opined the weight to be afforded to the conflicting opinions of each expert was to be decided by the jury.<sup>108</sup>

Next, as discussed in the preceding section, in *Aregood v. Givaudan Flavors Corp.*, several microwave popcorn factory workers alleged that their exposure to butter flavors containing diacetyl caused them respiratory problems.<sup>109</sup> For their failure to warn claims, the plaintiffs alleged that the manufacturer purposely

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96. *Id.*

97. *Id.*

98. *Id.* at \*1-2

99. *Id.* at \*2.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.* at \*3-5, 8.

104. *Id.* at \*9.

105. *Id.*

106. *Id.* (citing *Jarrell v. Monsanto Co.*, 528 N.E.2d 1158, 1162 (Ind. Ct. App. 1988)).

107. *Id.* at \*10-11.

108. *Id.* at \*10 (citing *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 765 (7th Cir. 2013)).

109. No. 1:14-cv-00274-LJM-TAB, 2017 WL 2378258 (S.D. Ind. June 1, 2016).

failed to warn them about the dangers of butter flavors causing permanent lung damage by withholding information from them that people working with diacetyl should use full face respirators.<sup>110</sup> The court first noted Indiana's non-delegable general rule that a manufacturer has a duty to warn users of all latent dangers inherent in the use of a product before turning to a very thorough and thoughtful analysis of the sophisticated intermediary doctrine, which creates an exception to the general rule absolving a manufacturer of liability.<sup>111</sup> The sophisticated intermediary doctrine applies if three criteria are met.<sup>112</sup> First, the product must be sold to an intermediary with knowledge or sophistication equal to that of the manufacturer.<sup>113</sup> Second, the manufacturer must give adequate warnings about the dangers inherent in the product.<sup>114</sup> Third, the manufacturer can reasonably rely on the intermediary to adequately warn the ultimate user.<sup>115</sup>

The court granted the butter flavoring supplier's motion for summary judgment against the plaintiffs' defective warning claims because their employer, who had purchased the butter flavor for use in manufacturing microwave popcorn, was a sophisticated intermediary.<sup>116</sup> Significantly, during the relevant timeframe neither the manufacturer of the flavoring, the trade association it was a part of, nor the professionals it or the trade association hired had discovered a link between respiratory problems and butter flavor.<sup>117</sup> Hence, the manufacturer did not have knowledge of a latent danger or known safety information that had been withheld.<sup>118</sup> Second, the plaintiffs' employer was as sophisticated and had as much knowledge, if not more, about the risks posed by diacetyl in butter flavor as the manufacturer did and had used diacetyl in several plants for many years.<sup>119</sup> In addition, the plaintiffs' employer was a large sophisticated company with its own occupational health department and had become aware of a purported link between diacetyl exposure and lung disease at another plant.<sup>120</sup> The plaintiffs' employer was also part of an ad hoc industry work group developing best practices for microwave popcorn worker safety.<sup>121</sup> Finally, the plaintiffs' employer had taken affirmative steps to protect its workers from diacetyl exposure consistent with industry standards as well as state and local agencies.<sup>122</sup> Hence, summary judgment was appropriately granted against the plaintiffs'

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110. *Costanza*, 2016 WL 7048799 at \*10.

111. *Id.*

112. *Id.*

113. *Id.* (citation omitted).

114. *Id.* (citation omitted).

115. *Id.* (citation omitted).

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.* at \*11.

120. *Id.*

121. *Id.*

122. *Id.*

failure to warn claims.<sup>123</sup>

In the third case in this group, *Fisk v. Medtronic, Inc.*, the plaintiff sued the manufacturer of an allegedly defective pain pump catheter.<sup>124</sup> The complaint asserted, among other things, a failure to warn claim.<sup>125</sup> Specifically, the plaintiff alleged that the manufacturer failed to report problems with the device to the FDA—had that information been provided timely, her doctors would not have implanted the device.<sup>126</sup> The manufacturer moved to dismiss the claim arguing (1) that it was barred by the “learned intermediary” doctrine because the manufacturer had a duty to warn only the plaintiff’s doctors, and not the plaintiff directly; (2) that Indiana does not require manufacturers to disclose product failure information to third parties, like the FDA; (3) that the claim was preempted; and (4) that the complaint inadequately pleaded causation.<sup>127</sup> The court rejected all of these arguments.<sup>128</sup> First, the court found that the learned intermediary doctrine was inapplicable—the complaint did not claim that the manufacturer should have warned the plaintiff directly; rather, it alleged that the manufacturer failed to disclose the information to the FDA.<sup>129</sup> Second, the court noted that Indiana law does, under some circumstances, require manufacturers to disclose information to third parties.<sup>130</sup> Third, the court found the claim was not preempted because it was predicated on a failure to comply with FDA reporting guidelines and did not purport to impose additional reporting obligations on the manufacturer.<sup>131</sup> Finally, the court found that causation was adequately pleaded.<sup>132</sup> Although the plaintiff’s complaint asserted an indirect chain of causation that could be difficult to prove, it was sufficiently asserted to survive a motion to dismiss.<sup>133</sup>

*3. Manufacturing Defect Theory.*—A manufacturing defect typically results from some type of unintended problem during the manufacturing process.<sup>134</sup> Such problems are often the result of human or mechanical error in the manufacturing facility.<sup>135</sup> The most common manufacturing defects involve contaminated formulations or products that otherwise fail in some way to conform to their

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123. *Id.*

124. No. 3:17-CV-032 JD, 2017 WL 4247983, at \* 1 (N.D. Ind. Sept. 25, 2017).

125. *Id.* at \*6.

126. *Id.*

127. *Id.* at \*6-7.

128. *Id.*

129. *Id.* at \*6.

130. *Id.*

131. *Id.* at \*7.

132. *Id.*

133. *Id.*

134. *Product Liability: Manufacturing Defects vs. Design Defects*, FINDLAW, <https://corporate.findlaw.com/litigation-disputes/product-liability-manufacturing-defects-vs-design-defects.html> [<https://perma.cc/XP3Y-LSVL>] (last visited Apr. 19, 2018).

135. *See generally id.*

intended design specifications.<sup>136</sup> As noted above, the manufacturing defect theory is the only method of proving defectiveness in Indiana that is amenable to so-called “strict” liability to the extent that the term equates with liability imposed absent a finding of negligence or fault.<sup>137</sup> Indeed, the IPLA allows for manufacturing defect liability even if the seller has “exercised all reasonable care.”<sup>138</sup>

The majority of the recent decisions in Indiana have involved design or warning theories, but a few have involved manufacturing defect theories.<sup>139</sup> *Fisk v. Medtronic, Inc.*, a 2017 case also discussed above in connection with an alleged warning defect, is the most recent one addressing a manufacturing defect theory.<sup>140</sup> Recall that *Fisk* involved an allegedly defective pain pump catheter.<sup>141</sup> The plaintiff alleged that the site of the catheter became infected and that the catheter protruded from her abdomen.<sup>142</sup> This defect allegedly occurred due to the manufacturer’s failure to comply with the product’s manufacturing specifications.<sup>143</sup> The defendant argued that this claim was preempted because it did not sufficiently plead that her injuries were caused by the violation of a specific FDA regulation.<sup>144</sup> The court rejected this argument, concluding that at the motion to dismiss stage, the plaintiff was not required to “plead around” the affirmative defense of preemption.<sup>145</sup> The plaintiff’s claim—that a manufacturing defect caused her injury—was a sufficient allegation of a state law claim, and the Plaintiff had not “pleaded herself out of court by relying on requirements that would necessarily be different from or in addition to those imposed by federal law.”<sup>146</sup>

#### *E. Regardless of the Substantive Legal Theory*

Indiana Code section 34-20-1-1 makes clear that the IPLA governs all claims for “physical harm” (as the IPLA defines that term) caused by the manufacture or sale of an allegedly defective product “regardless of the substantive legal theory or theories upon which the action is brought.”<sup>147</sup> At the same time, Indiana

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136. *See generally id.*

137. *See generally* IND. CODE § 34-6-2-2(1) (2017)

138. IND. CODE § 34-20-2-2(1). “Strict” liability for defects “in manufacturing and preparation” is also subject to the additional requirement that the “user or consumer has not bought the product from or entered into any contractual relation with the seller.” *Id.* § 34-20-2-2(2).

139. *See, e.g.,* *The Cincinnati Insurance Co. v. Lennox Industries, Inc.*, No. 3:14-CV-1731, 2016 WL 495600 (N.D. Ind. Feb. 9, 2016).

140. No. 3:17-CV-032-JD, 2017 WL 4247983 (N.D. Ind. Sept. 25, 2017).

141. *Id.*

142. *Id.* at \*5.

143. *Id.*

144. *Id.*

145. *Id.*

146. *Id.* at \*6.

147. IND. CODE § 34-20-1-1 (2017).

Code section 34-20-1-2 provides that the IPLA “shall not be construed to limit any other action from being brought against a seller of a product.”

Indiana federal and state courts in recent years have nevertheless wrestled with identifying exactly which claims the IPLA does not otherwise subsume or eliminate in light of the “regardless of substantive legal theory” language of section 34-20-1-1.<sup>148</sup> The Indiana Supreme Court has made it clear that the IPLA does not provide a remedy for purely economic loss claims that are rooted in contract, warranty, and Uniform Commercial Code (UCC) theories of recovery.<sup>149</sup> Those claims may be pursued, if at all, only under a contract-based or a UCC-based theory of recovery and, thus, seem to be the obvious group of “other actions” to which Indiana Code section 34-20-1-2 refers.<sup>150</sup> Such an interpretation is entirely consistent with Indiana’s economic loss doctrine, which precludes tort recovery for purely economic losses.<sup>151</sup> Indeed, several cases recently have addressed issues in the context of the economic loss doctrine,<sup>152</sup> including at least four during the 2017 survey period: *Watts Water Technologies v. State Farm Fire & Casualty Co.*,<sup>153</sup> *Affinity Mutual Insurance Co. v. NIDEC Avtron Automation Corp.*,<sup>154</sup> *Constructora Mi Casita v. Nibco, Inc.*,<sup>155</sup> and *Direct Enterprises, Inc. v. Sensient Colors LLC*.<sup>156</sup>

When it comes to losses that are not purely economic in nature, however, the law is not as clear as it probably should be. The “regardless of substantive theory”

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148. *Id.*

149. A few years earlier, the Indiana Supreme Court in *Gunkel v. Renovations, Inc.*, 822 N.E.2d 150, 153 (Ind. 2005), likewise made clear that remedies for contract-based economic losses and IPLA-based personal injuries or property damage are two fundamentally different things: “Indiana law under the [IPLA] and under general negligence law is that damage from a defective product or service may be recoverable under a tort theory if the defect causes personal injury or damage to the other property, but contract law governs damage to the product or service itself and purely economic loss arising from the failure of the product or service to perform as expected.” *Accord* *Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1024 (N.D. Ind. 2011) (recognizing that the remedies available under the IPLA and the UCC are different and independent from one another).

150. IND. CODE § 34-20-1-1.

151. Such a reading of the statute is consistent with the “economic loss doctrine” cases that preclude a claimant from maintaining a tort-based action against a defendant when the only loss sustained is an economic as opposed to a “physical” one. *See, e.g.*, *Gunkel v. Renovations, Inc.*, 822 N.E.2d 150, 151 (Ind. 2005); *Fleetwood Enters., Inc. v. Progressive N. Ins. Co.*, 749 N.E.2d 492, 495-96 (Ind. 2001); *Progressive Ins. Co. v. Gen. Motors Corp.*, 749 N.E.2d 484, 488-89 (Ind. 2001); *see generally* *Corry v. Jahn*, 972 N.E.2d 907 (Ind. Ct. App. 2012).

152. *See* *Venturedyne, Ltd. v. Carbonyx, Inc.*, No. 2:14-CV-00351-RL, 2016 WL 3402807 (N.D. Ind. June 21, 2016); *Indianapolis-Marion Cnty. Pub. Library v. Charlier Clark & Linard, P.C.*, 929 N.E.2d 722 (Ind. 2010).

153. 66 N.E.3d 983, 991-93 (Ind. Ct. App. 2016).

154. No. 1:16-CV-155-TLS, 2017 WL 3478851, at \*2 (N.D. Ind. Aug. 14, 2017).

155. No. 3:16-CV-565-PPS-MGG, 2017 WL 3438182, at \*5 (N.D. Ind. Aug. 9, 2017).

156. No. 1:15-cv-1333-JMS-TAB, 2017 WL 3314793, at \*9 (S.D. Ind. Aug. 3, 2017).

language in Indiana Code section 34-20-1-1 would seem to make the IPLA the exclusive remedy in all cases in which a claimant contends that the sale or manufacture of a defective product caused physical harm to a person or property that is not purely economic. Indeed, ordinary principles of statutory construction would require that any tension between Indiana Code section 34-20-1-1 and Indiana Code section 34-20-1-2 be resolved in favor of the exclusivity provision.<sup>157</sup> The majority of recent decisions applying Indiana law have recognized the exclusivity of the IPLA remedy when a claimant tries to use common law negligence or breach of implied warranty theories to sue for personal injuries or property damage attributable to the sale or manufacture of an allegedly defective product.<sup>158</sup> In those situations, the non-IPLA-based claims are preempted and should be dismissed.<sup>159</sup>

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157. The U.S. Supreme Court has often held that a “statute’s saving clause cannot in reason be construed as allowing a common law right, the continued existence of which would be absolutely inconsistent with the provisions of the act. In other words, the act cannot be held to destroy itself.” *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 343 (2011) (internal quotation marks, brackets, and citations omitted).

158. *See Fisk v. Medtronic, Inc.*, No. 3:17-CV-032-JD, 2017 WL 4247983, at \*7 (N.D. Ind. Sept. 25, 2017) (common-law negligence theories that duplicated IPLA theories, breach of warranty theories, and negligent misrepresentation theory all dismissed in recognition of IPLA’s exclusivity); *see also Lyons v. Leatt Corp.*, No. 4:15-CV-17-TLS, 2015 WL 7016469 (N.D. Ind. Nov. 10, 2015); *Stuhlmacher v. Home Depot U.S.A., Inc.*, No. 2:10-CV-00467-JTM-APR, 2013 WL 3201572, at \*15-16 (N.D. Ind. June 21, 2013); *Hathaway v. Cintas Corp. Servs., Inc.*, 903 F. Supp. 2d 669, 673 (N.D. Ind. 2012); *Lautzenhiser v. Coloplast A/S*, No. 4:11-cv-86-RLY-WGH, 2012 WL 4530804 (S.D. Ind. Sept. 29, 2012); *Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1024 (N.D. Ind. 2011); *Gardner v. Tristar Sporting Arms, LTD.*, No. 1:09-cv-0671-TWP-WGH, 2010 WL 3724190, at \*2 (S.D. Ind. Sept. 15, 2010); *Kovach v. Coligar Midwest*, 913 N.E.2d 193, 197 (Ind. 2009); *Cincinnati Ins. Companies v. Hamilton Beach/Proctor-Silex, Inc.*, No. 4:05-CV-49, 2006 WL 2990604, at \*2 (N.D. Ind. Feb. 7, 2006); *Henderson v. Freightliner, LLC*, No. 1:02-CV-01301-DFH-WTL, 2005 WL 775929, at \*3 (S.D. Ind. Mar. 24, 2005).

159. *See, e.g., Cavender v. Medtronic, Inc.*, No. 3:16-CV-232, 2016 WL 6599744, at \*3 (N.D. Ind. Nov. 8, 2016) (IPLA’s “regardless of the substantive legal theory” language is “pretty darn clear” in terms of its exclusivity when it comes to common law-based tort claims and, accordingly, the IPLA preempts common law-based negligence and breach of warranty claims); *Parks v. Freud Am., Inc.*, No. 2:14-cv-00036-LJM-WGH, 2016 WL 274875, at \*5 (S.D. Ind. Jan. 22, 2016) ([T]he “IPLA preempts any common law negligence theory of liability with respect to the burden of proof.”). The “preempting” of common law negligence and tort-based implied warranty claims is consistent with the IPLA in cases where the tortfeasor’s conduct that allegedly caused the personal injury or property damage is the manufacture or sale of a defective product. There are, however, some situations in which either the allegedly tortfeasor’s conduct was something other than manufacture or sale of a defective product, when the harm was not “physical” in nature, or when no “product” was involved in the first place. The IPLA does not preempt the common law theories in those types of cases because the liability does not arise from the sale or manufacture of a defective product, but rather some other type of negligent act or omission or harm. *See generally, Vaughn v. Daniels Co.*, 841 N.E.2d 1133 (Ind. 2006) (holding in a personal injury case, the injuries

Many recent decisions have recognized IPLA exclusivity in product liability cases, but describe the defunct common law-based claims as being “merged,” “subsumed,” or “consolidated” into the IPLA.<sup>160</sup> Although those terms are not incorrect in the context of common law personal injury negligence claims that would otherwise be covered by the negligence standard now applicable to design and warning defect theories under the IPLA, they do not aptly describe what should happen to tort-based breach of implied warranty claims because there is no analog for those claims in the IPLA. It is hard to imagine how such claims could survive on their own after being “merged,” “subsumed,” or “consolidated” when the very statute into which they are being folded does not endorse them as viable claims. The better term, therefore, seems to be “preempted,” particularly when it comes to tort-based breach of implied warranty theories. And, the better practice seems to be dismissal as opposed to allowing them to survive post-“merger” along with viable IPLA claims.

Notwithstanding the majority of the cases that recognize IPLA exclusivity or “preemption” in personal injury or property damage cases that involve the manufacture or sale of an allegedly defective product, a handful of peculiar decisions have allowed common law-based negligence claims to proceed *along with* or *in place of* IPLA-based claims when the tortfeasor’s conduct was the manufacture or sale of an allegedly defective product resulting in personal injuries or property damage.<sup>161</sup> Those decisions are difficult to square with the

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did not result from plaintiff’s use of a “product”); *Carson v. All Erection & Crane Rental Corp.*, 811 F.3d 993 (7th Cir. 2016) (holding that in a personal injury case, the allegedly tortfeasor’s conduct was not manufacture or sale of defective product, but rather the failure of the plaintiff’s employer to properly inspect the product after it was delivered to a work site); *Corry v. Jahn*, 972 N.E.2d 907 (Ind. Ct. App. 2012) (holding the allegedly tortfeasor’s conduct was the failure to employ adequate construction techniques rather than a defect in the manufacture or sale of a product); *Duncan v. M&M Auto Serv., Inc.*, 898 N.E.2d 338 (Ind. Ct. App. 2008) (holding that in a personal injury case, the allegedly tortfeasor’s conduct was the negligent repair and maintenance of a product as opposed to a defect in its manufacture or sale); *Smith & Wesson Corp. v. City of Gary*, 875 N.E.2d 422 (Ind. Ct. App. 2007) (holding the alleged was not “physical” in the form of deaths or injuries from gun violence, but rather the result of the increased availability or supply of handguns).

160. See, e.g., *Bowersock v. Davol, Inc.*, 236 F. Supp. 3d 1074, 1084 (S.D. Ind. 2017) (consolidated); *Roper v. Advanced Neuromodulation Sys.*, No. 3:16-CV-79, 2017 WL 1367194, at \*3-\*4 (N.D. Ind. Mar. 31, 2017) (merged); *Cavender v. Medtronic, Inc.*, No. 3:16-CV-232, 2017 WL 1365354, \*3-\*7 (N.D. Ind. Apr. 14, 2017) (subsumed or merged); *Estabrook v. Mazak Corp.*, No. 1:16-CV-87-TLS, 2017 WL 2166691, at \*3 (N.D. Ind. May 17, 2017) (merged); *Aregood v. Givaudan Flavors Corp.*, No. 1:14-cv-00274-LJM-TAB, 2017 WL 2378258, at \*9 (S.D. Ind. June 1, 2017) (subsumed); *The Cincinnati Ins. Co. v. Lennox Industries, Inc.*, No. 3:14-CV-1731, 2016 WL 495600, at \*3-4. (N.D. Ind. Feb. 9, 2016) (subsumed); *Lyons*, 2015 WL 7016469, at \*16 (subsumed); *Lautzenhiser*, 2012 WL 4530804 (merged); *Atkinson*, 813 F. Supp. 2d at 1024 (merged); *Gardner*, 2010 WL 3724190, at \*2 (subsumed).

161. See, e.g., *Kennedy v. Guess, Inc.*, 806 N.E.2d 776, 783-84 (Ind. 2004) (allowing a personal injury plaintiff who could not otherwise impose liability against the defendant under the

cases discussed above and the “regardless of substantive theory” language in the IPLA.<sup>162</sup>

## II. PLEADING REQUIREMENTS

Three key federal decisions during the 2017 survey period provided guidance to practitioners when it comes to the level of pleading specificity required to sustain product liability claims under Indiana law, particularly in light of the heightened federal pleading standards the U.S. Supreme Court established in the *Iqbal* and *Twombly* decisions.<sup>163</sup> In all three cases, the complaints at issue did not comply with the pleading standards.<sup>164</sup>

The first case, *Roper v. Advanced Neuromodulation Systems, Inc.*, involved an allegedly defective implantable pulse generator, which was a Class III medical device regulated by the FDA.<sup>165</sup> The device was subject to an express preemption provision, which, in essence, mandated the dismissal of any state law claims imposing obligations in addition to or different than the federal requirements.<sup>166</sup> The case was before the court on the plaintiff’s first amended complaint, which included a variety of claims based on common law, violations of federal law, and violations of the IPLA.<sup>167</sup> The manufacturer moved to dismiss the complaint based on preemption.<sup>168</sup> The court found it difficult to address the merits of the preemption issue because the amended complaint failed to satisfy federal pleading requirements under *Ashcroft v. Iqbal*<sup>169</sup> and *Bell Atlantic Corp. v. Twombly*.<sup>170</sup> Four of plaintiff’s counts “basically parrot some of the elements necessary to support the theory of liability without connecting any of the facts found elsewhere in the complaint to the legal theory. *Twombly* teaches that more

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IPLA to nevertheless pursue a negligence theory based upon section 400 of the Restatement (Second) of Torts when the only alleged tortfeasable conduct was the sale of a defective product); *Ritchie v. Glidden Co.*, 242 F.3d 713, 726-27 (7th Cir. 2001) (allowing a personal injury claimant to pursue a negligence theory based upon section 388 of the Restatement (Second) of Torts in a case in which the only alleged tortfeasable conduct was the sale of a defective product); *see generally* *Brosch v. K-Mart Corp.*, No. 2:08-CV-152, 2012 WL 3960787 (N.D. Ind. Sept. 10, 2012); *Warriner v. DC Marshall Jeep*, 962 N.E.2d 1263 (Ind. Ct. App. 2012); *see also* *Deaton v. Robison*, 878 N.E.2d 499, 501-03 (Ind. Ct. App. 2007).

162. IND. CODE § 34-6-2-115 (2017).

163. *See generally* *Roper*, 2017 WL 1367194, at \*1; *Bigsby v. Davol*, No. 1:16-cv-00288-TWP-MPB, 2017 WL 2472274, at \*1 (S.D. Ind. June 8, 2017); *Cavender*, 2016 WL 6599744, at \*1.

164. *See generally* *Roper*, 2017 WL 1367194, at \*1; *Bigsby*, 2017 WL 2472274, at \*1; *Cavender*, 2016 WL 6599744, at \*1.

165. 2017 WL 1367194, at \*1.

166. *Id.* at \*4.

167. *Id.* at \*1-2.

168. *Id.* at \*6.

169. 556 U.S. 662, 678 (2009).

170. 550 U.S. 544, 555 (2007).

is required than mere labels and conclusions.”<sup>171</sup> Ultimately, the court dismissed the case without prejudice and granted the plaintiff leave to file a second amended complaint, directing the plaintiff to clarify “the theories relied upon and the facts that serve as the basis for those theories of recovery.”<sup>172</sup> In doing so, the court also cautioned plaintiff that she would not be given “endless” chances to amend her complaint.<sup>173</sup>

*Cavender v. Medtronic, Inc.*, presents another lesson on pleading in the context of a defendant’s motion to dismiss on preemption grounds.<sup>174</sup> This case involved an allegedly defective medical device subject to an express preemption provision.<sup>175</sup> The plaintiff’s complaint set forth various theories of liability, but it included only a few allegations of fact.<sup>176</sup> The defendant moved to dismiss the complaint on a variety of substantive matters, including preemption and the failure to state valid warranty and IPLA claims.<sup>177</sup> Although the court discussed many of these substantive issues, it was unable to rule on the merits of many of the defendant’s arguments because the complaint was insufficiently pleaded.<sup>178</sup> The complaint was virtually devoid of factual assertions and merely recited the elements of various legal theories in a conclusory way: “[the plaintiff’s] precise claims, and the legal bases for them, are difficult to discern given that she fails to include facts to define them. It is not sufficient to pay lip service to a cause of action—a plaintiff must allege facts that tender the claim *plausible*.”<sup>179</sup> The remedy here was to dismiss the bulk of plaintiff’s claims without prejudice and allow her to amend her complaint.<sup>180</sup>

The third pleading case in the survey period, *Bigsby v. Davol, Inc.*, involved the dismissal with prejudice of a *pro se* plaintiff’s second amended complaint.<sup>181</sup> That case involved an allegedly defective “hernia patch kit.”<sup>182</sup> Although the second amended complaint set forth the elements of an IPLA claim, it did so in a conclusory manner without “sufficient factual support [for] a specific cause of action.”<sup>183</sup> The court relied on *Ashcroft v. Iqbal*<sup>184</sup> and *Bell Atlantic Corp. v. Twombly*<sup>185</sup> when it reiterated the pleading sufficiency standard: the complaint should contain “a short and plain statement of the claim showing that the pleader

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171. *Roper*, 2017 WL 1367194, at\*6.

172. *Id.*

173. *Id.* at \*7.

174. No. 3:16-CV-232, 2016 WL 6599744, at \*1 (N.D. Nov. 8, 2016).

175. *Id.*

176. *Id.* at \*7.

177. *Id.* at \*2.

178. *Id.*

179. *Id.* at \*7 (emphasis original).

180. *Id.*

181. No. 1:16-cv-00288-TWP-MPB, 2017 WL 2472274, at \*1 (S.D. Ind. June 8, 2017).

182. *Id.*

183. *Id.* at \*4.

184. 556 U.S. 662, 678 (2009).

185. 550 U.S. 544, 555 (2007).

is entitled to relief—a right to relief that rises above the speculative level and that is plausible on its face. This requires more than mere labels, conclusions, or recitations of the elements of a cause of action.<sup>186</sup> The court also noted that a previous court order had directed the plaintiff to correct these pleading deficiencies in his second amended complaint.<sup>187</sup> Because the plaintiff failed to do so, dismissal with prejudice was appropriate.<sup>188</sup>

### III. EVIDENTIARY REQUIREMENTS

Indiana state and federal courts frequently address evidentiary issues that arise in product liability cases and often those evidentiary issues resolve the case if, for example, the only admissible evidence of causation is excluded. In most instances, decisions involving evidentiary requirements do not interpret or apply the IPLA in the same ways as the cases addressed in the sections above.<sup>189</sup> They are, however, valuable for product liability practitioners because they provide guidance as to the proof necessary to establish liability in cases in which the operative theory of recovery is one that the IPLA embraces.<sup>190</sup> Admissibility of opinion witness testimony to establish causation has been the most frequently addressed issue in this context.<sup>191</sup> The 2017 survey period brought five more key decisions involving the admissibility of opinion causation testimony and another that addressed evidentiary requirements for product identification.<sup>192</sup> We begin our analysis with the product identification case and next address the opinion causation cases.

#### *A. Product Identification Evidence*

In *Smith v. Covidien, LLC*, the plaintiff developed complications following a surgical procedure in which her surgeon used absorbable sutures to close subcutaneous tissue in her neck.<sup>193</sup> Thereafter, an undissolved suture was

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186. *Bigsby*, 2017 WL 2472274, at \*4.

187. *Id.* at \*5.

188. *Id.*

189. *See supra* Part II.

190. *Id.*

191. *See generally* *The Cincinnati Ins. Co. v. Lennox Industries, Inc.*, No. 3:14-CV-1731, 2016 WL 495600 (N.D. Ind., Feb. 9, 2016) (case involved admissibility of opinion witness reports from a fire investigator and an engineer); *Piltch v. Ford Motor Co.*, 778 F.3d 628 (7th Cir. 2015) (role of expert testimony in context of both design defect theory and manufacturing defect theory); *see also* *Timm v. Goodyear Dunlop Tires N. Am., Ltd.*, No. 2:14-CV-232-PPS-JEM, 2016 U.S. Dist. LEXIS 89063, at \*2 (N.D. Ind. July 8, 2016) (case involved admissibility of opinion testimony related to allegedly defective tires); *Leal v. TSA Stores, Inc.*, No. 2:13-CV-318, 2014 WL 7272751, at \*1 (N.D. Ind. Dec. 17, 2014) (need for expert testimony in design case); *Simmons v. Philips Elec. N. Am. Corp.*, No. 2:12-CV-39-TLS, 2015 WL 1418772, at \*1 (N.D. Ind. Mar. 27, 2015) (technical requirements for expert affidavits).

192. *See* the cases discussed *supra* note 191.

193. No. 1:14-CV-326-TLS, 2017 WL 2335991 (N.D. Ind. May 30, 2017).

discovered during a second surgical procedure and removed three months after her initial surgery.<sup>194</sup> Plaintiff sued Covidien, a manufacturer of dissolvable sutures, claiming that one of its absorbable sutures had been used in the first surgery and was defective because it had not dissolved.<sup>195</sup> The second surgeon had not retained the undissolved suture and it had not been examined to determine whether its manufacturer could be identified.<sup>196</sup> In addition, the second surgeon was unable to identify the manufacturer of the removed suture.<sup>197</sup>

Plaintiff's counsel wrote the first surgeon seeking to identify the manufacturer of the undissolved suture.<sup>198</sup> The surgeon's response was not part of the record before the court, but apparently was signed by him and purportedly identified Covidien as the manufacturer;<sup>199</sup> however, in his deposition, the first surgeon did not recall authoring or signing the letter and testified that even though it bore his signature and purported to come from him, the letter would have been processed through someone else in his office in charge of inventory management.<sup>200</sup> During his deposition, the first surgeon testified that he did not know who manufactured the suture used in the first surgery, nor did he know whether the sutures used were tracked or coded in any way.<sup>201</sup> Because the letter purporting to identify the suture manufacturer was not part of the record and would not contain admissible evidence of the suture's manufacturer even if it was, the court granted summary judgment to Covidien.<sup>202</sup>

### *B. Opinion Witness Causation Testimony*

The first of the quintet of significant opinions related to expert witnesses and causation decided this survey period is *Bowersock v. Davol, Inc.*<sup>203</sup> In *Bowersock*, Georgia Bowersock had a mesh hernia patch installed in her abdomen.<sup>204</sup> A little more than one year later, she reported to a local hospital with an abdominal wall abscess that was draining pus and blood.<sup>205</sup> A culture was taken and found to contain a common type of skin bacteria.<sup>206</sup> She returned to the hospital nine days later and within days was placed on a ventilator.<sup>207</sup> Within two weeks, she had

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194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

198. *Id.* at \*4.

199. *Id.* at \*4-5.

200. *Id.* at \*4.

201. *Id.* at \*3.

202. *Id.* at \*5.

203. 236 F. Supp. 3d 1074 (S.D. Ind. 2017).

204. *Id.* at 1078.

205. *Id.*

206. *Id.*

207. *Id.*

passed away.<sup>208</sup> A second culture of the abdominal wall abscess revealed the presence of a bacteria that is commonly found in the gastrointestinal tract.<sup>209</sup> An autopsy was performed and her cause of death was listed as pneumonia and renal failure.<sup>210</sup>

Bowersock's estate disclosed several experts to support its claims the hernia patch was defective and had come in contact with the decedent's bowel, causing the abscess to form, and ultimately, her death.<sup>211</sup> The estate's lead injury causation expert was a well-qualified general surgeon<sup>212</sup> who specialized in gastrointestinal surgery.<sup>213</sup> The doctor's primary opinion was that the defective hernia patch buckled and came into contact with Bowersock's abdomen, which caused her to develop sepsis and ultimately lead to her death.<sup>214</sup> Ultimately, the court did not allow the opinion for a number of different reasons: (1) the doctor's theory was not supported by pertinent medical literature or studies; (2) the condition he described was not identified in Bowersock's medical records; (3) even though the expert opined he had seen the condition in other patients, he was unable to identify any of them or provide their records for review and confirmation; (4) his theory had never been peer reviewed; and (5) the failure mode to which he was opining occurred had not been identified in other, similar hernia patches.<sup>215</sup>

Another of the estate's purported opinion witnesses was a university professor and biomedical engineer.<sup>216</sup> As with the well-qualified surgeon, the court determined that his opinion that the design of the hernia patch was defective was similarly unreliable.<sup>217</sup> He performed no testing, he was unable to identify the amount of deformation required for the hernia patch to come in contact with the bowel, he had never examined the patch at issue, and was relying on the opinion of another expert who had been excluded.<sup>218</sup> His opinion was likewise disallowed.<sup>219</sup>

Finally, the estate identified the doctor who performed Bowersock's autopsy, Dr. Roland Kohr, as a "fact" witness, but, other than the initial autopsy report, did not provide a written report authored by him.<sup>220</sup> Thereafter, the estate provided

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208. *Id.* at 1079.

209. *Id.*

210. *Id.*

211. *Id.* at 1079-82.

212. *Id.* at 1079. Dr. Stephen Ferzoco was the former director of Brigham Women's Hernia Center at Faulkner Hospital.

213. *Id.* at 1079, 1087.

214. *Id.* at 1079-80.

215. *Id.* at 1085-87.

216. *Id.* at 1082. Plaintiff's second expert was Dr. William Hyman, a professor of biomedical engineering at Texas A&M University and former chair of the university's biomedical engineering program.

217. *Id.* at 1079.

218. *Id.*

219. *Id.*

220. *Id.* at 1088.

Dr. Kohr with additional information and sought to expand his role and have him testify to matters not contained within his original autopsy report; specifically, that had he known about the safety issues with the hernia patch he would have rendered a different cause of death.<sup>221</sup> The court did not allow the doctor to testify to newly formed opinions and limited the doctor to only those opinions contained within his autopsy report (that the decedent's death was caused by pneumonia and renal failure).<sup>222</sup>

The court noted the estate had to prove causation to establish its claims against the hernia patch manufacturer.<sup>223</sup> Because the court determined the purported expert opinions did not withstand *Daubert*<sup>224</sup> and Federal Rule of Evidence 702 scrutiny, the estate failed to put forth evidence linking the decedent's injuries to a product-related defect.<sup>225</sup> As a result, the court entered summary judgment against the plaintiff.<sup>226</sup>

In *Lyons v. Leatt Corp.*, the plaintiff, a professional ATV racer and motocross rider, suffered a thoracic spinal cord injury during a mid-race crash, which left him paralyzed.<sup>227</sup> He sued the manufacturer of a neck brace he was wearing at the time of the crash under a variety of product liability theories.<sup>228</sup> The manufacturer contended the brace was designed to reduce or eliminate cervical spine injuries.<sup>229</sup> After excluding plaintiff's expert witnesses,<sup>230</sup> the court granted the brace manufacturer's motion for summary judgment.<sup>231</sup>

Citing *Piltch v. Ford Motor Co.*,<sup>232</sup> the court opined that Indiana law requires expert testimony establish both defect and causation when the issues involved are outside the understanding of a layperson.<sup>233</sup> The court reasoned that the plaintiff's catastrophic thoracic injuries were not the type of injury against which the brace

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221. *Id.*

222. *Id.*

223. *Id.* at 1089.

224. *Id.* at 1084 (citing *Ammons v. Aramark Unif. Servs., Inc.*, 368 F.3d 809, 816 (7th Cir. 2004) (“Under Rule 702 and *Daubert*, the Court follows a two-prong framework: the Court must determine whether ‘(1) the proposed witness would testify to valid scientific, technical, or other specialized knowledge[,] and (2) [the Court must determine whether] his testimony will assist the trier of fact.’”) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993); and FED. R. EVID. 702).

225. *Id.* at 1089.

226. *Id.* Plaintiff filed a motion to amend or alter the judgment, but the court denied the motion for the same reasons it had ruled against the plaintiff previously. *Id.* at 1089-91.

227. No. 4:15-CV-17-PRC, 2017 WL 4117775 \*1, \*5-7 (N.D. Ind. Sep. 14, 2017).

228. *Id.* at \*1.

229. *Id.* at \*2.

230. The opinion does not go into any depth or detail to explain why it excluded plaintiff's proffered experts.

231. *Lyons*, 2017 WL 4117775, at \*1, 13.

232. 778 F.3d 628, 632 (7th Cir. 2015).

233. *Lyons*, 2017 WL 4117775, at \*8.

was designed to protect.<sup>234</sup> The court did not find the plaintiff's references to the manufacturer's product literature persuasive and concluded that, without expert testimony to support the claims, the plaintiff could not prevail on his manufacturing defect claims.<sup>235</sup> Similarly, plaintiff's attempts to maintain a claim of negligent product design could not succeed: "[T]o allow a plaintiff to establish the existence of a design defect by his mere assertion is ludicrous."<sup>236</sup> For his final defect theory, the plaintiff claimed the manufacturer had a duty to warn him of latent defects present in the use of the brace.<sup>237</sup> Plaintiff relied upon his expert's opinions, but because the court had excluded the reports and opinions, this claim failed as well.<sup>238</sup> Finally, the court noted that in addition to proving defect, the plaintiff's claims also failed because, without expert testimony, the plaintiff was unable to establish a causal link between his thoracic spine injuries and any defect in the brace.<sup>239</sup> The court wrote, "as with defect, expert testimony is required to establish causation if the issue is outside the understanding of a lay person."<sup>240</sup>

In *Costanza v. Vulcan Ladder Co.*, the ladder manufacturer defendant sought to exclude the opinion of the plaintiff's expert witness and thereafter obtain summary judgment.<sup>241</sup> The defendant contended the plaintiff's expert's opinion lacked foundation, and, the defense argument proceeded, its expert's opinion established the plaintiff's expert's opinion was incorrect.<sup>242</sup> The court opined that it must first determine whether the expert was qualified.<sup>243</sup> It then must analyze whether the expert's reasoning or methodology was reliable.<sup>244</sup> Finally, the court had to determine whether the opinions were helpful.<sup>245</sup> The defendant conceded the opposing expert possessed the requisite credentials to qualify as an expert and that, if allowed, the expert's testimony would be helpful to the jury.<sup>246</sup> The court rejected the defendant's arguments that the expert's reasoning and methodology were insufficient, noting that the plaintiff's expert reviewed the pertinent documents and information available, followed the applicable standards, and

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234. *Id.* at \*9.

235. *Id.* at \*9-11.

236. *Id.* at \*12 (quoting *McClellon v. Thermo King Corp.*, No. 1:11-cv-01337-SEB-MJD, 2013 WL 6571946, at \*10 (S.D. Ind. Dec. 13, 2013) (quoting *Whitted v. Gen. Motors Corp.*, 58 F.3d 1200, 1206 (7th Cir. 1995) (citing *Bishop v. Firestone Tire & Rubber Co.*, 814 F.2d 437 (7th Cir. 1987))).

237. *Id.* at \*12.

238. *Id.*

239. *Id.* at \*13.

240. *Id.* (citations omitted).

241. No. 1:13-CV-260-TLS, 2016 WL 7048799, \*1 (N.D. Ind. Dec. 5, 2016). For a discussion of the facts of the *Costanza* case, see *supra* Part I.D.2.

242. *Id.* at \*2.

243. *Id.* at \*3-5.

244. *Id.* at \*4-6.

245. *Id.*

246. *Id.*

relied upon the testimony of the plaintiff, all of which were appropriate.<sup>247</sup> The court, however, did not allow the plaintiff's expert's opinion related to feasible alternative design to proceed because the expert had not established the feasibility of his proposed alternative through any type of testing or validation.<sup>248</sup> Because the remainder of the expert's opinions was allowed, the plaintiff was able to establish a triable issue related to the adequacy of the warnings and instructions on the ladder, i.e. defect, and causation between the plaintiff's injury and the claimed defect.<sup>249</sup>

The case of *Dalton v. Teva North America*,<sup>250</sup> is a cautionary tale. The plaintiff sued Teva North America under several product liability based theories claiming that her intrauterine device caused her pain, discomfort and excessive bleeding a few years after it was inserted.<sup>251</sup> She attempted to have the device removed, but a portion of it remained imbedded in her uterus.<sup>252</sup> After the plaintiff did not disclose any expert witnesses, the defendant moved for summary judgment.<sup>253</sup> Plaintiff claimed she did not need experts.<sup>254</sup> She maintained that once the jury heard the doctor testify about the unsuccessful removal of the entire device, saw the x-rays demonstrating that a portion of the device remained imbedded in her uterine wall, and reviewed the medical records, the jury's verdict would not be based upon speculation.<sup>255</sup>

The court disagreed,<sup>256</sup> noting that experts are generally required to establish the existence of design defects and causation under Indiana law when such matters are outside the understanding of a lay jury.<sup>257</sup> In the case at hand, a jury would be speculating about whether a defect in the IUD caused the plaintiff any injury.<sup>258</sup> The court noted that, based upon the evidence, it was equally likely that a defect in the IUD, improper use, improper installation, or something else could

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247. *Id.* at \*5.

248. *Id.* at \*6-7.

249. *Id.* at \*10-11.

250. No. 3:15-cv-00162-RLY-MPB, 2017 WL 1365404 (S.D. Ind. Apr. 14, 2017).

251. *Id.* at \*1.

252. *Id.*

253. *Id.*

254. *Id.* Plaintiff also made what the court construed as an alternative argument that if she needed experts, she had them. The court rejected this argument too because plaintiff filed her expert witness list after the defendant moved for summary judgment, but even then did not disclose any opinions, provide any expert reports to support her claims or identify in her briefing what the experts' opinions were that supported her claims. *See id.* at \*2.

255. *Id.* at \*1.

256. *Id.* at \*1-2.

257. *Id.* at \*1 (citing *Hartman v. Ebsco Indus.*, 758 F.3d 810, 818 (7th Cir. 2014)). The court noted that in some cases experts may not be needed, but in cases involving pharmaceuticals (citing *Tucker v. SmithKline Beechman Corp.*, 701 F. Supp. 2d 1040, 1047 (S.D. Ind. 2010)) and when issues involved complicated questions of medical causation (citing *Hannan v. Pest Control Servs.*, 734 N.E.2d 674, 679 (Ind. Ct. App. 2000)), experts were required.

258. *Id.* at \*1.

be the cause of the plaintiff's injuries.<sup>259</sup> Similarly, all of these in addition to improper removal of the device could have caused the plaintiff's post-removal symptoms.<sup>260</sup> Plaintiff's failure to provide expert testimony to support her claims compelled the court to grant the defendant's motion for summary judgment because she was unable to establish a defect in the product as the cause of her alleged injury.<sup>261</sup>

Finally, recall that in *Smith v. Covidien*, the plaintiff sued Covidien, claiming that an absorbable suture had not dissolved causing her to suffer physical injury.<sup>262</sup> In addition to her claim failing because she was unable to identify the manufacturer of the undissolved suture,<sup>263</sup> the inability of plaintiff's expert to establish causation between a product defect and the injury also proved fatal to plaintiff's claim.<sup>264</sup> Initially, Smith disclosed three experts, all of whom were medical doctors.<sup>265</sup> She later withdrew two and attempted to rely solely upon the testimony of her first surgeon to establish a product defect.<sup>266</sup> Relevant to her claims, during the second surgical procedure, an undissolved suture was found wrapped half to two-thirds around the accessory nerve in her neck.<sup>267</sup> This caused her to experience significant pain and weakness, among other things.<sup>268</sup>

The surgeon testified that damage to the accessory nerve is a known complication of the surgery he performed, but he attempted, as he always does, to avoid injuring her nerve during the procedure.<sup>269</sup> Nonetheless, he was unable to testify whether he did or did not wrap the suture partially around the accessory nerve during the surgery, but admitted a suture could come in contact with the nerve during the procedure.<sup>270</sup> Further, after a suture was tied, he would not expect it to move.<sup>271</sup> The surgeon testified that either the suture or the suture placement was most likely the cause of Smith's injuries and admitted that Smith's pain and numbness complaints began immediately following the first surgery, which was consistent with nerve contact.<sup>272</sup> Subsequently, the surgeon contradicted this testimony with an affidavit that he did not come in contact with the nerve or wrap the suture around it during the surgery.<sup>273</sup>

The court rejected Smith's claims, noting that her defect claims were not

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259. *Id.*

260. *Id.*

261. *Id.* at \*2.

262. No. 1:14-CV-326-TLS, 2017 WL 2335991, at \*1 (N.D. Ind. May 30, 2017).

263. *See supra* discussion in Part III.A.

264. *Smith*, 2017 WL 2335991, at \*7.

265. *Id.* at \*1.

266. *Id.* at \*2.

267. *Id.* at \*1.

268. *Id.* at \*6.

269. *Id.* at \*5.

270. *Id.* at \*6.

271. *Id.*

272. *Id.*

273. *Id.* at \*5.

supported because she had not ruled out other causes of her injury or of the suture not dissolving.<sup>274</sup> The court reasoned that the expert's affidavit averring that it is unknown for a suture not to dissolve within ninety days was unreliable because the expert testified that he only "occasionally" performed exploratory procedures and "usually" the sutures would not be present.<sup>275</sup> Moreover, Smith did not establish that a defect caused the suture to be partially wrapped around her nerve because the doctor did not opine about factors that may affect the absorption rate of a dissolvable suture, could not opine that a defect caused the suture to migrate around her nerve, or, despite his best efforts, it was tied too close to or in contact with the nerve.<sup>276</sup> Finally, the doctor never identified a defect in the suture.<sup>277</sup> As a result, the court concluded that Smith's defect claims were based upon speculation.<sup>278</sup>

#### IV. STATUTES OF LIMITATION AND REPOSE

The IPLA contains a statute of limitation and a statute of repose for product liability claims.<sup>279</sup> The limitations period is two years from the date of accrual.<sup>280</sup> The repose period is ten years from the date the product at issue was first delivered to the initial user or consumer.<sup>281</sup> If, however, the action accrues more than eight years, but less than ten years, after initial delivery, then the claimant's full two-year limitations period is preserved even if the repose period would otherwise expire in the interim.<sup>282</sup> The General Assembly created an exception to the statute of repose for certain types of asbestos-related actions, but in 2016, a narrow majority of the Indiana Supreme Court held that this exception violates the Equal Privileges and Immunities Clause of the Indiana Constitution.<sup>283</sup>

Indiana courts have issued a handful of other decisions in the last decade involving the statutory limitations and repose periods, including one during the 2017 survey period.<sup>284</sup> In *Fisk v. Medtronic, Inc.*, the plaintiff's complaint was

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274. *Id.* at \*7.

275. *Id.*

276. *Id.*

277. *Id.*

278. *Id.*

279. IND. CODE § 34-20-3-1 (2017).

280. *Id.* § 34-20-3-1(b)(1).

281. *Id.* § 34-20-3-1(b)(2).

282. *Id.*

283. *Id.* § 34-20-3-2 provided the statutory exception. The majority in *Myers v. Crouse-Hinds Division of Cooper Industries, Inc.*, 53 N.E.3d 1160 (Ind. 2016), found that the statute violates the Indiana Constitution. *See also* Alberts et al., *supra* note 70, at 1321-23.

284. *See, e.g.*, *Hartman v. Ebsco Indus., Inc.*, No. 3:10-CV-528-TLS, 2013 WL 5460296, at \*1 (N.D. Ind. Sept. 30, 2013); *Technisand, Inc. v. Melton*, 898 N.E.2d 303, 303 (Ind. 2008); *Ott v. AlliedSignal, Inc.*, 827 N.E.2d 1144, 1147 (Ind. Ct. App. 2005); *C.A. v. Amlis at Riverbend, L.P.*, No. 1:06-cv-1736-SEB-JMS, 2008 WL 140801, at \*8 (S.D. Ind. Jan. 10, 2008); *Campbell v. Supervalu, Inc.*, 565 F. Supp. 2d 969, 977 (N.D. Ind. 2008).

based on injuries sustained in connection with a pain pump catheter that was implanted in 2000.<sup>285</sup> In 2008, the pain pump was replaced, but the original catheter remained implanted.<sup>286</sup> The second pain pump was removed in 2013, but the catheter remained implanted after that surgery as well.<sup>287</sup> Sometime in late 2014, the site of the catheter became infected, and the catheter pierced through the skin of the plaintiff's abdomen.<sup>288</sup> On January 7, 2015, the plaintiff's catheter was removed through surgery.<sup>289</sup> The plaintiff filed her complaint on December 12, 2016, alleging that the catheter was defective.<sup>290</sup> The manufacturer argued that the plaintiff's claims were barred by the two-year statute of limitations in Indiana Code Section 34-20-3-1(b)(1).<sup>291</sup> Specifically, the manufacturer argued that the claims based on the first pain pump and the second pain pump were barred since they were removed from the plaintiff's body in 2013.<sup>292</sup> The plaintiff did not dispute this argument, and the court agreed that any claims involving the pain pumps were time-barred.<sup>293</sup> The crux of the plaintiff's claims, however, centered on difficulties with the catheter, which arose in "late 2014."<sup>294</sup> Because the complaint was ambiguous as to the precise date on which the catheter began to cause injury, the catheter claim was not, on its face, time-barred.<sup>295</sup> Accordingly, dismissal of the catheter claims arising from the "late 2014" injury and subsequent surgery was inappropriate.<sup>296</sup>

#### V. FEDERAL PREEMPTION

Federal laws preempt state laws in three circumstances: "(1) when the federal statute explicitly provides for preemption; (2) when Congress intended to occupy the field completely; and (3) where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."<sup>297</sup>

Indiana state and federal courts frequently have wrestled with federal preemption in product liability cases.<sup>298</sup> The *Fisk v. Medtronic, Inc.* case,

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285. No. 3:17-CV-032-JD, 2017 WL 4247983, at \*1 (N.D. Ind. Sept. 25, 2017).

286. *Id.*

287. *Id.*

288. *Id.*

289. *Id.*

290. *Id.* at \*2.

291. *Id.* at \*3.

292. *Id.*

293. *Id.*

294. *Id.*

295. *Id.*

296. *Id.*

297. *Thornburg v. Stryker Corp.*, No. 1:05-cv-1378-RLY-TAB, 2007 WL 1742172, at \*5 (S.D. Ind. June 12, 2007) (quoting *JCW Invs., Inc. v. Novelty, Inc.* 482 F.3d 910, 918 (7th Cir. 2007)).

298. *See, e.g.*, *Ward v. Soo Line Railroad Co.*, No. 2:14-CV-00001, 2016 WL 3402772, at \*2 (N.D. Ind. June 21, 2016); *Lane v. Boston Sci. Corp.*, No. 3:14-CV-1982, 2016 WL 5369596, at

discussed above in connection with some other product liability issues, also involved a federal preemption argument.<sup>299</sup> *Fisk* involved an allegedly defective pain pump catheter.<sup>300</sup> The catheter was a Class III medical device; as such, it was regulated by the FDA and subject to an express preemption provision that prohibited states from establishing “any requirements that are different from or in addition to those imposed by federal law.”<sup>301</sup> The plaintiff’s complaint asserted a variety of state law claims, including claims for manufacturing defect and warning defect.<sup>302</sup> In its motion to dismiss, the manufacturer argued that the state law claims were expressly preempted because they imposed obligations different from or in addition to the federal requirements.<sup>303</sup>

The court disagreed.<sup>304</sup> With regard to the manufacturing defect claim, the plaintiff alleged that she was injured when the “catheter developed infections and protruded through her skin because it was manufactured out of compliance with its specifications.”<sup>305</sup> The manufacturer argued that to survive preemption, the plaintiff had to specifically plead that the device did not comply with federal requirements.<sup>306</sup> The court began its discussion by noting the procedural posture of the case.<sup>307</sup> A plaintiff is not required to anticipate and plead facts to defeat the affirmative defense of preemption.<sup>308</sup> Rather, a complaint will only be dismissed based on an affirmative defense when “the plaintiff pleads herself out of court” by expressly relying on “a state-law duty that would differ from the federal requirements.”<sup>309</sup> Such was not the case here because the plaintiff stated a valid state law claim for manufacturing defect, and she did not “plead[] herself out of court by relying on requirements that would necessarily be different from or in addition to those imposed by federal law.”<sup>310</sup> The court reached a similar conclusion on the plaintiff’s failure to warn claim, which alleged that the

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\*1-2 (N.D. Ind. Sept. 26, 2016); *Ossim v. Anulex Tech.*, No. 1:14-cv-00254-TWP-DKL, 2014 WL 4908574, at \*2 (S.D. Ind. Sept. 30, 2014); *Wilgus v. Hartz Mountain Corp.*, No. 3:12-CV-86, 2013 WL 653707, at \*1 (N.D. Ind. Feb. 19, 2013); *Cook v. Ford Motor Co.*, 913 N.E.2d 311 (Ind. Ct. App. 2009), *trans. denied*, 929 N.E.2d 785 (Ind. 2010); *Roland v. Gen. Motors Corp.*, 881 N.E.2d 722, 727 (Ind. Ct. App.), *trans. denied*, 898 N.E.2d 1218 (Ind. 2008); *Tucker v. SmithKline Beecham Corp.*, 596 F. Supp. 2d 1225, 1238 (S.D. Ind. 2008). *See also* *Alberts et al.*, *supra* note 70, at 1323-26; *Alberts et al.*, *supra* note 62, at 1143-45.

299. *See generally Fisk*, 2017 WL 4247983.

300. *Id.*

301. *Id.* at \*3.

302. *Id.* at \*5-6.

303. *Id.* at \*3-4.

304. *Id.* at \*7.

305. *Id.* at \*5.

306. *Id.*

307. *Id.*

308. *Id.*

309. *Id.*

310. *Id.* at \*6

manufacturer failed to report information to the FDA.<sup>311</sup> The manufacturer argued that “the state-law duty to warn [was] not ‘identical’ to the federal requirement to disclose information to the FDA”; accordingly, the state law claim was preempted.<sup>312</sup> The court disagreed, finding that the plaintiff’s failure to warn claim was rooted in the manufacturer’s alleged violation of a federal law requiring the reporting of certain information to the FDA.<sup>313</sup> The court reasoned that if the plaintiff could prove that her injuries were caused by this violation of federal law, the claims would not be barred by preemption.<sup>314</sup> Thus, the court denied the manufacturer’s motion to dismiss this claim as well.<sup>315</sup>

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311. *Id.*

312. *Id.* at \*7.

313. *Id.*

314. *Id.*

315. *Id.*