

RECENT DEVELOPMENTS IN PRODUCTS LIABILITY

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This article presents a summary of significant products liability cases from October 1, 2014, to September 30, 2015. It covers a range of developments concerning a variety of subjects, including the adoption of a new approach to strict products liability in Pennsylvania, application of the “stream-of-commerce” test for personal jurisdiction, federal preemption, and the admissibility of expert testimony to prove causation. It also discusses developments concerning the learned intermediary defense; class action standing requirements and settlements; and case management issues, including the use of *Lone Pine* orders.

I. THEORIES OF LIABILITY—DESIGN DEFECT

In *Tincher v. Omega Flex, Inc.*,¹ the Pennsylvania Supreme Court embarked on a new approach to strict products liability, overruling its decades-old decision in *Azzarello v. Black Brothers Co.*² Under *Azzarello*, the trial court was required to perform a risk-utility analysis and to determine whether a product was “unreasonably dangerous” under Section 402A of the Restatement (Second) of Torts.³ Once the trial court conducted this assessment, it was up to the jury to decide whether the product was in a defective condition because it lacked elements necessary to make the product safe for its intended use. *Azzarello* precluded juries from determining whether the product was “unreasonably dangerous” because, the court reasoned, the term reflects negligence principles and would be confusing to the jury. Thus, the trial court was to decide whether the product was “unreasonably dangerous” as a matter of policy. The court instructed the jury to consider only whether the product was safe for its intended use. Under *Azzarello*, the risk-utility assessment was not a matter for the jury to decide. This approach to products liability has been termed both idiosyncratic and “almost unfathomable.”⁴

The Pennsylvania Supreme Court took a new path in *Tincher*. There, the plaintiff homeowners sought damages caused by a lightning strike

1. 104 A.3d 328 (Pa. 2014).

2. 391 A.2d 1020 (Pa. 1978).

3. Section 402A imposes strict liability for the sale of a product that is “in a defective condition unreasonably dangerous to the user or consumer. . . .” Restatement (Second) of Torts § 402A (Am. Law Inst. 1965).

4. James A. Henderson Jr. & Aaron D. Twerski, *Achieving Consensus on Defective Product Design*, 83 CORNELL L. REV. 867, 897 (1998); see also John M. Thomas, *Defining “Design Defect” in Pennsylvania: Reconciling Azzarello and the Restatement (Third) of Torts*, 71 TEMP. L. REV. 217 (1998).

that punctured corrugated steel tubing used to transport natural gas to a fireplace in their house. The homeowners sued the manufacturer of the system, claiming that the walls of the tubing were too thin to withstand the effects of lightning and that had the gas conduit been made of black iron pipe the chances of a puncture caused by lightning would have been vastly reduced. The manufacturer argued that the system's flexible design was preferable because it provided greater resistance to corrosion, structural shifts, and mechanical ruptures. The jury returned a verdict in favor of the manufacturer on the homeowners' claim for negligence, but in favor of the homeowners on their strict liability cause of action. On appeal to the Pennsylvania Supreme Court, the homeowners raised a single issue—whether the court should jettison Section 402A of the Second Restatement and instead adopt the Restatement (Third) of Torts.⁵

Given the long-standing criticisms directed at *Azzarello*, the court's decision in *Tincher* to chart a new path was not surprising. The court gave a number of reasons for this decision, including the fact that the standard for liability in *Azzarello* was "impracticable."⁶ By way of example, the court in *Tincher* observed that *Azzarello* had declared that a manufacturer is a "guarantor," but not an "insurer," of its product. But the court provided no explanation or guidance on the "practical import" of these terms.⁷ The court in *Tincher* also questioned *Azzarello*'s separation of the question of whether a product is "defective" from the inquiry of whether it is "unreasonably dangerous." And it expressed doubt that courts have the expertise needed to "conduct the social policy inquiry into the risks and utilities of a plethora of products and to decide, as a matter of law, whether a product is unreasonably dangerous except perhaps in the most obvious of cases."⁸ The *Tincher* court therefore rejected *Azzarello* because *Azzarello* imposed a strict demarcation between negligence and strict liability and removed from the jury's consideration whether a product was unreasonably dangerous.

Despite overruling *Azzarello*, and contrary to predictions,⁹ the court declined to adopt the Third Restatement, saying that to do so would be "problematic."¹⁰ A main source of the court's reluctance to embrace the Third Restatement is the need for a plaintiff to offer proof of an

5. Among other changes, the Third Restatement eliminates the "consumer expectations" test for determining defective design; it reduces the test to a mere factor to be considered in conducting a risk-utility analysis. The Third Restatement also requires a plaintiff to demonstrate a reasonable alternative design for the product in order to demonstrate a design defect. Restatement (Third) of Torts: Products Liability § 2(b), § 2 cmts. f, g (Am. Law Inst. 1998).

6. *Tincher*, 104 A.3d at 379.

7. *Id.*

8. *Id.* at 380.

9. See *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 40, 53–58 (3d Cir. 2009).

10. *Tincher*, 104 A.3d at 395.

alternative design. The court reasoned that adoption of this requirement would limit claims for strict liability based on defective design to products for which “that sort of evidence” is available. Moreover, certain “novel products” for which no alternative is available would be exempt from claims for defective design.¹¹ Proof of an alternative design, the court said, would be “highly probative” on a strict liability claim, but the court eschewed an “evidence-based” rule of strict liability in favor of a “principle-based” rule.¹²

Thus, the court focused on the two standards for ascertaining whether a product is defective that have emerged from the case law. First, under the consumer expectations test, a defective condition is “a condition [that], upon normal use, [is] dangerous beyond the reasonable consumer’s contemplations.”¹³ Second, under the risk-utility standard, “a product is in a defective condition if a ‘reasonable person’ would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions.”¹⁴ The risk-utility test is post hoc and assesses whether a manufacturer’s conduct in designing the product was reasonable.¹⁵ Reviewing these two approaches, the court embraced a “composite standard” for strict products liability, allowing a plaintiff to establish a strict liability claim by relying on either standard, or both.¹⁶

Finally, having overruled *Azzarello*, the court clarified the functions of judge and jury in this new framework. In contrast to *Azzarello*, the determination of product defect, including the risk-utility calculus, is now the function of the jury. On the other hand, the role of the trial court “is to prepare a jury charge that explicates the meaning of ‘defective condition’ within the boundaries of the law.”¹⁷ The *Timcher* court was careful to observe that its decision “does not purport to foresee and account for the myriad implications or potential pitfalls as yet unarticulated or unappreciated.”¹⁸ Thus, *Timcher* resets the law in Pennsylvania, but it will be for future cases to address these many complications.¹⁹

11. *Id.*

12. *Id.* at 397–98.

13. *Id.* at 387.

14. *Id.* at 389.

15. *Id.*

16. *Id.* at 401.

17. *Id.* at 408.

18. *Id.* at 406.

19. See generally Am. L. Prod. Liab. § 28:3 (3d ed. 2015) (finding that the requirement of a reasonable alternative design has been adopted by courts in Florida and Iowa, but has been rejected by courts in other states, including Missouri, Connecticut, Kansas, New Hampshire, and Wisconsin).

II. PERSONAL JURISDICTION

A. *Stream-of-Commerce Test*: Book v. Doublestar Dongfeng Tyre Co., Ltd.

In *Book v. Doublestar Dongfeng Tyre Co., Ltd.*,²⁰ the Iowa Supreme Court was called upon to address the continuing vitality of the “stream-of-commerce” theory of personal jurisdiction in products liability cases. The phrase was first introduced by the U.S. Supreme Court in *World-Wide Volkswagen Corp. v. Woodson*, in which the Court declared that consistent with due process, a state could exercise jurisdiction over a corporation that “delivers its products into the stream-of-commerce with the expectation that they will be purchased by consumers in the forum State.”²¹ Shortly afterward, in *Svendson v. Questor Corp.*,²² the Iowa Supreme Court adopted the stream-of-commerce test as a basis for exercising personal jurisdiction in products liability cases.

Subsequently, the U.S. Supreme Court engendered confusion and uncertainty concerning the validity of the stream-of-commerce test with its fractured 1987 decision in *Asahi Metal Industry Co., Ltd. v. Superior Court of California*.²³ Justice O’Connor’s plurality opinion in *Asahi* stated that mere “awareness that the stream-of-commerce may or will sweep the product into the forum State” is not sufficient to support jurisdiction.²⁴ Justice O’Connor articulated a “foreseeability plus” test, reasoning “the placement of a product into the stream-of-commerce, without more, is not an act of the defendant purposefully directed toward the forum State.”²⁵ In contrast, Justice Brennan’s concurring opinion declared that if there is a “regular and anticipated flow of products” into the forum, jurisdiction can properly be exercised “[a]s long as a participant in this process is aware that the final product is being marketed in the forum State. . . .”²⁶ Four members of the Court joined in each opinion, and there was no majority holding concerning the stream-of-commerce test. The Court did not address the test again for more than twenty years. When it did, in *ℳ. McIntyre Machinery, Ltd. v. Nicaastro*,²⁷ the Court was again fragmented with no majority approach.

20. 860 N.W.2d 576 (Iowa 2015).

21. 444 U.S. 286, 297–98 (1980).

22. 304 N.W.2d 428 (Iowa 1981).

23. 480 U.S. 102 (1987).

24. *Id.* at 112.

25. *Id.*

26. *Id.* at 117.

27. 131 S. Ct. 2780 (2011). In *ℳ. McIntyre Machinery*, the Court held that New Jersey courts lacked personal jurisdiction over a manufacturer based in the United Kingdom. Justice Kennedy’s plurality decision, joined by three other members of the Court, endorsed Justice O’Connor’s views from *Asahi* and suggested that “it is not enough that the defendant might have predicted that its goods will reach the forum State.” *Id.* at 2788. Two justices

Against this background, this year the Iowa Supreme Court in *Book* considered the stream-of-commerce test in a case alleging that tires made by a Chinese company and sold in Iowa through an American distributor were defective.²⁸ The court concluded that because there was no majority opinion in *J. McIntyre Machinery*, the stream-of-commerce test articulated in *World-Wide Volkswagen Corp.* and adopted in *Svendsen* “remains good law and controlling precedent” in Iowa.²⁹ Moreover, the court declined to overrule *Svendsen* and to adopt a more stringent test for exercising jurisdiction “that would limit access to justice in Iowa courts for residents of our state injured by allegedly defective products purchased here.”³⁰ In support of this decision, the court relied on stare decisis as well as policy considerations. The court noted, for example, that the purpose of products liability, i.e., to ensure that the costs of injuries resulting from defective products are borne by the manufacturer, would be undermined by closing “the local courthouse door to injured consumers.”³¹ The court noted, moreover, that the hazardous nature of the product—a tire “with an allegedly dangerous design”—also supported the exercise of jurisdiction.³² In addition, any inconvenience to the manufacturer by being forced to litigate in Iowa was mitigated because the manufacturer conceded that it was subject to personal jurisdiction in Tennessee, where one of its distributors was based; the manufacturer failed to “identify any material burden it would face in defending this case in Iowa instead of Tennessee.”³³ Finally, the court distinguished *J. McIntyre Machinery* on the ground that the defendant had sold over three million tires in the first nine months of 2009, including hundreds of thousands to its U.S. distributors. Thus, the case did not involve “an isolated sale or a small manufacturer.”³⁴

Having decided to adhere to the stream-of-commerce test, the court found that the tire manufacturer was subject to personal jurisdiction in Iowa.³⁵ The court noted that between 2008 and 2009, the manufacturer had directly shipped 12,681 tires to Iowa and that its Tennessee distributor shipped another 16,700 tires to the state (out of a total of 180,000 sold

concurrent in the judgment but declined to embrace a broad jurisdictional test. *Id.* at 2784. In a dissent joined by two other Justices, Justice Ginsburg asserted that the New Jersey courts could properly exercise jurisdiction over the defendant because it targeted a nationwide U.S. market through its distributor. *Id.* at 2800–01.

28. *Book v. Doublestar Dongfeng Tyre Co., Ltd.*, 860 N.W.2d 576 (Iowa 2015).

29. *Book*, 860 N.W.2d at 592.

30. *Id.* at 594.

31. *Id.* at 595.

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.* at 596.

to the distributor).³⁶ The court concluded that the manufacturer “at least indirectly served the Iowa market through [its distributor] ‘with the expectation that [its tires] would be purchased by consumers in the forum State.’”³⁷ The fact that the manufacturer relied on a distributor did not defeat jurisdiction since, under Justice Brennan’s formulation in *Asahi*, jurisdiction could be exercised over the manufacturer provided “[it] is aware that the final product is being marketed in the forum State.”³⁸ Here, the manufacturer’s awareness was shown by its direct shipments to Iowa, even though the risk of loss passed in China because the tires were delivered F.O.B. at the Chinese port.³⁹ Finally, the court concluded that the exercise of personal jurisdiction would be consistent with fair play and substantial justice because the manufacturer had conceded that it was subject to jurisdiction in Tennessee, but failed to show that defending the case in Iowa would be more burdensome than in Tennessee. The exercise of jurisdiction was also supported by the State of Iowa’s interest in protecting its residents from damages due to the tortious acts of nonresident defendants and by the plaintiffs’ interest in obtaining relief “at home” rather than in another state. “Systemic judicial interests,” the court said, likewise favored the exercise of jurisdiction in Iowa, where the “key occurrence and damages witnesses” were located.⁴⁰

Thus, Iowa joins other states that have continued to adhere to the stream-of-commerce test for personal jurisdiction, despite fractured guidance from the U.S. Supreme Court.⁴¹ In a caveat, however, the court left open “the possibility of revising the stream-of-commerce test for small nonresident sellers.”⁴²

B. *General Jurisdiction: BNSF Railway Co. v. Superior Court*

In *BNSF Railway Co. v. Superior Court*,⁴³ a California appellate court rejected the plaintiffs’ effort to limit the reach of the U.S. Supreme Court’s 2014 decision in *Daimler AG v. Bauman*⁴⁴ and to fashion a singular

36. *Id.*

37. *Id.*

38. *Id.* at 597 (quoting *Asahi Metal Indus. Co., Ltd. v. Super. Ct. of Calif.*, 480 U.S. 102, 117 (1987)).

39. *Id.*

40. *Id.* at 598.

41. See *Ex Parte Edgetech I.G., Inc.*, 159 So. 3d 629, 640–42 (Ala. 2014) (following stream-of-commerce test in *World-Wide Volkswagen* given the fractured opinions in *Asahi* and *J. McIntyre*); *Andra v. Left Gate Prop. Holding, Inc.*, 453 S.W.3d 216, 231–33 (Miss. 2015) (en banc) (finding that exercise of personal jurisdiction is proper under the stream-of-commerce test); *but see* *N.H. v. N. Atl. Refining Ltd.*, 999 A.2d 396 (N.H. 2010) (adopting stream-of-commerce “plus” test for products liability cases).

42. *Book v. Doublestar Dongfeng Tyre Co., Ltd.*, 860 N.W.2d 576, 596 (Iowa 2015).

43. 185 Cal. Rptr. 3d 391 (2015), *review granted* (Cal. July 22, 2015).

44. 134 S. Ct. 746 (2014). In *Daimler*, the Supreme Court held the California courts could not exercise jurisdiction over Daimler, a German public company, in an action arising out of

jurisdictional standard for asbestos products liability cases. The plaintiffs in *BNSF Railway Co.* brought a wrongful death action against the railway and numerous other defendants in California, alleging that the decedent died from mesothelioma caused by exposure to asbestos-containing products. As to the railway, they claimed that the decedent had been exposed to asbestos while working at a facility in Kansas. The court rejected the plaintiffs' effort to distinguish *Daimler* on the ground that the defendant there was based in a foreign country rather than in a sister state.⁴⁵ The test endorsed in *Daimler*, the court declared, is "broadly applicable" and applies "whenever courts must consider and resolve the issue of general jurisdiction" (i.e., whenever the conduct that gives rise to the claim is unrelated to the forum).⁴⁶

The fact that the railway conducted "substantial" business in California was not sufficient to confer jurisdiction over the railway because its business in California was "a relatively small portion of its overall operations."⁴⁷ California was home to just 8 percent of the railway's workforce and 5 percent of its track infrastructure and accounted for only 6 percent of the railway's revenue.⁴⁸ Moreover, the railway's business in California was performed "in service of [the railway's] principal hub in Texas."⁴⁹ Because general jurisdiction for claims unrelated to conduct in the forum must be assessed on a corporation's "activities in their entirety, nationwide and worldwide,"⁵⁰ the court concluded that the railway was not "at home" in California and could not be sued there based on alleged asbestos exposure in Kansas.⁵¹

The plaintiffs also argued that jurisdiction was proper, even though the railway was not incorporated in California and did not have its principle place of business there because asbestos exposure results in an "indivisible injury" and that in such "exceptional" circumstances, the requirements of *Daimler AG* should not apply.⁵² They argued that they should not be forced to sue numerous individual defendants wherever each is incorporated or has

events that occurred in Argentina, based on its United States subsidiary's contacts with California. *Daimler* was not "at home" in California because it was not incorporated in California and did not maintain its principal place of business there.

45. *BNSF*, 185 Cal. Rptr. 3d at 400.

46. *Id.*

47. *Id.* Following *Daimler*, other courts have also found that "substantial, continuous, and systematic course of business" in the forum state is insufficient for an exercise of general personal jurisdiction where the defendant is neither incorporated in nor has its principal place of business in the forum state. See, e.g., *Loyalty Conversion Sys. Corp. v. Am. Airlines, Inc.*, 66 F. Supp. 3d 795, 806-07 (E.D. Tex. 2014).

48. *BNSF*, 185 Cal. Rptr. 3d at 400.

49. *Id.* at 400-01.

50. *Id.* at 400.

51. *Id.*

52. *Id.* at 401.

its principle place of business; otherwise, the result would be burdensome to the courts, unjust to the plaintiffs, and would enable the defendants to avoid liability. The court expressed sympathy to these concerns but rejected the plaintiffs' arguments, stating "the due process rights of defendants cannot vary with the types of injury alleged by plaintiffs."⁵³ Moreover, the court noted, its ruling would not leave the plaintiffs without any forum to obtain relief against the railway.⁵⁴

III. PREEMPTION

A. *Medical Devices: McClellan v. I-Flow Corp.*

In *McClellan v. I-Flow Corp.*,⁵⁵ a surgical patient brought a product liability action, asserting claims for negligent failure to warn and strict liability against the manufacturer and distributors of a pump used to administer pain medication. Judgment was entered in favor of the defendants following trial, and the plaintiff appealed. The Ninth Circuit vacated and remanded the case for a new trial, holding that jury instructions requested by the plaintiff were not preempted by Medical Device Amendments of 1976 (MDA) to the Food, Drug & Cosmetics Act (FDCA).⁵⁶

The plaintiff in *McClellan* underwent two shoulder surgeries and was prescribed continuous infusion of a painkiller, delivered through a continuous infusion pump device, after both surgeries.⁵⁷ A continuous infusion pump contains a portable reservoir attached to a catheter that delivers the medication to the site—in this case, the shoulder joint.⁵⁸ During her recovery from the second surgery, the plaintiff was diagnosed with chondrolysis of the shoulder, which causes articular cartilage loss.⁵⁹ As a result of the plaintiff's complete loss of cartilage, she developed a spontaneous fusion of her shoulder due to the ball and socket growing together, an untreatable condition that severely restricts motion in the joint.⁶⁰

The plaintiff claimed that the manufacturer was negligent because it failed to warn her that the pump should not be used in intra-articular spaces (such as the glenohumeral joint) and that the pump was unreasonably dangerous due to a lack of adequate warnings.⁶¹ The district court declined to give certain instructions requested by the plaintiff, reasoning that they were preempted by the MDA.

53. *Id.*

54. *Id.*

55. 776 F.3d 1035 (9th Cir. 2015).

56. *Id.* at 1037–38.

57. *Id.* at 1037.

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.*

Under the MDA, manufacturers must provide reasonable “assurance of the safety and effectiveness” of a medical device to the U.S. Food and Drug Administration (FDA) before introducing the device to the market.⁶² The premarket approval process is not required for devices marketed and sold before 1976 (“grandfathered device[s]”) and devices that are “substantially equivalent” to grandfathered devices.⁶³ For the latter category, once the FDA determines that a device is “substantially equivalent” to a grandfathered device, no additional showing of safety or effectiveness is required.⁶⁴

Given the FDA’s regulation of the safety requirements for medical devices, the district court refused jury instructions requested by the plaintiff concerning negligence and federal standards because it found that the instructions were barred by conflict preemption.⁶⁵ Conflict preemption arises where “there is an actual conflict between state and federal law,” i.e., “when [1] ‘compliance with both federal and state regulations is a physical impossibility,’ . . . or [2] when state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”⁶⁶

In arguing that the plaintiff’s requested jury instructions were preempted based on the MDA, the defendant relied on the U.S. Supreme Court’s 2001 decision in *Buckman Co. v. Plaintiffs’ Legal Committee*.⁶⁷ *Buckman* involved claims made under state law that the defendant improperly obtained market clearance for the bone screws it manufactured by making fraudulent representations to the FDA concerning the use of the bone screws. The Supreme Court held that the claims enjoyed no presumption against preemption, were in conflict with the MDA, and were therefore preempted.⁶⁸ The conflict, the Court said, “stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against [the agency]. . . .”⁶⁹ Moreover, because policing fraud against a federal agency is “hardly a field which the States have traditionally occupied,” a presumption against preemption was not warranted in *Buckman*.⁷⁰

The Ninth Circuit rejected the defendant’s reliance on *Buckman*. First, the court recognized that the widely recognized presumption against

62. *Id.* at 1037–38 (quoting 21 U.S.C. § 360c(a)(1)(A)(i), (B), (C)(i) (2012)).

63. *Id.* at 1038 (quoting 21 U.S.C. § 360e(b)(1)(B)).

64. *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996)).

65. *Id.* at 1038–39; Oregon Uniform Civil Jury Instruction 20.03, 20.04.

66. *Id.* at 1039 (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76–77 (2008), and *Hillsborough Cty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)).

67. 531 U.S. 341 (2001).

68. *Id.* at 347–48.

69. *Id.* at 348.

70. *Id.* at 347–48 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

express preemption applies equally to conflict preemption.⁷¹ Distinguishing *Buckman*, the Ninth Circuit explained that, unlike the plaintiff there, the plaintiff in *McClellan* did not allege that a fraud had been committed on the FDA by the defendant manufacturer. Instead, the plaintiff in *McClellan* alleged failure to warn theories that “clearly concerned the labeling and regulation of medical devices,” a field that was “left largely to the States” before enactment of the MDA.⁷² The court thus concluded that the plaintiff’s case was not controlled by *Buckman* and applied the presumption against preemption.⁷³ Moreover, in *Buckman*, the federal statute was a “critical element” because the claims were based on alleged misrepresentations made “during the market approval process.” In contrast, in *McClellan*, the jury instructions the plaintiff requested had “little to do with the regulatory interaction with the FDA.”⁷⁴ The court in *McClellan* rejected the defendant’s contention that a jury instruction that would use federal law to establish a standard of care is equivalent to an attempt “to enforce the underlying federal provisions.”⁷⁵ The court further concluded that nothing about the plaintiff’s requested instructions conflicted with congressional intent since Congress did not enact the MDA “to displace traditional tort law [and] mak[e] all policing of medical labels and warnings the exclusive province of the FDA.”⁷⁶ The court vacated the judgment and remanded for a new trial.

B. *Nonprescription Drugs*: *Reckis v. Johnson & Johnson*

In *Reckis v. Johnson & Johnson*,⁷⁷ a child and her parents brought a products liability action against a manufacturer of ibuprofen alleging that the child developed toxic epidermal necrolysis (TEN), a rare life-threatening skin disorder, after receiving multiple doses of the medication. The plaintiffs claimed that the warning label on the ibuprofen bottle rendered the product defective because it failed to warn consumers adequately about the risk of developing life-threatening disease.⁷⁸ The defendants appealed a \$63 million judgment entered in favor of the plaintiffs after trial. Among other issues, the Supreme Judicial Court of Massachusetts considered whether the defendants were entitled to judgment as a matter of law

71. *McClellan v. I-Flow Corp.*, 776 F.3d 1039 (9th Cir. 2015).

72. *Id.* at 1040.

73. *Id.*

74. *Id.*

75. *Id.* at 1041.

76. *Id.* at 1040–41.

77. 28 N.E.3d 445, 448 (Mass. 2015), *petition for cert. filed*, 2015 WL 5895924 (U.S. Oct. 9, 2015) (No. 15-449).

78. *Id.*

because the plaintiffs' failure to warn claim was preempted by the Federal Food, Drug, and Cosmetic Act (FDCA).⁷⁹

Under 21 U.S.C. § 379r, entitled "National Uniformity for Nonprescription Drugs," state law requirements concerning the labeling of over-the-counter medications that are "different from or in addition to" requirements imposed under the FDCA are expressly preempted.⁸⁰ The plaintiffs, however, relied on § 379r(e), which states that "nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."⁸¹ The court acknowledged that the savings clause in § 379r(e) removes tort actions from the scope of the express preemption clause of § 379r, but reasoned that the savings clause "does not foreclose . . . the possibility that a federal [law] will pre-empt a state common-law tort action with which it conflicts."⁸² The court explained that "conflict preemption would still bar the plaintiffs' claim if the result the plaintiffs sought would require the defendants to use a warning label that conflicted with [federal] requirements."⁸³ Accordingly, the court interpreted the savings clause to "spare the plaintiffs' State law claims from express preemption by the FDCA," but the plaintiffs' claims remained "susceptible" to conflict preemption.⁸⁴

The *Reckis* court then turned to the defendants' argument that the plaintiffs' claim of failure to warn was preempted based on "exceptionally clear evidence" that the FDA would not have approved the warning that the plaintiffs argued was needed and that it was therefore impossible for the defendant to meet the requirements of both state tort law and federal regulations.⁸⁵ The defendants pointed to the fact that the FDA considered, and ultimately rejected, a portion of a citizen petition that proposed a requirement that ibuprofen labels include the term "TEN" and instead required manufacturers to warn consumers about three specific symptoms associated with TEN—reddening of the skin, rash, and blisters.⁸⁶ Accordingly, the court agreed that the plaintiffs' claim that the ibuprofen warning label should have specifically referenced TEN was preempted.⁸⁷

79. *Id.* at 449.

80. 21 U.S.C. § 379r(a) (2012) ("no State . . . may establish or continue in effect any requirement . . . that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]").

81. *Reckis*, 28 N.E.3d at 455 (quoting 21 U.S.C. § 379r(e)).

82. *Id.* (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869–70 (2000)).

83. *Id.*

84. *Id.*

85. *Id.* at 456.

86. *Id.* at 452–54.

87. *Id.* at 458.

However, the plaintiffs in *Reckis* also claimed that the ibuprofen label should have warned that redness, rash, or blisters might be a pathway to life-threatening disease.⁸⁸ The court concluded that this claim was not preempted, noting that the FDA had rejected only the proposal to place “TEN” on ibuprofen labels, but that the FDA had required manufacturers to identify specific symptoms of the disease.⁸⁹ Given the FDA’s response to the citizen petition, the court reasoned that there was no “clear evidence” that the FDA would have rejected a warning on ibuprofen labels stating that redness, rash, and blisters may lead to life-threatening disease.⁹⁰

Since it determined that the plaintiffs’ claim that the ibuprofen label should have referenced TEN by name was preempted, the court considered whether the jury might have based its finding of liability on this preempted theory; a new trial was necessary only where one of multiple theories of liability presented to a jury was improper and there was “no way of knowing on which basis the jury reached its verdict.”⁹¹ But the court was “reasonably confident” that the jury did not base liability on the defendants’ failure to warn of TEN by name based on the plaintiff’s own testimony that he had never heard of TEN. Moreover, counsel in closing arguments stated explicitly that the plaintiffs did not contend that the warning should have mentioned TEN by name.⁹² Accordingly, the court found no reason to disturb the verdict.⁹³

C. *Food Products: Guttman v. Nissin Foods (U.S.A.) Co. Inc.*

In *Guttman v. Nissin Foods (U.S.A.) Co. Inc.*,⁹⁴ the plaintiff brought a putative class action against the defendant alleging five California state law claims based on the presence of artificial transfat, a purportedly dangerous substance, in the defendant’s noodle products. Among other issues, the court addressed whether the lawful use of a dangerous substance in a food product can constitute an unfair business practice under California’s Unfair Competition Law.⁹⁵ The court found that the plaintiff stated a plausible claim under the Unfair Competition Law and that the defendant failed to show that the claim was preempted by federal law.⁹⁶

88. *Id.* at 454.

89. *Id.* at 459.

90. *Id.* at 459–60.

91. *Id.* at 461.

92. *Id.*

93. *Id.*

94. No. C 15-00567 WHA, 2015 WL 4309427, at *1 (N.D. Cal. July 15, 2015).

95. *Id.* at *4.

96. *Id.* at *4–5. There were two preemption issues raised in this case: (1) federal preemption of the plaintiff’s mislabeling claims and (2) federal preemption of the plaintiff’s use claims under the Unfair Competition Law. The court found that the plaintiff’s mislabeling claims were preempted by FDA regulation of nutrition labels on food products. *Id.* at *2–3.

The defendant, Nissin Foods (U.S.A.) Company Inc., manufactured food products that contained partially hydrogenated oil, a food additive derived from low-cost oils.⁹⁷ The manufacturing process for partially hydrogenated oils produces artificial transfat with a chemical structure different from most naturally occurring fats.⁹⁸ In their complaint, the plaintiffs cited numerous studies that purportedly linked the consumption of artificial transfat to an increased risk of several diseases.⁹⁹ In particular, the plaintiffs alleged that there is no safe level of artificial transfat intake and that any increase in transfat increases the risk of cardiovascular disease.¹⁰⁰

The plaintiff alleged that Nissin's use of artificial transfat constituted an unfair business practice under California law. Citing the Ninth Circuit's decision in *Lozano v. AT&T Wireless Services, Inc.*, the court explained that whether a particular practice is "unfair" under the statute is generally determined by either a "balancing test" or a "tethering test."¹⁰¹ The balancing test involves "balancing the harm to the consumer against the utility of the defendant's practice."¹⁰² Under the tethering test, a determination of "unfairness must be tethered to some legislatively declared policy or proof of some actual or threatened impact on competition."¹⁰³ Focusing on the balancing test, the court determined that the plaintiff plausibly alleged that Nissin's conduct violated the Unfair Competition Law: the complaint provided great detail on the serious harm artificial transfat poses to public health, whereas the only utility in the use of partially hydrogenated oils is that they are less expensive than alternative substances.¹⁰⁴

Nissin also argued that the plaintiff's claim was preempted by federal law because (until recently) certain partially hydrogenated oils were expressly designated "generally recognized as safe" by the FDA.¹⁰⁵ However, that designation did not apply to the particular types of oils used by Nissin, and the FDA had declined to expressly prohibit or allow other partially hydrogenated oils and artificial transfat. Because the FDA decided not to list all artificial transfat as "generally recognized as

97. *Id.* at *1.

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.* at *4 (citing *Lozano v. AT&T Wireless Servs. Inc.*, 504 F.3d 718, 736 (9th Cir. 2007)).

102. *Id.* (citing *Lozano*, 504 F.3d at 736).

103. *Id.* (citing *Lozano*, 504 F.3d at 736).

104. *Id.*

105. *Id.* On June 17, 2015, while Nissin's motion was pending, the FDA issued a final determination that partially hydrogenated oils are no longer "generally recognized as safe," allowing manufacturers three years to remove the oils from their products.

safe,” the designation did not provide a safe harbor protecting use of that ingredient from the reach of California law. The court therefore denied Nissin’s motion to dismiss as to the plaintiff’s claims under California’s Unfair Competition Law. While the impact of the ruling with respect to foods containing partially hydrogenated oils may be limited in light of the FDA’s June 2015 determination to remove transfat from food products, the court’s reliance on the balancing test in *Guttman* could open the door to claims involving other food products alleged to pose serious health risks.

IV. CAUSATION AND EXPERTS

A. *Differential Etiology Analysis Rejected: C.W. ex rel. Wood v. Textron, Inc.*

*C.W. ex rel. Wood v. Textron, Inc.*¹⁰⁶ illustrates the difficulty of proving causation in a toxic tort case when there is a dearth of directly applicable scientific evidence showing that the exposure in question has the capacity to cause the claimed injury. There, the plaintiffs claimed that their infant children had suffered a variety of health problems caused by exposure to vinyl chloride released from the defendant’s manufacturing plant. The court acknowledged that vinyl chloride, a toxic gas, presents serious health risks to humans, but held that the plaintiffs’ experts did not adequately answer critical questions: “in what quantity” and “for how long” does the exposure need to occur before the health risks can “materialize”?¹⁰⁷ The Seventh Circuit affirmed the district court’s decision to exclude the plaintiffs’ expert evidence on the ground that the experts’ opinions were not based on a reliable methodology.¹⁰⁸

The court focused on the experts’ failure to “connect the dots” from published studies of the health effects of vinyl chloride to the illnesses suffered by the children.¹⁰⁹ One study, for example, analyzed the carcinogenic effect of vinyl chloride on laboratory rats, and another analyzed the effect of vinyl chloride on workers. In both studies, the amount of exposure was far greater and for longer periods of time than had been experienced by the plaintiffs’ children. Because of these differences, the “analytical gap” between the data and the experts’ opinion was “simply too great. . . .”¹¹⁰ The court rejected the plaintiffs’ argument, i.e., that there are no studies available on the impact of vinyl chloride on children, because scientists have developed “computer-based models to extrapolate

106. No. 14-3448, 2015 WL 5023926 (7th Cir. Aug. 26, 2015).

107. *Id.* at *1.

108. See generally *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

109. *C.W.*, 2015 WL 5023926, at *7.

110. *Id.* (citing *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997)).

from animal data to human subjects, and from high doses to lower doses.”¹¹¹ The court noted, moreover, that the U.S. Environmental Protection Agency recognizes these methods of extrapolation as a means of “bridging the gap between the studies and the general public.”¹¹² The plaintiffs’ experts, however, did not mention or rely upon this method of extrapolation from the available studies to the children’s actual exposure.

Instead, the plaintiffs’ experts sought to rely on a “differential etiology” analysis to support their opinions.¹¹³ While the court acknowledged that “a rigorous differential etiology” might be sufficient to prove causation, it rejected the plaintiffs’ analysis in this case. First, the court stated that one expert’s opinion that the children’s doctors would have detected potential alternative causes of their health problems was not scientific, but rather was based on mere “faith” in the treating physicians.¹¹⁴ Moreover, this approach was flawed because it assumed that vinyl chloride was a possible cause of the injuries “in the first place.”¹¹⁵ According to the court, the plaintiffs’ experts engaged in “a leap of faith” by presuming that vinyl chloride had the “capacity” to cause the claimed injuries.¹¹⁶ Finally, the court also rejected one expert’s reliance on evidence that the amount of vinyl chloride in the family’s drinking water exceeded permissible regulatory levels because the expert did not know the particular danger that led the regulatory agency to set the specified safety level.¹¹⁷ Having affirmed the district court’s decision to exclude the plaintiffs’ expert evidence, the court also affirmed the lower court’s decision granting summary judgment in the manufacturer’s favor.

B. *Differential Etiology Analysis Upheld: Cooper v. Takeda Pharmaceuticals America, Inc.*

In *Cooper v. Takeda Pharmaceuticals America, Inc.*,¹¹⁸ on the other hand, where the court found significant evidence linking the product to the claimed injuries, the plaintiffs were successful in relying upon a differential diagnosis analysis to prove causation. In that case, the plaintiffs claimed that a diabetes medication, Actos, made by the defendant caused

111. *Id.*

112. *Id.*

113. The term “differential etiology” is often used by courts to describe the process by which an expert “arrive[s] at an opinion on cause through a process of ruling out or eliminating other causes. . . .” See, e.g., Henifin et al., *Reference Guide on Medical Testimony*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 439, 470 n.112 (2d ed. 2000).

114. *C.W.*, 2015 WL 5023926, at *8.

115. *Id.*

116. *Id.*

117. *Id.*

118. 191 Cal. Rptr. 3d 67 (Ct. App. 2015).

the plaintiff's bladder cancer. Based on a number of epidemiological and clinical studies showing an increased risk of bladder cancer among patients who were treated with Actos, the plaintiffs' expert testified that there is "very powerful data" concerning the association between bladder cancer and Actos and that Actos causes bladder cancer.¹¹⁹ The plaintiffs' expert also performed a differential diagnosis to determine the specific cause of the plaintiff's cancer. Although he did not speak to or examine the plaintiff at any time, he reviewed extensive medical records to determine whether the plaintiff had any risk factors for bladder cancer, other than taking Actos.¹²⁰

Based on this analysis, the plaintiffs' expert determined that his use of Actos and history of smoking were the two greatest risk factors for bladder cancer present in the case.¹²¹ But the expert testified that the plaintiff would have to be a "current, heavy smoker" in order for his history of smoking to pose the same risk of bladder cancer that Actos poses and that the plaintiff did not currently smoke and was never a heavy smoker.¹²² Accordingly, the plaintiffs' expert concluded that Actos was the most substantial factor in causing the plaintiff's bladder cancer.¹²³

Following a jury verdict in favor of the plaintiffs, the trial court ruled that the plaintiffs' expert's differential diagnosis was "speculative and unreliable" and granted the defendants' motion for judgment notwithstanding the verdict or, in the alternative, for a new trial.¹²⁴ The trial court found that the plaintiffs' expert failed to rule out other possible causes of bladder cancer "*as to [the plaintiff] specifically.*"¹²⁵ Also the expert did not perform a reliable differential diagnosis because he never spoke with the plaintiff and failed to clarify a discrepancy in the plaintiff's medical records concerning how long ago the plaintiff had quit smoking.¹²⁶

The appellate court reversed. First, the court held that the trial court misapplied the substantial factor test for causation because it is not necessary for a plaintiffs' expert to "*exclude every other possible cause*" of the plaintiff's claimed injuries.¹²⁷ Rather, it is enough for a plaintiff to show that it is "*more probable than not*" that the defendant's negligence was the cause-in-fact of the plaintiff's injury.¹²⁸ Thus, the court said, the plaintiffs' expert was not required to "present for consideration every possible

119. *Id.* at 74.

120. *Id.* at 75-76.

121. *Id.* at 76-78.

122. *Id.* at 76, 78.

123. *Id.* at 79.

124. *Id.* at 80.

125. *Id.* at 81.

126. *Id.* at 82.

127. *Id.* at 85.

128. *Id.*

alternative cause of [the plaintiff's] cancer."¹²⁹ Moreover, there was no indication that any physical examination or clinical tests by the expert "would have shed any further light" on the cause of the plaintiff's cancer.¹³⁰ Nor was the defendant able to point to "any substantial evidence" to indicate that another cause of bladder cancer was "ignored" by the expert.¹³¹ The "bare" possibility that other causes of bladder cancer "might have" affected the plaintiff, unsupported by "substantial evidence," was not a proper basis to exclude the expert's opinion.¹³²

In addition, the jury was free to accept the expert's testimony that Actos was the most substantial factor in causing the plaintiff's cancer because the studies he relied on controlled for smoking. And, even though it was unclear from the medical records whether the plaintiff had quit smoking in 1974 or in 1994, the expert testified that in either instance, Actos was "still more likely to have been the *most* substantial factor" in causing the plaintiff's bladder cancer.¹³³ This testimony, the court said, made it unnecessary for the expert to clarify the discrepancy in the records.¹³⁴

Finally, the court found that the trial court abused its discretion in deciding that the plaintiffs' expert was unreliable because "the epidemiological studies on which [the expert] relied lacked scientific validity."¹³⁵ The trial court erred when it engaged in a "piecemeal" analysis and failed to consider the studies "as a whole."¹³⁶ Further, the expert's reliance on the studies was proper because the studies showed a relative risk of bladder cancer associated with Actos ranging from 2.54 to 6.97. A relative risk of that magnitude (greater than 2.0) is enough to show that the product in question "was more likely than not responsible for causing a particular person's disease."¹³⁷ Having found that the trial court abused its discretion, the court reversed the trial court's ruling granting the defendants' post-trial motions and directed the trial court to enter judgment for the plaintiffs pursuant to the jury verdict.

Cooper thus illustrates a plaintiff's successful use of a differential etiology analysis supported by epidemiological data found to be reliable, in contrast to *C.W. ex rel. Wood*, where such data were lacking.

129. *Id.* at 92.

130. *Id.* at 91.

131. *Id.*

132. *Id.* at 92.

133. *Id.* at 89.

134. *Id.* at 90.

135. *Id.* at 94.

136. *Id.* at 95.

137. *Id.* at 98.

V. LEARNED INTERMEDIARY DEFENSE

A. *Pennsylvania*: In re Avandia Marketing, Sales Practices and Products Liability Litigation

*In re Avandia Marketing, Sales Practices and Products Liability Litigation*¹³⁸ illustrates how the learned intermediary doctrine is applied as a defense in favor of pharmaceutical manufacturers.¹³⁹ The case involved a claim for alleged failure to warn of the risk of bone fractures resulting from the use of a diabetes medication. The defendant manufacturer argued that it discharged its duty to warn by providing a warning to the plaintiff's physician about the dangers associated with the medication. The plaintiff's physician testified that even with updated knowledge of the correlation between use of the medication and bone fractures, he would have prescribed the medication to a patient with the plaintiff's medical history at the time he began treating her. The doctor also testified, however, that a "black box" warning regarding the risk of bone fractures might have "caught his eye" and that he routinely uses black box warnings to weigh risks and benefits.¹⁴⁰ This testimony, the court ruled, was not sufficient to raise a genuine issue of material fact as to whether such a warning would have deterred the physician from prescribing the medication for the plaintiff. Moreover, the doctor's decision to substitute a different medication *after* the plaintiff was injured was not sufficient to raise a genuine issue of fact as to whether the doctor would have changed the medication *before* the plaintiff suffered her fractures.

The plaintiff's reliance on an expert opinion that the package warning label should have been updated was also insufficient to raise a genuine issue of fact for trial, both because the expert relied on studies published after the plaintiff suffered her fracture and because the plaintiff was younger than the women in the studies.¹⁴¹ Concluding that the plaintiff failed to establish a genuine issue of material fact as to whether the treating doctor would have prescribed a different medication if given a different or more prominent warning, the court granted the manufacturer's motion for summary judgment.¹⁴²

138. MDL No. 1871, 2015 WL 1383070 (E.D. Pa. Mar. 24, 2015).

139. In general, under the learned intermediary doctrine, a prescription drug manufacturer discharges its duty to warn by informing the prescribing physician about the risks of the product, and the prescribing physician is then responsible for informing the patient of the medication's possible benefits and risks. See Restatement (Third) of Torts § 6(d)(1), cmt. b (Am. Law Inst. 1998).

140. *In re Avandia*, 2015 WL 1383070, at *4.

141. *Id.*

142. *Compare* Bee v. Novartis Pharm. Corp., 18 F. Supp. 3d 268, 290 (E.D.N.Y. 2014) (finding that testimony by the plaintiff's doctors raised genuine issues of material fact as to the extent of information available on the defendant's drugs).

B. New York: McDowell v. Eli Lilly and Co.

Another illustrative case is *McDowell v. Eli Lilly and Co.*,¹⁴³ an action brought against a pharmaceutical manufacturer for alleged failure to warn of the risk of withdrawal upon discontinuation of a prescription antidepressant. In New York, the court said, a pharmaceutical maker's duty to warn is discharged by giving adequate warning through the physician, rather than directly to the patient. Moreover, a treating physician's independent knowledge of the risks surrounding a certain drug is "an intervening event relieving the manufacturer of any liability to a patient under the failure to warn theory."¹⁴⁴

The plaintiff's central claim in *McDowell* was that the warning label was misleading because it stated that withdrawal rates were "1% or greater," when the manufacturer allegedly knew the rates were between 44% and 50%, an allegation the manufacturer denied.¹⁴⁵ The court rejected the claim, finding that the manufacturer's warning was adequate as a matter of law. It relied, in part, on testimony by the treating physician that rejected the plaintiff's interpretation of the warning label. The physician testified that the "1% or greater" reference in the warning did not suggest that there was only a 1% chance that a patient would suffer withdrawal symptoms. Moreover, the court found, the use of a numerical threshold was an "appropriate, standard methodology" pursuant to FDA regulations and guidelines.¹⁴⁶ In addition, citing the treating physician's testimony that, based on her experience and training, she was aware of the risk and the specific withdrawal symptoms, the court also found that the warning label was not the proximate cause of the plaintiff's injuries.¹⁴⁷ And, since the treating physician testified that she did not interpret the warning label the way the plaintiff had contended, the doctor was not misled about the rate of discontinuance symptoms.¹⁴⁸ The fact that the treating physician may have lacked precise information from the manufacturer about the frequency with which symptoms occur upon cessation did not foreclose summary judgment because there is no requirement that the physician be aware of the "precise frequency of an adverse event."¹⁴⁹ Since the plaintiff could not show that her physician would have prescribed differently if given different warnings, the court dismissed her claims.

143. 58 F. Supp. 3d 391 (S.D.N.Y. 2014).

144. *Id.* at 406.

145. *Id.* at 395, 406–07.

146. *Id.* at 406.

147. *Id.* at 406–07.

148. *Id.* at 407.

149. *Id.* at 409–10. Citing *Obuche v. Merck & Co., Inc.*, 903 F. Supp. 2d 143 (S.D.N.Y. 2012), the court ruled that proximate cause was lacking because "the physician had independent, general knowledge about the possibility of side effects."

C. *Arizona*: *Watts v. Medicis Pharmaceutical Corp.*

In *Watts v. Medicis Pharmaceutical Corp.*,¹⁵⁰ the Arizona Supreme Court reversed a lower court's rejection of the learned intermediary doctrine and adopted the doctrine, as set forth in the Third Restatement, for the first time.¹⁵¹ The plaintiff in that case alleged that she had relied on informational publications that failed to disclose the risk of autoimmune disease allegedly arising from long-term use of a prescription medication. She claimed, moreover, that she did not receive the full prescribing information provided to physicians, which stated that long-term use of the medication was associated with autoimmune disorders and that patients exhibiting related symptoms should be advised to stop the prescription immediately and seek medical attention.

Although the Arizona Supreme Court had never addressed the doctrine, appellate courts in Arizona had applied the doctrine since 1978.¹⁵² In *Watts*, however, the Arizona Court of Appeals departed from prior rulings and refused to apply the doctrine on the ground that it had been displaced by Arizona's Uniform Contribution Among Tortfeasors Act (UCATA), which had been adopted in 1984 and amended in 1987.¹⁵³ The court also reasoned that the doctrine lacked support given "the realities of modern-day pharmaceutical marketing."¹⁵⁴ As the court explained, consumers obtain medical information from manufacturers' direct advertising, Internet sites, and medical databases and no longer rely solely on their prescribing physicians for information about medication.¹⁵⁵ The Arizona Supreme Court rejected this reasoning and reversed.

First, the supreme court recognized that the learned intermediary doctrine is based on principles related to the concept of duty rather than proximate causation: under the doctrine, "if the manufacturer provides complete, accurate, and appropriate warnings about the product to the

150. No. CV-15-0065-PR, 2016 WL 237777 (Ariz. Jan. 21, 2016).

151. "A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings. . . ." Restatement (Third) of Torts: Products Liability § 6(d) (Am. Law Inst. 1998).

152. *Dyer v. Best Pharmacal*, 577 P.2d 1084, 1088 (1978).

153. ARIZ. REV. STAT. ANN. §§ 12-2501-2509 (1984).

154. *Watts v. Medicis Pharm. Corp.*, 342 P.3d 847, 855 (Ariz. Ct. App. 2015), *rev'd*, 2016 WL 237777 (Ariz. Jan 21, 2016). See also State ex rel. *Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 913-14 (W.Va. 2007) (declining to adopt the learned intermediary doctrine given the proliferation of direct-to-consumer advertising); *but see DiBartolo v. Abbott Lab.*, 914 F. Supp. 2d 601 (S.D.N.Y. 2012) (finding that extensive direct-to-consumer advertising did not justify recognition of an exception to the informed intermediary doctrine).

155. *Watts*, 342 P.3d at 855.

learned intermediary, it fulfills its duty to warn the consumer.”¹⁵⁶ Explaining its decision to adopt the doctrine, the court said it would join the majority of jurisdictions that have done so.¹⁵⁷ Rejecting the plaintiff’s argument that the doctrine would create “a blanket immunity” for pharmaceutical manufacturers, the court noted the doctrine would not shield a manufacturer for failing to provide adequate warnings to the prescribing physician.¹⁵⁸ The court also rejected the appellate court’s determination that the underlying rationale for the doctrine is no longer viable in light of modern pharmaceutical marketing; instead, the court adhered to the reasoning of the Texas Supreme Court that the prescribing physician “is best suited to weigh the patient’s individual needs in conjunction with the risks and benefits of the prescription drug. . . .”¹⁵⁹

The court also refused to adopt a direct-to-consumer (DTC) advertising exception to the learned intermediary doctrine on the ground that the Third Restatement provides sufficient protection to consumers.¹⁶⁰ The court noted, moreover, that since New Jersey’s adoption of an exception to the doctrine for DTC marketing in 1999, no other state has followed its lead, and several courts have explicitly rejected such an exception.¹⁶¹

Finally, the court addressed the appellate court’s ruling that the learned intermediary doctrine is inconsistent with the UCATA, which eliminates joint liability and imposes liability on tortfeasors only to the extent of their individual degree of fault in causing the claimed injuries.¹⁶² The lower court had reasoned that the learned intermediary doctrine was inconsistent with the UCATA because the doctrine protects a pharmaceutical manufacturer “from possible liability for its own actions in distributing a product, simply because another participant in the chain of distribution is also expected to act. . . .”¹⁶³ But the Arizona Supreme Court found no inconsistency. The purpose of the UCATA, the court said, is to protect a defendant from “bearing more than [its] fair share

156. *Watts*, 2016 WL 237777, at *3; *see also* *Davis v. Cessna Aircraft Corp.*, 893 P.2d 26, 38 (Ariz. Ct. App. 1994) (applying the learned intermediary doctrine to issue of whether manufacturer satisfied its duty to warn).

157. *Id.* (citing *Centocor, Inc. v. Hamilton*, 373 S.W.3d 140, 158 n.17 (Tex. 2012) (finding that “the highest courts of at least thirty-five states have adopted some form of the learned intermediary doctrine within the prescription drug products-liability context or cited favorably to its application within this context.”)).

158. *Id.* at *4.

159. *Id.* (quoting *Centocor*, 372 S.W.3d at 159).

160. *Id.* The Third Restatement requires manufacturers to warn consumers “when the manufacturer knows or has reason to know that health care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.” Restatement (Third) of Torts: Products Liability § 6(d)(2) (Am. Law Inst. 1998).

161. *Watts*, 2016 WL 237777, at *4.

162. *Id.* at *6.

163. *Watts*, 342 P.3d at 854.

of liability for a plaintiff's injuries under the harsh common-law rule of joint and several liability."¹⁶⁴ The learned intermediary doctrine and the UCATA are not "mutually exclusive," the court reasoned, because they address different concepts.¹⁶⁵ Under the learned intermediary doctrine, a manufacturer that provides an adequate warning to the prescribing physician has not breached a duty, while the UCATA specifies how liability is apportioned among joint tortfeasors. In other words, the UCATA "presuppose[s] a breach of duty."¹⁶⁶ Because a manufacturer that provides an adequate warning to the prescribing doctor is not at fault in the first place, the learned intermediary doctrine neither protects a manufacturer from liability "in proportion to its share of fault" nor "shifts a disproportionate share to someone else."¹⁶⁷ Accordingly, the supreme court found the lower court erred in concluding that the learned intermediary doctrine is incompatible with the UCATA.¹⁶⁸

The court directed that on remand, the manufacturer would be entitled to summary judgment if there was no genuine issue of material fact that it provided "complete, adequate warnings" concerning the medication to the plaintiff's health care providers who were in a position to reduce the risks of harm to the plaintiff.¹⁶⁹

VI. CLASS ACTIONS

A. *Standing*

Given the continuing proliferation of claims based on purported economic injury due to alleged product misrepresentation, standing has become an increasingly significant issue in products liability litigation.¹⁷⁰

1. Consumer Products: *Estrada v. Johnson & Johnson*

In *Estrada v. Johnson & Johnson*,¹⁷¹ the plaintiff alleged that the defendant failed to warn of health risks allegedly due to the use of its baby powder. She did not claim damages for personal injuries, but argued that she would not have purchased the product had she known the truth about its supposed dangers. She brought claims on behalf of herself and others similarly situated under California's Consumer Legal Remedies Act and

164. *Watts*, 2016 WL 237777, at *6.

165. *Id.*

166. *Id.*

167. *Id.* at *7.

168. *Id.* at *6.

169. *Id.* at *8.

170. See generally Edward Sherman, "No Injury" Plaintiffs and Standing, 82 GEO. WASH. L. REV. 834, 835 (2014) (finding that courts have "wrestled" with standing issues in cases involving economic loss or risk of future injury).

171. No. 2:14-cv-01051-TLN-EFB, 2015 WL 1440466 (E.D. Cal. Mar. 27, 2015).

Unfair Competition Law and for negligent misrepresentation and breach of implied warranty. The court granted the defendant's motion to dismiss on the ground that the plaintiff failed to specify which alleged statements were material to her purchase decision. The court went further, however, and also found that she lacked standing to bring her claims. The court recognized that economic injury can serve as the basis for standing if a plaintiff can show that she was deceived and either paid a premium for the product or would have purchased an alternative product had she not been deceived. The court also noted, however, that standing is absent if the plaintiff "received the benefit-of-the-bargain because the product performed as promised."¹⁷²

Here, the plaintiff could not claim that she paid a premium for the baby powder because she received all the "benefits of the bargain."¹⁷³ The court noted that the plaintiff had purchased the baby powder "for decades" and that her "continued purchase of the baby powder indicated that she received the benefits she expected and believed the product was worth the price."¹⁷⁴ On this basis, the court distinguished other cases in which the plaintiff alleged that the product in question was defective or mislabeled.¹⁷⁵ Unlike those cases, the plaintiff in *Estrada* received "exactly what she paid for."¹⁷⁶ The court therefore concluded that the plaintiff could not claim that she "spent money that she would not have otherwise spent by paying a premium or by not purchasing the product."¹⁷⁷ The plaintiff was also unable to allege that she would have purchased an alternative product had she known the product's alleged dangers because she asserted that all talc-based products pose the same health risk.¹⁷⁸ Since the plaintiff failed to allege an injury resulting from the defendant's alleged misrepresentations, the court granted the defendant's motion to dismiss but allowed the plaintiff to amend.¹⁷⁹

172. *Id.* at *2-3.

173. *Id.* at *4.

174. *Id.*

175. See *Kane v. Chobani, Inc.*, 973 F. Supp. 2d 1120, 1124 (N.D. Cal. 2014) (plaintiffs claimed that defendant falsely stated that its yogurts were "all natural" when they contained artificial colors); *Garrison v. Whole Foods Mkt. Grp., Inc.*, No. 13-cv-05222-VC, 2014 WL 2451290, *1 (N.D. Cal. June 2, 2014) (plaintiffs alleged that defendant's products were mislabeled "all natural" when they contained a synthetic ingredient).

176. *Estrada*, 2015 WL 1440466, at *4.

177. *Id.*

178. *Id.* at *5.

179. The plaintiff has since filed an amended complaint, which the defendant has moved to dismiss on the same grounds as the original complaint. As of January 4, 2015, the court had not yet ruled on the motion to dismiss.

2. Food Products: *Riva v. PepsiCo, Inc.*

Likewise, the court in *Riva v. PepsiCo, Inc.*¹⁸⁰ dismissed the plaintiffs' negligence and strict liability claims for lack of standing. In *Riva*, the plaintiffs proposed a class action seeking medical monitoring for lung cancer based on the defendant's use of an additive that is listed as a "known carcinogen" under California's Proposition 65 in its soft drinks. To satisfy the standing requirement, plaintiffs must establish a "credible threat of harm sufficient to constitute actual injury."¹⁸¹ That is, an increased risk of injury can be enough to establish injury-in-fact if "the increased risk of injury is credible and not conjectural."¹⁸²

The court found that these requirements were not met in *Riva*. Exposure alone was not enough to show that the alleged risk of cancer was "both credible and substantial."¹⁸³ Moreover, while the plaintiffs alleged that mice experienced increased levels of cancer at very high exposures to the additive used in the defendant's products, the plaintiffs failed to establish that humans experience the same increased risk, especially at the alleged levels.¹⁸⁴ According to the court, the studies cited by the plaintiffs failed to support an inference that the plaintiffs experienced significant exposure to the additive. Moreover, the mere fact that the additive was listed as a "known carcinogen" was not sufficient to support the plaintiffs' claims because a claim for medical monitoring must be supported by a higher level of proof than is required for a substance to be listed under Proposition 65. Finally, the causation analysis was further complicated by the fact that there are many dietary sources of the additive. It would be "implausible" to conclude that any alleged increase in cancer was more likely than not caused by the defendant's soda products.¹⁸⁵ Therefore, for a variety of reasons, the court dismissed the case with prejudice.¹⁸⁶

3. Corrugated Stainless Steel Tubing: *Kerin v. Titeflex Corp.*

In *Kerin v. Titeflex Corp.*,¹⁸⁷ a consumer brought design defect, manufacturing defect, and failure to warn claims against the manufacturer of

180. 82 F. Supp. 3d 1045 (N.D. Cal. 2015).

181. *Id.* at 1052 (quoting *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 950 (9th Cir. 2002)).

182. *Id.*

183. *Id.* at 1053.

184. *Id.*

185. *Id.* at 1062.

186. *Compare* *Trujillo v. Ametek, Inc.*, No. 3:15-cv-1394-GPC-BGS, 2015 WL 7313408, at *6-7 (S.D. Cal. Nov. 18, 2015) (finding that there was a credible threat of harm sufficient to confer standing because the plaintiffs "have established the health risks that TCE, PCE, and other present chemicals have upon humans" and have also "quantified the increased cancer risk" presented by the chemicals).

187. 770 F.3d 978, 979 (9th Cir. 2014).

corrugated stainless steel tubing (CSST) that he used to provide gas for his outdoor fire pit. The plaintiff claimed that the manufacturer disregarded the risk that direct or indirect lightning strikes to the tubing could cause a fire. The plaintiff sought to certify a class seeking to recover as damages “his overpayment” or “the cost of remedying the safety issue,” rather than an actual, manifest harm.¹⁸⁸ The district court dismissed the plaintiff’s complaint for lack of standing, however, because the plaintiff’s injury was speculative.¹⁸⁹

On appeal, the First Circuit noted “it is conceivable that product vulnerability to lightning might, in some circumstances, constitute injury.”¹⁹⁰ But the court ultimately held that the plaintiff failed to allege risk sufficient to amount to injury in fact.¹⁹¹ Injury in fact, an element that must be alleged to satisfy the standing requirement, is “an invasion of a legally protected interest which is (a) concrete and particularized, and (b) ‘actual or imminent, not conjectural or hypothetical.’”¹⁹² Here, the court determined that the plaintiff’s claims were premised not on an identified present injury, but on a harm—“overpayment for a defective product and the cost of replacement”—that was contingent upon the “unsupported conclusion that the [product at issue] was defective, coupled with a speculative risk of future injury (fire in the event of a lightning strike).”¹⁹³

Analyzing the plaintiff’s specific allegations, the court concluded that the plaintiff failed to plead that the risk of the CSST causing a fire as a result of a lightning strike was not remote.¹⁹⁴ In reaching this conclusion, the court noted that the plaintiff failed to allege facts sufficient to calculate or estimate the risk of fire.¹⁹⁵ While the plaintiff alleged that “as of August 2011,” there were 141 reported fires that involved lightning and CSST, he did not provide any context for interpreting this figure, such as “the frequency of lightning strikes, the proportion of homes struck by lightning, the relevant time frame, or the likelihood of lightning fires in homes without CSST.”¹⁹⁶ Furthermore, the court determined that the figures cited by the plaintiff indicated a low probability of lightning fires occurring in homes that have CSST.¹⁹⁷ Even in cases where the plaintiff alleged there had been actual damages, it was unclear whether

188. *Id.* at 980.

189. *Id.*

190. *Id.* at 980–81.

191. *Id.* at 981.

192. *Id.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)).

193. *Id.* at 983.

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

CSST was the cause.¹⁹⁸ Finally, a consideration given “particular weight” was that state regulations specifically allowed the use of CSST, despite the known danger due to fire and lightning.¹⁹⁹ Although this consideration was not dispositive, it was significant because the regulators “concluded that such risk is both permissible and manageable.”²⁰⁰ The court therefore rejected the plaintiff’s “conclusory and subjective allegations that the product is ‘defective’ and presents an ‘unreasonable risk.’”²⁰¹

B. Settlements

In *Pearson v. NBTY, Inc.*,²⁰² consumers filed a class action alleging that a vitamin and nutritional supplement manufacturer violated state consumer protection laws by making false claims about the efficacy of glucosamine pills, which are dietary supplements designed to prevent or alleviate joint disorders.²⁰³ The plaintiffs alleged that the defendants falsely claimed that the pills would “help rebuild cartilage,” “support renewal of cartilage,” “help maintain the structural integrity of joints,” “lubricate joints,” and “support [] mobility and flexibility.”²⁰⁴ Several months after the plaintiffs filed suit, the parties negotiated a nationwide settlement, which was submitted to the court for approval.²⁰⁵ The district judge approved the settlement after significant modification.²⁰⁶

As approved, the settlement included awards of \$1.93 million in fees to class counsel; \$1.13 million to the Orthopedic Research and Education Foundation; \$865,284 to 30,245 class members who submitted claims; and \$5,000 each to the six named class representatives.²⁰⁷ As part of the settlement, the defendants also agreed not to challenge any attorney fee request by class counsel up to \$4.5 million (known as a “clear-sailing agreement”).²⁰⁸ The settlement further provided that any portion of the \$4.5 million in fees found to be excessive would revert to the manufacturer, rather than becoming available for distribution to the class members (known as a “reversion” or a “kicker” clause).²⁰⁹ Finally, the approved settlement included an injunction preventing the manufacturer from

198. *Id.*

199. *Id.* at 984.

200. *Id.*

201. *Id.* at 985.

202. 772 F.3d 778, 779 (7th Cir. 2014).

203. *Pearson* and other recent decisions in the Seventh Circuit reflect significant judicial skepticism towards class action settlements. See *Eubank v. Pella Corp.*, 753 F.3d 718 (7th Cir. 2014); *Redman v. RadioShack Corp.*, 768 F.3d 622 (7th Cir. 2014).

204. *Pearson*, 772 F.3d at 779.

205. *Id.* at 779–80.

206. *Id.* at 780.

207. *Id.*

208. *Id.*

209. *Id.*

making certain claims in its marketing of glucosamine products for thirty months.²¹⁰

A number of class members appealed from the approval of the settlement. Class counsel cross-appealed, claiming that the district court went too far in modifying the settlement. The Seventh Circuit held that the district court abused its discretion in approving the settlement, not because the modifications went too far, but because they did not go far enough.²¹¹

The Seventh Circuit first addressed the amount of attorney fees provided by the settlement agreement as approved and pointed to a number of flaws in the district court's ruling:

- The district court valued the settlement at the maximum potential payment that class members could receive—a total of \$20.2 million.²¹² But the appellate court determined that the \$20.2 million figure had “barely any connection to the settlement’s value to the class.”²¹³
- The district court also found that the class received a \$14.2 million benefit, but the Seventh Circuit called this a “fiction” as well—only 30,245 claims were filed, yielding total compensation to the class of less than \$1 million.²¹⁴
- Because the amount of the attorney fees that the district judge awarded to counsel, i.e., \$1.93 million, was only 9.6 percent of the \$20.2 million, the district judge ruled the fee award was reasonable.²¹⁵ Once again, the appellate court rejected this reasoning. It explained that the relevant ratio is “the ratio of (1) the fee to (2) the fee plus what the class members received.”²¹⁶ Since the class received only \$865,284, the fee award of \$1.93 million represented “an outlandish” 69 percent of the aggregate.²¹⁷

Notably, the court endorsed a “presumption . . . that attorneys’ fees awarded to class counsel should not exceed a third or at most a half of the total amount of money going to class members and their counsel.”²¹⁸

After discussing the amount of attorney fees provided by the settlement agreement, the court turned to the claims process. Citing numerous links

210. *Id.*

211. *Id.*

212. *Id.*

213. *Id.* at 781.

214. *Id.*

215. *Id.*

216. *Id.* (quoting *Redman v. RadioShack Corp.*, 768 F.3d 622, 630 (7th Cir. 2014)).

217. *Id.*

218. *Id.* at 782.

on the claims website, lengthy documents that had to be read, the documentation required to submit a claim, the low amount recoverable by an individual claimant (\$3), and the requirement to certify the accuracy of all information submitted under penalty of perjury, the court declared:

It's hard to resist the inference that [defendant] was trying to minimize the number of claims that class members would file, in order to minimize the cost of the settlement to it. Class counsel also benefited from minimization of the claims, because the fewer the claims, the more money [defendant] would be willing to give class counsel to induce settlement.²¹⁹

The court went further, stating that class counsel “could have done much better by the class” by accepting lower fees, “[b]ut realism requires recognition that probably all that class counsel *really* care about *is* their fees—for \$865,284 spread over 12 million class members is only 7 cents apiece.”²²⁰

Next, the court turned to the \$1.13 million allocated to the Orthopedic Research and Education Foundation and determined that this was a cy pres award.²²¹ Under the cy pres doctrine, a benefit can be given to an entity other than the original intended beneficiary where it is impossible to effectuate the original intent due to changed circumstances.²²² The selection of the orthopedic institute as the recipient of settlement funds was consistent with cy pres, the court said, because glucosamine is supposed to alleviate joint problems, a matter in the domain of orthopedic medicine.²²³ But the supposed cy pres award in this case was improper, the court found, because a cy pres award should be comprised of funds “that can't feasibly be awarded to the intended beneficiaries,” i.e., the class members.²²⁴ Here it would have been feasible to award more money to the class by enhancing the notice process.²²⁵ Indeed, through pharmacy loyalty programs and other sources, 4.72 million people were known purchasers of the glucosamine. Knowing this, the manufacturer could simply have mailed a \$3 check to all of them.²²⁶ Thus, there was no showing that the award to the foundation was appropriate under the cy pres doctrine.²²⁷

219. *Id.* at 783.

220. *Id.* at 783–84; *see also* Seidman v. Am. Mobile Sys., 965 F. Supp. 612, 621 (E.D. Pa. 1997) (finding that “there is an acute need for close judicial scrutiny of fee arrangements in common fund class action settlements because of ‘the danger . . . that the lawyers might urge a class settlement at a low figure or a less-than-optimal basis in exchange for red-carpet treatment for fees.’”).

221. Pearson v. NBTY, Inc., 772 F.3d 778, 784 (7th Cir. 2014).

222. *Id.*

223. *Id.*

224. *Id.*

225. *Id.*

226. *Id.*

227. *Id.* When the intent of the original settlor or testator becomes impossible or impracticable to implement, the cy pres doctrine allows courts to substitute the charitable trust or class settlement for another charitable objective that is as close to the original purpose as

The court was also critical of the injunction called for by the settlement agreement. Pursuant to the injunction, the defendant had to replace the claims on its label with alternate language.²²⁸ The court noted that the substitute language was “purely cosmetic” and “substantively empty,” while “dubious” claims on the original product label would remain unchanged.²²⁹ The proposed changes were “superfluous” at best and potentially “adverse” to consumers because the injunction provided a “judicial imprimatur” for the substance of the manufacturer’s marketing claims.²³⁰

The final concern addressed by the court was the kicker clause, which the court called “a gimmick for defeating objectors,” explaining:

If the class cannot benefit from the reduction in the award of attorneys’ fees, then the objector, as a member of the class, would not have standing to object, for he would have no stake in the outcome of the dispute. The simple and obvious way for the judge to correct an excessive attorney’s fee for a class action lawyer is ‘to increase the share of the settlement received by the class at the expense of class counsel.’ (citation omitted). This route is barred unless the judge invalidates the kicker clause.²³¹

The court could not articulate a legitimate justification for the kicker clause and stated that “at the very least, there should be a strong presumption of its invalidity.”²³²

In closing, the court rejected class counsel’s argument, which was based on a 1980 decision that the judiciary’s role in approving a class action settlement is “limited” and that judges “should not substitute their own judgment as to the optimal settlement terms,” because a class action settlement is a “bargained exchange” like any other.²³³ The court disagreed, noting that judicial experience over the decades since that statement has demonstrated “that class action settlements are often quite different from settlements of other types of cases. . . .”²³⁴ The court recognized “an acute conflict of interest between class counsel, whose pecuniary interest is in their fees, and class members, whose pecuniary interest is in the award to the class.”²³⁵ Further, “[d]efendants are interested

possible. George G. Bogert & George T. Bogert, *THE LAW OF TRUSTS AND TRUSTEES* § 431 (3d ed., rev. 2008). Some form of the *cy pres* doctrine exists in a majority of states, and “the judicial *cy pres* power has been generally accepted in the United States as a part of the authority of the court of equitable jurisdiction.” *Id.* § 433.

228. *Pearson v. NBTY, Inc.*, 772 F.3d 778, 784–85 (7th Cir. 2014).

229. *Id.* at 785.

230. *Id.*

231. *Id.*

232. *Id.* at 786–87.

233. *Armstrong v. Bd. of Sch. Dir. of City of Milwaukee*, 616 F.2d 305, 315 (7th Cir. 1980).

234. *Pearson*, 772 F.3d at 787.

235. *Id.*

only in the total costs of the settlement to them, and not in the division of the costs between attorneys' fees and payment to the class members."²³⁶ In light of these considerations, the court summarized the difficulties with the settlement as follows:

[T]he incentive of class counsel, in complicity with the defendant's counsel, to sell out the class by agreeing with the defendant to recommend that the judges approve a settlement involving a meager recovery for the class but generous compensation for the lawyers—the deal that promotes the self-interest of both class counsel and the defendant and is therefore optimal from the standpoint of their private interests.²³⁷

Calling the settlement agreement a “selfish deal” between class counsel and the defendant, the court reversed the district court's approval of the settlement agreement and remanded the case.²³⁸

At a minimum, the court's ruling in *Pearson* should restrict the use of cy pres awards in class action settlements to situations in which it is not practical to identify class members. Moreover, the court's strongly worded opinion, coupled with other recent appellate decisions, suggests that class action settlements will be subjected to increasingly close scrutiny by the courts, particularly to assess the value of the settlement to the class and amount of attorney fee awards.²³⁹

VII. CASE MANAGEMENT

A. Asbestos Case Management

In *In re New York City Asbestos Litigation*,²⁴⁰ the New York Appellate Division recently held that the trial court had the authority to enter an order permitting punitive damage claims in New York asbestos litigation, but held that a portion of the order deprived the defendants of their right to due process.

Since 1996, New York asbestos litigation had been governed by a case management order (CMO) that deferred claims for punitive damages “until such time as the Court deems otherwise, upon notice and hearing.”²⁴¹ In 2013, all plaintiffs moved to modify the CMO to permit punitive damages claims to proceed.²⁴² Over the defendants' objections, the

236. *Id.*

237. *Id.* (quoting *Eubank v. Pella Corp.*, 753 F.3d 718, 720 (7th Cir. 2014)).

238. *Id.*

239. *See Eubank*, 753 F.3d at 721 (rejecting settlement agreement that the court found both “scandalous” and “inequitable”); *Redman v. RadioShack Corp.*, 768 F.3d 622 (7th Cir. 2014).

240. 13 N.Y.S. 3d 398 (App. Div. 2015).

241. *Id.* at 403.

242. *Id.*

trial court granted the plaintiffs' motion and entered an order allowing punitive damages claims to proceed upon application to the assigned trial court. Moreover, under the CMO, applications to proceed with a charge to the jury on punitive damages in an individual case "shall be made at the conclusion of the evidentiary phase of the trial upon notice to the affected defendant(s). . . ." ²⁴³

On appeal, the Appellate Division held that the trial court had authority to modify the CMO under New York's Uniform Rules for Trial Courts, which allows the Coordinating Justice to "issue case management orders after consultation with counsel." The Appellate Division rejected the defendants' argument that the order modifying the CMO was an improper advisory opinion. ²⁴⁴ However, the appellate court found that the trial court exceeded its authority by directing that requests for a jury charge on punitive damages be made at the conclusion of the evidentiary phase of trial. ²⁴⁵ Due process, the court said, "requires that a defendant be provided with 'an opportunity to conduct discovery and establish a defense with respect to [plaintiffs' punitive damages claims]' since such claims involve 'different elements and standards of proof, and potentially subject defendants to far greater and different dimension of liability. . . .'" ²⁴⁶ The appellate court held that the CMO, as modified, would deprive the defendants of due process "by leaving them guessing, until the close of evidence at trial, whether or not punitive damages will be sought." ²⁴⁷

Moreover, although the motion court had ruled in a later order in December 2014 that nothing in the CMO prevented the defendants from serving discovery requests related to punitive damages or moving to dismiss punitive damages claims, the motion court's "explanations" did not alleviate the due process concerns: as the appeals court stated, "[d]efendants cannot seek discovery in connection with, and the court cannot dismiss, a claim which a plaintiff has not yet actively asserted." ²⁴⁸ Accordingly, the appellate court remanded the matter to the Coordinating Justice to determine procedural protocols by which the plaintiffs may apply for the jury to be charged on punitive damages. ²⁴⁹ Alternatively, the Coordinating Justice would be allowed to determine whether to permit punitive damages claims under the CMO.

243. *Id.*

244. *Id.*

245. *Id.*

246. *Id.* (quoting *Heller v. Louis Provenzano, Inc.*, 756 N.Y.S.2d 26 (N.Y. App. Div. 2003)).

247. *Id.*

248. *Id.* at 404.

249. *Id.*

B. *Lone Pine Orders*

Lone Pine orders, named for an unpublished New Jersey state court opinion,²⁵⁰ are a recognized case management tool in toxic tort and products liability cases in federal and some state courts. Such an order requires a plaintiff, prior to discovery, to provide evidence to establish a prima facie case of injury, exposure, and causation. Orders of this kind are seen as a means of promoting efficient case management and reducing needless litigation.²⁵¹ Despite federal case law permitting the use of *Lone Pine* orders, the Supreme Court of Colorado, in *Antero Resources Corp. v. Strudley*, found that Colorado courts did not have the authority to issue such orders.²⁵²

The plaintiffs in that case sought damages for physical injuries and property damage allegedly caused by the defendant's natural gas drilling operations near their residence. The trial court issued a case management order directing the plaintiffs to provide prima facie evidence to support their allegations concerning exposure, injury, and causation before it would allow full discovery. Subsequently, the trial court dismissed the case based upon its finding that the plaintiffs had failed to do so.

Lone Pine orders are permitted under Rule 16 of the Federal Rules of Civil Procedure, which allows courts “[a]t any pretrial conference” to adopt “special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems.”²⁵³ This provision is absent in the corresponding Colorado Rules of Civil Procedure (CRCP) Rule 16.²⁵⁴ As the court in *Antero Resources* explained, CRCP 16 is “markedly different” from the corresponding federal rule and “does not contain a grant of authority for complex cases or otherwise afford trial courts the authority to require a plaintiff to make a prima facie showing before the plaintiff exercises discovery rights. . . .”²⁵⁵ Moreover, although the comments to CRCP 16 explain that its purpose is “to accomplish early purposeful and reasonably economic management of the cases,” the court refused to infer authority to issue a *Lone Pine* order because the actual rule did not provide for it.²⁵⁶

250. *Lore v. Lone Pine Corp.*, No. L-33606-85, 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986).

251. *See, e.g., Acuna v. Brown & Root Inc.*, 200 F.3d 335, 340 (5th Cir. 2000) (“*Lone Pine* orders are designed to handle the complex issues and potential burdens on defendants and the court in mass tort litigation. In the federal courts, such orders are issued under the wide discretion afforded district judges over the management of discovery under [rule] 16.”).

252. 347 P.3d 149 (Colo. 2015).

253. FED. R. CIV. P. 16(c)(2)(L).

254. *Antero Resources*, 347 P.3d at 156.

255. *Id.*

256. *Id.* at 156–57.

According to the court, Colorado courts have long emphasized the importance of allowing discovery without imposing on the plaintiff a requirement to make a threshold showing.²⁵⁷ Instead, Colorado courts have resorted to other Rules of Civil Procedure to manage complex cases.²⁵⁸ In contrast, by cutting off or limiting discovery, a *Lone Pine* order “closely resembles summary judgment” but without proper safeguards.²⁵⁹ Discovery, the court stated, “might expose the very support sought to prove a claim.”²⁶⁰ Thus, a *Lone Pine* order could have the effect of “forcing dismissal before affording plaintiffs the opportunity to establish the merits of their cases.”²⁶¹ The dissenting opinion called for “active case management” for the purpose of “running an efficient docket and administering justice,” concluding the trial court’s order was authorized by CRCP Rule 16 because the rule allows a court to “adjust timelines for disclosure and discovery.”²⁶²

Given a defendant’s inability to narrow discovery by seeking a *Lone Pine* order in Colorado, defendants will likely seek to invoke other provisions to limit or streamline discovery in toxic tort and products liability suits.²⁶³

257. *Id.* at 157–58.

258. *Id.* at 157, 159.

259. *Id.* at 159.

260. *Id.*

261. *Id.*

262. *Id.*

263. After *Strudley* was decided, the Colorado Supreme Court issued changes to the Colorado Rules of Civil Procedure. Although the changes did not include a provision modeled after Fed. R. Civ. P. 16(c)(2)(L), which serves as the basis for a *Lone Pine* order in federal courts, the amendments to Rule 26 require the trial court to consider “the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit” in determining whether the discovery is “proportional to the needs of the case.” COLO. R. CIV. P. 26(b)(1) (2015).