

RECENT DEVELOPMENTS IN PRODUCTS LIABILITY

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This article presents a summary of significant products liability cases from October 1, 2015, to September 30, 2016. It covers a range of developments concerning failure to warn claims, the exercise of personal jurisdiction, federal preemption, expert testimony as to causation, the learned intermediary doctrine, and class actions.

I. THEORIES OF LIABILITY—FAILURE TO WARN

New York’s highest court issued a significant ruling, *In the Matter of New York City Asbestos Litigation*,¹ extending the scope of a manufacturer’s duty to warn to include risks arising from the combined use of its product with

1. 59 N.E.3d 458 (N.Y. 2016).

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a product made by another company. The New York Court of Appeals held that a valve manufacturer had a duty to warn regarding the dangers inherent in using the valves—which did not contain asbestos—in combination with asbestos-containing gaskets designed and manufactured by other entities.

The court based its ruling on a number of factors, including its conclusion that the manufacturer “is in a superior position” to the consumer to be aware of and warn against the hazards of the product.² Moreover, the court stated that the fact the valve was a “durable” product while the gasket “deteriorates quickly and is designed to be replaced” weighed in favor of requiring the gasket manufacturer to provide a warning. “[T]he end user is more likely to interact with the durable product over an extended period of time” and would be more likely to inspect warnings on the valve than to review warnings provided by the gasket maker.³ The court also reasoned that consumers often lack the ability to detect the inherent dangers of a product; where two products are used together, the consumer “rarely has access to sufficient technical information about both products to anticipate the perils of their joint use.”⁴

Accordingly, the court adopted the following rule:

[T]he manufacturer of a product has a duty to warn of the danger arising from the known and reasonably foreseeable use of its product in combination with a third-party product which, as a matter of design, mechanics or economic necessity, is necessary to enable the manufacturer’s product to function as intended.⁵

The justification for this rule, the court said, “becomes particularly strong if the manufacturer intends that customers engage in the hazardous combined use of the products in issue . . .”⁶

The court in *New York City Asbestos Litigation* departed from the approach taken by a number of other courts, which “disfavor” holding manufacturers liable for failure to warn in this context. The court justified this departure by reasoning that other courts impose strict liability for failure to warn, whereas New York adopts a negligence approach; in those jurisdictions, it is necessary to place “stricter limits” on the existence and scope of the duty to warn in order to avoid “widespread” liability.⁷

2. *Id.* at 471.

3. *Id.* at 472.

4. *Id.* at 473.

5. *Id.* at 474.

6. *Id.*

7. *Id.* at 477 (citing cases).

Additionally, other courts have rejected a duty to warn of the hazards of using the manufacturer's product jointly with another product on the ground that the defendant manufacturer "has no control over the third-party product and in fairness cannot be expected to inspect for the dangers of the synergistic use"⁸ The court in *New York City Asbestos Litigation* was not persuaded by this concern where the defendant manufacturer "substantially participates" in the integration of the products and "gains the same knowledge of the peril as it would have acquired via inspection or testing"⁹ The court reasoned that a manufacturer that substantially participates in the integration of the products "can surely be expected to learn of and warn of the relevant dangers."¹⁰

While the full reach of the decision in *New York City Asbestos Litigation* is not clear, the decision extends the duty to warn for manufacturers in New York with respect to products that need to be combined for use where the defendant substantially participates in integrating the products. Perhaps most significantly, the court's decision places the duty to warn on the manufacturer (here, the valve manufacturer) that makes a durable item that is combined for use with another, often-replaced component (here, a gasket).

II. PERSONAL JURISDICTION

A. General Jurisdiction

Two cases, *Genuine Parts Co. v. Cepec*¹¹ and *Brown v. Lockheed Martin Corp.*,¹² demonstrate the impact of the U.S. Supreme Court's decision in *Daimler AG v. Bauman*¹³ on the ability of courts to assert general jurisdiction over an out-of-state corporation based merely on the defendant's limited activities, or registration to do business, in the forum.

8. *Id.* at 477–78; *see also* *Walton v. Harnischfeger*, 796 S.W.2d 225, 226–27 (Tex. App. 1990); *Baughman v. Gen. Motors Corp.*, 780 F.2d 1131, 1133 (4th Cir. 1986).

9. *In re N.Y.C. Asbestos Litig.*, 59 N.E.3d 458, 478 (N.Y. 2016).

10. *Id.* A concurring opinion took the view that the test articulated by the majority "opens too broad an avenue of liability." *Id.* at 483 (Garcia, J., concurring). Instead, the concurrence focused on the fact that the defendant manufacturer had originally sold its valves with asbestos-containing internal parts, had marketed asbestos-containing replacement parts under its own name, and recommended and promoted the use of asbestos-containing replacement parts. *Id.* at 484. A duty to warn, the concurring opinion suggested, should only be imposed where the manufacturer takes "some action" originally to market with, or to promote or recommend, asbestos-containing replacement parts. *Id.* at 485.

11. 137 A.3d 123 (Del. 2016).

12. 14 F.3d 619, 626 (2d Cir. 2016).

13. 134 S. Ct. 746 (2014) (holding that a corporation is subject to general jurisdiction only if it is considered "at home" in the state or, in other words, if it is incorporated or has its principal place of business in the jurisdiction).

In *Genuine Parts*, the plaintiff sued his former employer in Delaware, alleging that he developed mesothelioma as a result of his exposure to asbestos at a Georgia warehouse where he worked.¹⁴ The defendant, a Georgia corporation with its principal place of business in Georgia, moved to dismiss the complaint for lack of personal jurisdiction. In opposition, the plaintiff, relying on the Delaware Supreme Court's 1988 ruling in *Sternberg v. O'Neil*,¹⁵ argued that the defendant consented to the general jurisdiction of Delaware courts by registering to do business in Delaware and by appointing an agent for service of process. In *Sternberg*, the Delaware Supreme Court held that a non-Delaware corporation that was registered to do business in Delaware and that was required to appoint an agent for service of process in the state had consented to general jurisdiction in Delaware courts. Thus, in *Genuine Parts*, the Delaware courts were called upon to reassess *Sternberg* in light of the U.S. Supreme Court's ruling in *Daimler*.

The trial court adhered to *Sternberg* and held that the defendant had consented to Delaware's general jurisdiction "merely by registering to do business in Delaware."¹⁶ The Delaware Supreme Court reversed, holding that in light of *Daimler*, Delaware's corporate registration statutes should be read as "providing a means for service of process and not as conferring general jurisdiction."¹⁷ In reaching this conclusion, the Delaware Supreme Court stressed the "at-home" test for general jurisdiction promulgated in *Daimler*: "[a] corporation that operates in many places can scarcely be deemed at home in all of them. Otherwise, 'at home' would be synonymous with 'doing business' tests framed before specific jurisdiction evolved in the United States."¹⁸

Similarly, in *Brown*, the decedent's daughter sued defendant Lockheed Martin in Connecticut for injuries her father allegedly suffered from asbestos exposure during his employment as an Air Force mechanic at locations in Europe and other places in the United States outside Connecticut.¹⁹ The defendant was a major aerospace company incorporated and headquartered in Maryland and registered to do business in Connecticut. It moved to dismiss the complaint based on lack of personal jurisdiction.²⁰ The district court granted the defendant's motion, concluding that while the defendant was subject to Connecticut's long-arm statute because it was registered to do business in Connecticut, the defendant's activities

14. *Genuine Parts*, 137 A.3d 123.

15. 550 A.2d 1105 (Del. 1988).

16. *Genuine Parts Co. v. Cepec*, 137 A.3d 123, 125 (Del. 2016).

17. *Id.* at 148.

18. *Id.* at 136 (quoting *Daimler*, 134 S. Ct. at 762 n.20).

19. *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 622 (2d Cir. 2016).

20. *Id.* at 624.

in the forum were not “substantial enough” to support the exercise of jurisdiction over it with respect to the plaintiff’s claims.²¹

The plaintiff appealed, arguing that (1) the defendant’s activities in Connecticut were such that it could be considered “essentially at home” in the state and (2) the defendant’s registration to do business and appointment of an agent to receive service in Connecticut constitute “consent” to the exercise of jurisdiction by Connecticut courts.²²

The Second Circuit rejected both of the plaintiff’s arguments and affirmed the district court’s decision. First, the court noted that under *Daimler*, a court “must assess the company’s local activity not in isolation, but *in the context of the company’s overall activity*.”²³ Accordingly, the court found that the defendant could not be considered “at home” in Connecticut because its activities in the state “while not insubstantial, constitute[d] a very small part of its portfolio”—only 0.05% of defendant’s workforce was based in Connecticut and the revenue it generated from its Connecticut operations over five years never exceeded 0.107% of its annual revenue.²⁴ The court noted that these figures were “far less” than those in *Daimler*, where the California subsidiary’s sales made up to 2.4% of the German parent’s worldwide sales.²⁵ The court also rejected the plaintiff’s arguments that *Daimler* addressed personal jurisdiction only in an “international context” and that exercise of general jurisdiction over the defendant would be consistent with *Asahi Metal Industry Co. v. Superior Court*.²⁶ The court concluded that the “multipronged” analysis in *Asahi* applies only to specific jurisdiction because if the corporation is “at home” and subject to general jurisdiction in the forum, it would be “superfluous” for the court to consider whether it would be reasonable for it to exercise jurisdiction over the particular claims.²⁷

Second, the court rejected the plaintiff’s argument that Lockheed Martin consented to the general jurisdiction of Connecticut courts by registering to do business and appointing an agent for service of process in the state.²⁸ The court acknowledged that the U.S. Supreme Court had

21. *Id.*

22. *Id.* at 625.

23. *Id.* at 629.

24. *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 629 (2d Cir. 2016).

25. *Id.*

26. *Id.* at 630. In *Asahi Metal Industry Co.*, the U.S. Supreme Court identified five factors that bear on reasonableness to determine whether exercise of jurisdiction complies with “traditional notions of fair play and substantial justice”—(1) “the burden on the defendant,” (2) “the interests of the forum State,” (3) the plaintiff’s interest in obtaining relief, (4) the interstate judicial system’s interest in obtaining the most efficient resolution of controversies, and (5) the shared interest of states to further substantive social policies. 480 U.S. 102, 113 (1987).

27. *Id.* (quoting *Daimler*, 134 S. Ct. at 762 n.20).

28. *Id.* at 630–31.

historically upheld the exercise of jurisdiction when a corporation is registered to do business in the forum on the theory that the corporation's registration to do business constitutes "consent" to jurisdiction. The Second Circuit noted, however, that this "consent" "has . . . always been something of a fiction, born of the necessity of exercising jurisdiction over corporations outside their state of incorporation."²⁹ The court analyzed Connecticut's long-arm statute and concluded that the statute does not expressly provide that registration to do business in Connecticut subjects foreign corporations to general jurisdiction.³⁰

Finally, the court considered the decisions relied upon by the plaintiff, *Talenti v. Morgan Brother Manhattan Storage Co.*³¹ and *Pennsylvania Fire Insurance Co. of Philadelphia v. Gold Issue Mining & Milling Co.*³² The court disagreed with *Talenti*, reasoning that registering to business in Connecticut does not constitute consent to general jurisdiction, especially because the long-arm statute does not expressly provide general jurisdiction and that *Talenti* "casually" dismisses due process concerns.³³

The court also rejected the plaintiff's reliance upon the U.S. Supreme Court's 1917 decision in *Pennsylvania Fire*, which held that a Pennsylvania company's registration to do business in Colorado, and its related filing of a power of attorney consenting to service of process in the forum, permitted the exercise of jurisdiction over the Pennsylvania company in Colorado.³⁴ The court reasoned that *Pennsylvania Fire* was "outdated" and "simply too much at odds with the approach to general jurisdiction adopted in *Daimler* to govern as categorically as [plaintiff] suggest[ed]."³⁵

Genuine Parts and *Brown* are significant for corporations that are registered to do business in a number of states and reflect the increasing difficulty faced by plaintiffs in establishing general jurisdiction over a corporation in a forum that is not its state of incorporation or principal place of business.³⁶ While these rulings do not foreclose express consent as a basis for general jurisdiction in all circumstances, they reflect judicial reluctance to view a foreign corporation's mere registration to do business as

29. *Id.* at 632–33.

30. *Id.* at 634.

31. 113 Conn. App. 845 (2009).

32. 243 U.S. 93 (1917).

33. *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 636 (2d Cir. 2016).

34. 243 U.S. 93, 95–96 (1917).

35. *Brown*, 814 F.3d at 638.

36. See, e.g., *Smith v. Union Carbide Corp.*, No. 1422-CCOO457, 2015 WL 191118 (Mo. Cir. Ct. Jan. 12, 2015) (defendant Delaware corporation with its principal place of business in Delaware was not subject to general jurisdiction in Missouri in connection with claims arising out of asbestos exposure in Oklahoma); *Locke v. Ethicon Inc.*, 58 F. Supp. 3d 757, 765 (S.D. Tex. 2014) (corporations incorporated and headquartered in New Jersey were not subject to general jurisdiction in Texas relating to product liability claims by out-of-state plaintiffs injured outside of Texas).

the basis for exercising jurisdiction concerning claims unrelated to the corporation's activities in the forum.

B. Specific Jurisdiction: Activities Related to the Forum

On the other hand, in *Bristol-Myers Squibb Co. v. Superior Court*³⁷ and *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*,³⁸ courts in California and Illinois considered the effect of *Daimler* on their ability to exercise specific personal jurisdiction with respect to claims made by nonresident plaintiffs, including the relationship between the manufacturers' contacts with the forum and the claims of the nonresidents. Both courts adopted an expansive view of specific personal jurisdiction and found that the defendants' activities in the forum were sufficiently related to the plaintiffs' claims to confer specific personal jurisdiction.

In *Bristol-Myers*, a group of eighty-six California residents and 592 nonresidents sued a pharmaceutical maker in California for damages allegedly arising out of their use of the prescription drug Plavix, claiming that the manufacturer was liable for wrongful conduct related to the design, development, marketing, and labeling of the drug.³⁹

The defendant manufacturer moved to quash service of process on the ground that the court lacked personal jurisdiction over it with respect to the claims made by the nonresidents. The manufacturer was incorporated in Delaware and headquartered in New York; it argued that its research and development of Plavix did not take place in California, nor was any work related to the drug's labeling, packaging, regulatory approval, or its advertising or marketing strategy performed in California.⁴⁰ Nevertheless, the defendant maintained "substantial operations in California, including five offices that are primarily research and laboratory facilities employing approximately 164 people . . . [and] employ[ed] approximately 250 sales representatives in the state."⁴¹

The California Supreme Court relied upon *Daimler* to conclude that the defendant was not "at-home" in the state and was therefore not subject to general jurisdiction in California. The court stated that the defendant "may be regarded as being at home in Delaware, where it is incorporated, or perhaps in New York and New Jersey, where it maintains its principal business centers[.]" but *not* in California despite its substantial activities in the state.⁴²

37. 377 P.3d 874 (Cal. 2016), *cert. granted sub nom.*, *Bristol-Myers Squibb Co. v. Super. Ct.*, No. 16-466, 2017 WL 215687 (U.S. Jan. 19, 2017).

38. 61 N.E.3d 1026 (Ill. App. Ct. 2016), *appeal denied sub nom.*, *M.M. v. GlaxoSmithKline LLC*, 65 N.E.3d 842 (Ill. 2016).

39. *Bristol-Myers*, 377 P.3d at 874, 878.

40. *Id.* at 879.

41. *Id.*

42. *Id.* at 883.

However, the court held that the defendant was subject to specific personal jurisdiction in California based upon a three-prong test:

The question of whether a court may exercise specific jurisdiction over a nonresident defendant involves examining (1) whether the defendant has purposefully directed its activities at the forum state; (2) whether the plaintiff's claims arise out of or are related to these forum-directed activities; and (3) whether the exercise of jurisdiction is reasonable and does not offend traditional notions of fair play and substantial justice.⁴³

The defendant acknowledged that it had “purposefully availed itself” of the benefits and privileges of conducting business in California because it “market[ed] and advertise[d] Plavix in th[e] state, it employ[ed] sales representatives in California, contracted with a California-based pharmaceutical distributor, operate[d] research and laboratory facilities in th[e] state, and even ha[d] an office in the state capitol to lobby the state on the company’s behalf.”⁴⁴

The defendant denied, however, that its activities in California had a sufficient relationship to the claims of nonresident plaintiffs to support the exercise of specific jurisdiction. The court rejected the defendant’s argument, holding that its California contacts were directly related to the company’s nationwide marketing, sales, and distribution efforts, thus satisfying the second prong of the specific jurisdiction test.⁴⁵ The court further found that the defendant would not be unduly burdened by being forced to litigate in California; that California courts have an interest in protecting consumers from potentially defective products; and that judicial economy would be achieved by litigating all of the claims in California, thus satisfying the third prong of the specific jurisdiction test.⁴⁶

Similarly, in *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*,⁴⁷ eight plaintiffs, including Illinois residents and nonresidents, brought a products liability suit against a pharmaceutical manufacturer in Illinois based upon birth defects allegedly caused by the drug Paxil. The defendant was a limited liability company incorporated in Delaware, and its sole member, GSK Holdings Inc., was a Delaware corporation with its principal place of business in Delaware. The defendant maintained corporate and administrative headquarters in Pennsylvania and North Carolina and moved to dismiss the nonresidents’ claims based upon a lack of personal jurisdiction.

43. *Id.* at 885 (quoting *Asahi Metal Indus. Co. v. Super. Ct.*, 480 U.S. 102, 113 (1987); *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 (1984); *Keeton v. Hustler Mag., Inc.* 465 U.S. 770, 774 (1984) (internal quotation marks omitted)).

44. *Id.* at 886.

45. *Id.* at 889–90.

46. *Id.* at 891–94.

47. 61 N.E. 3d 1026 (Ill. App. Ct. 2016).

The defendant argued that personal jurisdiction could be exercised only in states in which it was “at home” (i.e., Delaware, Pennsylvania, and North Carolina), or in the states where the individual nonresident plaintiffs were injured. The Illinois Appellate Court rejected this contention and affirmed the trial court’s denial of the defendant’s motion to dismiss. The court held that Illinois courts may assert specific personal jurisdiction over the defendant with respect to claims by nonresident plaintiffs alleging birth defects allegedly caused by Paxil.

The court’s analysis was substantially similar to the California Supreme Court’s analysis in *Bristol-Myers*: “(1) the corporate, nonresident defendant must have minimum contacts with Illinois in that (a) it purposefully directed its activities at that state and (b) plaintiffs’ claims arose from or related to those contacts with Illinois; and (2) it must be reasonable for Illinois to exercise jurisdiction over the defendant.”⁴⁸

The defendant conceded that it maintained purposeful contacts with Illinois, which included contracting with seventeen Illinois physicians to conduct between eighteen and twenty-one clinical trials of Paxil in Illinois on a continuous basis from 1985 to 2003.⁴⁹ The defendant contended, however, that the nonresidents’ alleged claims did not arise out of, nor were they related to, its contacts with Illinois. In reply, the nonresident plaintiffs argued that the Paxil studies conducted in Illinois were aggregated with other national studies “to inform the warning label content for Paxil, upon which the out-of-state plaintiff mothers relied in making their decision to take the drug.”⁵⁰ The court held that even though the Illinois Paxil tests represented a relatively small portion—5 percent—of the defendant’s national clinical trials, they were sufficient to meet “the ‘lenient and flexible’ ‘arising from’ and ‘related to’ standard” standards for specific personal jurisdiction.⁵¹

The court also determined that it was reasonable for Illinois courts to exercise jurisdiction over the defendant with respect to claims by nonresidents for injuries allegedly caused by Paxil. In determining that the exercise of specific jurisdiction was reasonable, the court noted that: (1) Illinois had an indisputable interest in resolving the case where Illinois doctors and facilities were used in the manufacturer’s research; (2) judicial economy would be achieved by having a single lawsuit with the plaintiffs in Illinois, rather than multiple suits across the country; and (3) any burden on the defendant in being forced to litigate in Illinois was not sufficient to

48. *Id.* at 1036 (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980)) (internal quotations removed).

49. *Id.*

50. *Id.* at 1037–38.

51. *See id.* at 1038–39.

decline jurisdiction.⁵² Accordingly, the Illinois Appellate Court affirmed the trial court's denial of the defendant's motion.

Thus, despite the U.S. Supreme Court's limitations on personal jurisdiction in *Daimler*, the California and Illinois courts held that defendant corporations not subject to general jurisdiction could still be sued on claims that did not directly arise in the forum, based upon a tenuous relationship between the claims and the forum. Notably, the Supreme Court has granted defendant's petition for a writ of certiorari in *Bristol-Myers*. The Court's ultimate ruling in *Bristol-Myers* will be significant for U.S. corporations with nationwide operations and foreign corporations doing business in the United States, especially in the context of mass-tort cases.

III. PREEMPTION

A. *Dietary Supplements*

In *Kaufman v. CVS Caremark Corp.*,⁵³ the First Circuit allowed a consumer class action to proceed where a series of scientific studies cited by the plaintiff in her complaint purportedly showed that Vitamin E may have both beneficial and harmful effects on heart health, depending on the dose consumed. This dual-effect allowed the plaintiff to overcome the defendant's argument that her claims were preempted by the Federal Food, Drug and Cosmetic Act (FDCA).

The plaintiff in *Kaufman* alleged that the labels on a Vitamin E supplement sold by the defendant retailer were misleading because there was no scientific foundation for its assertion that the supplement "supports heart health."⁵⁴ The plaintiff advanced two causes of action: violation of the New York Consumer Protection Act (NYCPA) and unjust enrichment.⁵⁵ The district court held that the plaintiff's claims were preempted by the FDCA and granted the retailer's motion to dismiss the complaint,⁵⁶ but the First Circuit reversed.⁵⁷

The pertinent provision of the FDCA prohibits the states from establishing any requirement regarding labeling claims as to a nutrient's relationship to a health-related condition that is "not identical" to the require-

52. *Id.* at 1042.

53. 836 F.3d 88 (1st Cir. 2016).

54. *Id.* at 90.

55. *Id.* at 91.

56. *Kaufman v. CVS Caremark Corp.*, No. CV 14-216-ML, 2016 WL 347324 (D.R.I. Jan. 28, 2016).

57. *See also* *Gallagher v. Bayer AG*, No. 14-CV-04601, 2015 WL 4932292, at *4-6 (N.D. Cal. Aug. 18, 2015) (plaintiffs had plausibly alleged the falsity of a manufacturer's structure/function claim concerning a vitamin supplement's effects on heart health).

ments of federal law.⁵⁸ The plaintiff argued, however, that her claims were not preempted because the retailer's labels did not comply with federal standards.

As this was an appeal from a motion to dismiss, the court's inquiry was limited to assessing the plausibility of the plaintiff's assertion that the retailer's labeling had violated the FDCA. In conducting this analysis, the court treated the label's "heart health" assertion as a "structure/function claim" under FDCA § 343(r)(6)(A).⁵⁹ To include such a claim on its labeling, the manufacturer of a dietary supplement must have "substantiation that such statement is truthful and not misleading."⁶⁰ Here, the plaintiff argued that substantiation for the retailer's "heart health" claim was lacking.

The court concluded that the studies cited by the plaintiff in her complaint did not "on their face render" her claims implausible for two reasons.⁶¹ First, the studies did not by themselves show that the heart health claims could be substantiated; rather, expert testimony was needed.⁶² Second, the studies could be plausibly construed, in the aggregate, as indicating that Vitamin E can actually damage the heart even if taken in the dosage provided by the retailer.⁶³

The potentially conflicting roles of Vitamin E in relation to heart health proved decisive. As the court explained, the FDCA grants a retailer a preemptive license to describe in its label "*the* role of a nutrient or dietary ingredient."⁶⁴ The court reasoned that a label describing merely "*a* role," while omitting reference to a possible conflicting role at a different dosage, was "misleading" within the meaning of the statute.⁶⁵ The court stated that if Vitamin E's actual role "is both to support and to harm heart health, depending on the dosage actually supplied," a label on a product packaged at the harmful dose level—but referencing only the supportive role played by Vitamin E—would be "incomplete."⁶⁶ Therefore, the plaintiff had adequately pled that the retailer's labeling of its Vitamin E supplement was inconsistent with the FDCA.⁶⁷ The court stressed the limits of its holding and noted that its ruling was not conclusive because

58. See 21 U.S.C. §§ 343-1(a)(5) (providing that no state may "establish . . . any requirement respecting any claim of the type described in section 343(r)(1) of [the FDCA], made in the label or labeling of food that is not identical to the requirement of section 343(r)[.]").

59. The FDCA allows a statement for a dietary supplement to be made if, *inter alia*, the statement "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans . . ." 21 U.S.C. § 343(r)(6)(A).

60. 21 U.S.C. § 343(r)(6)(B).

61. Kaufman v. CVS Caremark Corp., 836 F.3d 88, 94 (1st Cir. 2016).

62. *Id.*

63. *Id.* at 94–95.

64. *Id.* at 95 (quoting 21 U.S.C. § 343(r)(6)(B)).

65. *Id.*

66. *Id.*

67. *Id.* at 96.

it concerned only the plausibility of the plaintiff's complaint. Indeed, expert testimony and additional studies, if available, might "shed a different light" on the plaintiff's claims.⁶⁸

B. Prescription Medications

The New Jersey Supreme Court's decision in the case of *In re Reglan Litigation*⁶⁹ reflects a divergence in cases addressing the preemptive effect of federal law on state law claims for failure-to-warn against generic drug manufacturers.

This case involved metoclopramide, a drug typically prescribed to treat gastroesophageal reflux; its brand name is Reglan. According to the plaintiffs' allegations, accumulating evidence over the years has indicated that long-term use of the drug can cause tardive dyskinesia, a neurological disorder. In 2004, the brand name manufacturer received approval from the Food and Drug Administration (FDA) to include in the drug's label a warning that "[t]herapy should not exceed 12 weeks in duration."⁷⁰ The plaintiffs had taken generic metoclopramide beyond the twelve-week period and claimed to have suffered injuries as a result.⁷¹ They alleged that their injuries were caused by the failure of the generic manufacturers to timely update their labeling to reflect the FDA-approved warning for the branded product; the time lag varied by manufacturer from six months to four-and-a-half years after the FDA approved the revised warning label on the branded medication.⁷²

The defendants moved to dismiss the consolidated cases on the ground that federal law preempted the state law claims. The New Jersey Supreme Court unanimously held that the "plaintiffs' state law failure-to-warn claims based on the alleged inadequate labeling of metoclopramide—

68. *Id.* The court also rejected the plaintiff's argument that evidence showing that a supplement does not reduce heart disease necessarily implies that the nutrient has "no function" in maintaining heart health. *Id.* at 95. This was because the statute expressly allows sellers of dietary supplements to describe the "role" of a nutrient, but simultaneously to disavow a claim that the product is intended to "prevent any disease." *Id.* at 96. The court acknowledged that such a distinction between the nutrient's "function" and its lack of impact on disease could "trick[]" consumers, but stated that the statute allows this "form of finesse." *Id.* 69. 142 A.3d 725 (N.J. 2016).

70. *Id.* at 729. A generic drug manufacturer is able to "piggyback" on the FDA's approval of the equivalent brand name drug, including its labeling. *Id.* at 734 (citing Drug Price Competition and Patent Term Restoration Act of 1981, Pub. L. No. 98-417, 98 Stat. 1585 (1984)). While the brand name manufacturer is responsible for ensuring the accuracy and adequacy of the drug's labeling, the generic manufacturer need only ensure that the labeling of its product "is the same as the labeling approved for the [brand name] drug." *Id.* (quoting *Pilva, Inc. v. Mensing*, 564 U.S. 604, 612–13 (2011)). Pursuant to this requirement, the manufacturer of a generic drug cannot deviate from the labeling on the drug's brand name equivalent. *Id.*

71. *Id.* at 728.

72. *Id.* at 729, 741–42.

labeling that did not mimic the brand name labeling—were not preempted by federal law.”⁷³

The defendant’s preemption arguments were based on the Supreme Court’s 2011 ruling in *PLIVA, Inc. v. Mensing*.⁷⁴ There, the Court held that federal law preempts state law failure-to-warn claims against generic manufacturers for not utilizing a stronger warning label than the federally approved, brand name label.⁷⁵ The rationale for the Supreme Court’s ruling was “it was impossible for the [generic] [m]anufacturers to comply with both their state law duty to change the label and their federal law duty to keep the label the same.”⁷⁶

The New Jersey Supreme Court rejected this argument, distinguishing *Mensing* on the basis that *Mensing* did not address whether the preemption doctrine applies where a generic manufacturer *fails* to provide the same warning as the brand name manufacturer.⁷⁷ The court reasoned that the case at bar was more analogous to *Wyeth v. Levine*.⁷⁸ There, the Supreme Court held that federal preemption did not apply because it was not impossible for the brand name manufacturer to comply simultaneously with its federal and state law duties.⁷⁹ Moreover, the Court in *Wyeth* observed that state law tort suits serve as a “complementary form of drug regulation” that Congress did not intend to preempt in passing the FDCA.⁸⁰

The court relied on a number of federal and state court decisions holding that “state-law claims arising from the failure of generic drug manufacturers to update labeling to conform to that of the brand name” are not preempted,⁸¹ but refused to follow a contrary decision

73. *Id.* at 742.

74. 564 U.S. 604 (2011).

75. *Id.* at 618.

76. *Id.*

77. *In re Reglan Litig.*, 142 A.3d 725, 736 (N.J. 2016) (“*Mensing* does not directly address the issue before us because, here, defendant generic manufacturers of metoclopramide tablets did not comply with the FDCA requirement that their labeling mimic the brand name labeling. The question is whether the preemption doctrine is applicable to plaintiffs’ failure-to-warn claims when the generic drug manufacturers not only could have given stronger warnings, but also were required to do so under federal law.”).

78. 555 U.S. 555 (2009).

79. *See id.* at 573 (the defendant-appellant “failed to demonstrate that it was impossible for it to comply with both federal and state requirements”).

80. *Id.* at 578.

81. *In re Reglan*, 142 A.3d at 740 (citing *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 580–82, 585–86 (6th Cir. 2013); *In re Fosamax Prods. Liab. Litig.*, 965 F. Supp. 2d 413, 417 (S.D.N.Y. 2013); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1063–66 (D. Or. 2013); *Teva Pharms. USA, Inc. v. Super. Ct.*, 158 Cal. Rptr. 3d 150, 156–61 (Ct. App. 2013), *review denied*, 2013 Cal. LEXIS 7909 (Cal. 2013), *cert. denied*, 135 S. Ct. 1152 (2015); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 364 (Iowa 2014), *cert. denied*, 135 S. Ct. 1699 (2015); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676, 679 (Mo. Ct. App. 2014)).

of the Fifth Circuit.⁸² The court disagreed with “the notion that a plaintiff can proceed with a state law failure-to-warn claim against a brand name drug manufacturer that used FDA-approved warnings, as was true in *Wyeth*, but not against a generic manufacturer that provides warnings that do not even match the FDA-approved brand name labeling.”⁸³ The court said this would be “an absurd result.”⁸⁴ Moreover, the court said, the plaintiffs’ claims did not arise “solely by virtue” of federal regulation, but were based on “protections long available” under New Jersey law.⁸⁵

The court did acknowledge that some “lag time” was inevitable in a generic manufacturer’s adoption of an updated brand name warning.⁸⁶ It commented, however, that generic drug makers have “easy access to information about brand name labeling changes” and that the need to make warning changes is “time sensitive.”⁸⁷ The question whether the manufacturers had updated their labeling “at the earliest time possible” was left to the trial court’s determination.⁸⁸

Given the split in the lower courts,⁸⁹ the U.S. Supreme Court will likely need to address when federal law preempts state law claims against generic drug makers for alleged failure to adopt brand name warnings on a timely basis. Moreover, the impact of the court’s ruling has yet to be determined because plaintiffs will still need to show that the defendant manufacturers failed to provide adequate warnings and that this claimed failure was a proximate cause of their claimed injuries.⁹⁰

82. *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (per curiam) (“a claim that [defendant] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted”).

83. *In re Reglan Litig.*, 142 A.3d 725, 741 (N.J. 2016).

84. *Id.*

85. *Id.* at 742

86. *Id.* at 741.

87. *Id.*

88. *Id.* at 742.

89. *Compare* *Moretti v. Wyeth, Inc.*, 579 F. App’x 563 (9th Cir. 2014); *Fullington v. Pfizer, Inc.*, 720 F.3d 739 (8th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (per curiam); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654 (D. Md. 2011); *Couick v. Wyeth, Inc.*, 2011 WL 5826020 (W.D.N.C. 2011) *with* *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 580–82, 585–86 (6th Cir. 2013); *In re Fosamax Prods. Liab. Litig.*, 965 F. Supp. 2d 413, 417 (S.D.N.Y. 2013); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1063–66 (D. Or. 2013); *Lyman v. Pfizer, Inc.*, 2012 WL 2970627 (D. Vt. 2012); *Teva Pharms. USA, Inc. v. Super. Ct.*, 158 Cal. Rptr. 3d 150, 156–61 (Cal. Ct. App. 2013), *review denied*, 2013 Cal. LEXIS 7909 (Cal. 2013), *cert. denied*, 135 S. Ct. 1152 (2015); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 364 (Iowa 2014), *cert. denied*, 135 S. Ct. 1699 (2015); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676, 679 (Mo. Ct. App. 2014)).

90. *In re Reglan Litig.*, 142 A.3d 725, 742 (N.J. 2016). In 2004, the brand name manufacturer obtained approval for a labeling change to caution users that “[t]herapy should not exceed 12 weeks in duration.” *Id.* at 729. In 2009, the FDA issued a “black box warning” (a warning that appears on the package insert and that is formatted with a border around the text), which described these dangers in even stronger terms: “Treatment with metoclopra-

C. Aviation

In *Sikkelee v. Precision Airmotive Corp.*,⁹¹ the Third Circuit considered whether federal aviation law preempts a state law claim for defective design relating to an aircraft engine. The court held that federal aviation law does not preempt the entire field of state products liability law and that aircraft products liability cases could proceed “subject to traditional principles of conflict preemption.”⁹²

The case was brought by the widow of a pilot who was killed when his Cessna aircraft lost power and crashed shortly after take-off.⁹³ The plaintiff sued the aircraft’s engine manufacturer and others, alleging that the crash was due to a malfunction or defect in the engine’s carburetor.⁹⁴ The Federal Aviation Administration (FAA) had issued both a “type certificate,” as well as a “production certificate” for the engine.⁹⁵ The plaintiff initially asserted state law claims for strict liability and breach of warranty, among others.⁹⁶ The district court granted the defendants’ motion for judgment on the pleadings, holding that the plaintiff’s claims based on state law standards of care were within the preempted field of “air safety,” based upon the Third Circuit’s decision in *Abdullah v. American Airlines*.⁹⁷ The plaintiff later filed an amended complaint incorporating federal standards of care, along with renewed state law claims, which were subsequently narrowed to include only defective design and failure to warn.⁹⁸ The district court granted the defendants’ summary judgment motion, concluding that the FAA’s issuance of a type certificate for the engine

midic can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . [t]reatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.” *Id.* at 729–30 (internal quotation marks omitted).

91. 822 F.3d 680 (3d Cir. 2016), *cert. denied sub nom.*, *AVCO Corp. v. Sikkelee*, 137 S. Ct. 495 (2016).

92. *Id.* at 683. Field preemption occurs where Congress has clearly manifested an intent to occupy the field in a certain area, thereby precluding enforcement of state laws on the same subject. *See* *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Conflict preemption exists when state law conflicts with federal law such that compliance with both is impossible, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), or when the applicable state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of a federal law.” *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 330 (2011) (internal quotation marks omitted).

93. *Sikkelee*, 822 F.3d at 685.

94. *Id.*

95. *Id.* A type certificate certifies that the engine is “properly designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under [49 U.S.C. § 44701(a)].” 49 U.S.C. § 44704(a)(1). A production certificate certifies that a duplicate part will conform to the type certificate. 49 U.S.C. § 44704(c).

96. *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 685 (3d Cir. 2016).

97. *Abdullah v. Am. Airlines, Inc.*, 181 F.3d 363 (3d Cir. 1999).

98. *Sikkelee*, 822 F.3d at 685–86.

meant that the federal standard of care had been satisfied as a matter of law.⁹⁹ The Third Circuit granted interlocutory review.¹⁰⁰

On appeal, the Third Circuit was called upon to interpret its prior holding in *Abdullah*, where the plaintiffs suffered serious injuries when a flight operated by the defendant airline encountered turbulence.¹⁰¹ The plaintiffs alleged that the flight crew had illuminated the seatbelt sign in accordance with federal regulations, but had neglected to provide additional warnings of the expected turbulence and the steps the plaintiffs could have taken to protect themselves.¹⁰² A jury found the airline liable and awarded the plaintiffs damages aggregating over \$2 million.¹⁰³ On appeal, the Third Circuit held that “federal law establishes the applicable standards of care in the field of air safety, generally, thus preempting the entire field from state and territorial regulation.”¹⁰⁴

The *Sikkelee* court was required to decide whether the plaintiff’s state law product liability claims fell within the preempted field of “air safety” described in *Abdullah*. The court concluded that the claims did not.¹⁰⁵ In reaching this conclusion, the Third Circuit stressed the limits of its holding in *Abdullah*, which referred only to “in-air operations” of an aircraft and not to its design or manufacture.¹⁰⁶ The court noted that this narrow reading was reflected in the treatment of *Abdullah* by subsequent authorities, including a decision of the Third Circuit.¹⁰⁷

The court determined that it could not find clear and manifest congressional intent to preempt state law aviation products liability claims.¹⁰⁸ It began its analysis by invoking the presumption against preemption, which disfavors preemption in “areas of law traditionally occupied by the states,” absent “clear and manifest” congressional intent.¹⁰⁹ The court reasoned that the presumption had particular force in the present case because of the historically “uniform treatment of aviation products liability cases as state law torts[.]”¹¹⁰

99. *Sikkelee v. Precision Airmotive Corp.*, 45 F. Supp. 3d 431, 451–56 (M.D. Pa. 2014).

100. *Sikkelee*, 822 F.3d at 683, 687.

101. *See Abdullah*, 181 F.3d at 365.

102. *Id.*

103. *Id.*

104. *Id.* at 367.

105. *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 685, 688–90 (3d Cir. 2016).

106. *Id.* at 689.

107. *Id.* at 689–90 (citing cases). In *Elassaad v. Independent Air, Inc.*, 613 F.3d 119, 121 (3d Cir. 2010), the court held that a flight crew’s oversight of passenger disembarkation after the airplane came to a complete stop was not within the preempted field. The Third Circuit in *Sikkelee* stated that its decision in *Elassaad* “made clear that the field of aviation safety described in *Abdullah* was limited to in-air operations.” *Id.* at 689.

108. *Id.* at 698.

109. *Id.* at 690 (citation omitted).

110. *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 685, 691 (3d Cir. 2016).

The court concluded that: (1) neither the text nor the legislative history of the FAA reveals a clear and manifest congressional intent to overcome the presumption against preemption;¹¹¹ (2) the federal aviation regulations do not provide a comprehensive standard of care governing the manufacture and design of aircraft, and the certification system established by the regulations cannot alone displace the need for compliance with state standards of care;¹¹² and (3) the federal General Aviation Revitalization Act of 1994 contains a statute of repose barring state law claims against manufacturers of aircraft parts delivered or installed eighteen years prior to an accident and necessarily implies that such suits are not preempted.¹¹³

The court next considered the defendants' argument that the Supreme Court and other circuit precedents supported a finding of field preemption. First, the court considered the Supreme Court decisions concerning purportedly analogous federal regulations of locomotives and oil tankers offered by the defendants as support.¹¹⁴ The Third Circuit found these analogies were inapposite and that the Supreme Court's dicta on aviation preemption did not support a finding of field preemption.¹¹⁵

Second, the defendants asserted that, based upon *Riegel v. Medtronic*,¹¹⁶ the FAA's type certification process carried a preemptive effect similar to the preapproval process for medical devices under the FDCA.¹¹⁷ In rejecting this argument, the Third Circuit observed that *Riegel* hinged on the FDCA's express preemption clause, which had no parallel in the aviation context.¹¹⁸

111. *Id.* at 692–93. The court pointed out that the FAA contains no express preemption provision. *Id.* at 692. Moreover, the court observed that the statute merely provides that the FAA may establish “minimum standards” for aviation safety, language that is insufficient to support a finding of preemption. *Id.* (citing 49 U.S.C. § 44701). In addition, the court cited the “savings clause” contained in the FAA, which provides that “[a] remedy under this part is *in addition* to any other remedies provided by law.” *Id.* (citing 49 U.S.C. § 40120(c)) (emphasis added).

112. *Id.* at 693–696.

113. *Id.* at 696–99.

114. *Id.* at 699–701.

115. *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 685, 699–701 (3d Cir. 2016). Among various other statutory regimes, the Third Circuit found that the National Traffic and Motor Safety Act of 1966 and the Federal Boat Safety Act of 1971 were most analogous because both statutes contain a savings clause and authorize the pertinent regulatory agency to adopt safety standards. *Id.* (citing 49 U.S.C. §§ 30101(1), 30103(e) (National Traffic and Motor Safety Act); 46 U.S.C §§ 4302(a)(1), 4311(g) (Federal Boat Safety Act)). Nevertheless, the court reasoned that the Supreme Court has held that neither statute supports field preemption. *Id.* at 700–01 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002)).

116. 552 U.S. 312 (2008) (holding that the Medical Devices Act's preemption clause bars common law claims challenging the safety or effectiveness of a medical device marketed in a form that received premarket approval from the FDA).

117. *Sikkelee*, 822 F.3d at 701.

118. *Id.* at 704 (“unlike the Federal Aviation Act, the statute governing medical devices includes an express preemption clause”).

Finally, the court rejected the defendants' reliance on decisions from other federal appellate courts. Although various federal appeals courts have stated that the field of aviation safety is preempted, the court in *Sikkelee* said those rulings were "carefully circumscribed" and that, in any event, other courts had taken the contrary view.¹¹⁹ The court stated that the defendants were "unable to identify a single decision from any court . . . that has held the mere issuance of a type certificate conclusively establishes a defendant's compliance with the relevant standard of care."¹²⁰

Under the Third Circuit's lengthy and nuanced opinion, the preempted field of "aviation safety" does not encompass product manufacture and design.¹²¹

IV. CAUSATION AND EXPERTS IN ASBESTOS-RELATED LITIGATION

The "every exposure" theory at the heart of many asbestos and toxic tort cases continues to be controversial. Courts in California, Florida, and Georgia recently addressed the applicability of the doctrine.¹²² While California's Court of Appeal determined that expert testimony based on the "every exposure" theory was admissible in *Davis v. Honeywell International Inc.*,¹²³ the Florida District Court of Appeal and the Supreme Court of Georgia took different views regarding the theory and excluded the plaintiff's expert testimony on different grounds.¹²⁴

In *Davis*, a California appeals court upheld the trial court's decision to allow the plaintiff's expert to testify in accordance with the "every exposure" theory, concluding that the "theory is the subject of legitimate scientific debate."¹²⁵ The court held that the trial court did not abuse its discretion in allowing the testimony because "in ruling on the admissibility of expert testimony the trial court 'does not resolve scientific controversies'"—rather, "it is for the jury to resolve the conflict between the every exposure theory and any competing expert opinions."¹²⁶

119. See *id.* at 705–07 (citing cases).

120. *Id.* at 707.

121. *Id.* at 708–09.

122. To meet their burden of showing causation, many plaintiffs in asbestos cases present testimony by medical experts claiming that every exposure to asbestos, however slight, was a substantial factor in causing the plaintiff's disease. See, e.g., *Lindstrom v. A-C Prod. Liab. Tr.*, 424 F.3d 488, 493 (6th Cir. 2005); *Gregg v. V-J Auto Parts Co.*, 943 A.2d 216, 223 (Pa. 2007).

123. 199 Cal. Rptr. 3d 583 (2016).

124. See *Crane Co. v. DeLisle*, 2016 WL 4471438 (Fla. Dist. Ct. App. Nov. 9, 2016); *Scapa Dryer Fabrics, Inc. v. Knight*, 788 S.E.2d 421 (Ga. 2016).

125. *Davis*, 199 Cal. Rptr. 3d at 586.

126. *Id.* (citing *Rutherford v. Owens-Ill., Inc.*, 941 P.2d 1203 (Cal. 1997) (internal citations omitted)).

The plaintiff in *Davis* brought an action against numerous defendants, including a brake manufacturer, and alleged that the brake linings contained chrysotile asbestos fibers that caused her father's death from mesothelioma.¹²⁷ In addition to his exposure to chrysotile asbestos from brake linings, the decedent was also exposed to amphibole asbestos while working with a joint compound in his second job as a home remodeler.¹²⁸

At trial, the brake manufacturer was the only remaining defendant.¹²⁹ The plaintiff's expert, Dr. James Strauchen, testified that both forms of asbestos cause mesothelioma and that mesothelioma can result from very low doses of asbestos exposure.¹³⁰ In response to a hypothetical question, Dr. Strauchen testified that, for a person exposed to the same levels of chrysotile asbestos as the decedent was while working with the defendant's brake linings, the exposure "was a substantial contributing factor in the causation of that person's mesothelioma."¹³¹ The jury returned a \$2 million verdict in the plaintiff's favor and allocated 85 percent of the fault to the brake manufacturer. The jury allocated the remaining 15 percent of the fault in equal shares to eight companies responsible for the decedent's asbestos exposure during his home remodeling jobs.¹³²

The brake manufacturer appealed, arguing that the trial court should have excluded Dr. Strauchen's expert testimony.¹³³ The manufacturer argued that the California Supreme Court's decision in *Rutherford v. Owens-Illinois*¹³⁴ required any asbestos-related "causation analysis [to] proceed from an estimate concerning how great a dose was received" and that Dr. Strauchen's testimony fell short of providing any dose level estimation.¹³⁵

The court in *Davis* rejected this argument, stating that "*Rutherford* does not require a 'dose level estimation.' Instead, it requires a determination, to a reasonable medical probability, that the plaintiff's (or decedent's) exposure to the defendant's asbestos-containing product was a substantial factor in contributing to the risk of developing mesothelioma."¹³⁶ Further, the court noted that Dr. Strauchen did provide a dose level estima-

127. *Id.* at 585–86.

128. *Davis v. Honeywell Int'l Inc.*, 199 Cal. Rptr. 3d 583, 587 (2016).

129. *Id.* at 587 n.4.

130. *Id.* at 588.

131. *Id.*

132. *Id.* at 590.

133. *Davis v. Honeywell Int'l Inc.*, 199 Cal. Rptr. 3d 583, 586 (2016). The California Supreme Court recently clarified standards that govern admissibility of expert testimony—a court should act as a "gatekeeper" and exclude expert opinion testimony that is: (1) based on matter of a type on which an expert may not reasonably rely; (2) based on reasons unsupported by the material on which he relies; and (3) speculative. *Sargon Enters., Inc. v. Univ. of S. Cal.*, 288 P.3d 1237, 1252 (2012).

134. 941 P.2d 1203 (Cal. 1997).

135. *Davis*, 199 Cal. Rptr. 3d at 595–96.

136. *Id.* (citing *Rutherford*, 941 P.2d at 1218–20).

tion in his testimony in a hypothetical based on the facts surrounding the decedent's exposure to dust from his work around the brake linings. He also testified as to "estimates of the amount of asbestos fibers contained in visible dust."¹³⁷

The court was not persuaded by decisions in other states rejecting the "every exposure" theory.¹³⁸ First, the court reasoned, *Rutherford* held that in California, a plaintiff's burden in asbestos-related cancer cases is "to demonstrate that the defendant's product was a substantial factor in contributing to the plaintiff's aggregate dose of asbestos and hence to the risk of developing mesothelioma." The court determined that this burden was satisfied through expert testimony "that each exposure to asbestos contributed to the aggregate dose and hence to the risk of cancer."¹³⁹

Second, unlike jurisdictions that require a plaintiff to show that asbestos exposure at least doubled the risk of disease¹⁴⁰ or that asbestos was a "probable," not just a "possible,"¹⁴¹ cause of the disease, a plaintiff in California can prevail by demonstrating simply that asbestos exposure was a substantial factor in "contributing to the *risk* of developing" disease.¹⁴² Finally, the court disagreed with courts in other jurisdictions that the "every exposure" theory could not be reconciled with the dose-response relationship between the exposure and the risk of disease—the court accepted the expert's explanation that asbestos exposure is cumulative and that each exposure is a substantial factor in contributing to the disease.¹⁴³

In contrast, in *Crane Co. v. DeLisle*,¹⁴⁴ the Florida District Court of Appeal rejected the "every exposure" theory upon which the plaintiff's expert relied. In *Crane*, the jury returned a verdict for the plaintiff, who claimed that he developed mesothelioma as a result of his exposure to chrysotile asbestos contained in gaskets made by the defendant.¹⁴⁵ Dr. James Dahlgren, the plaintiff's toxicologist, testified that "every exposure" above background levels to friable, inhaled asbestos, regardless of product, fiber type, and dose, would be considered a substantial contributing factor in causing the plaintiff's mesothelioma.¹⁴⁶ On appeal, the defendant challenged the admissibility of this testimony under Flor-

137. *Id.* at 596.

138. *Davis v. Honeywell Int'l Inc.*, 199 Cal. Rptr. 3d 583, 596 (2016).

139. *Id.* (citing *Rutherford*, 941 P.2d at 1226).

140. *Id.* (quoting *Bostic v. Ga.-Pac. Corp.*, 493 S.W.3d 332, 350 (Tex. 2014)).

141. *Id.* (quoting *Moeller v. Garlock Sealing Techs., LLC*, 660 F.3d 950, 954 (6th Cir. 2011)).

142. *Id.* (citing *Rutherford*, 941 P.2d at 1226).

143. *Id.*

144. 2016 WL 6658470 (Fla. Dist. Ct. App. Nov. 9, 2016).

145. *Id.* at *1–2.

146. *Id.* at *2–3.

ida Statute § 90.702, which adopts the *Daubert* criteria for expert witness testimony.¹⁴⁷

Dr. Dahlgren testified that he followed a two-step process in determining whether the defendant's products caused the plaintiff's mesothelioma: (1) he determined the ability of asbestos to cause mesothelioma, and (2) he analyzed whether the plaintiff's exposure to asbestos was sufficient to cause mesothelioma.¹⁴⁸ He testified that he relied on the so-called Bradford Hill criteria, his own experience and training, and animal studies to conclude that asbestos could cause mesothelioma, but did not conduct any research of his own concerning the amount of asbestos required to cause mesothelioma.¹⁴⁹ The only study he recalled was of crocidolite, not chrysotile asbestos, and its author had later concluded that "there was no clear evidence that chrysotile asbestosis caused mesothelioma tumors."¹⁵⁰

The plaintiff's expert was also unable to testify unequivocally that all commercial types of asbestos are similar in terms of their potential to cause disease or cite particular studies to support his assertion that they were "probably" comparable, except for one paper that involved mixed types of asbestos.¹⁵¹ None of these studies was provided to the court.¹⁵²

Last, Dr. Dahlgren testified that "every exposure" to asbestos of any kind above background levels would be a substantial contributing cause of the plaintiff's mesothelioma.¹⁵³ Yet, he was unable to point to any study that established the threshold between background levels of exposure and levels at which there is an increased risk of disease, conceding that he did not think such a study could be done.¹⁵⁴ He also acknowledged that none of the studies he relied upon "actually said that each and every exposure above background contribute[d] to . . . mesothelioma risk[.]"¹⁵⁵

Citing *Daubert*, the court gave a number of reasons as to why Dr. Dahlgren's testimony should have been excluded.¹⁵⁶ First, the court pointed out that he failed to explain the methodology he used to determine that low levels of chrysotile asbestos found in defendant's products

147. *Id.* at *3; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993).

148. *DeLisle*, 2016 WL 6658470, at *6.

149. *Crane Co. v. DeLisle*, 2016 WL 6658470 (Fla. Dist. Ct. App. Nov. 9, 2016). The Bradford Hill criteria for assessing causality include the strength, consistency, specificity, temporal relationship, biological gradient, plausibility, and coherence of an association between an exposure and disease, as well as experimental evidence and judgment by analogy. *Id.*; see also Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, *PROC. R. SOC. MED.*, 58, 295–300 (May 1965).

150. *DeLisle*, 2016 WL 6658470, at *6.

151. *Id.*

152. *Id.*

153. *Id.* at *7.

154. *Crane Co. v. DeLisle*, 2016 WL 6658470, at *7 (Fla. Dist. Ct. App. Nov. 9, 2016).

155. *Id.*

156. *Id.*

could cause mesothelioma.¹⁵⁷ Second, his testimony was not supported by any data demonstrating (1) the association between mesothelioma and chrysotile asbestos “at low levels,” (2) his assumptions that all types of asbestos were equivalent in their “potency” to cause disease, or (3) that exposures “significantly” above background level could cause mesothelioma.¹⁵⁸ Notably, the court observed that courts in other jurisdictions have repeatedly rejected the “every exposure” theory because it is “insufficiently supported by data or testing to satisfy *Daubert*.”¹⁵⁹

Similarly, in *Scapa Dryer Fabrics, Inc. v. Knight*, the Supreme Court of Georgia ruled that expert testimony based on the “every exposure” theory of causation (called the “cumulative exposure theory” by the court) should have been excluded at trial.¹⁶⁰ Unlike the court in *Crane*, the court’s decision was based not on the admissibility of the expert’s testimony under *Daubert*, but on whether the expert’s testimony satisfied the legal standard for causation under Georgia law.¹⁶¹

In *Scapa*, the plaintiff, who had worked as a sheet metal worker at a facility operated by the defendant textile manufacturer,¹⁶² claimed that he had been exposed to asbestos and developed mesothelioma as a result of the defendant’s negligence.¹⁶³ The manufacturer appealed following a verdict for the plaintiff, arguing, among other things, that the trial court erred when it admitted the expert testimony of Dr. Jerrold Abraham, a pathologist.¹⁶⁴

Dr. Abraham testified that while exposure to ambient asbestos present in the air (“background asbestos”) is not known to cause mesothelioma, cumulative exposure may lead to mesothelioma when it builds to a point that it “exceeds the capacity of the lungs to absorb the exposure.”¹⁶⁵ Dr. Abraham further testified that “the precise point at which cumulative exposure is sufficient to cause any particular person to develop mesothelioma is not scientifically knowable, and for that reason, when a person actually has mesothelioma, it can only be attributed to his cumulative exposure as a whole”; thus, “each exposure in excess of the background is a contributing cause of the resulting mesothelioma, regardless of the extent of each exposure.”¹⁶⁶ Dr. Abraham stated that he did not need to deter-

157. *Id.*

158. *Id.* at *8.

159. *Id.* (listing cases cited by Vedros v. Northrop Grumman Shipbuilding, Inc., 119 F. Supp. 3d 556, 562–63 (E.D. La. 2015)).

160. 788 S.E.2d 421 (Ga. 2016).

161. *Id.* at 425–26.

162. *Id.* at 423 n.1.

163. *Id.* at 423.

164. *Id.* at 423–24.

165. *Scapa Dryer Fabrics, Inc. v. Knight*, 788 S.E.2d 421, 423 (Ga. 2016).

166. *Id.* at 423–24.

mine the extent of the plaintiff's workplace exposure, as long as it was more than zero, because even "one fiber" above ambient levels would be causative for someone who had mesothelioma.¹⁶⁷

In considering the admissibility of this testimony under Georgia's rules of evidence, the court focused on whether the testimony was relevant, i.e., whether it fit the causation issue and therefore assisted the jury in deciding the facts.¹⁶⁸

The court concluded that Dr. Abraham's testimony did not satisfy the legal standard for causation and therefore was not helpful to the jury in assessing causation.¹⁶⁹ To prove causation under Georgia law, the plaintiff had to show that exposure to asbestos was a "contributing factor" in bringing about his mesothelioma.¹⁷⁰ At the same time, the court cautioned that a *de minimis* contribution was not enough to establish causation under Georgia law.¹⁷¹ In other words, while the plaintiff "did not have to prove that exposure to asbestos at [the defendant's] facility made a *substantial* contribution to his mesothelioma, [the plaintiff] had to show that it made a *meaningful* contribution."¹⁷²

The court explained that the jury "had to determine not only whether exposure to asbestos at [the defendant's] facility contributed in some way to [the plaintiff] developing mesothelioma, but also whether the extent of that contribution was something more than *de minimis*."¹⁷³ By testifying that any amount of asbestos, as long as it was more than zero, contributed to the plaintiff's mesothelioma, Dr. Abraham "essentially told the jury that it was unnecessary to resolve the extent of exposure at the [the defendant's facility]," inviting "the jury to find that causation was established by any exposure at all."¹⁷⁴ For this reason, the court concluded that the trial court should have excluded Dr. Abraham's testimony.¹⁷⁵

Markedly, the court did not discuss the defendant's argument that the "every exposure" or "cumulative exposure" theory was not scientifically reliable.¹⁷⁶ In fact, the court noted that this theory could be relevant to causation under Georgia law, as in other jurisdictions,¹⁷⁷ if an expert cou-

167. *Id.* at 427.

168. *Id.* at 425-26.

169. *Id.* at 425.

170. *Scapa Dryer Fabrics, Inc. v. Knight*, 788 S.E.2d 421, 425 (Ga. 2016).

171. *Id.* at 426.

172. *Id.* at 425-26.

173. *Id.* at 426.

174. *Id.* at 426-27.

175. *Scapa Dryer Fabrics, Inc. v. Knight*, 788 S.E.2d 421, 427 (Ga. 2016).

176. *Id.* at 424.

177. *Id.* at 426-27 (citing *Schwartz v. Honeywell Int'l, Inc.*, 2016 WL 3018615, at *5 (Ohio Ct. App. May 26, 2016); *Robertson v. Doug Ashy Bldg. Materials, Inc.*, 168 So. 3d 556, 578-579 (La. Ct. App. 2014); *Quirin v. Lorillard Tobacco Co.*, 23 F. Supp. 3d 914, 920 (N.D. Ill. 2014)).

pled his reliance on the cumulative exposure theory with reliable data sufficient to show that the exposure was more than de minimis or qualified his opinion by stating that more than de minimis exposure was necessary.¹⁷⁸ The court explained, however, that Dr. Abraham did not “estimate the extent of exposure in any meaningful way” or qualify his opinion “by limiting it to such estimate of exposure.”¹⁷⁹

These three rulings, which arrive at different conclusions, illustrate the ongoing debate among U.S. courts concerning “every exposure” theory—a debate that seems likely to continue.

V. LEARNED INTERMEDIARY DEFENSE

Two recent decisions, *Niedner v. Ortho-McNeil Pharmaceuticals, Inc.*¹⁸⁰ and *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*,¹⁸¹ illustrate different approaches courts can take to claims for failure to warn against pharmaceutical manufacturers. Both decisions uphold the dismissal of such claims, even though direct consumer warnings were required by FDA regulation, but utilize different reasoning.¹⁸²

In *Niedner*, the plaintiff alleged that her daughter died from a pulmonary embolism caused by the daughter’s use of a birth control patch prescribed by her pediatrician.¹⁸³ The complaint centered on a claim that the manufacturer failed to provide adequate warnings of the dangers of using the patch.¹⁸⁴ In particular, the plaintiff claimed that the manufacturer failed to warn “that the risk of suffering a blood clot is significantly increased with use of the patch as compared to an oral contraceptive.”¹⁸⁵ The court affirmed the trial court’s ruling granting summary judgment in favor of the defendants based upon the learned intermediary doctrine.¹⁸⁶

In opposing the defendant’s motion, the plaintiff relied upon an exception to the learned intermediary doctrine, recognized in *MacDonald v.*

178. *Id.* at 426.

179. *Id.*

180. 58 N.E.3d 1080 (Mass. App. Ct. 2016).

181. 808 F.3d 281 (6th Cir. 2015).

182. Under the “learned intermediary” doctrine, a manufacturer discharges its duty to warn about the particular risks associated with a prescription drug product by giving the warning to the prescribing health care provider. The health care provider then has the duty to inform the patient of these risks. This doctrine is based on the assumption that the health care provider is better placed to assess the risks and benefits associated with the drug in question. *See generally* RESTATEMENT (THIRD) OF TORTS § 6(d)(1), cmt. b (Am. Law Inst. 1998); *see also Niedner*, 58 N.E.3d at 1084.

183. *Niedner*, 58 N.E.3d at 1082–83.

184. The plaintiff’s additional claims included design defect, manufacturing defect, breach of express warranty, and negligent misrepresentation. *Id.* at 1086–87.

185. *Niedner v. Ortho-McNeil Pharms., Inc.*, 58 N.E.3d 1080, 1083 (Mass. App. Ct. 2016).

186. *Id.* at 1084–87.

*Ortho Pharmaceutical Corp.*¹⁸⁷ There, in a case involving oral contraceptives, the Supreme Judicial Court of Massachusetts held that the manufacturer could not rely on warnings provided to the medical profession to satisfy its duty to warn, but had a duty directly to warn consumers of the risks of taking birth control pills. The court in *MacDonald* based this ruling on a number of considerations, including the “heightened participation” of patients in decisions to use the pill, limited participation by the physician, and a lower degree of medical supervision in comparison to other prescription medications.¹⁸⁸ In addition, federal regulations required manufacturers of oral contraceptives to directly warn consumers of the risks.¹⁸⁹ Since the patch, like the pill, is a hormonal birth control product, the court in *Niedner* followed *MacDonald* and determined that the manufacturer had a duty to directly warn the plaintiff’s daughter of the risks associated with the patch.¹⁹⁰

That was not the end of the court’s analysis, however. The court went on to find that the manufacturer was not liable for failure to warn because the box containing the patch included an insert that explained how to use the patch, disclosed the attendant risks, and informed consumers to consult their physicians about the product.¹⁹¹ In at least four places, the insert described the risk of developing blood clots from using the patch and cautioned consumers to consult with a health care professional.¹⁹² The court held that as matter of law, the insert provided an adequate warning of the increased risk of developing blood clots, compared to the risk of using the birth control pill, “in terms understandable to a lay person.”¹⁹³ Unlike in *MacDonald*, the court said, the insert included language “that would have been understandable to an average user.”¹⁹⁴ The warnings in the insert were “plain, numerous, and comprehensive.”¹⁹⁵

In *Yates*, the Sixth Circuit also affirmed a trial court decision granting summary judgment in favor of the defendant pharmaceutical company,

187. 475 N.E.2d 65 (Mass. 1985).

188. *See id.* at 69–70.

189. *Id.*

190. *Niedner v. Ortho-McNeil Pharms., Inc.*, 58 N.E.3d 1080, 1084–85 (Mass. App. Ct. 2016).

191. *Id.* at 1086.

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.* The court in *Niedner* also upheld the dismissal of the plaintiff’s claim for design defect based on Massachusetts law requiring proof of a safer alternative design. The court rejected the plaintiff’s contention that oral contraceptives (taken daily) are a feasible and safer alternative design to the patch, which is applied once a week for three weeks followed by a fourth week without the patch. The court noted that both the pill and the patch are hormonal contraceptives, but that the pill and the patch are “fundamentally different” because of the “difference in the drug delivery method.” *Id.* at 1087.

but based its ruling on the nature and extent of the warnings provided by the plaintiff's health care provider as well as on the content of the package insert.¹⁹⁶ First, the court rejected the plaintiff's argument that the defendants' warnings were inadequate because they did not convey the "degree" of the risk of stroke associated with use of the patch; the package label explicitly warned of the risk of stroke and thereby satisfied the manufacturer's duty under New York law to warn of the "precise malady" suffered by the plaintiff.¹⁹⁷ Second, the court held that it was not necessary for the label to warn that the risk of stroke from using the patch was higher than the risk of stroke from using birth control pills. Rather, the duty to warn of "comparative risks" extends to patients with "different underlying risk factors, not to different drugs treating the same ailment."¹⁹⁸ The fact that the FDA required the defendants to change the warning regarding the risk of stroke was not evidence that the previous label was insufficient.¹⁹⁹

Turning to the learned intermediary doctrine, the court in *Yates* recognized that an exception to the doctrine arises when FDA regulations require the manufacturer to provide direct consumer warnings.²⁰⁰ The court held, however, that this exception applies only if an "in-depth" analysis of the benefits and risks of the drug to the patient "appears to be unlikely."²⁰¹ The court found that the latter requirement was not satisfied because the plaintiff received meaningful counseling from her medical provider.²⁰² In reaching this conclusion, the court cited deposition testimony of the plaintiff's health care provider that she was aware of personal considerations that affected the plaintiff's birth control selection, that she utilized "independent medical judgment" when prescribing birth control to patients, and that she discussed the risks and benefits of using the patch with the plaintiff. "While there may be cases in which a health care provider of birth control medication does not function as a learned intermediary, this is not such a case."²⁰³

196. *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 287 (6th Cir. 2015). The case was governed by New York law because the case was filed in New York state court, removed to federal court, and then transferred to the U.S. District Court for the Northern District of Ohio for consolidated pretrial proceedings in connection with *In re Ortho Evra Products Liability Litigation*, 2010 WL 320064 (MDL 1742) (D. Ohio Jan. 20, 2010).

197. *Id.* at 290–91.

198. *Id.* at 291–92.

199. *Id.* at 292.

200. *Id.* at 292–93.

201. *Id.* at 292 (quoting *Samuels v. Am. Cyanamid Co.*, 184 N.Y.S.2d 1006, 1013 (N.Y. Sup. Ct. 1985)).

202. *Id.* at 293.

203. *Id.*

Thus, in cases in which the FDA required direct patient warnings, the courts in *Niedner* and *Yates* adopted different approaches but achieved the same result. *Niedner* reviewed, but did not apply the learned intermediary doctrine—instead the court held that the patient received adequate warnings as a matter of law. *Yates*, on the other hand, applied the learned intermediary doctrine based on the testimony of the patient’s own health care provider.

VI. CLASS ACTIONS — RULE 23 CLASS CERTIFICATION

A trio of U.S. Supreme Court decisions—*Wal-Mart Stores, Inc. v. Dukes*,²⁰⁴ *Amgen Inc. v. Connecticut Retirement Plans & Trust Fund*,²⁰⁵ and *Comcast Corp. v. Behrend*²⁰⁶—have raised the bar for class action certification in recent years. The Eleventh Circuit decision in *Brown v. Electrolux Home Products, Inc.*²⁰⁷ illustrates the impact of these cases on judicial application of the predominance requirement under Rule 23(b)(3) in the product liability context. In *Brown*, purchasers of front-loading washing machines filed a putative class action against a washing machine manufacturer, based upon the washing machines’ allegedly defective rubber seals, known as bellows.²⁰⁸ The plaintiffs’ consumer claims “include[d] violations of the California Unfair Competition Law and violations of the Texas Deceptive Trade Practices-Consumer Protection Act.”²⁰⁹

The district court certified two classes—the California class and the Texas class. The court concluded “that the questions of law or fact common to class members predominate[d] over any questions affecting only individual members” and that with respect to the consumer claims, “every element was susceptible to class-wide proof.”²¹⁰ On appeal, the manufacturer argued that class certification was improper because “the district court articulated the wrong standard for class certification and [the class representatives] cannot satisfy the predominance requirement of Rule 23(b)(3).”²¹¹

The Eleventh Circuit agreed that the district court had misstated the standard for class certification when it determined that it would “resolve [] doubts related to class certification in favor of the certifying class” and would “accept [] the allegations in the complaint as true.”²¹²

204. 564 U.S. 338 (2011).

205. 133 S. Ct. 1184 (2013).

206. 133 S. Ct. 1426 (2013).

207. 817 F.3d 1225 (11th Cir. 2016).

208. *Id.* at 1231.

209. *Id.*

210. *Id.* at 1232.

211. *Id.* at 1233.

212. *Brown v. Electrolux Home Prods., Inc.*, 817 F.3d 1225, 1233 (11th Cir. 2016).

The appeals court noted, rather, that the party seeking the class has the burden of proof and must therefore demonstrate that the Rule 23 requirements are “in fact” satisfied.²¹³

With respect to predominance, the manufacturer made four independent arguments as to why the plaintiffs had not met the requirements of Rule 23: (1) causation could not be proven on a class-wide basis, (2) predominance could not be satisfied for the warranty claims without first resolving preliminary questions concerning state law, (3) the plaintiffs could not prove damages on a class-wide basis, and (4) the manufacturer’s affirmative defense of misuse necessarily requires an individual inquiry.²¹⁴

The Eleventh Circuit vacated the class certification and remanded the case for further proceedings. The court agreed that causation could not be proven on a class-wide basis because causation under the California Unfair Competition Law and the Texas Deceptive Trade Practices–Consumer Protection Act requires individual proof.²¹⁵ The California Unfair Competition Law claim asserted that the defendant “engag[ed] in both ‘unfair’ and ‘fraudulent’ business practices when it failed to mention the defective bellows or mildew problem in its advertisements.”²¹⁶ However, as noted by the court, not every plaintiff was exposed to the purported misrepresentation in the advertisement that was the subject of the claims.²¹⁷ Therefore, the claim under the California Unfair Competition Law was “unsuitable for class treatment.”²¹⁸

Likewise, the court found that the Texas Deceptive Trade Practices–Consumer Protection Act claim required the plaintiffs to prove actual reliance on the defendant’s statement or omission. The court noted that such an inquiry is individual in nature and that “prov[ing] reliance on a class-wide basis is ‘a near-impossibility,’ according to the Texas Court of Appeals.”²¹⁹ Thus, the Eleventh Circuit determined that the plaintiffs’ claims did not satisfy the predominance requirement under both the Texas and California statutes “because their elements of causation require individual proof.”²²⁰

The Eleventh Circuit further agreed with the defendant’s second basis for appeal, holding that “the district court could not determine predominance without first deciding whether California and Texas law require pre-suit notice, an opportunity to cure, and manifestation of the de-

213. *Id.* at 1234.

214. *Id.* at 1235.

215. *Id.* at 1235–38.

216. *Id.* at 1236.

217. *Brown v. Electrolux Home Prods., Inc.*, 817 F.3d 1225, 1236 (11th Cir. 2016).

218. *Id.*

219. *Id.* (citing *Tex. S. Rentals, Inc. v. Gomez*, 267 S.W.3d 228, 237 (Tex. App. 2008)).

220. *Brown*, 817 F.3d at 1237.

fect.”²²¹ Without first resolving these questions of law, the district court could not determine whether class-wide questions of law and fact predominated over individual questions of law and fact.²²²

The Eleventh Circuit was not persuaded, however, that the plaintiffs could not prove damages on a class-wide basis. As the court explained, “[t]he ‘black letter rule’ recognized in every circuit is that ‘individual damage calculations generally do not defeat a finding that common issues predominate.’”²²³

Concerning the defendant’s fourth basis for appeal, the Eleventh Circuit referred back to the district court the question whether the affirmative defense of misuse would defeat predominance, noting “[c]ourts traditionally have been reluctant to deny class action status under Rule 23(b)(3) simply because affirmative defenses may be available against individual members.”²²⁴ The court observed, however, that affirmative defenses could defeat predominance if the affirmative defenses “could apply to the vast majority of class members and raise complex individual questions.”²²⁵

Based on the predominance issues raised by the defendant, the Eleventh Circuit vacated the class certification and remanded the case to the trial court for further review, stating “[w]e express no view about them and leave them, like all questions of class certification, to the discretion of the district court.”²²⁶

The decision in *Brown* reflects the increased scrutiny of purported class actions based on the U.S. Supreme Court’s recent decisions raising the standards for class certification.

221. *Id.*

222. *Brown v. Electrolux Home Prods., Inc.*, 817 F.3d 1225, 1237 (11th Cir. 2016).

223. *Id.* at 1239 (quoting WILLIAM B. RUBENSTEIN ET AL., *NEWBERG ON CLASS ACTIONS* § 4:54 (5th ed. 2013)).

224. *Id.* at 1240 (citing *NEWBERG ON CLASS ACTIONS*, *supra* note 204, § 4:55).

225. *Id.* at 1241 (citing *Sacred Heart Health Sys., Inc. v. Humana Military Healthcare Servs., Inc.*, 601 F.3d 1159, 1177–83 (11th Cir. 2010)).

226. *Id.*

