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Product Liability

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This Article surveys developments in Georgia product liability law between June 1, 2009 through May 31, 2010.[1] It covers noteworthy cases decided during this period by the Georgia appellate courts, the United States Court of Appeals for the Eleventh Circuit, and the United States district courts located in Georgia.

I. FAILURE TO WARN

A. *Existence of a Duty*

"In failure to warn cases, the duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product."[2] The manufacturer has constructive knowledge if "by the application of reasonable, developed human skill and foresight," it should have known of the danger.[3] The plaintiff bears the burden of proving that the manufacturer has actual or constructive

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1. For analysis of Georgia product liability law during the prior survey period, see Franklin P. Brannen, Jr. & Jacob E. Daly, *Product Liability, Annual Survey of Georgia Law*, 61 MERCER L. REV. 267 (2009).

2. Chrysler Corp. v. Batten, 264 Ga. 723, 724, 450 S.E.2d 208, 211 (1994); *see also* Ford Motor Co. v. Stubblefield, 171 Ga. App. 331, 335, 319 S.E.2d 470, 476 (1984) (holding that "the manufacturer of a product which, to its actual or constructive knowledge, involves danger to users, has a duty to give warning of such danger"). A seller may also owe a duty to warn under certain limited circumstances. *See, e.g.*, Farmer v. Brannan Auto Parts, Inc., 231 Ga. App. 353, 355, 498 S.E.2d 583, 585 (1998) (en banc).

3. Bishop v. Farhat, 227 Ga. App. 201, 206, 489 S.E.2d 323, 328 (1997) (internal quotation marks omitted).

knowledge of the danger,[4] and this burden may be satisfied with evidence of prior complaints or injuries, documentation of the danger in relevant literature, recognition of the danger by industry experts, or alerts issued by relevant governmental agencies.[5] But even if the manufacturer has actual or constructive knowledge of a danger associated with its product, it does not have a duty to warn users if that danger is open and obvious.[6] Thus, the existence of a duty "depends upon [the] foreseeability of the use in question, the type of danger involved, and the foreseeability of the user's knowledge of the danger."[7]

The manufacturer's knowledge of the alleged danger was the central issue in *Mather v. L'Oreal USA, Inc.*[8] The plaintiff used L'Oreal Paris Sublime Bronze self-tanning lotion twice a day for three days while she was vacationing at a beach. During that time she did not experience any problems, but while she was driving home, her skin became red with small pustules when it was exposed to direct sunlight through the windows of her car. Once she got home, her symptoms became progressively worse. She developed pus-filled abscesses that turned into a systemic infection, and she had to be given IV antibiotics. Lesions appeared all over her body, and her multiple sclerosis was exacerbated. She sued L'Oreal, the manufacturer of the lotion, alleging that it failed to warn her about the potential dangers of using the product. The manufacturer moved for summary judgment, and trial court granted the motion.[9]

The Georgia Court of Appeals affirmed on the ground that the manufacturer had neither actual nor constructive knowledge of the allergic reaction experienced by the plaintiff.[10] The plaintiff first argued that the manufacturer knew about this danger because its own expert testified that the active ingredient in the lotion, hydroxyacetone, is generally accepted by dermatologists as safe for most people to use. Because the expert said "most" and not "all," the plaintiff argued that the lotion should have had a warning since it was not safe for some people to use.[11] The court rejected this argument based on comment j

4. John Crane, Inc. v. Wommack, 227 Ga. App. 538, 540, 489 S.E.2d 527, 530 (1997).

5. *Bishop*, 227 Ga. App. at 206, 489 S.E.2d at 328. These are by no means the only ways of proving the manufacturer's actual or constructive knowledge.

6. Vickery v. Waste Mgmt., Inc., 249 Ga. App. 659, 661, 549 S.E.2d 482, 484 (2001).

7. Battersby v. Boyer, 241 Ga. App. 115, 117, 526 S.E.2d 159, 162 (1999) (alteration in original) (internal quotation marks omitted).

8. 304 Ga. App. 163, 695 S.E.2d 693 (2010).

9. *Id.* at 163-64, 695 S.E.2d at 694.

10. *Id.* at 165, 695 S.E.2d at 695.

11. *Id.* at 164, 695 S.E.2d at 695.

to section 402A of the *Restatement (Second) of Torts*,[12] which provides as follows:

> The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a *substantial* number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger.[13]

The plaintiff was unable to satisfy this standard because "there [was] no evidence that the product contained an ingredient to which a substantial number of the population is allergic, rather, just the opposite."[14]

Next, the plaintiff attempted to satisfy her burden of proving the manufacturer's knowledge by arguing that the manufacturer improperly excluded certain people during its testing of the lotion. The manufacturer excluded people who had an illness that contraindicated participation, who had certain skin conditions, and who were using medications that could either affect the skin's tolerance of the lotion or enhance or suppress adverse effects of the lotion. What the plaintiff failed to answer, however, was that it would have been unethical for the manufacturer to have included these people. Finally, the plaintiff contended that the manufacturer knew or should have known about the danger because of problems experienced by testing participants and consumers. During testing, seven out of forty-two people who had sensitive skin reported an adverse event.[15] However, the court disregarded the reactions experienced by these seven people because they "were characterized as 'mild' and . . . in no way resembled the reaction experienced by [the plaintiff]."[16] After testing, the manufacturer received six complaints from consumers who had used the lotion, but the court held that these complaints did not satisfy the plaintiff's burden because "[t]here were no complaints of any reaction of the type

12. *Id.* at 164-65, 695 S.E.2d at 695.
13. RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965) (emphasis added).
14. *Mather*, 304 Ga. App. at 165, 695 S.E.2d at 695.
15. *Id.*
16. *Id.*

experienced by [the plaintiff]."[17] Accordingly, the court held that the manufacturer was entitled to summary judgment.[18]

The open and obvious nature of the alleged danger was at issue in *Cochran v. Brinkmann Corp.*[19] The plaintiffs' son sustained severe burns when he knocked over a turkey fryer and hot peanut oil spilled onto his back. In their complaint, the plaintiffs alleged that the turkey fryer was defective, unfit for use, inherently dangerous, and lacked adequate warnings. The manufacturer moved for summary judgment, and as to its alleged failure to warn, it argued that it did not owe a duty to warn because the dangers associated with the turkey fryer were open and obvious.[20] Noting that the plaintiffs did not contend that the dangers of using a turkey fryer were latent, the court agreed with the manufacturer and held that "[t]he dangers associated with the turkey fryer here are inherent, objectively open and obvious, and no reasonable jury could conclude otherwise, nor would they require a warning for the obvious danger at issue in this case."[21]

B. Causation

Proximate cause is an essential element of a failure-to-warn claim.[22] Many failure-to-warn claims are improper as a matter of law because the plaintiff failed to read the available warnings, which means that additional warnings would not have altered the plaintiff's conduct that resulted in the injuries at issue in the lawsuit.

This shortcoming was present in *Mascarenas v. Cooper Tire & Rubber Co.*,[23] a lawsuit in which the plaintiffs sued both the tire manufacturer and the vehicle manufacturer for an allegedly defective tire that ruptured and caused the rollover of a sport-utility vehicle.[24] In their failure-to-warn claim against the SUV manufacturer, the plaintiffs contended that the sun visor warning in the SUV "did not mention the stability and handling/skate risks posed by the automobile at all."[25] But the driver of the SUV admitted that she did not read the owner's

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17. *Id.*
18. *Id.*
19. No. 1:08-cv-1790-WSD, 2009 WL 4823854 (N.D. Ga. Dec. 9, 2009).
20. *Id.* at *2-3, *7.
21. *Id.* at *7; *see also* Biles v. Tyson Foods, Inc., No. 1:95-CV-777WBH, 1996 WL 684134, at *3 (N.D. Ga. Aug. 21, 1996) (holding "that the danger of cooking food in hot oil over an open flame is plainly an open and obvious danger and that a reasonable jury could not conclude otherwise").
22. Powell v. Harsco Corp., 209 Ga. App. 348, 349-50, 433 S.E.2d 608, 609-10 (1993).
23. 643 F. Supp. 2d 1363 (S.D. Ga. 2009).
24. *Id.* at 1367.
25. *Id.* at 1374-75.

manual that accompanied the SUV, and she could not remember whether she had read the sun visor warning label on the subject vehicle or on a different vehicle.[26]

The district court held that the driver's failure to read the sun visor warning barred her failure-to-warn claim as a matter of law.[27] The plaintiffs were "not challenging the adequacy of [the manufacturer's] efforts to communicate the warning, just the warning itself."[28] Because the driver did not read the available warnings, there was no evidence in the record that additional warnings would have changed the driver's conduct.[29] Accordingly, the plaintiffs failed to show that the absence of the additional warnings was the proximate cause of the underlying accident.[30]

In *Silverstein v. Proctor & Gamble Manufacturing Co.*,[31] the plaintiffs contended that their use of Crest Pro-Health Rinse mouthwash caused a decrease in their ability to taste food. In addition, the plaintiffs claimed that the mouthwash stained their teeth and tongue. The plaintiffs brought a failure-to-warn claim against the mouthwash manufacturer, alleging that the label did not adequately warn consumers of the harms that could result from the use of the product.[32] As part of a motion for summary judgment, the manufacturer argued that the failure-to-warn claim should be dismissed because the plaintiffs failed to read the available warnings.[33] The plaintiffs countered that their recovery should not be barred because they were "challenging the adequacy of the efforts of the manufacturer to communicate the dangers of the product to the consumer."[34] Relying on precedent from the Eleventh Circuit, the district court concluded that because the plaintiffs did not read the warning label, any inadequacy of the warning label could not have been the proximate cause of their injuries.[35] The court distinguished the facts here from those in *Rhodes v. Interstate Battery System of America, Inc.*[36] on the ground that the plaintiff in that case could not read the warning label because there was insufficient light.[37]

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26. *Id.* at 1375.
27. *Id.*
28. *Id.*
29. *Id.*
30. *Id.*
31. 700 F. Supp. 2d 1312 (S.D. Ga. 2009).
32. *Id.* at 1315.
33. *Id.* at 1321.
34. *Id.*
35. *Id.* (citing Thornton v. E.I. DuPont De Nemours & Co., 22 F.3d 284, 289-90 (1994)).
36. 722 F.2d 1517 (11th Cir. 1984).
37. *Silverstein*, 700 F. Supp. 2d at 1321 (citing *Rhodes*, 722 F.2d at 1520).

Instead, the court found these facts to be akin to the facts in *Thornton v. E.I. DuPont De Nemours & Co.*,[38] in which the plaintiff had an opportunity to read the warning label but chose not to read the warnings.[39] Accordingly, the district court granted summary judgment for the defendant on this issue.[40]

In *Swicegood v. Pliva, Inc.*,[41] the plaintiff brought suit against two pharmaceutical companies because she contended her ingestion of their medication metoclopramide, the generic form of Reglan, caused her to develop tardive dyskinesia, a medical disorder that produces involuntary muscle contractions.[42] The plaintiff's claims against the defendants included an allegation that they failed to warn of the risk that this medical condition could develop through the use of the medication.[43]

As part of their summary judgment motion, the manufacturers contended that the plaintiff's failure-to-warn claim should be dismissed because the prescribing doctor never reviewed the warning label for the defendants' generic medicine. Instead, the doctor testified that he only read the warning label for Reglan, the name-brand drug. The defendants argued that because the doctor did not read their label, any actions or inactions by them in their design of the label could not be the proximate cause of the plaintiff's injuries.[44] But the district court held that because the warning label for a generic medicine is generally identical to the warning label for the name-brand version, it was a fact issue for the jury to decide whether the prescribing doctor became aware of any changes to the generic medication label.[45] Accordingly, the defendants were not entitled to summary judgment on this issue.[46]

C. Failure to Recall

Many failure-to-warn claims are based on the manufacturer's alleged failure to warn the purchaser at the time of sale about a danger associated with the product, but a failure-to-warn claim can also be based on the manufacturer's alleged failure to warn the purchaser about a danger that it discovers after the sale.[47] Thus, a manufacturer may

38. 22 F.3d 284 (11th Cir. 1994).
39. *Silverstein*, 700 F. Supp. 2d at 1321.
40. *Id.* at 1322.
41. No. 1:07-CV-1671-TWT, 2010 WL 1138455 (N.D. Ga. Mar. 22, 2010).
42. *Id.* at *1.
43. *Id.* at *3.
44. *Id.* at *4.
45. *Id.*
46. *Id.*
47. Victor Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine*, 58 N.Y.U. L. REV. 892, 892-93, 894 (1983).

owe a point-of-sale duty to warn and a post-sale duty to warn.[48] A duty to recall a product and a post-sale duty to warn about its dangers are not the same, but they are similar insofar as each arises after the product is sold, and a recall notice is essentially an extremely strong warning.

Most courts have held that manufacturers do not have a duty to recall a product that is found to have a defect after the initial sale, unless the government orders a recall.[49] The rationale for refusing to impose a duty to recall is that "[a] product's design generally has been evaluated as of the time of manufacture" and that "[e]xpanding a manufacturer's duty in this manner is analogous to a retroactive judgment about product design."[50] This is an important point that seems to get lost in the debate, but the Michigan Supreme Court explained it well in *Gregory v. Cincinnati, Inc.*[51] If the product contains a defect that the manufacturer is not aware of at the time of sale but subsequently discovers, the manufacturer may have a post-sale duty to warn about the defect.[52] Proponents of a duty to recall, however, argue that the manufacturer should be required to recall a product that was not defective at the time of sale but that became "defective" because of improvements in technology after that time.[53] This argument is inconsistent with the general rule that a manufacturer's liability depends on whether the product was defective at the time of sale and that "a manufacturer is under no duty to modify its product in accordance with the current state of the art safety features."[54] Moreover, public policy considerations weigh against imposing a duty to recall on manufacturers:

> The imposition of post-sale tort law obligations that include the duty to remedy or replace products already in the marketplace has significant implications. Attorneys who counsel manufacturers about how to fulfill their obligations and avoid liability must inform them that by developing new and safer products they may be exposed to liability for harm caused by an older product made and sold before the safety improvements were developed. This advice may discourage the very conduct society seeks to foster. Progress and innovation should

48. *Id.* at 893.

49. Lisa Anne Meyer, Annotation, *Products Liability: Manufacturer's Postsale Obligation to Modify, Repair, or Recall Product*, 47 A.L.R.5TH 395, 405 (1997 & Supp. 2010); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 11(a)(1) (1997).

50. Schwartz, *supra* note 47, at 900.

51. 538 N.W.2d 325 (1995).

52. *Id.* at 329.

53. *Id.* at 330.

54. *Id.* at 336-37.

> not be penalized by attaching to them a duty to go out into the marketplace to find and fix old products.
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> Furthermore, courts that impose a post-sale obligation to remedy or replace products already in the marketplace arrogate to themselves a power equivalent to that of requiring product recall. Product recalls, however, are properly the province of administrative agencies, as the federal statutes that expressly delegate recall authority to various agencies suggest. As Congress has recognized, administrative agencies have the institutional resources to make fully informed assessments of the marginal benefits of recalling a specific product. Because the cost of locating, recalling, and replacing mass-marketed products can be enormous and will likely be passed on to consumers in the form of higher prices, the recall power should not be exercised without extensive consideration of its economic impact. Courts, however, are constituted to define individual cases, and their inquiries are confined to the particular facts and arguments in the cases before them. Decisions to expand a manufacturer's post-sale duty beyond making reasonable efforts to warn product users about newly discovered dangers should be left to administrative agencies, which are better able to weigh the costs and benefits of such action.[55]

Prior to the survey period, the existence of a duty to recall was unsettled in Georgia. In 1988 the Georgia Court of Appeals held in *Blossman Gas Co. v. Williams*[56] "that when a dealer voluntarily agrees to notify its customers of a product recall and to mail notices provided by the manufacturer, . . . its negligence in failing to perform this obligation will give rise to a cause of action to one who suffers injuries as a proximate result thereof."[57] The court noted that "the dealer is not obligated to conduct the recall program" but that "once it undertakes to do so a duty devolves upon the dealer to exercise ordinary care."[58] Five years later, in *Mack Trucks, Inc. v. Conkle*,[59] the Georgia Supreme Court noted that the jury had found for the plaintiffs on their claim for negligent failure to recall or warn, but the issue on appeal did not involve the validity of that claim.[60] In 2001 the court of appeals held in *Smith v. Ontario Sewing Machine Co.*[61] that "[w]hen the manufacturer subsequently learns that its products have been sold with dangerous defects, it is under a duty to recall the product from the

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55. Schwartz, *supra* note 47, at 900-01 (footnotes omitted).
56. 189 Ga. App. 195, 375 S.E.2d 117 (1988) (physical precedent).
57. *Id.* at 198, 375 S.E.2d at 120.
58. *Id.*
59. 263 Ga. 539, 436 S.E.2d 635 (1993).
60. *Id.* at 539-40, 436 S.E.2d at 636-37.
61. 249 Ga. App. 364, 548 S.E.2d 89 (2001) (physical precedent), *aff'd on other grounds*, Ontario Sewing Mach. Co. v. Smith, 275 Ga. 683, 572 S.E.2d 533 (2002).

market and to remedy the defect or replace the product in some cases in the exercise of ordinary care."[62] The manufacturer in *Smith* appealed, and although the supreme court disapproved of the court of appeals holding on this issue, it found that there was no need to resolve this issue because the only issue on appeal related to proximate cause.[63] Thus, the existence of a duty to recall was an open question following the supreme court's decision in *Smith*.

The court of appeals provided a definitive answer to this question during the survey period. In *Ford Motor Co. v. Reese*,[64] the plaintiffs' mother died as a result of a rear-impact collision between the car she was driving, a 1994 Ford Tempo, and a dump truck. The plaintiffs alleged that their mother sustained more severe injuries than she otherwise would have because the impact caused the seatback to collapse rearward so that her head and shoulders struck the rear seat, which caused a spinal fracture and fatal injuries to her head and brain. The plaintiffs sued Ford for, among other things, negligent failure to recall the seatback. At trial the plaintiffs' experts testified that the seatback was defectively designed and that Ford could have warned drivers about the potential risk of seatback collapse upon rear impact. The plaintiffs' experts also testified that Ford could have used an alternative seat design that was safer or could have retrofitted the Tempo with a safer seat through a recall campaign. According to the plaintiffs' experts, either of these alternatives would have prevented the injuries to and death of the plaintiffs' mother. Ford countered with expert testimony of its own, which showed that the design of the seatback was reasonable and consistent with the prevailing state of the art and industry standards at the time of its manufacture and that the seatback protected occupants better than other types of seatbacks in most collisions. After the close of the evidence, the trial court instructed the jury with respect to a claim for negligent failure to warn or recall. The jury then returned a verdict for the plaintiffs.[65]

On appeal, Ford argued that the trial court erred by instructing the jury about a claim for negligent failure to recall because Georgia law does not impose a duty to recall on manufacturers.[66] The court of appeals agreed and held "that absent special circumstances, no common law duty exists under Georgia law requiring a manufacturer to recall a

62. *Id.* at 368, 548 S.E.2d at 95.

63. Ontario Sewing Mach. Co. v. Smith, 275 Ga. 683, 685-86, 572 S.E.2d 533, 535 (2002).

64. 300 Ga. App. 82, 684 S.E.2d 279 (2009).

65. *Id.* at 82-84, 684 S.E.2d at 282-83.

66. *Id.* at 84, 684 S.E.2d at 283.

product after the product has left the manufacturer's control."[67] The court explained that "a manufacturer's duty to implement alternative safer designs is limited to the time the product is manufactured, not months or years later when technology or knowledge may have changed."[68] And although Georgia law recognizes a post-sale duty to warn, this continuing duty does not encompass a duty to recall.[69] Finally, the court noted that its decision was consistent with the *Restatement* and the majority of other jurisdictions that have considered this issue and that public policy concerns favor administrative agencies making recall decisions rather than courts.[70] Accordingly, the court held that the trial court's jury instructions were harmful error and that Ford was entitled to a new trial.[71] The plaintiffs filed a petition for a writ of certiorari with the supreme court, but the supreme court denied their petition in a 4-3 decision.[72]

Reese is a good decision not because it put Georgia in line with most other states and the *Restatement* but rather because it adheres to fundamental principles of Georgia product liability law. As the court of appeals recognized in *Reese*, a manufacturer is entitled to have the design and safety of its product judged as of the time of manufacture.[73] "Any other rule would render a manufacturer a perpetual insurer of the safety of its products, contrary to established Georgia law."[74] As the Michigan Supreme Court explained in *Gregory*, a decision about whether a product should be recalled should not be left to judges and juries but rather to administrative agencies that have the experience, expertise, and resources necessary to weigh the costs and benefits of a recall.[75]

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67. *Id.* at 85, 684 S.E.2d at 283-84 (footnote omitted). The court noted, however, that a federal or state statute or governmental agency may require a manufacturer to recall a product, which would impose a duty, and that a manufacturer must exercise ordinary care in conducting a recall campaign if it chooses to recall a product voluntarily. *Id.* at 85 n.2, 684 S.E.2d at 284 n.2.

68. *Id.* at 85, 684 S.E.2d at 284.

69. *Id.* at 85-86, 684 S.E.2d at 284.

70. *Id.* at 86-87, 684 S.E.2d 284-85.

71. *Id.* at 87-88, 684 S.E.2d at 285.

72. Reese v. Ford Motor Co., No. S10C0186, 2010 Ga. LEXIS 161, at *1 (Ga. Feb. 8, 2010). Information about the plaintiffs' petition and the supreme court's denial is available on the supreme court's website at http://www.gasupreme.us/docket_search/results_one_record.php?caseNumber=S10C0186.

73. 300 Ga. App. at 85, 684 S.E.2d at 284.

74. *Id.*

75. 538 N.W.2d at 334.

II. PROXIMATE CAUSE

A. *Asbestos Litigation*

Proof that a manufacturer's product proximately caused the plaintiff's injuries is an essential element of all product liability claims regardless of whether the plaintiff is proceeding under a strict liability or negligence theory.[76] Proving proximate cause is particularly problematic in asbestos litigation because "of the length of time between exposure and perceived injury and the migratory nature of much of the employment involving asbestos exposure."[77] Such problems, however, do not justify easing an asbestos plaintiff's burden of proof.[78] After all, "[a] manufacturer has the absolute right to have his strict liability [or negligence] for injuries adjudged on the basis of the design of his own marketed product and not that of someone else."[79] Thus, to prove proximate cause in an asbestos case, "the plaintiff must present evidence that a particular defendant's asbestos-containing product was used at the job site and that the plaintiff was in proximity to that product at the time it was being used."[80]

Because asbestos-related diseases, such as mesothelioma, can have latency periods of several decades, this is a difficult burden to satisfy since memories fade and witnesses disappear or die.[81] The plaintiff may be able to satisfy this burden with his own testimony, but if he cannot do so, he may offer testimony from a coworker who has personal knowledge of the plaintiff's use of a particular manufacturer's asbestos-containing product or who used a particular manufacturer's asbestos-containing product in the same vicinity as the plaintiff.[82] It is not enough for the plaintiff to prove only that he worked at a place where asbestos-containing products were used; no presumption of exposure arises under those circumstances.[83] Instead, proof of exposure to a particular manufacturer's asbestos-containing product is required

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76. O.C.G.A. § 51-1-11(b)(1) (Supp. 2010); Hoffman v. AC&S, Inc., 248 Ga. App. 608, 610, 548 S.E.2d 379, 382 (2001).

77. Blackston v. Shook & Fletcher Insulation Co., 764 F.2d 1480, 1486 (11th Cir. 1985).

78. *Id.* at 1485.

79. Talley v. City Tank Corp., 158 Ga. App. 130, 135, 279 S.E.2d 264, 269 (1981).

80. *Hoffman*, 248 Ga. App. at 611, 548 S.E.2d at 382 (internal quotation marks omitted).

81. *Blackston*, 764 F.2d at 1486 (noting that the requirement of proving exposure to a particular manufacturer's asbestos-containing product "sets a standard that is difficult to meet").

82. *Hoffman*, 248 Ga. App. at 611, 548 S.E.2d at 382-83.

83. *Blackston*, 764 F.2d at 1483-85.

because guesses or speculation that raise only a possibility of such exposure are insufficient to satisfy the plaintiff's burden.[84] Without this proof, manufacturers of asbestos-containing products would essentially be liable on a market-share or industrywide basis.[85] Georgia law, however, does not permit market-share or industrywide liability.[86]

The sufficiency of the plaintiff's proof under this standard was at issue in one case decided during the survey period. In *Adamson v. General Electric Co.*,[87] the plaintiff's father died from mesothelioma that he allegedly contracted while working as an electrician and an electrical crew supervisor for thirty-five years at no fewer than eighteen job sites.[88] The plaintiff alleged that his father was exposed to asbestos-containing products that were "mined, manufactured, processed, imported, converted, compounded, sold or distributed by . . . 119 named defendants."[89] Five of the defendants who manufactured asbestos-containing products—A.W. Chesterton Company, Garlock Sealing Technologies, LLC, CBS Corporation (as successor to Westinghouse Electric Corporation), General Electric Company, and Union Carbide Corporation—moved for summary judgment on the ground that the plaintiff lacked proof of his father's exposure to their products, and the trial court granted their motions.[90]

On appeal, the court of appeals reviewed the evidence relating to the five manufacturers and concluded that the plaintiff's evidence as to each was insufficient to satisfy his burden.[91] With respect to Chesterton, although the plaintiff presented evidence that Chesterton's asbestos-containing products were used at a job site where his father worked, he was unable to present any evidence that his father worked in proximity to those products or that those products were used at the time his father worked there.[92] The same fate befell the plaintiff's claim against Garlock: the plaintiff presented evidence that Garlock's asbestos-containing products were used at the same job site where Chesterton's asbestos-containing products were used, but he had no evidence that his

84. *Hoffman*, 248 Ga. App. at 612, 548 S.E.2d at 383.

85. *Blackston*, 764 F.2d at 1483.

86. O.C.G.A. § 51-1-11(d); Starling v. Seaboard Coast Line R.R. Co., 533 F. Supp. 183, 186 (S.D. Ga. 1982) (holding "that recognition of market share or industrywide liability would result in an unprecedented departure from traditional Georgia tort law").

87. 303 Ga. App. 741, 694 S.E.2d 363 (2010).

88. *Id.* at 741, 694 S.E.2d at 365.

89. *Id.* (internal quotation marks omitted).

90. *Id.* at 741-42, 694 S.E.2d at 365-66.

91. *Id.* at 744-48, 694 S.E.2d at 367-70.

92. *Id.* at 745-46, 694 S.E.2d at 368.

father used Garlock's asbestos-containing products or that they were used in proximity to his father.[93] With respect to CBS and General Electric, the plaintiff presented evidence that his father worked with products that may have contained asbestos, but the evidence also showed that those same products were made without asbestos.[94] The plaintiff did not present any evidence as to when and where the asbestos-containing products were used, so the evidence did not justify an inference that the plaintiff's father used those products; it was just as probable that he used only the products that did not contain asbestos.[95] With respect to Union Carbide, the plaintiff presented evidence that his father worked with a product named "Bakelite," but the evidence also showed that his father used that term to describe other similar products manufactured by different companies, did not know whether the product contained asbestos, did not know who manufactured it, and was unable to identify any product manufactured by Union Carbide.[96] Thus, the plaintiff's evidence was insufficient to show that his father worked with or in proximity to Union Carbide's asbestos-containing products.[97]

B. Necessity of Expert Testimony

Under Georgia law, a plaintiff must come forward with reliable expert testimony to prove causation in most product liability cases.[98] The expert must "state an opinion regarding proximate causation in terms stronger than that of medical possibility, i.e., reasonable medical probability or reasonable medical certainty."[99] To show that exposure to a product was the cause of a plaintiff's injuries, the plaintiff must prove general causation—that the product can cause injury—and specific causation—that the specific product at issue caused the plaintiff's injuries.[100]

In *Silverstein v. Proctor & Gamble Manufacturing Co.*,[101] the plaintiff brought suit against a mouthwash manufacturer because the mouthwash allegedly stained teeth and reduced taste sensations.[102] In response to a summary judgment motion, the plaintiff came forward with testimony from a periodontology professor who discussed his past

93. *Id.* at 746, 694 S.E.2d at 368-69.
94. *Id.* at 747, 694 S.E.2d at 369.
95. *Id.*
96. *Id.* at 748, 694 S.E.2d at 370.
97. *Id.*
98. Rodrigues v. Ga.-Pac. Corp., 290 Ga. App. 442, 444, 661 S.E.2d 141, 143 (2008).
99. Ambling Mgmt. Co. v. Purdy, 283 Ga. App. 21, 29, 640 S.E.2d 620, 627 (2006).
100. Siharath v. Sandoz Pharm. Corp., 131 F. Supp. 2d 1347, 1352 (N.D. Ga. 2001).
101. 700 F. Supp. 2d 1312 (2009).
102. *Id.* at 1315.

studies, which concluded that a chemical in the mouthwash would cause tooth staining and taste impairment in a certain percentage of consumers.[103] With this evidence, the district court concluded that the plaintiff had sufficient evidence of general causation.[104] To prove specific causation, the plaintiff relied on an affidavit from his dentist who testified that because the plaintiff developed the staining immediately after using the mouthwash and the staining subsided after the plaintiff stopped using the mouthwash, the mouthwash was the likely cause of the plaintiff's stained teeth.[105]

The defendant first attacked the affidavit by highlighting the plaintiff's testimony that he did not know whether his teeth were stained before he began using the mouthwash; the defendant contended that the plaintiff had provided insufficient evidence from which the dentist could conclude that the mouthwash caused the plaintiff's stained teeth.[106] But the district court concluded that because the affiant was the plaintiff's own dentist and had cared for the plaintiff for years, if the staining had been present before the plaintiff used the mouthwash, this dentist would have been aware of the pre-use staining.[107]

Next, the defendant argued that the dentist's conclusion was based solely on the chronology of events and thereby used the forbidden methodology of *post hoc ergo propter hoc*.[108] The district court disagreed again.[109] The district court reasoned that with the dentist's historical knowledge of treating the plaintiff's teeth and review of literature on the active chemical in the mouthwash, the dentist had more evidence to reach his causation opinion than just the timing of the stained teeth in relationship to the use of the mouthwash.[110]

The defendant's final substantive argument was that the dentist's opinion should be disregarded because he did not use a differential diagnosis methodology in reaching his specific causation opinion.[111] The district court disagreed and emphasized that differential diagnosis is not the only way to prove causation.[112] The court offered little additional justification for why differential diagnosis was not required here but concluded that with this affidavit, the plaintiff had provided

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103. *Id.* at 1317.
104. *Id.* at 1318.
105. *Id.*
106. *Id.*
107. *Id.*
108. *Id.*
109. *Id.* at 1319.
110. *Id.*
111. *Id.*
112. *Id.*

sufficient evidence of specific causation to survive summary judgment.[113]

III. EVIDENTIARY ISSUES

A. *Expert Testimony*

In February 2005, Georgia adopted the *Daubert*[114] standard for assessing the admissibility of testimony from expert witnesses in civil actions.[115] While the Georgia appellate courts have provided guidance regarding the application of the *Daubert* standard in other types of lawsuits, there have been few *Daubert* opinions from the Georgia appellate courts in product liability cases.[116] Without state appellate court guidance, practitioners and judges must rely on decisions from the federal courts as persuasive authority.[117] The following cases from federal courts within the Eleventh Circuit offer recent guidance on *Daubert* issues in product liability cases.

In *Walker v. Blitz USA, Inc.*,[118] the plaintiff brought a strict liability and negligence action against the manufacturer of a plastic gas can contending that the can was defective because it did not contain a "flame arrester," a metal device in the spout of the container that would prevent flames from entering the can through the spout, a condition known as a "flashback."[119] The plaintiff retained Andrew Armstrong, Ph.D., to determine the conditions required to produce an explosive environment in a plastic container and whether a flame arrester would mitigate any volatile propensity of the container. In addition, the plaintiff retained Jason Mardirosian to determine the source of the "boom" noise in the fire at issue in the lawsuit to determine whether the ignition of gasoline

113. *Id.* at 1318-19.

114. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

115. Ga. S. Bill 3, § 7, Reg. Sess., 2005 Ga. Laws 1, 8-10 (codified at O.C.G.A. §§ 24-9-67 to -67.1 (2010)).

116. *See, e.g.*, Condra v. Atlanta Orthopaedic Group, P.C., 285 Ga. 667, 681 S.E.2d 152 (2009) (medical malpractice); Mays v. Ellis, 283 Ga. App. 195, 641 S.E.2d 201 (2007) (medical malpractice); Cotten v. Phillips, 280 Ga. App. 280, 633 S.E.2d 655 (2006) (medical malpractice).

117. To interpret the application of Georgia's *Daubert* statute, courts may seek guidance from the decisions of the Supreme Court of the United States in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), and other federal court interpretations of these decisions. O.C.G.A. § 24-9-67.1(f).

118. 663 F. Supp. 2d 1344 (N.D. Ga. 2009).

119. *Id.* at 1347.

vapor or the later explosion most likely caused the death of the plaintiff's daughter.[120]

Dr. Armstrong, a chemist, conducted numerous tests of the type of plastic container at issue and was able to create flashbacks within the container but was unable to recreate a situation in which the container ruptured.[121] In assessing the defendant's challenge under Federal Rule of Evidence 702,[122] the district court found that Dr. Armstrong's testing did not fit the underlying facts.[123] Given the plaintiff's allegation that a flashback caused the container to explode, Dr. Armstrong's testing needed to show a flashback that resulted in an explosion.[124] Because he did not replicate the conditions on the day of the fire at issue, Dr. Armstrong's methodology did not fit the facts of the case and thus was inadmissible under the *Daubert* standard.[125]

The methodology of Mardirosian suffered from similar infirmities. The district court found that Mardirosian failed to adequately consider other potential sources of the explosion at issue.[126] Although he reviewed depositions from the plaintiff and other scene witnesses, Mardirosian did not have sufficient information regarding the possible items at the scene that may have exploded because these witnesses did not testify about those items.[127] Without this testimony, Mardirosian was unable to know what items he should have considered as part of his analysis.[128] With this flaw in Mardirosian's methodology, the district court held that his testimony regarding the cause of the explosion was inadmissible.[129]

In *Sands v. Kawasaki Motors Corp. U.S.A.*,[130] the defendants challenged the admissibility of testimony from the plaintiff's expert witness, Michael Burleson, whom the plaintiff retained to provide evidence of alternative designs for a personal watercraft (PWC)[131] that injured the plaintiff when she fell off it.[132] Specifically, the defendants argued that Burleson's opinion was unreliable because there had been no testing of his alternative designs. In addition, the defendants

120. *Id.* at 1353-54.
121. *Id.* at 1354.
122. FED. R. EVID. 702.
123. *Walker*, 663 F. Supp. 2d at 1353, 1356.
124. *Id.* at 1356.
125. *Id.* at 1355-56.
126. *Id.* at 1357.
127. *Id.*
128. *Id.*
129. *Id.* at 1361.
130. No. CV608-009, 2009 WL 3152859 (S.D. Ga. Sept. 30, 2009).
131. *Id.* at *3.
132. *Id.* at *1.

questioned whether Burleson had sufficient peer-reviewed literature and publications supporting his opinions.[133]

After reviewing Burleson's expert report and testimony, the district court concluded that Burleson had shown sufficient testing of seatbacks on other PWCs to show that his methodology was reliable.[134] The absence of peer-reviewed literature and publications was not a dispositive factor here because the defendants failed to show how the absence of these documents indicated that Burleson's methodology was unreliable.[135] Because the plaintiff was able to come forward with evidence of Burleson's testing, the district court found that Burleson's methodology was reliable and denied the defendants' motion.[136]

In *Guinn v. AstraZeneca Pharmaceuticals LP*,[137] the plaintiff contended that her use of Seroquel caused her to develop diabetes and retained Dr. Jennifer Marks to provide specific causation testimony.[138] In ruling on the defendants' Rule 702 motion challenging the admissibility of Dr. Marks' testimony, the district court concluded that Dr. Marks did not undertake a reliable methodology to show that Seroquel caused the plaintiff's weight gain and diabetes. The district court excluded her testimony.[139]

On appeal, the Eleventh Circuit affirmed the exclusion of Dr. Marks' testimony, holding that she undertook an unreliable methodology to reach her conclusions.[140] First, the court concluded that Dr. Marks did not properly perform a differential diagnosis because she did not consider other alternative causes for the plaintiff's weight gain and diabetes.[141] Instead, Dr. Marks explained that other risk factors were present before the plaintiff took Seroquel and the plaintiff did not develop diabetes until after she took Seroquel.[142] The court explained that "[t]emporal proximity is generally not a reliable indicator of a causal relationship."[143] Dr. Marks' own testimony indicated that diabetes develops over the course of many years, and the diagnosis is typically made after the patient has actually had diabetes for up to five

133. *Id.* at *3.
134. *Id.*
135. *Id.* at *4.
136. *Id.* at *3-4.
137. 602 F.3d 1245 (11th Cir. 2010) (per curiam).
138. *Id.* at 1248.
139. *Id.* at 1251-52.
140. *Id.* at 1254-55, 1257.
141. *Id.* at 1254.
142. *Id.*
143. *Id.*

years.[144] Finally, the court concluded that Dr. Marks' conclusion did not fit the facts of the case because she made no effort to explain how the plaintiff's other risk factors could have contributed to the plaintiff's development of diabetes.[145]

B. Other Similar Incidents

Given the persuasive power of evidence of allegedly similar incidents, the admission of other incident evidence is a common battleground in product liability trials. To balance the prejudicial impact of this evidence with the probative value of truly similar events, the Georgia Supreme Court has required that other acts or omissions must be substantially similar to the defect alleged, adopting the following stringent standard for admissibility:

> In products liability cases, the "rule of substantial similarity" prohibits the admission into evidence of other transactions, occurrences, or claims unless the proponent first shows that there is a "substantial similarity" between the other transactions, occurrences, or claims and the claim at issue in the litigation. The showing of substantial similarity must include a showing of similarity as to causation. Before admitting proffered evidence of other transactions in products liability cases, the trial court must satisfy itself that the rule of substantial similarity has been met.[146]

The Georgia Court of Appeals applied this standard in *Ford Motor Co. v. Reese*,[147] an automotive product liability lawsuit arising from an allegedly defective seatback.[148] At trial, the plaintiffs introduced evidence of other complaints against Ford that alleged defects in seatbacks. On appeal, Ford contended that the plaintiffs had failed to show the requisite substantial similarity between these other complaints and this lawsuit.[149] But the court of appeals disagreed.[150] During discovery, Ford had admitted that the other incidents at issue involved similar seat designs in similar accident scenarios that resulted in similar seatback failures.[151] Given this evidentiary basis, the court of appeals

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144. *Id.* at 1257.
145. *Id.*
146. Cooper Tire & Rubber Co. v. Crosby, 273 Ga. 454, 455, 543 S.E.2d 21, 23-24 (2001) (footnotes omitted).
147. 300 Ga. App. 82, 684 S.E.2d 279 (2009).
148. *Id.* at 82, 684 S.E.2d at 282.
149. *Id.* at 89, 684 S.E.2d at 286.
150. *Id.*
151. *Id.* at 90, 684 S.E.2d at 287.

held that the trial court had not abused its discretion in allowing the admission of the other incidents.[152]

C. *Seat Belt Use*

Georgia courts and federal courts applying Georgia law have consistently held that the plain language of Georgia's seat belt statute prohibits the jury from considering evidence of an occupant's failure to use a seat belt.[153] The plain language of the relevant statute states,

> The failure of an occupant of a motor vehicle to wear a seat safety belt in any seat of a motor vehicle which has a seat safety belt or belts shall not be considered evidence of negligence or causation, shall not otherwise be considered by the finder of fact on any question of liability of any person . . . and shall not be evidence used to diminish any recovery for damages arising out of the ownership, maintenance, occupancy, or operation of a motor vehicle.[154]

The decision in *Denton v. DaimlerChrysler Corp.*[155] highlights the harsh consequences of this evidentiary prohibition. In that case, the district court allowed the defendant to present evidence of seat belt nonuse because the plaintiff introduced evidence of seat belt use by the plaintiff's decedent.[156] But at the conclusion of the trial, the district court charged the jury that evidence regarding seat belt use or nonuse could not be considered regarding liability or damages.[157]

In assessing the defendant's motion for a new trial, the district court clarified that by allowing the jury to receive seat belt use or nonuse evidence, the court did not implicitly authorize the jury to use this evidence during their deliberations.[158] To the contrary, the charge that was given prohibited the consideration of either type of evidence.[159] In response to the defendant's contention that the seat belt evidence pertained to the overall design of the restraint system and not the prohibited uses of showing negligence or causation, the court noted that the defendant failed to request a charge that would instruct the jury on

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152. *Id.*

153. C.W. Matthews Contracting Co. v. Gover, 263 Ga. 108, 428 S.E.2d 796 (1993); Crosby v. Cooper Tire & Rubber Co., 240 Ga. App. 857, 863-64, 524 S.E.2d 313, 320-21 (1999), *rev'd on other grounds*, Cooper Tire & Rubber Co. v. Crosby, 273 Ga. 454, 543 S.E.2d 21 (2001).

154. O.C.G.A. § 40-8-76.1(d) (Supp. 2010).

155. 645 F. Supp. 2d 1215 (N.D. Ga. 2009).

156. *Id.* at 1222.

157. *Id.*

158. *Id.*

159. *Id.*

this other use of seat belt evidence.[160] Because the defendant failed to request this jury instruction, the district court held that the defendant waived any objection.[161]

In sum, the district court allowed the jury to hear evidence of both seat belt use and nonuse and then instructed the jury not to consider either type of evidence.[162] With this ultimate result, it is unclear why the court ever allowed the evidence to be introduced when it was first offered.

IV. DEFENSES

A. *Preemption*

The Supremacy Clause of the United States Constitution provides that federal law is "the supreme Law of the Land[,] . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[163] Thus, state laws that conflict with federal law are "without effect."[164] A state law conflicts with a federal law "if it interferes with the methods by which the federal statute was designed to reach [its] goal," even if both the federal law and the state law have the same goal.[165] Although preemption issues are typically analyzed in connection with a federal statute, a federal regulation may have the same preemptive effect as a federal statute.[166] State laws subject to preemption include not only state statutes and regulations but also tort duties imposed by state common law and enforced by lawsuits.[167]

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160. *Id.*

161. *Id.* In addressing the procedural miscue of the defendant in failing to request the charge, the district court did not indicate—or even mildly forecast—whether it would have instructed the jury to consider the seat belt evidence as it related to the overall design of the restraint system if the charge had been properly requested. *Id.*

162. *Id.*

163. U.S. CONST. art. VI, cl. 2.

164. Maryland v. Louisiana, 451 U.S. 725, 746 (1981).

165. Int'l Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987).

166. La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 369 (1986) (holding that "a federal agency acting within the scope of its congressionally delegated authority may [also] preempt state regulation"); Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 154 (1982) (noting that a "narrow focus on Congress' intent to supersede state law [is] misdirected" when a state law is claimed to be preempted by a federal agency's regulation).

167. CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993); Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 521-22 (1992); *see also* San Diego Bldg. Trades Council, Millmen's Union, Local 2020 v. Garmon, 359 U.S. 236, 247 (1959) ("The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.").

"The critical question in any pre-emption analysis is always whether Congress intended that federal regulation supersede state law."[168] In fact, Congress's purpose in enacting the federal law is the "ultimate touchstone" of the preemption analysis.[169] Congress may manifest its intent to preempt state law in three ways:

> First, Congress can define explicitly the extent to which its enactments pre-empt state law. Pre-emption fundamentally is a question of congressional intent, and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one.
>
> Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. Such an intent may be inferred from a scheme of federal regulation so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, or where an Act of Congress touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.
>
> Finally, state law is pre-empted to the extent that it actually conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.[170]

Although Congress's purpose is important, there is a presumption that Congress did not intend to preempt state law, especially when it "has legislated . . . in a field which the States have traditionally occupied."[171] Because "the regulation of health and safety matters is primarily, and historically, a matter of local concern,"[172] state law regulating these matters is preempted only if Congress's intent to do so is "clear and manifest."[173] Thus, when faced with two or more plausible interpretations of a federal law, this presumption imposes on courts "a duty to accept the reading that disfavors pre-emption."[174]

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168. *La. Pub. Serv. Comm'n*, 476 U.S. at 369.

169. Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963).

170. English v. Gen. Electric Co., 496 U.S. 72, 78-79 (1990) (citations, punctuation, and internal quotation marks omitted).

171. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (internal quotation marks omitted).

172. Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 719 (1985); *see also* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) ("So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.").

173. *Hillsborough Cnty.*, 471 U.S. at 715 (internal quotation marks omitted).

174. Bates v. Dow AgroSciences LLC, 544 U.S. 431, 449 (2005).

1. Military Contractor Defense. Generally, state law is not preempted unless there is a clear federal statutory or regulatory prescription or a direct conflict between federal and state law, but there are "a few areas, involving uniquely federal interests, [that] are so committed by the Constitution and laws of the United States to federal control that state law is pre-empted and replaced, where necessary, by federal law of a content prescribed (absent explicit statutory directive) by the courts."[175] The procurement of military equipment by the United States is one such area of unique federal interest, so when there is a significant conflict between a state-law duty of care and the contractor's duty under its contract with the government, the state-law duty of care must yield.[176] This type of preemption[177] is referred to as the military contractor defense, and it precludes state-law liability for design defects in military equipment "when (1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States."[178] The rationale for this defense is that "[t]he imposition of liability on Government contractors will directly affect the terms of Government contracts: either the contractor will decline to manufacture the design specified by the Government, or it will raise its price. Either way, the interests of the United States will be directly affected."[179]

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175. Boyle v. United Techs. Corp., 487 U.S. 500, 504 (1988) (citation and internal quotation marks omitted).

176. *Id.* at 507-08.

177. This defense has also been characterized as a form of sovereign immunity. Gray v. Lockheed Aeronautical Sys. Co., 125 F.3d 1371, 1377 (11th Cir. 1997) (quoting Harduvel v. Gen. Dynamics Corp., 878 F.2d 1311, 1316 (11th Cir. 1989)) ("This 'defense derives from the principle that where a contractor acts under the authority and direction of the United States, it shares the sovereign immunity' that the government enjoys."), *rev'd and remanded*, 524 U.S. 924 (1998), *judgment reinstated in part and vacated on other grounds in part*, 155 F.3d 1343 (11th Cir. 1998) (per curiam).

178. *Boyle*, 487 U.S. at 512. The Eleventh Circuit has described this defense in much simpler terms: "Stripped to its essentials, the military contractor defense is available only when the defendant demonstrates with respect to its design and manufacturing decisions that 'the government made me do it.'" *Gray*, 125 F.3d at 1377 (quoting *In re* Joint E. & S. Dist. N.Y. Asbestos Litig., 897 F.2d 626, 632 (2d Cir. 1990)).

179. *Boyle*, 487 U.S. at 507. The Supreme Court also noted that "[t]he financial burden of judgments against the contractors would ultimately be passed through, substantially if not totally, to the United States itself, since defense contractors will predictably raise their prices to cover, or to insure against, contingent liability for the Government-ordered designs." *Id.* at 511-12.

The military contractor defense was involved in one case decided by the Eleventh Circuit during the survey period. In *Brinson v. Raytheon Co.*,[180] the plaintiff sued the manufacturer of the T-6A Texan II airplane that her husband, a captain in the United States Air Force Reserves, was copiloting when it crashed near Savannah.[181] The airplane was a single-propeller model that incorporated a trim aid device to compensate for the P Factor, which "is a natural aerodynamic property of single propeller-driven planes [that] causes the air[plane] to yaw and roll to the left."[182] Normally, the pilot of a single-propeller airplane has to adjust the airplane's rudder manually to compensate for the P Factor, but the trim aid device incorporated into the T-6A airplane was designed to adjust the rudder automatically through a series of bell cranks and pushrods.[183]

The plaintiff contended that the T-6A airplane was defectively designed in two ways. First, the trim aid device was designed such that the entire system would fail if one component failed, and the plaintiff argued that the manufacturer should have included redundancies to prevent a complete system failure in the event of a single point failure. Second, the pushrods were lined with Teflon to make them self-lubricating and easier to maintain, and the plaintiff argued that they were more likely to fracture and fail because of how Teflon reacts to humidity. According to the plaintiff, these two design defects caused the crash because one of the pushrods fractured during takeoff, when the P Factor is most pronounced, which then caused the entire trim aid device system to fail. Without the trim aid device to compensate for the P Factor, the airplane went into a severe, uncommanded left roll and crashed. The manufacturer of the airplane filed a motion for summary judgment based on the military contractor defense, and the district court granted the motion.[184]

On appeal, the plaintiff argued only that the manufacturer did not present sufficient evidence to satisfy the first and second prongs of the military contractor defense; she did not challenge the manufacturer's evidence on the third prong.[185] The first prong—government approval of reasonably precise specifications—"is meant to ensure that a government officer considered and approved 'the design feature in

180. 571 F.3d 1348 (11th Cir. 2009).
181. *Id.* at 1349.
182. *Id.*
183. *Id.*
184. *Id.* at 1350.
185. *Id.* at 1351.

question.'"[186] Although government officials were not involved in the initial design and patent of the T-6A airplane, Air Force engineers were heavily involved in the development of the airplane, and they reviewed and approved the design drawings for all systems, including the trim aid device.[187] Moreover, in January 2004, three months before the crash, the Air Force issued a Technical Compliance/Technical Order (TCTO), which acknowledged that some of the pushrods were defective and required that the pushrods be replaced with new, but identically designed, pushrods.[188] The Eleventh Circuit decided as a matter of first impression that post-design, post-production evidence such as the TCTO could be used to satisfy the first prong.[189] Based on the "ample undisputed evidence of a 'continuous back and forth' between [the manufacturer] and governmental representatives during the development of the T-6A," combined with the TCTO, the court held that the manufacturer satisfied its burden of showing meaningful government review and approval of reasonably precise specifications concerning the trim aid device.[190]

The second prong—the equipment's conformity to the specifications—was much easier for the court to resolve in the manufacturer's favor.[191] According to the court, the manufacturer's evidence showed that (1) the Air Force engineers reviewed the design drawings to ensure that the T-6A airplane was built according to the design specifications; (2) a government representative signed a Material Inspection and Receiving Report for the airplane that the plaintiff's husband was copiloting when the crash occurred, which stated that the airplane was accepted and that it conformed to the contract; and (3) there was a continuous exchange between the manufacturer and the government, which not only supported the first prong but also was indicative of conformity.[192] The plaintiff attempted to refute this evidence by arguing that the trim aid device did not comply with the Airworthiness Standards for Acrobatic Category Airplanes, but the court rejected this argument because compliance with these regulations had nothing to do

186. *Id.* (quoting *Boyle*, 487 U.S. at 512).

187. *Id.* at 1350, 1354-55.

188. *Id.* at 1350, 1355.

189. *Id.* at 1352. The court refused to question the wisdom of the Air Force's decision on how to address the defect that it acknowledged in the TCTO: "When faced with a potentially failing or defective part, the military may make a discretionary decision concerning how to address the problem. We do not want to 'second-guess' that judgment through a state law tort suit." *Id.* at 1353.

190. *Id.* at 1355-56.

191. *Id.* at 1357-58.

192. *Id.* at 1357.

with whether the T-6A airplane conformed to the government-approved specifications.[193] As the court explained, "[the plaintiff] points to no facts suggesting that the [trim aid device] or any other component of the rudder trim system was not built exactly as it was designed."[194] Essentially, the plaintiff's argument was that the T-6A airplane did not conform to its design specifications because the trim aid device system failed, but the court noted that nonconformity "must mean more than that the design does not work in compliance with some general admonition against an unwanted condition."[195] Thus, the plaintiff's argument would have eviscerated the military contractor defense because "[a] product involved in a design-induced accident would, as a definitional matter, always be deemed not to comply with such generalities since no performance specifications approved by the government would purposely allow a design that would result in an accident."[196] The court concluded that because the manufacturer had satisfied all the requirements of the military contractor defense, it was entitled to summary judgment.[197]

2. Federal Motor Vehicle Safety Standards. Pursuant to the National Traffic and Motor Vehicle Safety Act of 1966,[198] the National Highway Traffic Safety Administration has promulgated the Federal Motor Vehicle Safety Standards (FMVSS)[199] to further the Act's purpose of "reduc[ing] traffic accidents and deaths and injuries resulting from traffic accidents."[200] FMVSS 208 governs "performance requirements for the protection of vehicle occupants in crashes," and its purpose "is to reduce the number of deaths of vehicle occupants, and the severity of injuries, by specifying . . . equipment requirements for active and passive restraint systems."[201] The type of restraint system required depends on the type of vehicle and date of manufacture.[202] In *Geier v. American Honda Motor Co.*,[203] the Supreme Court of the United States held that when FMVSS 208 allows the manufacturer to choose a

193. *Id.* at 1358.
194. *Id.*
195. *Id.* at 1358 n.11 (internal quotation marks omitted).
196. *Id.* (internal quotation marks omitted).
197. *Id.* at 1358-59.
198. 15 U.S.C. §§ 1381-1431 (repealed 1994). Congress repealed the Act in 1994 and recodified it at 49 U.S.C. §§ 30101-30170 (2006).
199. 49 C.F.R. pt. 571 (2009).
200. 49 U.S.C. § 30101.
201. 49 C.F.R. § 571.208.S1-S2.
202. 49 C.F.R. § 571.208.S4.
203. 529 U.S. 861 (2000).

restraint system from among several options, and the manufacturer selects one of those options for a vehicle, a state-law tort claim premised on a duty to implement a different restraint system conflicts with and is preempted by FMVSS 208.[204] However, FMVSS 208 does not preempt a state-law tort claim based on an allegation that the design utilized by the manufacturer was defective.[205]

Prior to the survey period, few courts had considered whether FMVSS 208 preempts a state-law tort claim based on the absence of a side-impact airbag, but the Northern District of Georgia considered such a claim in *Ellison v. Ford Motor Co.*[206] This case involved a side-impact collision between the plaintiffs, who were in a 2004 F-250 truck, and Brandon Howard, who was in an F-450 truck. The restraint system in the plaintiffs' truck consisted of frontal impact airbags, knee bolsters, active lap/shoulder seatbelts with emergency locking retractor mechanisms, and other passive occupant protection devices, all of which were available for both front seating positions. The vehicle also utilized a collapsible steering column. In their complaint, the plaintiffs alleged that their truck was defectively designed because it did not include a side-impact airbag, and the manufacturer moved for summary judgment on the ground that FMVSS 208 preempted this claim.[207]

Preliminarily, the district court had to determine whether FMVSS 208 or FMVSS 214 governed the plaintiffs' claim.[208] The plaintiffs argued that the controlling standard was FMVSS 214, which "specifies performance requirements for protection of occupants in side impact crashes," and that this standard did not preempt their claim.[209] Importantly, however, the version of FMVSS 214 in effect at the time the plaintiffs' truck was manufactured did not provide requirements relating to airbags or other occupant restraint systems but instead specified crashworthiness requirements.[210] Because the plaintiffs challenged the type of restraint system chosen by the manufacturer and did not contend that their truck failed to satisfy FMVSS 214's side-impact crashworthiness requirements, the court concluded that FMVSS 208 governed their claim.[211] Moreover, the district court noted that

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204. *Id.* at 877-81.

205. Parks v. Hyundai Motor Am., Inc., 294 Ga. App. 112, 114, 668 S.E.2d 554, 557 (2008).

206. 650 F. Supp. 2d 1298 (N.D. Ga. 2009).

207. *Id.* at 1300-02.

208. *Id.* at 1302.

209. *Id.* (internal quotation marks omitted); *see also* 49 C.F.R. § 571.214.S1(a) (2009).

210. *Ellison*, 650 F. Supp. 2d at 1302-03.

211. *Id.* at 1303.

nothing in FMVSS 208 limited its applicability to front-impact collisions.[212]

The version of FMVSS 208 applicable to the plaintiffs' truck allowed the manufacturer to choose from among several alternatives for the truck's restraint system, and the frontal/angular automatic protection system chosen by the manufacturer complied with the requirements for that system.[213] None of the options allowed by FMVSS 208 at that time required side-impact airbags to be included, so the court found that the plaintiffs' claim "would require [the manufacturer] to adopt an additional crash protection system not specified in FMVSS 208, and essentially would foreclose the option specifically allowed by FMVSS 208–to include either manual Type 1 or Type 2 seat belts or to include passive restraints."[214] Because this additional requirement would conflict with FMVSS 208, the district court held that the plaintiffs' claim was preempted.[215]

The district court in *Ellison* found support for its decision in *Anthony v. Abbott*,[216] which involved a similar allegation about the manufacturer's failure to include a side-impact airbag in the plaintiffs' vehicle.[217] Relying entirely on *Geier* and the manufacturer's undisputed compliance with FMVSS 208, the District of the Virgin Islands held in *Anthony* that the manufacturer's alleged duty to install a side-impact airbag conflicted with FMVSS 208 and was therefore preempted.[218] After *Ellison*, however, the District of Hawaii held in *Durham v. County of Maui*[219] that FMVSS 208 did not preempt a claim alleging that a vehicle was defective because it did not have a side-impact airbag.[220] The court in *Durham* explained that the plaintiffs' claim did not conflict with the goal of reducing deaths and injuries caused by traffic accidents; to the contrary, allowing the plaintiffs' claim to proceed would "advance—not thwart—this statutory and regulatory purpose."[221] The court distinguished *Geier* on the ground that it involved multiple options from which the manufacturer could choose, including an option that allowed the

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212. *Id.* at 1302.
213. *Id.* at 1303-04.
214. *Id.* at 1305 & n.3.
215. *Id.* at 1305.
216. 289 F. Supp. 2d 667 (D.V.I. 2003).
217. *Ellison*, 650 F. Supp. 2d at 1305 (citing *Anthony*, 289 F. Supp. at 669). The district court also cited to an unpublished order from a California trial court holding that FMVSS 208 preempted a claim based on the absence of a side-impact airbag. *Id.* at 1306.
218. 289 F. Supp. 2d at 669-70 (citing *Geier*, 529 U.S. at 864-65).
219. 696 F. Supp. 2d 1150 (D. Haw. 2010).
220. *Id.* at 1161-62.
221. *Id.* at 1158.

manufacturer to forgo the feature that the plaintiff alleged should have been included, whereas FMVSS 208 did not provide the manufacturer in *Durham* with the option of excluding side-impact airbags.[222] Because FMVSS 208 did not include any requirements relating to side-impact airbags, the district court in *Durham* held that there could be no conflicting requirements between FMVSS 208 and a state-law duty to include side-impact airbags.[223] The district court in *Durham* acknowledged the contrary holdings in *Ellison* and *Anthony* but distinguished those cases on the ground that they involved different vehicles and therefore different requirements under FMVSS 208.[224] The requirements applicable to the vehicles in *Ellison* and *Anthony* provided the manufacturers with options, which meant that those cases were properly controlled by *Geier*.[225]

3. United States Food and Drug Administration Approval of Generic Drugs. In the wake of the Supreme Court's decision last year in *Wyeth v. Levine*,[226] which held that the FDA's approval of a brand-name drug does not preempt a state-law claim for failure to warn,[227] several courts faced preemption arguments with respect to the FDA's approval of generic drugs. This is an important issue because 70% of all prescriptions in the United States are filled with generic drugs.[228] At first glance, it seems that *Levine* would apply to brand-name and generic drugs, but the generic manufacturers have argued that the differences in the approval process and in the labeling requirements mandated a different result. Their arguments have not met with much success.

For example, in *Mensing v. Wyeth, Inc.*[229] the generic manufacturers argued that the plaintiff's state-law tort claims were preempted because (1) generic manufacturers do not have the same ability to change their labels as brand-name manufacturers,[230] and (2) the costs to generic manufacturers of proposing label changes to the FDA would thwart the goal of bringing low-cost generic drugs to market quickly.[231] The

222. *Id.* at 1159-61.
223. *Id.* at 1159.
224. *Id.* at 1161.
225. *Id.* at 1161-62.
226. 129 S. Ct. 1187 (2009).
227. *Id.* at 1196-204. For an in-depth discussion of the Supreme Court's decision in *Levine*, see Brannen & Daly, *supra* note 1, at 281-86.
228. Susan Okie, *Multinational Medicines—Ensuring Drug Quality in an Era of Global Manufacturing*, 361 NEW ENG. J. MED. 737, 738 (2009).
229. 588 F.3d 603 (8th Cir. 2009).
230. *Id.* at 608.
231. *Id.* at 611.

Eighth Circuit rejected these arguments and held that the plaintiff's state-law tort claims were not preempted.[232] First, although the label for a generic drug must be substantively identical to the label for its brand-name counterpart, the court held that this requirement does not render generic manufacturers impotent to affect label changes.[233] Generic manufacturers may propose label changes to the FDA, or they could suggest that the FDA send warning letters to physicians.[234] Whatever limitations they may face in comparison to the brand-name manufacturers, they may not "passively . . . accept the inadequacy of their drug's label as they market and profit from it."[235] The court explained,

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If [the plaintiff's] injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable.[236]

Second, the court was not persuaded that the cost of proposing label changes would be prohibitively expensive.[237] Although a requested label change must be supported by scientific validation, there is no requirement that a manufacturer obtain such scientific validation through its own clinical testing; it may rely on studies conducted by others.[238] Moreover, generic manufacturers are already required to collect and report adverse drug events to the FDA.[239] Thus, although Congress enacted a simplified process for getting generic drugs to market quickly and cheaply, it did not intend to relieve generic manufacturers from their obligation to ensure that their products are safe.[240] For all these reasons, the court held that state-law tort claims against generic manufacturers are not preempted.[241]

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232. *Id.* at 608-12.
233. *Id.* at 608-11.
234. *Id.* at 610.
235. *Id.* at 609.
236. *Id.* at 611.
237. *Id.* at 611-12.
238. *Id.*
239. *Id.* at 612.
240. *Id.*
241. *Id.*

The Fifth Circuit reached a similar result in *Demahy v. Actavis, Inc.*[242] earlier this year. In an attempt to distinguish the Supreme Court's decision in *Levine*, the generic manufacturer argued "that generic drugs are different because the manufacturer of a name brand drug may change its label unilaterally—through the 'changes being effected' (CBE) process—while seeking the FDA's approval of the change," whereas "a generic manufacturer . . . must produce the same drug and use the same label as the name brand drug manufacturer."[243] Because of this difference, the generic manufacturer argued that it could not comply with a state-law duty to modify its labeling without violating federal law.[244] The Fifth Circuit discounted this argument because "[t]he regulations on which [the generic manufacturer] relies . . . do not purport to bar generic label[] modifications following initial approval. Instead, they require only that a generic's label initially conform to the listed drug's [label] . . . . They do not address post-approval modifications at all."[245] In fact, "the regulatory framework makes plain that manufacturers–name brand and generic alike–must act to warn customers when they learn that they may be marketing an unsafe drug."[246] The court held that generic manufacturers may comply with this obligation by proposing label changes through the CBE process or the prior approval process, or by suggesting that the FDA communicate warnings to physicians through "Dear Doctor" letters.[247] The generic manufacturer also asserted the same argument about the cost of proposing label changes that the generic manufacturers asserted in *Mensing*, and the court rejected that argument for the same reason that the Eight Circuit rejected it.[248] Finally, the court offered a practical explanation for holding that state-law tort claims against generic manufacturers are not preempted: "To hold otherwise would leave us with the bizarre conclusion that Congress intended to implicitly deprive a plaintiff whose doctor prescribes a generic drug of *any* remedy, while under *Levine*, that same plaintiff would have a state-law claim had she only demanded a name brand drug instead."[249]

The Eleventh Circuit has not addressed this issue, but two district courts in Georgia did so during the survey period. In *Weilbrenner v.*

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242. 593 F.3d 428 (5th Cir. 2010).
243. *Id.* at 433.
244. *Id.* at 436.
245. *Id.*
246. *Id.* at 437.
247. *Id.* at 439-45.
248. *Id.* at 446-49; *see also Mensing*, 588 F.3d at 611-12.
249. *Demahy*, 593 F.3d at 449.

Teva Pharmaceuticals USA, Inc.,[250] which involved minocycline, a generic antibiotic used to treat bacterial infections such as acne,[251] the generic manufacturer asserted the same preemption arguments that the generic manufacturers in *Mensing* and *Demahy* asserted.[252] After extensively reviewing the opinions in *Mensing* and *Demahy* and noting that most district courts that have considered the issue since *Levine* have rejected the preemption defense, the court aligned itself with the Fifth and Eighth Circuits and held that the plaintiff's state-law tort claim was not preempted.[253] The court explained,

> Simply by proposing a label change or requesting that the FDA send out a "Dear Doctor" letter, generic manufacturers can comply with FDA rules and regulations and, at the same time, meet their state law duty to warn the public of any known risks. [The generic manufacturer's] argument that there is no assurance that a requested label change would have been granted by the FDA does not alter the Court's decision, as [what the FDA might have done once the manufacturer] suggested these changes is immaterial to the imposition of liability. There simply is no evidence in the record that suggests that the FDA would have rejected a labeling proposal from [the generic manufacturer]. Further, allowing state law failure-to-warn claims in no way obstructs the purposes of federal law. On the contrary, the purpose of all the FDA rules and regulations is to ensure that the public receives safe drugs. Allowing state law claims furthers consumer protection and safety.[254]

Twelve days later, the United States District Court for the Northern District of Georgia reached the same conclusion in *Swicegood v. Pliva, Inc.*,[255] a case involving metoclopramide, the generic form of Reglan used to treat gastroesophageal reflux disease.[256] Relying principally on *Mensing* and *Demahy*, the court rejected the same preemption arguments for the same reasons.[257]

B. Learned Intermediary Doctrine

As a general rule, a manufacturer owes a duty to foreseeable users of its product to warn about foreseeable dangers in the product.[258] The

250. 696 F. Supp. 2d 1329 (M.D. Ga. 2010).
251. *Id.* at 1331.
252. *Id.* at 1333-34.
253. *Id.* at 1334-38.
254. *Id.* at 1338 (citation and internal quotation marks omitted).
255. No. 1:07-CV-1671-TWT, 2010 WL 1138455 (N.D. Ga. Mar. 22, 2010).
256. *Id.* at *1.
257. *Id.* at *5-7.
258. Moore v. ECI Mgmt., 246 Ga. App. 601, 606, 542 S.E.2d 115, 120-21 (2000).

learned intermediary doctrine is an exception to this general rule that applies in the healthcare context to relieve manufacturers of prescription drugs and medical devices from liability for failure to warn.[259] The rationale for this doctrine stems from a respect for the doctor-patient relationship: "the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities."[260] Thus, under the learned intermediary doctrine, a manufacturer does not have a duty to warn the patient of the dangers associated with the drug or device.[261] Instead, the manufacturer has a duty to warn the patient's doctor, and it satisfies this duty by providing a reasonable or adequate warning under the circumstances of the case.[262] For a warning to be reasonable or adequate, "it must provide a complete disclosure of the existence and extent of the risk involved."[263] Whether a warning is reasonable or adequate is often a question of fact for the jury, but it can be decided by the court as a matter of law if the warning is accurate, clear, and unambiguous.[264]

During the survey period, two federal courts confronted the issue of whether the warning that accompanied a prescription drug reasonably or adequately informed the plaintiff's doctor about the risks associated with the drug. In the first case, *Swicegood v. Pliva, Inc.*,[265] Dr. Michael Reese prescribed metoclopramide, the generic form of Reglan that had been approved by the FDA, to treat the plaintiff's dyspepsia and gastroesophageal reflux disease. Alleging that she developed tardive dyskinesia, a neurological disorder that causes involuntary muscle

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259. Hawkins v. Richardson-Merrell, Inc., 147 Ga. App. 481, 482-83, 249 S.E.2d 286, 287-88 (1978) (en banc); Parke, Davis & Co. v. Mayes, 124 Ga. App. 224, 224, 183 S.E.2d 410, 410 (1971); Webb v. Sandoz Chem. Works, Inc., 85 Ga. App. 405, 409-10, 69 S.E.2d 689, 692-93 (1952).

260. McCombs v. Synthes (U.S.A.), 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003) (alteration in original) (internal quotation marks omitted).

261. *Id.*

262. *Id.*

263. Thornton v. E.I. Du Pont De Nemours & Co., 22 F.3d 284, 289 (11th Cir. 1994) (internal quotation marks omitted).

264. *Compare* McCombs v. Synthes (U.S.A.), 266 Ga. App. 304, 304, 596 S.E.2d 780, 780 (2004) (en banc) (holding that the warning included with the package insert was reasonable and adequate as a matter of law), *with* Bryant v. Hoffmann-La Roche, Inc., 262 Ga. App. 401, 410, 585 S.E.2d 723, 730 (2003) (physical precedent) (holding that factual disputes regarding the adequacy or reasonableness of the warning precluded summary judgment).

265. No. 1:07-CV-1671-TWT, 2010 WL 1138455 (N.D. Ga. Mar. 22, 2010).

contractions, the plaintiff sued Pliva, the manufacturer of metoclopramide, and Barr Pharmaceuticals, the manufacturer of Reglan, for strict liability, negligence, and breach of warranty.[266] Pliva moved for summary judgment on the plaintiff's claim for failure to warn, arguing that it adequately warned Dr. Reese about the risks of metoclopramide because its label warned doctors that metoclopramide could cause tardive dyskinesia, and Dr. Reese testified that he was aware of this risk.[267] However, based on Dr. Reese's other testimony, the district court held that "a reasonable juror could infer[] that Dr. Reese did not know the extent of the risk involved."[268] Accordingly, the court denied Pliva's motion on this claim.[269]

In the second case, *Weilbrenner v. Teva Pharmaceuticals USA, Inc.*,[270] the plaintiff, a fifteen-year-old girl, contracted optic disc edema, papilledema, and pseudotumor cerebri after ingesting fifty-four capsules of minocycline over a period of about four months. Minocycline is an antibiotic that the FDA has approved for the treatment of bacterial infections, including acne. At the time the plaintiff's primary care physician, Dr. Robert Hawes, prescribed minocycline to treat her acne, the package insert warned about an association between the use of tetracyclines and pseudotumor cerebri in adults, and it indicated that the usual symptoms were headache and blurred vision. The package insert went on to say that these conditions and symptoms usually resolved after discontinuation of the tetracycline, but it also acknowledged the possibility of permanent sequelae. Dr. Hawes did not review the package insert at that time, but he thought that he reviewed information about minocycline at some point before then, though he could not remember exactly when or where. The plaintiff alleged that her injuries were caused by minocycline, that the label was defective, and that the manufacturer did not adequately communicate to physicians the risk of pseudotumor cerebri and permanent vision loss in adolescents from using minocycline.[271]

The manufacturer moved for summary judgment on the ground that the learned intermediary doctrine barred the plaintiff's failure-to-warn claim because the warnings on the package insert were adequate as a matter of law. The plaintiff's expert testified that the label was inadequate and defective because (1) the warning as to pseudotumor

266. *Id.* at *1.
267. *Id.* at *3.
268. *Id.*
269. *Id.*
270. 696 F. Supp. 2d 1329 (M.D. Ga. 2010).
271. *Id.* at 1331-32.

cerebri was not specific as to minocycline, (2) it did not warn about a risk of pseudotumor cerebri or permanent vision loss in adolescents, and (3) it did not instruct users to be checked regularly for papilledema while using minocycline.[272] Noting that the adequacy of a warning is usually a question of fact but that it can be decided as a matter of law if the warning is clear, accurate, and unambiguous, the district court rejected the manufacturer's argument and held that the plaintiff's evidence created a question of fact regarding the adequacy of minocycline's label for a jury to decide.[273] The court first explained that "[t]he fact that the package insert mentioned [pseudotumor cerebri] does not make the warning adequate as a matter of law."[274] Instead, the question is whether a label reasonably informs physicians about the risks of the drug.[275] The court found that there was conflicting evidence on this point because the warning about pseudotumor cerebri was directed only to adults and not to pediatric patients, a group that includes adolescents such as the plaintiff.[276] Because "the FDA requires warning information for pediatric patients separate and apart from that provided for adult patients," the court declined to hold that "Dr. Hawes could, would, or should have assumed that the minocycline [pseudotumor cerebri] warning for adults also applied to adolescents or other pediatric subgroups."[277] In addition, the court questioned the reasonableness of minocycline's label because it referred only to risks associated with the use of tetracyclines.[278] Although minocycline is a type of tetracycline, the manufacturer's own expert testified that a warning related to one does not necessarily apply to the other.[279] For all of these reasons, the district court denied the manufacturer's motion on the ground that there was a factual dispute regarding the adequacy of minocycline's label.[280]

The district court then turned to the issue of proximate cause.[281] "Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided," the manufacturer usually will be entitled to summary judgment on the ground that the causal link between the allegedly

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272. *Id.* at 1339.
273. *Id.* at 1339-40.
274. *Id.* at 1339.
275. *Id.*
276. *Id.* at 1339-40.
277. *Id.* at 1340.
278. *Id.*
279. *Id.*
280. *Id.*
281. *Id.* at 1340-41.

inadequate warning and the plaintiff's injury is broken.[282] The manufacturer argued that the plaintiff could not prove proximate cause because Dr. Hawes did not read the label, and there was no evidence that he would have decided not to prescribe minocycline even if he had read the label and if the label had included additional warnings.[283] However, while it was true that Dr. Hawes did not read the label at the time he prescribed minocycline for the plaintiff,[284] his deposition testimony gave rise to a reasonable inference that he reviewed the prescribing information for minocycline sometime in the past.[285] Further, Dr. Hawes testified by affidavit after his deposition that he most likely would not have prescribed minocycline for the plaintiff if he had known about a risk of pseudotumor cerebri or permanent vision loss in adolescents, that he would have instructed the plaintiff to discontinue the drug and to come to his office if she had any headaches or visual disturbances, and that he would have had the plaintiff checked regularly for papilledema while using the drug.[286] The fact that Dr. Hawes gave arguably contradictory testimony in his deposition was a matter for cross-examination at trial, not a reason to grant summary judgment.[287]

The issue of proximate cause in the context of the learned intermediary doctrine also arose in one case decided by the Eleventh Circuit during the survey period. In *Dietz v. SmithKline Beecham Corp.*,[288] the plaintiff's husband went to his family practitioner, Dr. James Zuppa, complaining of anxiety, depression, insomnia, and stress, but he disclaimed any suicidal ideation and did not disclose any history of psychological illness. Dr. Zuppa diagnosed the plaintiff's husband with major depression and offered to hospitalize him for psychiatric treatment, but he declined. Dr. Zuppa then prescribed Paxil, an antidepressant drug, for the plaintiff's husband, instructed him to come back in three weeks or sooner if he experienced an acute crisis, and referred him to a psychologist. Eight days later, the plaintiff's husband committed suicide. The plaintiff sued the manufacturer for, among other things, failure to warn about the risk of suicide associated with Paxil.[289] The district court granted summary judgment for the manufacturer, and the Eleventh Circuit affirmed on the ground that the plaintiff could not

282. Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1363 (N.D. Ga. 1999).
283. *Weilbrenner*, 696 F. Supp. 2d at 1341.
284. *Id.* at 1332.
285. *Id.* at 1342-43.
286. *Id.* at 1341.
287. *Id.* at 1341-42.
288. 598 F.3d 812 (11th Cir. 2010).
289. *Id.* at 814.

prove that the allegedly inadequate warnings proximately caused her husband's suicide.[290] Because Dr. Zuppa testified that "even when provided with the most current research and FDA mandated warnings, he still would have prescribed Paxil for [the plaintiff's husband's] depression," the court held that "any potential chain of causation through which [the plaintiff] could seek relief" was severed.[291]

C. *Product Misuse or Alteration*

A manufacturer may be subject to strict liability for injuries proximately caused by a defect in its product only if the defect was present when the product was sold.[292] Indeed, "[o]ne of the conditions for imposition of strict liability against a manufacturer of defective products is that the product is expected to and does reach the user or consumer without substantial change in the condition in which it is sold."[293] Thus, it is a fundamental principle of Georgia product liability law that "[a] manufacturer has the absolute right to have his strict liability for injuries adjudged on the basis of the design of his own marketed product and not that of someone else."[294] After all, fairness dictates that "if the design of [the] product has been independently altered, eliminated and replaced by a third party after the sale and injuries then result, those injuries cannot be traced to or be the proximate result of the manufacturer's original design which did not exist at the time of injury."[295] In other words, if the manufacturer's original design has been sufficiently altered, "the thing being used was not the thing sold."[296]

In light of these principles, a plaintiff's misuse or alteration of the product can be a complete defense to a product liability claim if the misuse or alteration caused the injury and was not reasonably foreseeable to the manufacturer.[297] If the degree of misuse or alteration is only slight, a jury will have to determine "whether the proximate cause of the injuries sustained was the original defective design or the subsequent modification," but if "the original design of the manufacturer's product has been totally eliminated and replaced so that the only similarity between the old and the new is the mere basic function to be

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290. *Id.* at 816.

291. *Id.*

292. O.C.G.A. § 51-1-11(b)(1).

293. Talley v. City Tank Corp., 158 Ga. App. 130, 135, 279 S.E.2d 264, 269 (1981) (internal quotation marks omitted).

294. *Id.*

295. *Id.* at 134-35, 279 S.E.2d at 269.

296. *Id.* at 135, 279 S.E.2d at 269 (internal quotation marks omitted).

297. Center Chem. Co. v. Parzini, 234 Ga. 868, 869-70, 218 S.E.2d 580, 582 (1975); Pepper v. Selig Chem. Indus., 161 Ga. App. 548, 551, 288 S.E.2d 693, 696 (1982).

performed, no such issue remains."[298] It makes sense that a substantial misuse or alteration of the product is unforeseeable and therefore an insufficient predicate for liability to attach. To impose liability for what is essentially a different product "would place the unrealistic burden on manufacturers of all products which can be redesigned by consumers to warn and instruct as to the manner in which that redesign should be made and the resulting new product safely operated."[299]

A question regarding the nature of the misuse or alteration of a product arose in one case decided during the survey period. In *Dixie Group, Inc. v. Shaw Industries Group, Inc.*,[300] Daniel Stevens sustained fatal injuries while working on a carpet wrapping machine at his place of employment, Shaw Industries. Perpetual Machine Company manufactured the machine in 1999, and Shaw Industries bought it from Dixie Group as part of an asset purchase agreement in November 2003. To protect carpet during shipping and distribution, the machine wrapped plastic around rolls of carpet, cut and sealed the plastic with a heat seal bar, and after a person manually tucked the excess plastic into the ends of the rolled-up carpet, it pressed cardboard plugs into the ends of the rolled-up carpet with pneumatically operated paddle arms. On December 20, 2003, the operator of the machine called Stevens, who was a maintenance technician for Shaw Industries, because the machine was not working properly. Stevens discovered that a bolt on one of the paddle arms had become loose. This had been happening once every week or two (about fifty times total), and on those prior occasions Stevens instructed the operator to press and hold a button that caused the paddle arms to move inward and away from the machine's frame so that there would be room for Stevens to tighten the bolt. Stevens and the operator did the same on this occasion, but this time one of the paddle arms swung back outward to its home position despite the fact that the operator was still pressing the button. Stevens was pinned between the paddle arm and the frame of the machine. Stevens' widow sued Perpetual in strict liability and negligence, and Perpetual moved for summary judgment on the ground that the machine had been modified from its original design. The trial court denied Perpetual's motion.[301]

On appeal, Perpetual argued that the machine "was not in its 'when sold' condition" because it had been modified in four significant

298. *Talley*, 158 Ga. App. at 135, 279 S.E.2d at 269.
299. *Id.* at 138, 279 S.E.2d at 271.
300. 303 Ga. App. 459, 693 S.E.2d 888 (2010).
301. *Id.* at 459-61, 693 S.E.2d at 890-91.

ways.[302] First, the proximity switch, which was designed to prevent the paddle arms from moving outward to their home position based on the position of the heat seal bar, had been moved from its original position. Perpetual's president testified that the proximity switch had been placed in a position where the heat seal bar could hit and damage it, and he observed black marks on the switch which suggested to him that the heat seal bar had in fact hit and damaged the switch. Moreover, repositioning the proximity switch changed the distance from which it sensed the heat seal bar. Perpetual's president also testified that he saw loose and spliced wiring in and around the proximity switch when he inspected the machine several weeks after the incident, and that the condition of the wiring, either alone or in combination with the damage to the switch, caused the short circuit that caused the incident. The second modification related to the bolt that Stevens was tightening when he was injured. When Perpetual sold the machine, the bolt was secured by a lock washer, but the lock washer was not there at the time of the incident. Third, two of the three operator foot switches had been removed. Finally, there were air leaks around the cylinders that controlled the paddle arms and the heat seal bar, neither of which leaked when Perpetual first sold the machine. According to Perpetual, these modifications proximately caused the incident and Stevens' injuries, not the machine's original design.[303]

The plaintiff responded that Perpetual's original design of the interaction among the proximity switch, the heat seal bar, and the paddle arms proximately caused the incident and her husband's death, notwithstanding these modifications. The plaintiff presented evidence showing that the repositioning of the proximity switch did not cause the heat seal bar to hit and damage it because there was evidence that the heat seal bar had hit and damaged the proximity switch while it was in its original position, which was the reason why the proximity switch was moved. After the proximity switch was moved, it continued to operate as designed. As for the loosening of the bolt, the plaintiff's evidence showed that the bolt could have become loose by the proper operation of the machine. She also showed that the bolt could not be tightened without a maintenance technician positioning his body in the exact location where her husband had positioned himself at the time of the incident. In addition, the plaintiff's expert engineer testified that there were no maintenance problems with the machine that could have caused the incident, and he specifically testified that the spliced wiring and removal of the operator foot switches did not impair the operation of the

302. *Id.* at 461-62, 693 S.E.2d at 891-92.
303. *Id.*

machine. Finally, the software controlling the paddle arms contained a default setting that would cause them to move outward automatically to their home position without warning even if the operator was pressing the button, but the plaintiff presented evidence showing that the software could have been programmed to allow the operator's commands to override the default setting.[304] In light of this evidence, the Georgia Court of Appeals agreed with the trial court and held that Perpetual was not entitled to summary judgment because "[a] jury would be authorized to find that the [machine] was operating as it had been designed when sold and that the design proximately caused Daniel Stevens's fatal injuries."[305]

304. *Id.* at 463, 693 S.E.2d at 892-93.
305. *Id.* at 464, 693 S.E.2d at 893.

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