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Product Liability

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This Article surveys recent developments in Georgia product liability law.[1] It covers noteworthy cases decided during the survey period by the Georgia appellate courts, the United States Supreme Court, the United States Court of Appeals for the Eleventh Circuit, and the United States district courts located in Georgia. In addition, this Article discusses provisions in the Official Code of Georgia Annotated (O.C.G.A.) that are particularly relevant to product liability claims.

I. STRICT LIABILITY

A. *Successor Liability*

Under Georgia law, a successor corporation only assumes the liabilities of the original corporation if "(1) there is an agreement to assume liabilities; (2) the transaction is, in fact, a merger; (3) the transaction is a fraudulent attempt to avoid liabilities; or (4) the purchaser is a mere continuation of the predecessor corporation."[2] The policy behind these exceptions that extend liability to the successor corporation is based on the overlapping experience and expertise of employees from the first corporation to the second.[3] Due to this overlap, the successor corpora-

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1. The survey period is June 1, 2007 through May 31, 2008.

2. Bullington v. Union Tool Corp., 254 Ga. 283, 284, 328 S.E.2d 726, 727 (1985) (citing WILLIAM MEADE FLETCHER ET AL., FLETCHER CYCLOPEDIA OF THE LAW OF PRIVATE CORPORATIONS § 7122 (perm. ed., rev. vol. 2008)).

3. *Id.* at 284-85, 328 S.E.2d at 727-28 (citing Cyr v. B. Offen & Co., 501 F.2d 1145, 1154 (1st Cir. 1974)).

tion is better situated than the consumer to appreciate the risks inherent in the design of the challenged product, to insure for any perceived risks, to adjust the price of the product to account for these potential risks, and to improve the quality of the product.[4]

During the survey period, the Georgia Court of Appeals focused on the amount of evidence required to set forth a prima facie showing that a corporation assumed the liabilities of the predecessor corporation. In *First Support Services, Inc. v. Trevino*,[5] the plaintiff was injured when he fell approximately thirty feet from a wing stand, which is a large platform that is used by mechanics to service aircraft. The plaintiff contended that his fall was caused by a failure of the pins that are supposed to lock into position to ensure the rigidity of the platform.[6]

The plaintiff sued First Support Services, Inc. (First Support), doing business as SKE Support Services (SKE), which had a contract with the Department of Defense to maintain ground support equipment at Warner Robins Air Force Base. First Support had purchased SKE a month after the plaintiff's accident, but it did not assume SKE's liabilities and did not have the same owners.[7]

After the plaintiff presented his evidence at trial, First Support moved for a directed verdict, contending that it was not liable to the plaintiff under any product liability theory because it was not the proper party. Specifically, First Support argued that the plaintiff had failed to come forward with any evidence showing that First Support was a successor corporation to SKE.[8]

After reviewing the evidence presented in the plaintiff's case-in-chief, the Georgia Court of Appeals reversed the trial court's denial of First Support's motion for directed verdict and held that the plaintiff failed to come forward with sufficient evidence to show that First Support was a successor corporation of SKE.[9] The court noted that the plaintiff had presented evidence that First Support employed former SKE workers and had its headquarters on the same street as SKE, but this evidence was countered by testimony that the officers of the two entities were different.[10] In addition, the plaintiff offered into evidence a copy of an amendment to SKE's articles of incorporation which showed that SKE

4. *Id.* (citing *Cyr*, 501 F.2d at 1154).
5. 288 Ga. App. 850, 655 S.E.2d 627 (2008).
6. *Id.* at 850-51, 655 S.E.2d at 629.
7. *Id.* at 851, 655 S.E.2d at 629.
8. *Id.*
9. *Id.* at 854, 655 S.E.2d at 631.
10. *Id.* at 853, 655 S.E.2d at 631.

changed its name to First Support.[11] But even with this corporate name change, the plaintiff did not come forward with sufficient evidence to show that First Support was a successor corporation of SKE because the plaintiff failed to show that First Support had the same owners as SKE.[12] Without evidence of a unity of ownership, the plaintiff failed to show that First Support was a proper party to the action, and the court of appeals held that the trial court incorrectly denied First Support's motion for a directed verdict.[13]

The outcome of that appeal shows the importance of fundamental issues, like presenting sufficient evidence to show the defendant is a proper party.[14] Without this evidence, a seven-figure verdict was reversed on appeal.[15]

B. Manufacturing Defect

To establish a manufacturing defect claim under Georgia law, a plaintiff must show that a defect existed in the product when it left the manufacturer's control and that the defect was caused by the manufacture of the product.[16] In *Miller v. Ford Motor Co.*,[17] the Georgia Court of Appeals addressed the issue of whether the plaintiff's own testimony regarding the existence of a defect is sufficient to survive summary judgment in a manufacturing defect case.[18]

The plaintiffs in *Miller* sued Ford Motor Company for alleged defects in the side air bag system and the front passenger seat belt in a 1991 Lincoln Town Car.[19] Ford moved for summary judgment, contending that the plaintiffs had no evidence of a defect in the vehicle and had no proof that any defect was the cause of the plaintiff's injuries. In response, the plaintiffs offered their own testimony that the side air bag did not deploy and the front passenger seat belt did not lock in the collision. The plaintiffs failed to come forward with any expert testimony regarding the alleged defects and did not provide any evidence about either the history or the use of the car before the plaintiffs purchased it as a used vehicle.[20]

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11. *Id.*
12. *Id.*
13. *Id.* at 854, 655 S.E.2d at 631.
14. *Id.*
15. *Id.*
16. Jenkins v. Gen. Motors Corp., 240 Ga. App. 636, 636-37, 524 S.E.2d 324, 325 (1999).
17. 287 Ga. App. 642, 653 S.E.2d 82 (2007).
18. *Id.* at 644, 653 S.E.2d at 84.
19. *Id.* at 642, 653 S.E.2d at 83.
20. *Id.* at 643-44, 653 S.E.2d at 83-84.

In addition, the plaintiffs presented evidence of two recalls relating to the front seat belt assemblies.[21] However, a product recall serves as circumstantial evidence of a defect only if there is independent proof that the product has the defect at issue in the recall.[22] Here, the recall documents indicated that the recall only applied to belt assemblies that had been installed as replacement equipment.[23] Because the plaintiffs introduced no evidence that the seat belt system was a replacement part, there was no extrinsic evidence to link the recall to the defect at issue.[24]

The court of appeals summarily dismissed the plaintiffs' contention that the doctrine of res ipsa loquitur should create an evidentiary presumption of defectiveness.[25] According to the court, this "'doctrine does not apply to mechanical devices because they get out of working order, and sometimes become dangerous and cause injury without negligence on the part of anyone.'"[26] Furthermore, the doctrine does not apply here because the defendant did not have exclusive control over the car, which had been driven for fifty thousand miles over three years.[27] *Miller* reaffirms that to survive summary judgment under Georgia law, plaintiffs in product liability lawsuits must come forward with more evidence than just their self-serving testimony about an alleged defect.

II. FAILURE TO WARN

A. Liability of Brand-Name Manufacturer for Marketing of Generic Product

Only manufacturers may be strictly liable for injuries caused by their product,[28] but other suppliers of the product (for example, retailers, sellers, and distributors) may be liable in negligence for those injuries.[29] Because entities that played no role in the design or manufacture of the product cannot be liable for a design or manufacturing defect

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21. *Id.* at 644, 653 S.E.2d at 84.
22. *Id.*; *see also* Rose v. Figgie Int'l, 229 Ga. App. 848, 854, 495 S.E.2d 77, 84 (1997).
23. *Miller*, 287 Ga. App. at 644-45, 653 S.E.2d at 84.
24. *Id.* at 645, 653 S.E.2d at 84.
25. *Id.*
26. *Id.* (quoting Millar Elevator Serv. Co. v. O'Shields, 222 Ga. App. 456, 457-58, 475 S.E.2d 188, 190 (1996)).
27. *Id.*
28. O.C.G.A. § 51-1-11(b)(1) (2000); Farmex Inc. v. Wainwright, 269 Ga. 548, 550, 501 S.E.2d 802, 804 (1998); Ellis v. Rich's, Inc., 233 Ga. 573, 577, 212 S.E.2d 373, 376 (1975).
29. Farmer v. Brannan Auto Parts, Inc., 231 Ga. App. 353, 354, 498 S.E.2d 583, 584 (1998) (en banc).

(whether in strict liability or negligence), claims against "product sellers"[30] are generally based on a negligent failure to warn about the product's dangers.[31] In most cases, it is easy to determine the proper defendants because each entity's role in the manufacturing, distribution, and sale of the product is clear. But when the product is a generic prescription drug that is designed, manufactured, labeled, and marketed similar to its brand-name counterpart, is the brand-name manufacturer liable for injuries caused by the generic version of its product? The United States District Court for the Northern District of Georgia confronted this issue in one case during the survey period.[32]

In *Swicegood v. Pliva, Inc.*,[33] the plaintiff developed tardive dystonia and other neurological injuries after taking metoclopramide (the generic equivalent of Reglan) to treat nausea. Wyeth manufactured Reglan until December 2001, at which time Schwarz Pharma, Inc. purchased the rights to distribute Reglan tablets. The plaintiff's doctor prescribed Reglan in April 2005, but her pharmacist dispensed the generic equivalent, which Pliva, Inc. manufactured. The plaintiff took the generic equivalent until July 2005, when she suffered an adverse reaction. In addition to suing Pliva and its successor, Barr Pharmaceuticals, the plaintiff sued Wyeth and Schwarz based on the theory that the improper labeling of Reglan ensured that the generic equivalent would also be improperly labeled. The plaintiff alleged that all of the defendants knew that long-term use of Reglan created a greater risk of developing tardive dystonia than they disclosed to the Food and Drug Administration (FDA) or to the public. Among other theories, the plaintiff's claims were based on strict liability, negligence, and fraudulent and negligent misrepresentation. Wyeth and Schwarz moved to dismiss the claims against them on the grounds that they failed to state a claim upon which relief could be granted.[34]

As for the plaintiff's claims based on strict liability, the district court granted Wyeth and Schwarz's motion because they did not manufacture the allegedly defective product—the generic equivalent of Reglan.[35] Because the plaintiff did not take Reglan, there was no basis for Wyeth

30. A "product seller" is "a person who, in the course of a business conducted for the purpose leases or sells and distributes; installs; prepares; blends; packages; labels; markets; or assembles pursuant to a manufacturer's plan, intention, design, specifications, or formulation; or repairs; maintains; or otherwise is involved in placing a product in the stream of commerce." O.C.G.A. § 51-1-11.1(a) (2000).

31. *Farmer*, 231 Ga. App. at 355, 498 S.E.2d at 585.

32. *See* Swicegood v. Pliva, Inc., 543 F. Supp. 2d 1351 (N.D. Ga. 2008).

33. 543 F. Supp. 2d 1351 (N.D. Ga. 2008).

34. *Id.* at 1353-54.

35. *Id.* at 1354-55.

and Schwarz to be held strictly liable.[36] Similarly, the district court granted Wyeth and Schwarz's motion with respect to the plaintiff's claims for negligent failure to warn and fraudulent and negligent misrepresentation because they did not manufacture or distribute the generic version of Reglan that the plaintiff took and were not responsible for its labeling.[37] Because neither Wyeth nor Schwarz supplied the generic drug to the plaintiff, they had no duty to warn her about any dangers associated with it.[38]

The plaintiff argued that Wyeth and Schwarz had a duty to warn because they voluntarily undertook a duty to ensure that Pliva's label for metoclopramide was accurate by becoming the Referenced Listed Drug Holder for metoclopramide.[39] The district court acknowledged that the regulations promulgated pursuant to the Food, Drug, and Cosmetic Act (FDCA)[40] require new drug applicants to update the safety information for the drug as necessary, but it found that the pertinent regulation "does not require a name brand manufacturer to ensure that the generic brand's label is accurate."[41] In any event, the fact that Wyeth and Schwarz were responsible for the initial labeling of Reglan did not mean that they had assumed a duty to ensure that future generic equivalents of Reglan were labeled properly.[42] "After all, the generic manufacturer Pliva used its own label on its products, which it was free to alter with FDA approval."[43]

Additionally, the plaintiff argued that Wyeth and Schwarz had a duty to warn about the dangers associated with metoclopramide because generic manufacturers are required to use the safety information provided by brand-name manufacturers until the FDA approves the abbreviated new drug application for the generic version of the drug.[44] Although the district court recognized that the Hatch-Waxman

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36. *Id.* at 1355.

37. *Id.* at 1355-56. Wyeth and Schwarz argued that "the misrepresentation claims are merely masquerading as products liability claims," and the district court agreed. *Id.* at 1357. The district court explained that it was "not prepared to recognize the viability of misrepresentation claims distinct from products liability or failure to warn claims" because "misrepresentation claims against a manufacturer properly collapse into the failure to warn claims." *Id.*

38. *Id.* at 1355.

39. *Id.* at 1356.

40. 21 U.S.C. §§ 301 to -399a (2000 & Supp. V 2005).

41. *Pliva*, 543 F. Supp. 2d at 1356.

42. *Id.* (citing Smallwood v. United States, 988 F. Supp. 1479, 1482 (S.D. Ga. 1997)).

43. *Id.*

44. *Id.* at 1358.

Amendments[45] to the FDCA were intended to allow generic manufacturers to rely on the safety information provided by brand-name manufacturers, it rejected the plaintiff's argument because Pliva had already obtained the FDA's approval of its abbreviated new drug applications for metoclopramide when the plaintiff began using it.[46] As a result, "Pliva had the ability—albeit with approval from the FDA—to add or strengthen a contraindication, warning, precaution, or adverse reaction or [to] delete false[,] misleading, or unsupported indications for use."[47]

In the final analysis, the district court granted Wyeth and Schwarz's motion to dismiss because "permitting claims in negligence against a manufacturer for one of its competitor's products would result in an unprecedented departure from traditional Georgia tort law."[48] The district court explained its rationale, and the impracticality and unfairness of the plaintiff's arguments, as follows:

> [I]t is imprudent to hold a party liable for any manufacturing mistakes by another company. Name brand manufacturers undertake the expense of developing pioneer drugs . . .[.] Generic manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels. Further, the generic manufacturer benefits from exposure of the name brand drug, and consequently the generic manufacturer can ride on the coattails of its advertising. Additionally, perhaps most importantly, the name manufacturer has no control over the manufacturing process of its generic competitor. Taken together, these factors seem especially unfair to hold a name manufacturer liable for its generic competitors' mistakes.[49]

Georgia law has long adhered to the basic principle that a manufacturer is not responsible for another manufacturer's product.[50] As the Georgia Court of Appeals has recognized, "[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

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45. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. §§ 355 and 360cc (2000) and 35 U.S.C. §§ 156 and 271 (2000)).

46. *Pliva*, 543 F. Supp. 2d at 1358.

47. *Id.* (internal quotation marks omitted) (quoting Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 523 (E.D. Pa. 2006)).

48. *Id.* at 1357 (internal quotation marks omitted) (quoting Starling v. Seaboard Coast Line R.R. Co., 533 F. Supp. 183, 186 (S.D. Ga. 1982)).

49. *Id.* at 1358 (citations and internal quotation marks omitted) (quoting Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994)).

50. *See* O.C.G.A. § 51-1-11 (2000).

else."[51] After all, there is no reason why a generic manufacturer should not be responsible for its own products, just like any other manufacturer. This is an appropriate limitation on the scope of the duty to warn, and the federal courts in Georgia have consistently applied it in diversity cases.[52] The decision of the district court in *Swicegood* continues that trend.[53]

B. Evidence of Breach of Duty to Warn

"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."[54] Because this duty may arise after the product is sold to a consumer, the manufacturer may have a duty to recall the product from the market if the product poses a sufficient risk of danger.[55] The manufacturer breaches its duty to warn if it fails to adequately communicate the warning to the ultimate user or if it fails to provide an adequate warning of the product's potential danger.[56] Thus, an adequate warning is one that is reasonably calculated to reach users of the product and that is appropriate for those intended users.[57] Whether the manufacturer breached its duty to warn is usually a jury question.[58]

One case decided during the survey period by the Northern District of Georgia illustrates the difficulty a manufacturer faces in obtaining summary judgment on a failure to warn claim.[59] In *Woodard v. Ford*

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51. Talley v. City Tank Corp., 158 Ga. App. 130, 135, 279 S.E.2d 264, 269 (1981); *see also* Davis v. Wells Aluminum Se., Inc., 172 Ga. App. 357, 358, 323 S.E.2d 215, 216 (1984).

52. *See, e.g.*, Murphy v. Aventis Pasteur, Inc., 270 F. Supp. 2d 1368, 1377 (N.D. Ga. 2003) (holding that the developer or inventor of a product does not owe a duty to warn future users of a generic version of the product, even if the developer or inventor knows that generic versions of the product will be manufactured after the patent expires).

53. *See Swicegood*, 543 F. Supp. 2d at 1358.

54. Chrysler Corp. v. Batten, 264 Ga. 723, 724, 450 S.E.2d 208, 211 (1994).

55. Smith v. Ontario Sewing Mach. Co., 249 Ga. App. 364, 368, 548 S.E.2d 89, 95 (2001) (physical precedent). Because it was not necessary for the Georgia Court of Appeals to discuss the duties that a manufacturer owes with respect to warnings, the Georgia Supreme Court disapproved of this part of *Smith*. Ontario Sewing Mach. Co. v. Smith, 275 Ga. 683, 686, 572 S.E.2d 533, 535 (2002). On remand the court of appeals vacated its earlier opinion and adopted the supreme court's opinion. Smith v. Ontario Sewing Mach. Co., 259 Ga. App. 30, 30, 576 S.E.2d 38, 38 (2002).

56. Battersby v. Boyer, 241 Ga. App. 115, 117, 526 S.E.2d 159, 163 (1999) (citing Thornton v. E.I. Du Pont De Nemours & Co., 22 F.3d 284, 289 (11th Cir. 1994)).

57. *Id.*

58. *Id.*

59. *See* Woodard v. Ford Motor Co., No. 1:06-CV-2191-TWT, 2007 WL 4125519 (N.D. Ga. Nov. 2, 2007).

Motor Co.,[60] the plaintiff's wife died when her 1993 Ford Explorer was hit by another vehicle and rolled over two and a half times. The plaintiff sued the manufacturer of the Explorer under various theories, including failure to warn, and alleged that excessive roof crush broke his wife's neck, causing her death. The manufacturer filed a motion for summary judgment with respect to the failure to warn claim, arguing that the plaintiff had insufficient evidence to support the claim and the claim "merged" with the design defect claim such that it was barred by the statute of repose.[61]

Regarding the sufficiency of the plaintiff's evidence, the manufacturer broadly argued that there was no competent evidence supporting the failure to warn claim. However, the plaintiff offered expert testimony showing that the manufacturer knew about the risk of roof collapse in Explorer vehicles but failed to warn consumers about it.[62] The district court held that this evidence was sufficient to create a jury issue.[63]

The manufacturer's second argument concerned the sufficiency of the plaintiff's evidence. The manufacturer argued that there was no evidence showing the plaintiff's wife would have done anything different had there been a warning about the risk of roof collapse.[64] The district court rejected this argument because the plaintiff had presented evidence showing that his wife observed other warnings that were posted in the vehicle.[65] Those warnings involved wearing a seat belt, driving with care, and avoiding unnecessary sharp turns, and the undisputed evidence showed that the plaintiff's wife was wearing a seat belt and driving with care at the time the collision occurred.[66]

The manufacturer also argued that the failure to warn claim should be treated as a design defect claim because they "merged" together insofar as the failure to warn claim was based on an alleged defect in the design of the Explorer's roof.[67] The significance of this argument was that the design defect claim was barred by the statute of repose,[68] whereas the failure to warn claim was not.[69] Noting that the Georgia

60. No. 1:06-CV-2191-TWT, 2007 WL 4125519 (N.D. Ga. Nov. 2, 2007).

61. *Id.* at *1.

62. *Id.*

63. *Id.* The district court's opinion does not indicate whether the manufacturer filed a motion challenging the admissibility of the expert's testimony.

64. *Id.* at *2.

65. *Id.*

66. *Id.*

67. *Id.* at *1.

68. O.C.G.A. § 51-1-11(b)(2).

69. *Woodard*, 2007 WL 4125519, at *1. The statute of repose provides that "[n]o action shall be commenced pursuant to this subsection with respect to an injury after ten years

Supreme Court recognized a distinction between failure to warn claims and design defect claims, the district court held that the manufacturer's "merger" argument was inconsistent with the strict liability statute, which provides that "'[n]othing . . . shall relieve a manufacturer from the duty to warn of a danger arising from use of a product once that danger becomes known to the manufacturer.'"[70] The manufacturer also argued that its alleged failure to recall the Explorer "merged" into the alleged design defect, but the district court found that the plaintiff had presented sufficient evidence to avoid summary judgment because his expert testified that the manufacturer failed to recall older models of the Explorer after secretly improving the roof/pillar strength and roof crush resistance on later models.[71] Accordingly, the district court denied the manufacturer's motion for summary judgment.[72]

III. PROXIMATE CAUSE

Under the enhanced injury doctrine, a manufacturer may be liable when a defect in its product enhances the plaintiff's injuries even though the defect did not cause the injury-producing event.[73] Most frequently applied in cases involving automobile accidents, this doctrine deals with the crashworthiness of a vehicle when the accident consists of two collisions or impacts:

> First, there is an initial collision that presumably causes some injuries to the passengers of the vehicle. Second, there is another "collision" or accident caused by the unworthiness of the vehicle to protect the passengers from a crash, which may enhance or aggravate the injuries caused by the first collision.[74]

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from the date of the first sale for use or consumption of the personal property causing or otherwise bringing about the injury." O.C.G.A. § 51-1-11(b)(2). However, it does not apply to claims based on a failure to warn. O.C.G.A. § 51-1-11(c).

70. *Woodard*, 2007 WL 4125519, at *1 (alteration and ellipses in original) (quoting O.C.G.A. § 51-1-11(c)). In *Batten* the Georgia Supreme Court recognized that failure to warn claims and design defect claims are "separate and distinct" and "are not necessarily coextensive." 264 Ga. at 724, 450 S.E.2d at 211.

71. *Woodard*, 2007 WL 4125519, at *2.

72. *Id.* at *5. Interestingly, the same judge, Judge Thomas W. Thrash, decided *Woodard* and *Swicegood*. In *Swicegood*, which is discussed above in Part II.A, Judge Thrash agreed with a similar "merger" argument and held that "misrepresentation claims against a manufacturer properly collapse into the failure to warn claims." 543 F. Supp. 2d at 1357. Judge Thrash's acceptance of the "merger" argument in *Swicegood* and rejection of it in *Woodard* are certainly not inconsistent positions (since the allegedly "merged" claims were not the same), but his different conclusions are worth noting.

73. Ford Motor Co. v. Stubblefield, 171 Ga. App. 331, 336, 319 S.E.2d 470, 477 (1984).

74. Timmons v. Ford Motor Co., 949 F. Supp. 859, 861 (S.D. Ga. 1996). The two collisions or impacts must be part of a single accident; the enhanced injury doctrine does

In such an accident, "[t]he crashworthiness of the vehicle determines how severe any injuries suffered as a result of the second impact will be."[75] This doctrine represents an expansion of manufacturer liability because it does not depend on whether the defect caused the accident; indeed, it applies only when the defect did *not* cause the accident.[76] By focusing on whether the defect increased the severity of the plaintiff's injuries, rather than on whether the defect caused the plaintiff's injuries in the first place, this doctrine essentially imposes a duty on manufacturers to design their products in a way that minimizes the injuries resulting from accidents caused by others.[77]

The enhanced injury doctrine traces its origins in Georgia at least as far back as 1968. In *Friend v. General Motors Corp.*,[78] the plaintiffs lost control of their vehicle, crashed into a concrete culvert, and sustained enhanced injuries when the impact with the culvert caused their luggage and photographic equipment to move forward and strike the back of their seats. The second impact—the luggage and photographic equipment striking the seats—caused the seats to fold over and further injure the plaintiffs. The plaintiffs sued the manufacturer of the vehicle, alleging that the small bolt that secured the seats to the vehicle was defectively designed, manufactured, and installed and that as a result, the vehicle was neither merchantable nor reasonably suited for its intended use.[79] The trial court dismissed the claims against the manufacturer,[80] but the Georgia Court of Appeals reversed on the grounds that the plaintiffs stated a claim upon which relief could be granted[81] because the manufacturer was obligated "to provide the operator and a passenger sitting beside him with reasonable safety from injury by the collapse of the front seats caused by the impact of shifting cargo in the rear produced by a sudden stop, an occurrence which may

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not apply to multiple collisions or impacts that arise out of separate accidents. Smith v. Curtis, 226 Ga. App. 470, 471, 486 S.E.2d 699, 701 (1997); Brinks, Inc. v. Robinson, 215 Ga. App. 865, 866, 452 S.E.2d 788, 790 (1994) (en banc).

75. Higginbotham v. Ford Motor Co., 540 F.2d 762, 766 n.4 (5th Cir. 1976).

76. 63A AM. JUR. 2D *Products Liability* § 1020 (1997).

77. *Id.* Because automobile accidents are foreseeable by the manufacturer, *Stubblefield*, 171 Ga. App. at 335-36, 319 S.E.2d at 476-77, this duty is arguably encompassed within the manufacturer's obligation to produce vehicles that are reasonably suited for their intended use. However, this duty could also be construed as imposing an additional obligation on automobile manufacturers.

78. 118 Ga. App. 763, 165 S.E.2d 734 (1968) (en banc).

79. *Id.* at 763-64, 165 S.E.2d at 736.

80. *Id.* at 763, 165 S.E.2d at 736.

81. *Id.* at 764-65, 165 S.E.2d at 737.

reasonably be foreseen and anticipated in normal use on public highways."[82]

Simply recognizing that a manufacturer may be liable for enhanced injuries caused by a defect in its product, however, did not answer the important question of which party bears the burden of proof in such a case. The Georgia Supreme Court answered that question in *Polston v. Boomershine Pontiac-GMC Truck, Inc.*[83] when it adopted the following burden-shifting framework for enhanced injury or crashworthiness cases:

> In an enhanced injury or crashworthiness case, Georgia law places on the plaintiff the burden of proving that a design defect was a substantial factor in producing damages over and above those which were probably caused as a result of the original impact or collision. To the extent that the injuries suffered by the plaintiff are indivisible, the defendants are treated as joint tortfeasors. Once the plaintiff's burden has been borne, the burden of proof shifts to the defendant which wishes to limit its liability to demonstrate a rational basis for apportioning the liability for the injuries.[84]

The *Polston* rule was criticized immediately. Justice Willis Hunt, writing for himself as well as Justices Richard Bell and Norman Fletcher, dissented in *Polston* because "[t]here is no justification . . . on legal, or public policy grounds, for requiring the manufacturer to prove an essential element of the plaintiff's case."[85] According to the three dissenting justices, the initial tortfeasor and the manufacturer in an enhanced injury or crashworthiness case are not joint tortfeasors, which means that the manufacturer should be liable only "to the extent any defect in the design of its car enhanced, or aggravated, the plaintiff's injuries over and above what would have occurred absent the alleged defect."[86] In their view, the plaintiff should bear the burden of proving the extent of damages caused by the manufacturer's defective product, and if he cannot do so (by proving what would have happened without the alleged defect), then his claim against the manufacturer must fail for lack of proof that the alleged defect enhanced or aggravated his injuries.[87] In addition, Judges J.D. Smith and Gary Andrews of the court of appeals have criticized the *Polston* rule on the grounds that

82. *Id.* at 764, 165 S.E.2d at 736-37.
83. 262 Ga. 616, 423 S.E.2d 659 (1992).
84. *Id.* at 618-19, 423 S.E.2d at 662.
85. *Id.* at 621, 423 S.E.2d at 664 (Hunt, J., dissenting).
86. *Id.* at 619, 423 S.E.2d at 662.
87. *Id.* at 620-21, 423 S.E.2d at 663.

proof of the extent of damages caused by the injury-enhancing defect is often not available in wrongful death cases.[88]

Since its adoption, the *Polston* rule has been attacked on several grounds, but the appellate courts have consistently upheld it. In *Owens v. General Motors Corp.*,[89] for example, the court of appeals held that in a manufacturing defect case, expert testimony is not always required to prove that a plaintiff's enhanced injuries were proximately caused by the defect.[90] During the survey period, the supreme court considered whether the enhanced injury doctrine applies to claims based on a failure to warn or only to claims based on a design defect.[91]

In *Ford Motor Co. v. Gibson*,[92] the plaintiff's wife was stopped in her vehicle while waiting to make a turn when she was rear-ended by another vehicle, which set off a tragic sequence of events that culminated in her death. The impact forced the vehicle driven by the plaintiff's wife into oncoming traffic where it was struck by another vehicle. The vehicle driven by the plaintiff's wife had a trailer hitch that was attached by two bolts. The force of the second impact pushed the bolts into the fuel tank and jammed the doors shut. The fuel tank exploded, and a fire erupted in the back seat. The back of the seat on which the plaintiff's wife was sitting collapsed, which caused her head to be drawn into the fire. The plaintiff alleged that the manufacturer of the vehicle defectively designed the fuel system, seat back, and doors and failed to warn about these defects. The plaintiff also asserted design defect and failure to warn claims against the manufacturer of the trailer hitch. At trial, the judge instructed the jury on the enhanced injury doctrine, and the jury ultimately awarded $13 million against the two manufacturers jointly and severally.[93]

On appeal, the manufacturer of the trailer hitch argued that the trial court's jury instruction on the enhanced injury doctrine was improper because the doctrine does not apply to claims based on a failure to warn.[94] The supreme court rejected this argument because "nothing in *Polston* . . . suggest[s] that an enhanced injury claim cannot be based on a manufacturer's failure to warn a consumer regarding a dangerous or

88. Ford Motor Co. v. Tippins, 225 Ga. App. 128, 131, 483 S.E.2d 121, 125 (1997) (physical precedent). Judge Marion Pope wrote in his special concurrence that he disagreed with the majority's criticism of the *Polston* rule. *Id.* at 133, 483 S.E.2d at 127 (Pope, P.J., concurring specially).

89. 272 Ga. App. 842, 613 S.E.2d 651 (2005).

90. *Id.* at 847-48, 613 S.E.2d at 655-56.

91. *See* Ford Motor Co. v. Gibson, 283 Ga. 398, 659 S.E.2d 346 (2008).

92. 283 Ga. 398, 659 S.E.2d 346 (2008).

93. *Id.* at 399-401, 659 S.E.2d at 348-50.

94. *Id.* at 404-05, 659 S.E.2d at 352.

defective product."[95] The *Polston* rule refers only to claims based on a design defect because the only claim asserted in *Polston* was a design defect claim.[96] Accordingly, the jury was authorized to consider the extent to which the injuries sustained by the plaintiff's wife may have been enhanced by the manufacturer's failure to warn about the dangers presented by the vehicle and the trailer hitch.[97]

IV. EXPERT TESTIMONY

In February 2005 Governor Sonny Perdue signed into law new rules for the admission of expert testimony in civil lawsuits, essentially adopting the *Daubert* standard found in Federal Rule of Evidence 702.[98] This new *Daubert* standard was such a revolutionary development in the admissibility of expert witness testimony that one trial judge has characterized it as a "sea change in Georgia practice."[99]

From its adoption, legal commentators predicted that the statutory scheme in O.C.G.A. § 24-9-67.1[100] would be subject to constitutional attack.[101] In 2006 one appeal involving a constitutional challenge to this code section reached the Georgia Supreme Court but was withdrawn.[102] Finally, during the survey period, the Georgia Supreme Court considered and affirmed the constitutionality of the new expert witness evidentiary standard.[103]

In *Mason v. The Home Depot U.S.A., Inc.*,[104] the plaintiffs filed suit against the manufacturer and seller of Varathane, a floor covering product. The first trial of *Mason* took place within weeks after the enactment of the Tort Reform Act of 2005,[105] which included the challenged *Daubert* standard. Accordingly, the defendants filed a motion pursuant to that code section seeking to exclude the testimony of two of the plaintiffs' expert witnesses. The trial court denied the motion because discovery had been completed under the old rules governing the

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95. *Id.* at 405, 659 S.E.2d at 352.

96. *Id.*

97. *Id.*, 659 S.E.2d at 353.

98. *See* O.C.G.A. § 24-9-67.1 (Supp. 2008).

99. Transcript of Record at 28, Moran v. Kia Motors Am., Inc., 02A-6976 (State Ct. Cobb Cty. Mar. 21, 2005).

100. O.C.G.A. § 24-9-67.1 (Supp. 2008).

101. *See* Robert E. Shields & Leslie J. Bryan, *Georgia's New Expert Witness Rule: Daubert & More*, GA. B.J., Oct. 2005, at 17, 21.

102. Isuzu Motor Co. v. Jonah, *appeal docketed*, No. S06A1405 (Ga. Apr. 26, 2006).

103. Mason v. The Home Depot U.S.A., Inc., 283 Ga. 271, 280, 658 S.E.2d 603, 611 (2008).

104. 283 Ga. 271, 658 S.E.2d 603 (2008).

105. 2005 Ga. Laws 1.

admissibility of expert testimony, and by enforcing this new evidentiary rule, the court concluded it would have violated the proscription against retroactive laws found in the Georgia constitution. The first trial of *Mason* ended in a mistrial.[106]

Before the case was retried, the defendants renewed their motion to exclude the testimony of the plaintiffs' expert witnesses.[107] This time, the trial court held that subsection (b)(1) of O.C.G.A. § 24-9-67.1,[108] which limits expert testimony to reliance upon admissible evidence only,[109] denies due process because it conflicts with the part of subsection (a)[110] that permits experts to rely on certain inadmissible evidence.[111] The trial court resolved this constitutional issue by excising part of subsection (b)(1). In addition, the trial court found that subsection (f),[112] which directs the courts of Georgia to look to federal legal opinions,[113] violated the concept of separation of powers. Accordingly, the trial court severed subsection (f) from the statute. Using what the trial court deemed to be the constitutionally permissible remnants of the statute, the court entered an order that excluded the testimony of both of the plaintiffs' expert witnesses.[114]

On appeal to the Georgia Supreme Court, the plaintiffs first argued that the statute violated the equal protection provisions of the constitutions of the United States and Georgia[115] because it imposes more stringent requirements for the admissibility of expert testimony in civil actions than in criminal cases.[116] The supreme court held that civil litigants and criminal defendants are not similarly situated and stated:

> [F]or purposes of evidentiary standards, only those accused of the same offense are similarly situated in the criminal law arena, only those asserting or defending against the same cause of action are similarly situated in the civil law arena, and the parties to civil cases are not similarly situated to those engaged in criminal prosecutions.[117]

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106. *Mason*, 283 Ga. at 271-72, 658 S.E.2d at 605-06.
107. *Id.* at 272, 658 S.E.2d at 606.
108. O.C.G.A. § 24-9-67.1(b)(1).
109. *See id.*
110. *Id.* § 24-9-67.1(a).
111. *See id.*
112. *Id.* § 24-9-67.1(f).
113. *See id.*
114. *Mason*, 283 Ga. at 272-73, 658 S.E.2d at 606.
115. U.S. CONST. amend. XIV; GA. CONST. art. I, § 1, para. 2.
116. *Mason*, 283 Ga. at 273, 658 S.E.2d at 606.
117. *Id.* at 274, 658 S.E.2d at 607.

Because the plaintiffs could not show that they were similarly situated to a group that was being treated differently, they could not satisfy a prima facie element of their equal protection claims.[118]

Next, the plaintiffs contended that because subsections (a) and (b)(1) are contradictory, the statute violates due process and should be stricken. In response, the defendants argued that the plaintiffs did not have standing to make this due process challenge because the trial court had severed these subsections from the statute in its ruling below.[119] The supreme court concluded that the plaintiffs had standing to make this constitutional challenge because the trial court had not declared the whole statute to be unconstitutional.[120]

In analyzing the merits of the due process claim, the supreme court held that the language in subsection (a) contradicted subsection (b)(1).[121] The court was unable to harmonize the two subsections because one allowed the use of only admissible evidence as the basis for an expert opinion, while the other subsection permitted the use of inadmissible evidence.[122] With this irreparable contradiction, the supreme court affirmed the trial court's ruling that both subsections should be stricken.[123]

As a third constitutional challenge, the plaintiffs contended that subsection (f) was an impermissible delegation of legislative authority and a denial of due process because it allowed trial courts to graft judicial opinions into the statutory scheme, which arguably would violate the separation of powers doctrine.[124] But the supreme court held that the use of the word "may" in subsection (f) showed the permissive nature of the reference to federal judicial decisions and prevented the statute from improperly enforcing on trial courts a particular construction of the statutory language.[125] Although the supreme court reversed the trial court on this issue, because the trial court had merely stricken subsection (f) and applied the evidentiary standard, the supreme court did not need to reverse the judgment of the trial court.[126]

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118. *Id.* at 275, 658 S.E.2d at 607.
119. *Id.*, 658 S.E.2d at 607-08.
120. *Id.*, 658 S.E.2d at 608.
121. *Id.*
122. *Id.*
123. *Id.* at 276, 658 S.E.2d at 608.
124. *Id.*
125. *Id.*
126. *Id.* at 277, 658 S.E.2d at 609.

The supreme court then considered the plaintiffs' two other constitutional challenges to subsection (f).[127] First, the plaintiffs contended that the first sentence of subsection (f) improperly delegated the legislative authority to define the rules of evidence to the Georgia courts and to the courts and legislatures of other states. Then the plaintiffs claimed that the first sentence denied due process to litigants because it offered no clear guidance to Georgia courts regarding how the courts should execute their delegated powers.[128] The supreme court determined that these arguments were unpersuasive and deemed the subsection to be merely a statement of the goal of the statutory scheme, not an attempt to delegate to the judiciary the role of the legislature or vice versa.[129]

Next, the plaintiffs argued that they had a vested right in the previous evidentiary rules and that O.C.G.A. § 24-9-67.1, as applied to their pending lawsuit, violated the constitutional prohibition against retroactive laws.[130] The supreme court held this claim unpersuasive.[131] Drawing upon its recent opinion in another challenge to the Tort Reform Act of 2005, *Fowler Properties, Inc. v. Dowland*,[132] the supreme court restated its distinction between substantive and procedural law: "'substantive law creates rights, duties, and obligations while a procedural law prescribes the methods of enforcing those rights, duties, and obligations.'"[133] Here, the plaintiffs were unable to articulate a right that was abrogated by the adoption of the *Daubert* standard.[134]

After resolving all of the constitutional challenges, the supreme court turned to the application of the *Daubert* standard to the proffered testimony of the plaintiffs' expert witnesses and affirmed the trial court's exclusion of their testimony using the abuse of discretion standard of review.[135] For Dr. Ziem, an expert witness who offered causation

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127. *Id.* Because the trial court found subsection (f) to be unconstitutional based on the plaintiffs' first basis, denial of due process, it did not consider these other two constitutional challenges. *Id.* The supreme court exercised its judicial discretion and decided these other two questions. *Id.* at 277 n.4, 658 S.E.2d at 609 n.4 (citing Campbell v. State, 268 Ga. 44, 485 S.E.2d 185 (1997)).

128. *Mason*, 283 Ga. at 277, 658 S.E.2d at 609.

129. *Id.*

130. *Id.* at 278, 658 S.E.2d at 609.

131. *Id.* at 279, 658 S.E.2d at 610.

132. 282 Ga. 76, 79, 646 S.E.2d 197, 200 (2007) (holding that the offer of settlement section of the Tort Reform Act of 2005 was unconstitutional as a retrospective law).

133. *Mason*, 283 Ga. at 278, 658 S.E.2d at 609 (quoting *Fowler Props.*, 282 Ga. at 78, 646 S.E.2d at 200).

134. *Id.* at 279, 658 S.E.2d at 610.

135. *Id.* at 279-80, 658 S.E.2d at 610-11.

testimony, the plaintiffs contended that exclusion under *Daubert* was improper because differential diagnosis, the methodology employed by Dr. Ziem, was a recognized scientific process.[136] But the supreme court emphasized that when an expert witness uses the differential diagnosis method, the potential causes must be ruled in or ruled out using scientifically valid decisions.[137] Here, the trial court had concluded that Dr. Ziem based her conclusion solely on her own experience and opinions and provided no support for these opinions from published scientific journals.[138] The supreme court held this exclusion was not an abuse of discretion.[139] The supreme court held that the methodology of Dr. Huggins, a labeling expert, was lacking because he relied on toxicity data for the individual chemical components of Varathane without considering the specific amount of each chemical in Varathane.[140] In addition, Dr. Huggins used no reliable scientific literature and based his opinion solely on data from the Internet and the plaintiffs' counsel.[141]

In a brief concurrence, Justice Harold Melton disagreed with the majority of the court because he concluded that subsections (a) and (b)(1), dealing with the admissibility of evidence relied on by expert witnesses, could be harmonized without striking those parts of the statute.[142] Justice Melton explained that expert opinions can be based on both admissible and inadmissible evidence.[143] The inadmissible evidence may then become admissible subject to the prejudice analysis at the end of subsection (a).[144] Thus, there is no contradiction in the subsections.[145] Justice Melton criticized the majority for focusing on a narrow portion of each subsection instead of looking at the entire language.[146]

Presiding Justice Carol Hunstein authored a dissenting opinion in which she concluded that O.C.G.A. § 24-9-67.1 violated the plaintiffs' equal protection rights.[147] While she recognized the court's precedent holding that criminal and civil litigants were not similarly situated,

136. *Id.* at 279, 658 S.E.2d at 610.
137. *Id.* at 280, 658 S.E.2d at 610.
138. *Id.*, 658 S.E.2d at 611.
139. *Id.*
140. *Id.*
141. *Id.*
142. *Id.* (Melton, J., concurring).
143. *Id.* at 281, 658 S.E.2d at 611-12.
144. *Id.*, 658 S.E.2d at 612.
145. *Id.* at 282, 658 S.E.2d at 612.
146. *Id.*
147. *Id.* (Hunstein, P.J., dissenting).

Justice Hunstein emphasized that the supreme court was not constrained from recognizing that in this circumstance—involving the quality of expert witness testimony—civil and criminal parties are equally situated, not just similarly situated.[148] In addition, she found no rational basis for treating criminal and civil litigants differently with respect to the admissibility of expert testimony.[149] Justice Hunstein highlighted that certain evidence that is admissible in a criminal trial might not be admissible in a civil case because of the heightened admissibility requirements with the *Daubert* standard.[150] With the stakes at issue in criminal matters, one would expect that forum to be more demanding than civil actions.[151] Instead, the statutory scheme has created the opposite result.[152]

Justice Hunstein also attacked subsection (f) as "a blatant attempt by the Legislature to usurp judicial power."[153] She chastised the majority of the court, whose opinion, according to Justice Hunstein, "will open the floodgates to future legislative 'suggestions' directing the courts in the manner in which statutes 'may' be interpreted."[154]

The supreme court had the opportunity to define the timing of the *Daubert* challenge in *Ford Motor Co. v. Gibson*.[155] In that opinion, the court warned that any motions to exclude based on O.C.G.A. § 9-24-67.1 must be filed before the final pretrial conference.[156] Before the trial of this matter, one defendant moved to exclude the testimony of the plaintiff's expert witness but did not file this motion until after the final pretrial conference.[157] The supreme court held that because the plain language of the statute required that the "hearing and ruling [on a *Daubert* motion] shall be completed no later than the final pretrial conference," the motion to exclude was untimely.[158] This interpretation of subsection (d)[159] forces practitioners to be vigilant about the timing of any motions to exclude the testimony of an expert witness under O.C.G.A. § 24-9-67.1.

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148. *Id.*, 658 S.E.2d at 612-13.
149. *Id.* at 284, 658 S.E.2d at 613.
150. *Id.*
151. *Id.*
152. *Id.*
153. *Id.*
154. *Id.* at 287, 658 S.E.2d at 615.
155. 283 Ga. 398, 659 S.E.2d 346 (2008).
156. *Id.* at 404, 659 S.E.2d at 351.
157. *Id.*, 659 S.E.2d at 352.
158. *Id.* (citing O.C.G.A. § 24-9-67.1(d)).
159. O.C.G.A. § 24-9-67.1(d).

Without many opinions from the Georgia appellate courts interpreting the *Daubert* statute, practitioners and judges assessing the admissibility of testimony from expert witnesses must rely on decisions from the federal courts as persuasive authority.[160] The following cases from federal courts within the Eleventh Circuit offer recent guidance on *Daubert* issues.

In *Gibbs Patrick Farms, Inc. v. Syngenta Seeds, Inc.*,[161] the trial court denied a motion in limine pursuant to Federal Rule of Evidence 702[162] seeking to exclude the testimony of the plaintiff's expert witness, Dr. Ron Gitaitis, who opined that the bacterial leaf spot in a crop of bell peppers came from the Stiletto seeds produced and distributed by the defendants.[163] The court noted that evaluation of expert testimony in this area is challenging because, understandably, there has been little research and testing in the area of detection of disease in bell pepper plants.[164] Accordingly, there is no widely-accepted procedure that an expert should use.[165]

In applying the *Daubert* standards to Dr. Gitaitis's testimony, the court found that the basic tests that Dr. Gitaitis employed were generally accepted and performed using an appropriate methodology.[166] A very significant factor in the court's analysis was the fact that Dr. Gitaitis performed the research in his job as a university scientist instead of as a paid litigation consultant.[167] The defendants' motion to exclude was denied.[168]

In contrast, a court can properly exclude the testimony of an expert witness under *Daubert* when that expert's opinion is based on an improper assumption about a critical fact.[169] In *Ferguson v. Bombardier Services Corp.*,[170] the plaintiffs sued multiple defendants for the alleged wrongful deaths of thirteen passengers who were killed in a

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

161. No. 7:06-cv-48(HL), 2008 U.S. Dist. LEXIS 23923 (M.D. Ga. Mar. 26, 2008).

162. FED. R. EVID. 702.

163. *Gibbs Patrick Farms*, 2008 U.S. Dist. LEXIS 23923, at *41-*42.

164. *Id.* at *47.

165. *Id.* at *47-*48.

166. *Id.* at *50-*51.

167. *Id.* at *51-*52.

168. *Id.* at *62.

169. *See* Ferguson v. Bombardier Servs. Corp., 244 F. App'x 944 (11th Cir. 2007) (unpublished).

170. 244 F. App'x 944 (11th Cir. 2007) (unpublished).

plane crash. The plaintiffs contended that the autopilot system was defective and caused the crash.[171]

John Malley, an aviation engineer who was presented to provide testimony regarding the allegedly defective autopilot system, based his opinion on unique oscillations that were found in the data recorded by the plane's flight data recording system. In reaching this conclusion, Malley assumed that the plane was not overweight. On cross-examination during a hearing about the reliability of his testimony, Malley admitted that these oscillations also could have been produced by an overloaded airplane. The district court concluded that the other evidence in the record clearly proved that the plane was overloaded and excluded Malley's testimony.[172]

On appeal, the United States Court of Appeals for the Eleventh Circuit concluded that the decision by the trial court to exclude Malley's testimony was not clearly erroneous.[173] The plaintiffs' reference to conflicting evidence about whether the plane was overweight was not sufficient to show that the district judge abused his discretion in concluding that the plane was overweight.[174]

In *Phillips v. American Honda Motor Co.*,[175] the plaintiffs sought to recover for the injuries sustained by a diabetic whose feet were burned while using a Honda all-terrain vehicle (ATV). The plaintiff retained Mike Burleson, an expert in ATV design and safety, to determine whether the Honda ATV was unreasonably dangerous. Burleson conducted two tests on the Honda ATV, one in July and the other in September, to analyze the amount of heat generated by the ATV's engine. In one test, Burleson examined an alternative design to determine whether it produced an acceptable level of heat. As part of a motion for summary judgment, the defendants moved to exclude Burleson's testimony, and the district court granted the motion.[176]

On appeal, the Eleventh Circuit reviewed the conclusions of the district court and held that substantial evidence supported the exclusion of Burleson's testimony.[177] In assessing Burleson's methodology, the court of appeals noted that he used a plastic dummy, instead of a human, to perform his testing and did not account for any variations in heating properties that could be attributed to the material differences

171. *Id.* at 947.
172. *Id.*
173. *Id.* at 949.
174. *Id.*
175. 238 F. App'x 537 (11th Cir. 2007) (unpublished).
176. *Id.* at 538-39.
177. *Id.* at 539-40.

between a human and a plastic dummy.[178] Likewise, Burleson did not account for fluctuating temperatures in the ambient air.[179] Finally, there was an irregularity in Burleson's September test that appeared to violate the laws of physics: he recorded higher temperatures at a location that was farther away from the heat source than another location with a lower recorded temperature.[180] Burleson was unable to offer a satisfactory explanation for this discrepancy.[181] The existence of uncontrolled and unexplained variables in Burleson's testing show that the district court did not abuse its discretion in excluding Burleson's testimony because his methodology was unreliable.[182]

In *Reynolds v. General Motors Corp.*,[183] the plaintiffs brought a wrongful death action against General Motors regarding the crashworthiness of a 1995 Chevrolet Blazer.[184] The plaintiff retained Dr. Patricia Davis, a radiologist, to opine about injury causation and the conscious pain and suffering experienced by the decedent.[185] In addition, the plaintiff proffered testimony from Dr. Charles Benedict regarding the design and performance of the seat belt and door systems.[186] The defendant moved to exclude the testimony of both of the plaintiff's experts under Rule 702.[187]

For Dr. Davis, the defendant contended that she lacked qualification to opine about the cause of the decedent's injuries.[188] But the district court disagreed.[189] Dr. Davis limited the scope of her testimony to the medical aspects of the injuries and did not attempt to reconstruct the accident or determine the source of each injury.[190] Accordingly, the court concluded that Dr. Davis could testify about this limited scope of her opinions.[191] However, the court excluded Dr. Davis's testimony regarding the decedent's post-injury level of consciousness because this opinion was not included in her expert report.[192]

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178. *Id.* at 540.
179. *Id.* at 540-41.
180. *Id.* at 541.
181. *Id.*
182. *Id.* at 542.
183. No. 2:04-CV-0106-RWS, 2007 U.S. Dist. LEXIS 73101 (N.D. Ga. Sept. 28, 2007).
184. *Id.* at *2-*3.
185. *Id.* at *13.
186. *Id.* at *16.
187. *Id.* at *10.
188. *Id.* at *14.
189. *Id.* at *15.
190. *Id.* at *14-*15.
191. *Id.* at *15.
192. *Id.*

For Dr. Benedict, the defendant challenged his qualifications to opine about vehicle design.[193] The district court found that Dr. Benedict's thirty-five years of experience in investigating the design of seat belts was sufficient qualification.[194] It is important to note that the court reached this conclusion while recognizing that most of Dr. Benedict's experience and research in this area was developed in his role as a litigation consultant, not as an academic researcher or nonlitigation consultant.[195]

The defendant also questioned the reliability of Dr. Benedict's testimony regarding his theory that the seat belt experienced an inertial unlatch during the accident.[196] In 1999 the court had excluded similar testimony but found that more studies had been done since that time, which offered support for Dr. Benedict's theory.[197] The court found that the inertial unlatch theory had become the subject of substantial debate within the scientific community instead of having very little acceptance.[198]

In *Inam International, Inc. v. Broan-Nutone LLC*,[199] the plaintiff sued the manufacturer of an exhaust fan to recover for damage to a convenience store caused by a fire that allegedly started in the fan.[200] The plaintiff contended that the insulation used in the fan motor degraded, causing the fire.[201] In support of this theory, the plaintiff offered the testimony of Thomas Eager, a materials engineer, and Richard Underwood, an electrical engineer.[202] In conjunction with a motion for summary judgment, the defendant used Rule 702 to challenge the reliability of the methodology used by both expert witnesses in reaching their conclusions that the exhaust fan was the cause of the fire.[203]

First, the defendant argued that Thomas Eager was not qualified to offer his opinions.[204] But the district court found that Eager, a graduate of and current professor at Massachusetts Institute of Technology who has published over two hundred articles and received

193. *Id.* at *16.
194. *Id.* at *16-*17.
195. *Id.* at *17.
196. *Id.*
197. *Id.* at *17-*18.
198. *Id.* at *18.
199. No. 1:05-CV-0852-CAP, 2007 U.S. Dist. Lexis 96028 (N.D. Ga. Sept. 21, 2007).
200. *Id.* at *1.
201. *Id.* at *2-*3.
202. *Id.* at *5-*6.
203. *Id.* at *4-*5.
204. *Id.* at *10.

numerous awards, was sufficiently qualified.[205] The court emphasized that to show the proper qualification, the expert witness does not have to be recognized as one of the leading authorities in the area at issue.[206]

Next, the defendant contended that Eager did not undertake the proper testing or investigation to support his opinion.[207] In response, the plaintiff showed that Eager followed the standard procedure outlined in the National Fire Protection Agency fire investigation manual and used basic scientific principles, like Fourier's First Law of Heat Conduction, to develop his opinions.[208] The court concluded that fire investigation is not the type of practice in which a comprehensive test can serve as the sole basis for the opinion of an expert witness.[209] Instead, Eager's methodology was deemed appropriate because he followed a nationally recognized process and supported it with basic scientific principles.[210]

The defendant also challenged the qualifications of the plaintiff's other expert witness, Richard Underwood.[211] The court found that Underwood's thirty years of analysis of electric motor failures, which includes forty to fifty investigations of fires, was sufficient qualification to opine in this matter.[212]

For Underwood's methodology, the defendant contended that he did not test any fans to verify his theory of ignition and his opinion was contrary to the testimony of the only eyewitness to the fire.[213] Like Eager, Underwood used the National Fire Protection Agency guidelines for his investigation.[214] In addition, he used metallurgic analysis to support his opinion.[215] The court concluded that Underwood undertook a reasonable methodology even though the court questioned why he was unable to use a test to verify his fire causation theory.[216] Contrary to the defendant's assertion, the court did not find that the eyewitness testimony unambiguously contradicted Underwood's opinion.[217]

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205. *Id.* at *10-*11.
206. *Id.* at *10 (citing Leathers v. Pfizer, Inc., 233 F.R.D. 687, 692 (N.D. Ga. 2006)).
207. *Id.* at *13.
208. *Id.* at *15-*17.
209. *Id.* at *24-*25.
210. *Id.* at *25-*26.
211. *Id.* at *26.
212. *Id.* at *27-*28.
213. *Id.* at *29.
214. *Id.*
215. *Id.* at *30-*31.
216. *Id.* at *33-*34.
217. *Id.* at *35.

Instead, the testimony was subject to multiple interpretations.[218] The court denied the defendant's motion.[219]

With the Georgia Supreme Court affirming the constitutionality of O.C.G.A. § 24-9-67.1, practitioners in Georgia state courts can look forward to the continued use of the *Daubert* standard, which will lead to more appellate decisions refining the contours of the admissibility standard that we will cover in future articles.

V. DEFENSES

A. *Preemption*

When the federal government regulates the manufacture, use, or marketing of a product, the doctrine of federal preemption may provide a complete or partial defense to a product liability claim brought under state law. This doctrine is based on the Supremacy Clause of the United States Constitution,[220] which provides as follows:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.[221]

The essence of this doctrine is that "state law that conflicts with federal law is 'without effect.'"[222] 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.[223] In this context, the term "state law" is not limited to statutes and regulations; it also includes common-law liability because "[t]he obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[224]

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218. *Id.*
219. *Id.*
220. U.S. CONST. art. VI, cl. 2.
221. *Id.*
222. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (quoting Maryland v. Louisiana, 451 U.S. 725, 746 (1981)).
223. Int'l Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987).
224. San Diego Bldg. Trades Council, Millmen's Union, Local 2020 v. Garmon, 359 U.S. 236, 247 (1959).

"The critical question in any pre-emption analysis is always whether Congress intended that federal regulation supersede state law."[225] In fact, Congress's purpose in enacting the federal law is the "'ultimate touchstone'" of the preemption analysis.[226] Congress may manifest its intent to preempt state law "by express language in a congressional enactment [i.e., express preemption], by implication from the depth and breadth of a congressional scheme that occupies the legislative field [i.e., field preemption], or by implication because of a conflict with a congressional enactment [i.e., implied or conflict preemption]."[227] Because preemption is a matter of congressional intent, whether a state law is preempted depends on the nature of the federal regulation of the product at issue. The issue of preemption arose in two cases decided during the survey period—one involving federal regulation of childhood vaccines and the other involving federal regulation of medical devices.[228]

1. National Childhood Vaccine Injury Act of 1986. The National Childhood Vaccine Injury Act of 1986 (Vaccine Act)[229] "establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system" for injuries caused by vaccinations.[230] The United States Court of Appeals for the First Circuit, in an opinion written by then Judge and now Justice Stephen Breyer, has described Congress's purpose in enacting the Vaccine Act as follows:

> The National Childhood Vaccine Injury Act represents an effort to provide compensation to those harmed by childhood vaccines outside the framework of traditional tort law. Congress passed the law after hearing testimony 1) describing the critical need for vaccines to protect children from disease, 2) pointing out that vaccines inevitably harm a very small number of the many millions of people who are vaccinated, and 3) expressing dissatisfaction with traditional tort law as a way of compensating those few victims. Injured persons (potential tort plaintiffs) complained about the tort law system's uncertain recoveries, the high cost of litigation, and delays in obtaining compensation. They

225. Louisiana Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 369 (1986) (citing Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

226. *Cipollone*, 505 U.S. at 516 (quoting Malone v. White Motor Corp., 435 U.S. 497, 504 (1978)).

227. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 541 (2001) (internal citations omitted).

228. *See* Ferrari v. Am. Home Prods. Corp, 286 Ga. App. 305, 650 S.E.2d 585 (2007); Rigel v. Medtronic, Inc., 128 S. Ct. 999 (2008).

229. 42 U.S.C. §§ 300aa-1 to -34 (2000 & Supp. V 2005).

230. Shalala v. Whitecotton, 514 U.S. 268, 269 (1995).

> argued that government had, for all practical purposes, made vaccination obligatory, and thus it had a responsibility to ensure that those injured by vaccines were compensated. Vaccine manufacturers (potential tort defendants) complained about litigation expenses and occasional large recoveries, which caused insurance premiums and vaccine prices to rise, and which ultimately threatened the stability of the vaccine supply.[231]

To accomplish this purpose, the Vaccine Act created the National Vaccine Injury Compensation Program, which "tries more quickly to deliver compensation to victims, while also reducing insurance and litigation costs for manufacturers."[232] Under the Vaccine Act, a person who sustains a vaccine-related injury and seeks more than $1000 in damages must first file a petition for compensation with the United States Court of Federal Claims (Vaccine Court).[233] Once the Vaccine Court enters judgment on the petition, the person has the option of either accepting the judgment and abandoning his tort rights or rejecting the judgment and retaining his right to file a tort lawsuit, subject to certain restrictions on available tort remedies.[234] For example, a vaccine manufacturer is not liable "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[235]

This restriction has been almost universally interpreted as preempting state law claims based on an alleged design defect.[236] The one court that reached a contrary conclusion was the Georgia Court of Appeals in a case decided during the survey period.[237] In *Ferrari v. American*

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231. Schafer v. Am. Cyanamid Co., 20 F.3d 1, 2 (1st Cir. 1994).

232. *Id.*; *see also* 42 U.S.C. § 300aa-10(a) (2000) (establishing the National Vaccine Injury Compensation Program).

233. 42 U.S.C. § 300aa-11(a) (2000). A "vaccine-related injury" is "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. § 300aa-33(5) (2000).

234. 42 U.S.C. § 300aa-21(a) (2000). In addition, the person may withdraw his petition if the Vaccine Court does not act within the prescribed time. 42 U.S.C. § 300aa-21(b) (2000).

235. 42 U.S.C. § 300aa-22(b)(1) (2000). Vaccine manufacturers are also not liable for failing to warn the injured person about the potential dangers of the vaccine. 42 U.S.C. § 300aa-22(c) (2000).

236. *See, e.g.*, Sykes v. GlaxoSmithKline, 484 F. Supp. 2d 289, 301-03 (E.D. Pa. 2007); Blackmon v. Am. Home Prods. Corp., 328 F. Supp. 2d 659, 664-66 (S.D. Tex. 2004); Militrano v. Lederle Labs., 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006).

237. *See* Ferrari v. Am. Home Prods. Corp., 286 Ga. App. 305, 650 S.E.2d 585.

Home Products Corp.,[238] the plaintiffs' child sustained neurological damage after being inoculated with vaccines containing thimerosal, which is a preservative that contains mercury. The plaintiffs sued several vaccine manufacturers and others, alleging that their child's exposure to mercury caused his neurological injuries and that the vaccines were defective because they were manufactured with thimerosal. The vaccine manufacturers moved for summary judgment on numerous grounds, including that the plaintiffs' design defect claim was preempted by the Vaccine Act. The trial court agreed and granted summary judgment on that issue.[239]

On appeal, the court of appeals acknowledged the unanimity of prior cases holding that the Vaccine Act preempts design defect claims, but it declined to follow those cases because they were decided before or did not address the United States Supreme Court's opinion in *Bates v. Dow AgroSciences, LLC*,[240] which involved the preemption clause in the Federal Insecticide, Fungicide, and Rodenticide Act.[241] In *Bates* the Supreme Court held that it had a duty to interpret the preemption clause against preemption, even if the manufacturer had offered a plausible alternative interpretation.[242] The Georgia Court of Appeals interpreted this holding as "drastically chang[ing] traditional preemption analysis" in two ways:

> (1) There is no longer a rebuttable *presumption* against preemption, but a *duty to accept* the reading of an express preemption statute that disfavors preemption; and (2) preemption analysis ends with an examination of the statutory language alone. Under this approach, it appears that legislative history should no longer be examined to discern Congressional intent when an express preemption clause has two plausible alternative readings.[243]

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238. 286 Ga. App. 305, 650 S.E.2d 585 (2007).

239. *Id.* at 305-06, 650 S.E.2d at 586-87. Although thimerosal was added to the vaccines, it is not an adulterant or contaminant within the meaning of the Vaccine Act such that a person alleging an injury caused by mercury in thimerosal is not required to file a petition for compensation with the Vaccine Court. Murphy v. Aventis Pasteur, Inc., 270 F. Supp. 2d 1368, 1375-76 (N.D. Ga. 2003). In other words, a thimerosal-related injury is a vaccine-related injury for purposes of triggering the no-fault compensation system in the Vaccine Act. *Id.*

240. 544 U.S. 431 (2005). For a thorough discussion of *Bates*, see Franklin P. Brannen, Jr. et al., *Product Liability*, 58 MERCER L. REV. 313, 351-56 (2006).

241. *Ferrari*, 286 Ga. App. at 308-09, 650 S.E.2d at 588; Federal Insecticide, Fungicide, & Rodenticide Act, Pub. L. No. 92-516, 86 Stat. 973 (1973).

242. *Bates*, 544 U.S. at 449.

243. *Ferrari*, 286 Ga. App. at 310, 650 S.E.2d at 589.

The court of appeals determined that there are two plausible alternative interpretations of the preemption clause in the Vaccine Act: "One reading is that vaccine injuries are 'unavoidable' and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings. The other reading is that design defect claims are preempted only if the side effects are determined to be unavoidable on a case-by-case basis."[244] As a result, the court of appeals held that *Bates* is "outcome determinative," that it had a duty to accept the interpretation of the Vaccine Act that disfavors preemption, and that it could not look to the legislative history of the Vaccine Act to discern Congress's intent in enacting the preemption clause.[245] Nevertheless, the court of appeals agreed with prior cases, observing that "when the contemporaneous legislative history of the Vaccine Act is examined, Congress's intent to preempt this issue becomes clear."[246] Thus, the court of appeals acknowledged that its decision "is anomalous given the clear legislative history to the contrary," but it felt "constrained to follow the Supreme Court's explicit guidance in *Bates*."[247] The vaccine manufacturers argued that *Bates* does not apply to the preemption clause in the Vaccine Act, but the court of appeals disagreed because "[t]he language at issue is very broad and addresses preemption analysis generally."[248] Accordingly, the court of appeals held that the trial court erred in granting the vaccine manufacturers' motion for summary judgment.[249]

Since the court of appeals decided *Ferrari*, no other court has agreed with its rationale in a reported decision. In fact, the only other court that has even cited *Ferrari* in a reported decision was extremely critical of its analysis.[250] In *Bruesewitz v. Wyeth, Inc.*,[251] the United States District Court for the Eastern District of Pennsylvania held that "*Bates* does not require a court to automatically accept a plausible interpretation of a statute which disfavors preemption" and observed that "the *Ferrari* holding takes only one part of the *Bates* ruling out of its context, and gives it broader scope than is appropriate."[252] As the district court

244. *Id.* at 311, 650 S.E.2d at 590.
245. *Id.* at 312, 650 S.E.2d at 590.
246. *Id.* at 311, 650 S.E.2d at 590 (citing *Sykes*, 484 F. Supp. 2d at 301-03; Militrano v. Lederle Labs., 769 N.Y.S.2d 839, 843-44 (2003)).
247. *Id.* at 312, 650 S.E.2d at 590.
248. *Id.*
249. *Id.*
250. *See* Bruesewitz v. Wyeth, Inc., 508 F. Supp. 2d 430 (E.D. Pa. 2007).
251. 508 F. Supp. 2d 430 (E.D. Pa. 2007).
252. *Id.* at 444.

in *Bruesewitz* noted, *Ferrari*'s interpretation of *Bates* was flawed because "*Bates* itself relies on the congressional intent behind [the Federal Insecticide, Fungicide, and Rodenticide Act] when applying the rule."[253] Indeed, the United States Supreme Court has stated repeatedly since 1963 that congressional intent is the "ultimate touchstone" of the preemption analysis,[254] and nothing in *Bates* alters this focus. "Thus, even though there is a 'basic presumption against pre-emption,' a court must look to whether that presumption accords with Congress' intent in enacting a specific law."[255]

After the survey period, the Georgia Supreme Court granted the vaccine manufacturers' petition for writ of certiorari in *Ferrari*, and although the supreme court agreed with the Eastern District of Pennsylvania's criticism of the court of appeals interpretation of *Bates*, it nevertheless affirmed the decision of the court of appeals.[256] The supreme court held that the preemption clause in the Vaccine Act "clearly does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe."[257] The supreme court's opinion in *Ferrari* will be discussed in greater detail in next year's article.

2. Medical Device Amendments of 1976. Before Congress enacted the Medical Device Amendments of 1976 (MDA),[258] the FDCA did not regulate the introduction of new medical devices.[259] As medical technology advanced in the 1970s and the use of medical devices such as catheters, artificial heart valves, defibrillators, and pacemakers became increasingly common, there was a corresponding increase in the number of injuries caused by these complex devices.[260] In response to the public's and the FDA's concerns about injuries caused by medical devices, Congress enacted the MDA "'to provide for the safety and effectiveness of medical devices intended for human use.'"[261]

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253. *Id.* (citing *Bates*, 544 U.S. at 449).

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

255. *Bruesewitz*, 508 F. Supp. 2d at 444 (quoting *Bates*, 544 U.S. at 449).

256. Am. Home Prods. Corp. v. Ferrari, No. S07G1708, 2008 WL 4452358, at *2-*3 (Ga. Oct. 6, 2008).

257. *Id.* at *7.

258. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 15, 21, and 42 U.S.C.).

259. Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996).

260. *Id.* at 476.

261. *Id.* at 474 (quoting Medical Devices Amendments Act of 1976, 90 Stat. 539).

The regulatory scheme established by the MDA classifies medical devices into three categories based on their risks.[262] Class I devices present no unreasonable risk of harm and are subject to minimal regulation in the form of "general controls."[263] Class II devices present a greater risk of harm and must comply with federal performance regulations known as "special controls," though they may be marketed without advance approval by the FDA.[264] Class III devices present an unreasonable risk of harm or are designed to support or sustain human life or to prevent impairment of human health, and they may be marketed only with advance approval by the FDA.[265]

The premarket approval process for Class III devices is rigorous and requires a manufacturer to submit voluminous and detailed information about the device's safety and effectiveness.[266] The FDA spends an average of twelve hundred hours reviewing and evaluating each application.[267] The premarket approval process includes an evaluation of the proposed labeling to ensure that it is not false or misleading.[268] An application will be granted only if the FDA determines that there is a "reasonable assurance of [the device's] safety and effectiveness."[269] Once the device has received premarket approval, the manufacturer may not alter any aspect of the device that would affect its safety or effectiveness without first submitting a supplemental application and obtaining the FDA's approval.[270]

If a device was already sold before Congress enacted the MDA, the manufacturer may continue to sell it until the FDA promulgates a regulation requiring the manufacturer to subject it to the premarket approval process.[271] In addition, a manufacturer may avoid the premarket approval process for a device that is "substantially equivalent" to another device that is exempt from the process.[272] Most Class III devices on the market today have not been subjected to the rigorous premarket approval process but instead are marketed pursuant to one of these exemptions.[273] The FDA conducts only a limited review for

262. *See* 21 U.S.C. § 360c(a) (2000).
263. *Id.* § 360c(a)(1)(A).
264. *Id.* § 360c(a)(1)(B).
265. *Id.* § 360c(a)(1)(C).
266. *Lohr*, 518 U.S. at 477.
267. *Id.*
268. 21 U.S.C. § 360e(d)(1)(A) (2000).
269. *Id.*
270. 21 U.S.C. § 360e(d)(6) (2000).
271. 21 U.S.C. § 360e(b)(1) (2000).
272. *Id.*
273. *Lohr*, 518 U.S. at 477-80.

devices subject to the "substantially equivalent" exemption, spending only about twenty hours reviewing and evaluating the manufacturer's submission.[274]

The MDA contains a preemption clause that prohibits any state or local government from "establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement" that (1) "is different from, or in addition to, any requirement applicable under this chapter to the device," and (2) "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."[275] The United States Supreme Court's first opportunity to construe this clause was in *Medtronic, Inc. v. Lohr*,[276] which involved a pacemaker (a Class III device) that had been approved for marketing under the "substantially equivalent" provision in the MDA.[277] A plurality of the Court rejected as "unpersuasive" and "implausible" the manufacturer's "extreme position" that the MDA preempts all state common-law actions.[278] A majority of the Court rejected the manufacturer's arguments relating to preemption of the plaintiff's specific claims.[279] The manufacturer argued that the plaintiff's design defect claim was preempted because the FDA's determination that the pacemaker was "substantially equivalent" to another device amounted to a federal design requirement, but the Court held that this claim was not preempted because the pacemaker had never been reviewed for safety and effectiveness; the "substantial equivalence" review process focuses on equivalence, not safety.[280] As to the plaintiff's manufacturing-defect and failure to warn claims, the Court held that such claims are not preempted because MDA preemption occurs "only where a particular state requirement threatens to interfere with a specific federal interest."[281] Because the FDA's regulations impose only general manufacturing and labeling requirements, they "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements."[282] And because the

274. *Id.* at 479.

275. 21 U.S.C. § 360k(a) (2000). The FDA may exempt certain state and local requirements from the preemption clause. 21 U.S.C. § 360k(b) (2000).

276. 518 U.S. 470 (1996).

277. *Id.* at 480.

278. *Id.* at 487-90.

279. *Id.* at 492-502.

280. *Id.* at 492-94.

281. *Id.* at 500.

282. *Id.* at 501.

plaintiff's manufacturing-defect and failure to warn claims were based on the general duties that a manufacturer owes to use due care in manufacturing its product and to inform users about the risks of its product, the Court held that "their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers."[283]

In light of the importance of "device specificity" in determining the preemptive effect of the MDA, a plurality of the Court commented that "it is apparent that few, if any, common-law duties have been pre-empted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.'"[284] During the survey period, the Court decided a case that provided just such a rare opportunity.[285]

In *Riegel v. Medtronic, Inc.*,[286] the plaintiff was injured when an Evergreen Balloon Catheter ruptured during a coronary angioplasty. The catheter was a Class III device and had received premarket approval from the FDA in 1994. The plaintiff brought a full range of product liability claims against the manufacturer under New York common law. The district court found that most of the plaintiff's claims were preempted by the MDA and granted summary judgment to the manufacturer on the remaining claims. The United States Court of Appeals for the Second Circuit affirmed.[287]

To determine the preemptive effect of the MDA, the Court first considered whether there were any federal requirements applicable to the catheter.[288] In contrast to *Lohr*, which involved approval of a device under the "substantial equivalence" review process, the catheter in this case was approved under the rigorous premarket approval process.[289] Whereas the "substantial equivalence" review process involved in *Lohr* did not constitute a "requirement" as that term is used in the preemption clause, the premarket approval process involved in this case imposed many "requirements" on the manufacturer.[290] The Court described the difference between the "substantial equivalence" review process and the premarket approval process as follows:

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283. *Id.* at 501-02.
284. *Id.* at 502-03 (quoting 21 C.F.R. § 808.1(d)(6)(ii) (1995)).
285. *See* Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008).
286. 128 S. Ct. 999 (2008).
287. *Id.* at 1005-06.
288. *Id.* at 1006.
289. *Id.* at 1006-07.
290. *Id.* at 1007.

> Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it *is* federal safety review. Thus, the attributes that *Lohr* found lacking in § 510(k) review are present here. While § 510(k) is focused on *equivalence,* not safety, premarket approval is focused on safety, not equivalence. While devices that enter the market through § 510(k) have never been formally reviewed under the MDA for safety or efficacy, the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness. And while the FDA does not require that a device allowed to enter the market as a substantial equivalent take any particular form for any particular reason, the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.[291]

Having determined that there were several federal requirements applicable to the catheter, the Court next considered whether the plaintiff's common-law claims depended on any state requirements that were "different from, or in addition to" the federal requirements and that related to the safety and effectiveness of the catheter.[292] Because the safety and effectiveness of the catheter were at the heart of the plaintiff's claims, the only issue was whether the tort duties imposed by New York common law constituted "requirements."[293] The Court answered that question in the affirmative, holding that "[a]bsent other indication, reference to a State's 'requirements' [in a preemption statute] includes its common-law duties."[294] As the Court explained, "[s]tate tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."[295]

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291. *Id.* (citations and internal quotation marks omitted).

292. *Id.*

293. *Id.*

294. *Id.* at 1008.

295. *Id.* This conclusion seems to be somewhat at odds with the Court's conclusion in *Lohr* that the manufacturing-defect and failure to warn claims at issue in that case were based on duties that were too general to constitute "requirements." *Lohr*, 518 U.S. at 501-02. However, the Court in *Lohr* noted that the MDA does not necessarily preclude general state requirements from ever being preempted. *Id.* at 500. Moreover, the duties upon which the plaintiff relied in *Lohr* were quite general, whereas the duties upon which the plaintiff relied in *Riegel* appear to have been more specific.

Accordingly, the Court held that the MDA preempted the plaintiff's claims.[296]

As the Court recognized in both *Riegel* and *Lohr*, most new Class III devices enter the market pursuant to the "substantial equivalence" review process, rather than through the premarket approval process.[297] In 2005, for example, the FDA approved 3148 devices based on the "substantial equivalence" review process, compared to its approval of only thirty-two devices based on the premarket approval process.[298] Consequently, *Riegel* is a very narrow decision and will have limited application since it apparently applies only to Class III devices that are approved pursuant to the premarket approval process. *Lohr* will presumably continue to control cases involving devices marketed pursuant to the "substantial equivalence" review process.

While *Riegel* will have a relatively modest impact given its limited applicability, the next survey period will see the Court consider a preemption case with the potential to have a dramatic impact on pharmaceutical litigation. The Court granted certiorari in *Wyeth v. Levine*[299] to consider the Vermont Supreme Court's decision that the FDA's prescription drug labeling requirements do not impliedly preempt state law failure to warn claims.[300] The dissent in *Riegel* assumed that state law tort lawsuits are not preempted by the FDCA, but the issue will now be squarely addressed in the Court's 2008 Term. The Court heard oral argument in *Levine* on November 3, 2008, so stay tuned to next year's article for an update on this important issue.

B. Learned Intermediary Doctrine

Generally, a manufacturer owes a duty to foreseeable users of its product to warn about foreseeable dangers in the product.[301] The learned intermediary doctrine is an exception to this general rule that typically applies in the healthcare context, and it provides a defense to manufacturers of prescription drugs and medical devices against claims

296. *Riegel*, 128 S. Ct. at 1011.

297. *Id.* at 1004; *Lohr*, 518 U.S. at 477.

298. *Riegel*, 128 S. Ct. at 1004 (citing PETER HUTT ET AL., FOOD & DRUG LAW: CASES & MATERIALS 992 (3d ed. 2007)).

299. 128 S. Ct. 1118 (2008).

300. Levine v. Wyeth, 944 A.2d 179, 183-94 (Vt. 2006).

301. Moore v. ECI Mgmt., 246 Ga. App. 601, 606, 542 S.E.2d 115, 120-21 (2000). This general rule is discussed in more detail in Part II.

for failure to warn.[302] The Georgia Supreme Court has described the learned intermediary doctrine as follows:

> Under the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that 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.[303]

Ordinarily, then, a drug manufacturer does not owe a duty to warn to a patient; instead, it owes a duty to the patient's doctor and satisfies that duty by providing reasonable and adequate warnings of the drug's or device's risks.[304] As with most general rules, however, there are exceptions to the learned intermediary doctrine. One exception involves direct-to-consumer advertising, the theory being that the manufacturer loses the protection of the learned intermediary doctrine by circumventing the learned intermediaries (that is, the doctors) and directly promoting a drug to potential users, such as via television commercials or magazine advertisements.[305]

The Georgia Court of Appeals addressed the issue of direct-to-consumer advertising in its 1997 decision in *Presto v. Sandoz Pharmaceuticals Corp.*[306] In that case, the plaintiffs alleged that the manufacturer of Clozaril, an antipsychotic prescription drug, was liable for their son's suicide because it failed to warn him about the dangers of abrupt discontinuation. In fact, the package insert for Clozaril contained a warning about abrupt discontinuation and recommended that users gradually reduce their dosage over one to two weeks. The plaintiffs

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302. 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, 85 Ga. App. 405, 409-10, 69 S.E.2d 689, 692-93 (1952).

303. McCombs v. Synthes (U.S.A.), 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003) (alteration in original) (footnote and internal quotation marks omitted) (quoting McCombs v. Synthes (U.S.A.), 250 Ga. App. 543, 545, 553 S.E.2d 17, 20 (2001)).

304. *Id.*

305. Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5TH 1, 135-36 & Supp. at 15-16 (1998 & Supp. 2008). This exception has not been widely accepted. *See, e.g.*, Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1375-77 (S.D. Fla. 2007).

306. 226 Ga. App. 547, 487 S.E.2d 70 (1997).

acknowledged the learned intermediary doctrine but argued that the direct-to-consumer advertising exception should apply because the manufacturer provided their son with a pamphlet entitled "Understanding Clozaril (clozapine) Therapy: A Guide for Patients and Their Families." The plaintiffs relied on the voluntary undertaking doctrine and argued that the manufacturer was liable because it voluntarily undertook to provide some information directly to patients but failed to include a warning about abrupt discontinuation in the pamphlet.[307] The court of appeals rejected the plaintiffs' theory of liability because their son could not have reasonably relied on the pamphlet to warn him about all dangers associated with Clozaril.[308] Because the pamphlet stated that it was not intended to inform users about all of the dangers associated with Clozaril and specifically advised users to speak with their doctor, nurse, or pharmacist if they had any other questions, and because the plaintiffs' son relied on his doctor to prescribe and supervise his use of Clozaril, the court of appeals held that the manufacturer did not voluntarily undertake a duty to warn the plaintiffs' son about all dangers associated with Clozaril.[309]

Although the *Restatement (Third) of Torts: Products Liability (Restatement)*[310] was published in draft form when *Presto* was decided, the court of appeals did not discuss whether it had any effect on the consideration of the direct-to-consumer advertising exception.[311] In its final form, which the American Law Institute published in 1998, section 6 of the *Restatement* retained the learned intermediary doctrine but also included a variation on the direct-to-consumer advertising exception.[312] Under this exception, a warning must be provided to "the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings."[313] According to comment e of section 6, this provision "recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider. An example is the administration of a vaccine in clinics where mass inoculations are performed."[314] Comment e also

307. *Id.* at 547-49, 487 S.E.2d at 72-74.
308. *Id.* at 549, 487 S.E.2d at 74.
309. *Id.*
310. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998).
311. *Presto*, 226 Ga. App. at 549, 487 S.E.2d at 74.
312. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).
313. *Id.* § 6(d)(2).
314. *Id.* § 6 cmt. e.

suggests that "courts should consider imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers" when (1) "governmental regulatory agencies have mandated that patients be informed of risks attendant to the use of a drug," and (2) "manufacturers have advertised a prescription drug and its indicated use in the mass media."[315]

During the survey period, the United States District Court for the Northern District of Georgia re-examined the viability of the direct-to-consumer advertising exception in light of section 6 of the *Restatement*.[316] In *Porter v. Eli Lilly & Co.*,[317] Dr. Bernard Wolfberg treated the plaintiff's husband for anxiety, prescribed Prozac, and advised him to return for a follow-up visit in four weeks. The plaintiff's husband began taking Prozac as Dr. Wolfberg recommended and committed suicide less than two weeks later. During his deposition, Dr. Wolfberg testified at length about his knowledge of the risks and benefits of Prozac, and although he was not familiar with concerns about a link between Prozac and suicidality in adults with anxiety, he testified that he would have prescribed Prozac for the plaintiff's husband even if he had known about those concerns because the plaintiff's husband was not suicidal at the time of the initial treatment. The plaintiff sued the manufacturer of Prozac and alleged that it was liable for her husband's death because it failed to warn him adequately about the risks of suicide. The manufacturer filed a motion for summary judgment based on the learned intermediary doctrine.[318]

The plaintiff argued that the district court should adopt the direct-to-consumer advertising exception set forth in section 6 of the *Restatement* and explained further in comment e.[319] The district court rejected the plaintiff's argument and refused to adopt the *Restatement*'s suggestions because "there is no indication that courts in Georgia are moving toward a general requirement of direct warning to consumers of prescription drugs."[320] The underlying rationale for the *Restatement*'s direct-to-consumer advertising exception—that some drugs are dispensed or administered in an unsupervised environment—was inapplicable in this case because Dr. Wolfberg prescribed Prozac only after examining the

315. *Id.*

316. *See* Porter v. Eli Lilly & Co., No. 1:06-CV-1297-JOF, 2008 WL 544739 (N.D. Ga. Feb. 25, 2008).

317. No. 1:06-CV-1297-JOF, 2008 WL 544739 (N.D. Ga. Feb. 25, 2008).

318. *Id.* at *1-*5.

319. *Id.* at *7.

320. *Id.* at *9.

plaintiff's husband and considering his medical history.[321] Moreover, at the time the plaintiff's husband died, the FDA did not require the manufacturer to warn potential users about any suicide risks associated with Prozac.[322] Finally, the district court refused to impose a duty on the manufacturer to warn potential users about suicide risks associated with Prozac based on the manufacturer's direct-to-consumer advertising; such a requirement "would be an expansion of the current state of law as it exists in Georgia which affirmatively recognizes the learned intermediary doctrine."[323]

Despite ruling in favor of the manufacturer on the issue of the direct-to-consumer advertising exception, the district court could not grant the manufacturer's motion for summary judgment without first considering the effect of an arguably inadequate warning on the element of proximate cause.[324] For purposes of its motion, the manufacturer had assumed that the warning about the risk of suicide was not adequate.[325] The plaintiff argued that the manufacturer's motion should be denied because the learned intermediary doctrine applies only when a drug manufacturer has adequately warned the patient's doctor about the relevant risks.[326] Finding this intersection of the learned intermediary doctrine with proximate cause to be an issue of first impression in Georgia, the district court had to consider whether the learned intermediary doctrine applies—that is, whether the causal link is broken—when (1) the manufacturer assumes the inadequacy of the warning, (2) the prescribing doctor testifies that he had no knowledge about the alleged risks, and (3) the prescribing doctor also testifies that he would have prescribed the drug even if he had known about the alleged risks because those risks were not relevant to the patient.[327]

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321. *Id.* at *8.

322. *Id.*

323. *Id.*

324. *Id.* at *9.

325. *Id.* At the time Dr. Wolfberg prescribed Prozac for the plaintiff's husband, the package insert warned that "[t]he possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy." *Id.* at *4.

326. *Id.* at *9. Indeed, the Georgia Supreme Court has held that "the manufacturer's warnings to the physician must be adequate or reasonable under the circumstances of the case." *McCombs*, 277 Ga. at 253, 587 S.E.2d at 595.

327. *Porter*, 2008 WL 544739, at *9. Prior cases, including one case decided by the United States District Court for the Southern District of Georgia just four days before *Porter*, have held that a manufacturer is not entitled to summary judgment on the ground that there were factual disputes regarding the adequacy or reasonableness of the warning provided. *See, e.g.*, Bryant v. Hoffmann-La Roche, Inc., 262 Ga. App. 401, 410, 585 S.E.2d 723, 730 (2003) (physical precedent); Trickett v. Advanced Neuromodulation Sys., Inc., 542

To answer this question, the district court turned to comment j of section 402A of the *Restatement (Second) of Torts*,[328] which provides that "[w]here warning is given, the seller may reasonably assume that it will be read and heeded,"[329] because it assumed that the Georgia courts would adhere to this provision.[330] After reviewing precedent on this issue from other jurisdictions, the district court determined that some courts interpret this presumption as a "heeding presumption," meaning that the patient's doctor is presumed to have heeded and followed the manufacturer's warning, whereas other courts interpret this presumption as a rebuttable presumption, meaning that it may be rebutted by evidence that the doctor would have provided the same treatment even if he had known about the warning.[331] Because there is no support for the "heeding presumption" in Georgia law, especially since that presumption improperly relieves the patient of her burden of proving proximate cause, the district court adopted the rebuttable presumption and applied the following burden-shifting framework used by a majority of courts:

> (1) the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known; (2) assuming the plaintiff raises a triable issue on this question, a rebuttable presumption arises that the physician would have heeded an adequate warning had such a warning been provided; (3) defendant must then come forward with sufficient evidence to rebut that presumption; and (4) if the presumption is rebutted, plaintiff must produce sufficient evidence to create a triable issue on the question of causation.[332]

Given that the manufacturer had conceded the inadequacy of the warning for purposes of its motion for summary judgment, the district court found that the first requirement was satisfied and that the burden shifted to the manufacturer to rebut the presumption that Dr. Wolfberg would have heeded an adequate warning had such a warning been provided.[333] Based on Dr. Wolfberg's deposition testimony that he would have treated the plaintiff's husband in the same manner and with the same medication even if he had been warned about a risk of suicide

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F. Supp. 2d 1338, 1347-48 (S.D. Ga. 2008).

328. RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965).

329. *Id.*

330. *Porter*, 2008 WL 544739, at *9, *11.

331. *Id.* at *10-*11.

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

333. *Id.* at *11.

(because he did not consider the plaintiff's husband to be a suicide risk), the district court found that the manufacturer had rebutted the presumption.[334] In other words, the evidence showed that a different or an additional warning would not have affected Dr. Wolfberg's decision to prescribe Prozac for the plaintiff's husband.[335] Because the plaintiff offered no contradictory evidence, the district court held that the plaintiff's claims failed for lack of proximate cause and that the manufacturer was therefore entitled to summary judgment.[336]

The district court's decision in *Porter* represents an important victory for drug manufacturers. By refusing to recognize a direct-to-consumer advertising exception and applying only a rebuttable presumption to the issue of proximate cause, the decision reaffirms the strength and vitality of Georgia's learned intermediary doctrine. A strong learned intermediary doctrine is important for drug manufacturers defending lawsuits in Georgia because most claims in pharmaceutical litigation are based on a failure to warn theory. Although Georgia's learned intermediary doctrine remains strong, it also remains fair because it does not preclude failure to warn claims when the manufacturer has not provided an adequate or reasonable warning to the patient's doctor. These characteristics of Georgia's learned intermediary doctrine work in tandem to respect the doctor-patient relationship.

334. *Id.*
335. *Id.* at *12.
336. *Id.* at *12-*13.

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