Product Liability

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This Article surveys developments in Georgia product liability law between June 1, 2011 and May 31, 2012.¹ This Article covers noteworthy cases decided during this period by the Supreme Court of Georgia, the Court of Appeals of Georgia, the Supreme Court of the United States, the United States Court of Appeals for the Eleventh Circuit, and the United States district courts located in Georgia.

I. EXPERT TESTIMONY

More than six years ago Georgia adopted the *Daubert v. Merrell Dow Pharmaceuticals, Inc.*² standard for assessing the admissibility of testimony from expert witnesses in civil actions.³ While the Georgia appellate courts have provided guidance regarding the application of the *Daubert* standard in other types of lawsuits, there have been few *Daubert* opinions from the Georgia appellate courts in product liability cases.⁴ Without state appellate court guidance, practitioners and judges

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must rely on decisions from the federal courts as persuasive authority. The following recent opinions offer guidance on *Daubert* issues in product liability cases.

The limits that *Daubert* places on novel expert theory were addressed in *Sumner v. Biomet, Inc.*, a lawsuit in which the plaintiff underwent surgery involving the placement of a metal-on-metal hip joint prosthesis in her right hip. Over the next few months, multiple x-rays of the plaintiff's surgically repaired hip revealed that metal debris was floating in the area of the implant. To remedy this issue, the plaintiff's doctor decided to replace the original prosthesis with a new one. The plaintiff filed a lawsuit against the manufacturer of the prosthetic hip joint, alleging that the prosthetic device was defectively manufactured and that the manufacturer failed to warn about the defect.

The plaintiff's expert witness, Rex McLellan, who has a doctorate in metallurgy, served as the primary source of proof for the plaintiff's claim that the prosthesis was defectively manufactured. In his initial expert report, Dr. McLellan indicated that there were areas of chemical inhomogeneity on the surface of the ball of the prosthesis that caused particles to shed off of the prosthesis and that this chemical inhomogeneity resulted from improper manufacturing. Through a supplemental expert report and two depositions, Dr. McLellan's opinion wavered regarding which metals caused the inhomogenous surface, but he essentially maintained his theory that the loose particles were ejected from the prosthesis because of inhomogeneities in the metal used to make the ball of the prosthesis.

After discovery, the manufacturer moved to exclude the testimony of Dr. McLellan, and the trial court considered whether Dr. McLellan's particle ejection theory satisfied the mandates of *Daubert* and Rule 702 of the Federal Rules of Evidence. First, the court determined that Dr. McLellan had not tested his theory or shown that his theory was capable of being tested. Next, the court concluded that the plaintiff failed to establish that Dr. McLellan's theory had been the subject of publication.
and peer review. Then, the court highlighted that the plaintiff was unable to demonstrate a rate of error for Dr. McLellan's theory. In addition, Dr. McLellan had developed his theory solely as part of his work in this case. Accordingly, the trial court excluded Dr. McLellan's testimony, holding that Dr. McLellan's particle ejection theory was the product of unreliable methodology that did not satisfy the requirements of Rule 702. Without the testimony from Dr. McLellan, the trial court granted summary judgment to Biomet.

On appeal, the United States Court of Appeals for the Eleventh Circuit concluded that the trial court did not abuse its discretion in excluding Dr. McLellan's testimony. Importantly, the plaintiff failed to show how Dr. McLellan employed a reliable methodology. In reviewing Dr. McLellan's testimony, the appellate court emphasized that Dr. McLellan essentially agreed his defect theory was practically incapable of being tested. Likewise, the plaintiff failed to come forward with any scientific literature to support Dr. McLellan's theory showing either peer review or general acceptance in the scientific community. Finally, because Dr. McLellan developed his theory for this litigation only, his methodology was even less reliable. With this analysis of the Daubert factors, the Eleventh Circuit concluded that the exclusion of Dr. McLellan's testimony was not an abuse of discretion.

The inability of a plaintiff to show that his experts undertook a proper methodology in reaching their opinions was equally problematic in Udoinyion v. Michelin North America, Inc., a product liability lawsuit in which the plaintiff experienced a tire blowout on his car and brought suit against Michelin, the manufacturer of the tire. In response to Michelin's summary judgment motion, the plaintiff filed two affidavits from tire experts who both testified that, based on their inspection, the tire was defective. Michelin moved to exclude these affidavits based

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12. Id.
13. Id. at 842.
14. Id. at 840.
15. Id.
16. Id.
17. Id. at 841.
18. Id.
19. Id. at 842.
20. Id.
21. Id. at 842-43.
22. Id. at 843.
24. Id. at 248, 251, 721 S.E.2d at 192, 194.
25. Id. at 249-50, 721 S.E.2d at 193.
on the requirements of section 24-9-67.1 of the Official Code of Georgia Annotated, and the trial court granted the motion, finding that the affidavits were "totally inadequate."

The Georgia Court of Appeals agreed and concluded that the trial court did not abuse its discretion when it excluded the testimony from the affidavits. Both experts had merely performed a visual inspection and concluded that the tire was defective. This cursory analysis was insufficient. The affidavits were deficient because they (1) failed to provide the facts or data supporting the opinions; (2) did not describe the methodology used to formulate the opinions regarding the nature of the defect in the tire; and (3) did not explain how the experts had used a proper methodology to reach their conclusions based on their inspection of the tire in this case. Without this necessary support for the experts' opinions, the court of appeals affirmed the decision of the trial court.

The plaintiff in Butler v. Union Carbide Corp. also failed to show how the expert witness undertook a reliable methodology that satisfied the Daubert criteria. In that lawsuit, the plaintiff sought damages for her husband's death from mesothelioma allegedly caused by his exposure to asbestos-containing products sold by the defendants, including Union Carbide Corporation. The defendants moved to strike the testimony of the plaintiff's causation expert, Dr. John Maddox, a pathologist who opined that every exposure the plaintiff's decedent had to asbestos that was above the level of asbestos in ambient air contributed to causing the decedent's mesothelioma. The trial court granted the motion to strike and excluded Dr. Maddox's testimony from the case. Without this causation testimony from Dr. Maddox, the trial court granted summary judgment in favor of Union Carbide.

On appeal, the plaintiff argued that Dr. Maddox undertook a methodology that was generally accepted in the scientific community and supported by technical literature. However, the appellate court disagreed and clarified that the literature did not support a conclusion that the Union Carbide product was a sufficient source of asbestos to

28. Id. at 248, 721 S.E.2d at 192.
29. Id. at 251, 721 S.E.2d at 194.
30. Id.
31. Id.
33. Id. at 25, 712 S.E.2d at 541.
34. Id. at 21-22, 712 S.E.2d at 538-39.
35. Id. at 26, 712 S.E.2d at 541-42.
PRODUCT LIABILITY

have been a significant factor in causing the mesothelioma. Although Dr. Maddox’s opinion may have attained general acceptance in the scientific community, the trial court did not have to give dispositive weight to this factor. Under Daubert, the trial court may select the appropriate criteria for each case depending on the nature of the proffered testimony and the scientific methodology that should have been employed in that area.

Finally, the plaintiff complained that the testimony of Dr. Maddox was excluded because the trial court improperly assessed the credibility of Dr. Maddox. The appellate court, however, clarified that the trial court did not assess whether Dr. Maddox was generally credible; instead, the trial court concluded that Dr. Maddox did not follow a scientifically reliable methodology to reach his conclusion that asbestos in the Union Carbide product was a substantial factor in causing the mesothelioma. To the contrary, the trial court did not examine opposing expert opinions and conclude that the other opinions were better, nor did it somehow discredit Dr. Maddox because his opinions were not credible. The trial court correctly assessed whether Dr. Maddox employed a reliable scientific methodology to reach his causation opinion. With the trial court’s proper application of the Daubert criteria, the court of appeals concluded that the trial court did not abuse its discretion in excluding Dr. Maddox’s causation testimony.

II. DEFENSES

A. Preemption

The Supremacy Clause of the United States Constitution provides that federal law is “the supreme Law of the Land... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” Thus, state laws that conflict with federal law are “without effect.” 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

36. Id. at 26-27, 712 S.E.2d at 542.
37. Id. at 27-28, 712 S.E.2d at 542-43.
38. Id. at 28, 712 S.E.2d at 543.
39. Id.
40. Id. at 29, 712 S.E.2d at 543.
41. Id.
42. Id. at 30, 712 S.E.2d at 544.
43. Id.
44. U.S. CONST. art. VI, cl. 2.
both the federal law and the state law have the same goal.\textsuperscript{46} Although preemption issues are typically analyzed in connection with a federal statute, a federal regulation may have the same preemptive effect as a federal statute.\textsuperscript{47} State laws subject to preemption include not only state statutes and regulations, but also tort duties imposed by state common law and enforced by lawsuits.\textsuperscript{48}

"The critical question in any pre-emption analysis is always whether Congress intended that federal regulation supersede state law."\textsuperscript{49} In fact, Congress's purpose in enacting the federal law is the "ultimate touchstone" of the preemption analysis.\textsuperscript{50} 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]."\textsuperscript{51} Although Congress's purpose is important, there is a presumption that Congress did not intend to preempt state law, especially when it has "'legislated ... in a field which the States have traditionally occupied.'"\textsuperscript{52} Because "the regulation of health and safety matters is primarily, and historically, a matter of local concern," state law regulating these matters is preempted only if Congress's intent to do so is "clear and manifest."\textsuperscript{53} When faced with two or more plausible interpretations of a federal law, this presumption imposes on courts "a duty to accept the reading that disfavors pre-emption."\textsuperscript{54}

\textsuperscript{46} Int'l Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987).
\textsuperscript{47} La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 369 (1986) (noting that "a federal agency acting within the scope of its congressionally delegated authority may [also] preempt state regulation"); see also Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 154 (1982) (noting that a "narrow focus on Congress' intent to supersede state law [is] misdirected" when a state law is claimed to be preempted by a federal agency's regulation).
\textsuperscript{48} CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993); Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 521-22 (1992); see also San Diego Bldg. Trades Council, Millmen's Union, Local 2020 v. Garmon, 359 U.S. 236, 247 (1959) (noting that "the obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy").
\textsuperscript{50} Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963).
\textsuperscript{53} Hillsborough Cnty. v. Automated Med. Labs., Inc., 471 U.S. 707, 715, 719 (1985) (internal quotation marks omitted); see also Rice, 331 U.S. at 230 ("So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.").
During the survey period, the United States Supreme Court decided one case involving field preemption and one case involving implied preemption.55 The field preemption case involved the Locomotive Inspection Act, and the implied preemption case involved the United States Food and Drug Administration’s approval of generic drugs. In each case the Court found that the federal law preempted the state law.

1. Locomotive Inspection Act. Originally enacted in 1911 as the Locomotive Boiler Inspection Act, the Locomotive Inspection Act (LIA),56 as it is now known, provides that a railroad carrier may use a locomotive only when the locomotive, including its parts and appurtenances, “[is] in proper condition and safe to operate without unnecessary danger of personal injury.”57 In addition, the locomotive may be used only if it has been inspected as required by the act and by any regulations promulgated by the Secretary of Transportation, and if it has passed every test prescribed by the Secretary of Transportation.58 Although the LIA does not include a preemption provision, the United States Supreme Court addressed its preemptive scope eighty-six years ago in Napier v. Atlantic Coast Line Railroad Co.59 At the time Congress enacted its predecessor, the LIA applied only to boilers, but Congress expanded the LIA’s scope in the 1915 and 1924 amendments.60 By the time the Supreme Court decided Napier in 1926, Congress had conferred broad, general powers on the Interstate Commerce Commission (ICC) to administer and enforce the LIA’s requirements.61 These powers encompassed “the design, the construction, and the material of every part of the locomotive and tender and of all appurtenances.”62 Based on the breadth of the powers conferred on the ICC, the Supreme Court held that “state legislation is precluded, because the Boiler Inspection Act ... was intended to occupy the field.”63 Prior to the survey period, the Georgia Court of Appeals recognized the preemptive effect of the LIA pursuant to Napier.64

57. Id. § 20701(1).
58. Id. § 20701(2), (3).
60. Id. at 608.
61. Id. at 611.
62. Id.
63. Id. at 613.
During the survey period, the United States Supreme Court revisited this issue in *Kurns v. Railroad Friction Products Corp.* The case involved the death of George Corson, who worked as a welder and machinist by the Chicago, Milwaukee, St. Paul & Pacific Railroad from 1947 until 1974. His duties included installing brake shoes on locomotives and stripping insulation from locomotive boilers, and this work exposed him to asbestos. He was diagnosed with malignant mesothelioma in 2005, and in 2007 he filed a lawsuit in a Pennsylvania state court against fifty-nine defendants, including Railroad Friction Products Corp. (RFPC), a distributor of locomotive brake shoes that contained asbestos, and Viad Corp., the successor to a manufacturer of locomotive engine valves that contained asbestos. He died several months later. The complaint alleged that RFPC's brake shoes and Viad's engine valves were defectively designed because they contained asbestos and that RFPC and Viad failed to warn about the dangers of asbestos or to provide instructions for safely handling it. RFPC and Viad removed the case to federal court and moved for summary judgment on the ground that the LIA preempted the state-law claims against them. The district court granted the motion, and the United States Court of Appeals for the Third Circuit affirmed.

The plaintiffs, Corson's widow and the executrix of his estate, argued that the LIA did not preempt their state-law claims for two reasons. First, they argued that the preemptive effect of the LIA was narrowed by the preemption provision in the Federal Railroad Safety Act of 1970 (FRSA), which permits states to regulate railroad safety until the Secretary of Transportation promulgates a regulation or issues an order covering the same subject matter. Because the Secretary of Transportation had not promulgated a regulation or issued an order covering the use of asbestos in locomotives or locomotive parts, the plaintiffs argued that their state-law claims were not preempted. The Supreme Court rejected this argument because the FRSA specifically provides that it does not alter federal laws on railroad safety that existed at the time Congress enacted it. Because the LIA existed before Congress

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66. *Id.* at 1264-65.
67. *Id.* at 1266.
68. 49 U.S.C. ch. 201.
71. *Id.*; see also 49 U.S.C. § 20103(a).
enacted the FRSA, the preemptive effect of the LIA, as defined by Napier, was unchanged by the FRSA's preemption provision.\textsuperscript{72}

Second, the plaintiffs argued that their state-law claims were not included within the field preempted by the LIA.\textsuperscript{73} They first argued that the LIA's preempted field did not include state-law claims arising out of the repair and maintenance of locomotives, but the Supreme Court found that this argument was foreclosed by Napier.\textsuperscript{74} Because Napier held that the LIA was intended "to occupy the entire field of regulating locomotive equipment," and the plaintiffs' claims implicated locomotive equipment, the Supreme Court held that "[t]he pre-empted field as defined by Napier plainly encompasses the claims at issue here."\textsuperscript{75} Further, because Napier did not distinguish between hazards arising out of the repair and maintenance of locomotives and hazards arising out of the use of locomotives on a railroad line, this distinction was irrelevant.\textsuperscript{76} The plaintiffs also argued that their state-law claims for failure to warn were not preempted because these claims were not based on the design or manufacture of the products.\textsuperscript{77} The Supreme Court rejected this overly nuanced characterization because the gravamen of these claims was that Corson died because he was exposed to asbestos contained in locomotive parts and appurtenances.\textsuperscript{78} Characterized in that manner, the plaintiffs' state-law claims for failure to warn were directed at locomotive equipment, which is within the LIA's preempted field under Napier.\textsuperscript{79}

The plaintiffs' next argument for why their state-law claims were outside the preempted field was that the LIA did not apply to manufacturers during the time when Corson was exposed to asbestos.\textsuperscript{80} While it is true that manufacturers were not subject to the LIA's penalty provision until 1988, "Napier defined the field pre-empted by the LIA on the basis of the physical elements regulated—"the equipment of locomotives"—not on the basis of the entity directly subject to regulation."\textsuperscript{81} In any event, the Supreme Court noted that the plaintiffs' argument was "contrary to common sense" because "a railroad's ability

\textsuperscript{72} Kurns, 132 S. Ct. at 1267.
\textsuperscript{73} Id. Interestingly, the plaintiffs chose to distinguish Napier rather than argue that it should be overruled. Id.
\textsuperscript{74} Id. at 1267-68.
\textsuperscript{75} Id. (quoting Napier, 272 U.S. at 611).
\textsuperscript{76} Id. (citing Napier, 272 U.S. at 611-12).
\textsuperscript{77} Id. at 1268.
\textsuperscript{78} Id.
\textsuperscript{79} Id. (citing Napier, 272 U.S. at 611-12).
\textsuperscript{80} Id.
\textsuperscript{81} Id. at 1269 (quoting Napier, 272 U.S. at 612).
to equip its fleet of locomotives in compliance with federal standards is meaningless if manufacturers are not allowed to produce locomotives and locomotive parts that meet those standards.\footnote{82} Finally, the plaintiffs argued that the LIA preempts only state legislation and regulations but not state common-law claims.\footnote{83} Again, however, the Supreme Court noted that the LIA "occupies the entire field of regulating locomotive equipment" without exception.\footnote{84} In sum, because the plaintiffs' state-law claims were directed at locomotive equipment, they were included within the field preempted by the LIA, as that field was defined by \textit{Napier}.\footnote{85}

Justice Sotomayor, joined by Justices Ginsburg and Breyer, concurred in part and dissented in part.\footnote{86} Because of the principle of stare decisis, she agreed that \textit{Napier} required the conclusion that the LIA preempts state-law claims based on an alleged design defect.\footnote{87} However, she contended that \textit{Napier} would be decided differently today because the Supreme Court's more recent field preemption decisions have required some statutory language expressly requiring it or a scheme of federal regulation much more pervasive than that imposed by the LIA.\footnote{88} As to state-law claims based on an alleged failure to warn, she contended that such claims are not preempted because they are fundamentally different from state-law claims based on an alleged design defect.\footnote{89} She disagreed with the majority's treatment of these two types of claims as congruent because unlike the plaintiffs' design-defect claim, their failure-to-warn claims, "if successful, would have no necessary effect on the physical equipment of locomotives at all."\footnote{90} Justice Kagan wrote a concurring opinion in which she joined the majority's opinion in full while at the same time criticizing \textit{Napier} as an "anachronism" when it is "[v]iewed through the lens of modern preemption law."\footnote{91} Like Justice Sotomayor, Justice Kagan doubted that \textit{Napier} would be decided the same way today, but unlike Justice Sotomayor, Justice Kagan saw no distinction in \textit{Napier} between claims based on a design defect and claims based on a failure to warn.\footnote{92}

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\footnote{82. \textit{Id.}}
\footnote{83. \textit{Id.}}
\footnote{84. \textit{Id.} (quoting \textit{Napier}, 272 U.S. at 611).}
\footnote{85. \textit{Id.} at 1270.}
\footnote{86. \textit{Id.} at 1271-75 (Sotomayor, J., concurring in part and dissenting in part).}
\footnote{87. \textit{Id.} at 1271-72.}
\footnote{88. \textit{Id.}}
\footnote{89. \textit{Id.} at 1272-74.}
\footnote{90. \textit{Id.} at 1273.}
\footnote{91. \textit{Id.} at 1270 (Kagan, J., concurring).}
\footnote{92. \textit{Id.} at 1270-71.}
Justice Kagan explained, "if an agency has the power to prohibit the use of locomotive equipment, it also has the power to condition the use of that equipment on proper warnings."93

2. United States Food and Drug Administration Approval of Generic Drugs. Two years ago, this survey article discussed whether the approval by the United States Food and Drug Administration (FDA) of a generic drug preempts state-law tort claims against the manufacturer of the drug.94 At that time, neither the Supreme Court nor the United States Courts of Appeals for the Eleventh Circuit had decided this issue, but the United States Courts of Appeals for the Fifth and Eighth Circuits had held that such claims were not preempted.95 In addition, two federal district courts in Georgia reached the same conclusion, primarily by relying on the opinions of the Fifth and Eighth Circuits.96 Although there was not a split among the circuits on this issue, some federal district courts had held that these claims were preempted,97 and so the Supreme Court granted the petitions for writ of certiorari in the Fifth and Eighth Circuit cases so that it could decide this issue.98

In Pliva, Inc. v. Mensing,99 the plaintiffs in two consolidated cases alleged that they developed tardive dyskinesia, a severe neurological disorder, after using metoclopramide for several years. Metoclopramide is a drug used to treat digestive tract problems such as diabetic gastroparesis and gastroesophageal reflux disorder, and its brand-name version is Reglan, which is what the plaintiffs' doctors actually prescribed for them. The plaintiffs sued the manufacturers of the generic metoclopramide that they used, alleging that long-term use of metoclopramide caused their tardive dyskinesia and that the generic manufacturers failed to provide adequate warning labels.100

93. Id. at 1270.
95. Demahy v. Actavis, Inc., 593 F.3d 428, 449 (5th Cir. 2010); Mensing v. Wyeth, Inc., 588 F.3d 603, 612 (8th Cir. 2009).
97. Weilbrenner, 696 F. Supp. 2d at 1337-38 & n.15.
98. Actavis, Inc. v. Demahy, 131 S. Ct. 817 (2010); Pliva, Inc. v. Mensing, 131 S. Ct. 817 (2010); Actavis Elizabeth, LLC v. Mensing, 131 S. Ct. 817 (2010). The three appeals were consolidated for decision.
100. Id. at 2572-73.
The Supreme Court held that the plaintiffs' failure-to-warn claims were preempted because it was impossible for the generic manufacturers to comply with the state-law duty alleged by the plaintiffs and the labeling requirements imposed by federal law. Specifically, the plaintiffs alleged that the generic manufacturers should have changed the warning labels on their products because they knew or should have known that the labels inadequately conveyed the risks of long-term use of metoclopramide. However, federal law governing drug labels imposes different duties on brand-name manufacturers and generic manufacturers. Generic manufacturers are required to use a label that is the same as the brand-name label, and the FDA's position is that generic manufacturers are permitted to change a label only when the FDA instructs it to do so or when it is matching an updated brand-name label. In other words, generic manufacturers are not permitted to unilaterally change a label, even if the change is to strengthen the warning. Nor are generic manufacturers permitted to send “Dear Doctor” letters to healthcare professionals because the FDA considers such letters to be “labeling.” In the absence of any reason offered by the plaintiffs to find the FDA's position to be plainly erroneous, the Supreme Court deferred to the FDA's interpretation of its own regulations. Because the generic manufacturers could not simultaneously change their labels and keep them the same, their state-law duties and their federal-law duties were in irreconcilable conflict, which meant that their state-law duties had to yield.

The FDA does permit generic manufacturers to propose changes to a label if it believes changes are necessary. In fact, the FDA's position is that generic manufacturers have a duty to propose label changes when they become aware of safety issues with a drug. If the FDA agrees that changes are necessary, it will work with the brand-name manufacturer to create a new label, which the generic manufacturers then must adopt. The generic manufacturers in this case disputed the FDA's position that proposing label changes is a duty, but the Supreme Court
found it unnecessary to resolve this dispute. "The question for
'impossibility' is whether the private party could independently do under
federal law what state law requires of it." Here, however, the
generic manufacturers could only propose label changes to the FDA; they
were not permitted to make any changes unilaterally. Thus, although proposing label changes would have satisfied their federal-law
duty, this would not have satisfied their state-law duty. According
to the plaintiffs, the generic manufacturers were required to provide
stronger labels, and this duty would not have been satisfied merely by
communicating with the FDA about possible label changes. The
plaintiffs argued that when a generic manufacturer's ability to comply
with state law depends on the FDA's approval of a proposed label
change, the preemption analysis should turn on whether the manufacturer can prove that the FDA would have accepted or rejected the
change. The plaintiffs further argued that the generic manufacturers
in this case could not satisfy their burden of proving impossibility
because they had not even proposed a label change to the FDA. The
Supreme Court conceded that this was a "fair argument," but it
nevertheless rejected it:

Mensing and Demahy's argument would render conflict pre-emption
largely meaningless because it would make most conflicts between
state and federal law illusory. We can often imagine that a third party
or the Federal Government might do something that makes it lawful
for a private party to accomplish under federal law what state law
requires of it. . . .

If these conjectures suffice to prevent federal and state law from
conflicting for Supremacy Clause purposes, it is unclear when, outside
of express pre-emption, the Supremacy Clause would have any
force.

The general rule established by this case, therefore, is that "when a
party cannot satisfy its state duties without the Federal Government's
special permission and assistance, which is dependent on the exercise of
judgment by a federal agency, that party cannot independently satisfy

112. Id. at 2576-77.
113. Id. at 2579.
114. Id. at 2576.
115. Id. at 2578.
116. Id.
117. Id. at 2578-79.
118. Id. at 2579.
119. Id.
those state duties for pre-emption purposes. Because federal law prohibited the generic manufacturers in this case from doing what state law required them to do, the plaintiffs' state-law claims were preempted. Justice Sotomayor, joined by Justices Ginsburg, Breyer, and Kagan, dissented because she believed that the majority's decision was inconsistent with Wyeth v. Levine insofar as it did not require the generic manufacturers to show that the FDA would not have approved a proposed label change. Because the generic manufacturers never proposed a label change to the FDA, they had no evidence supporting their argument that it was impossible for them to comply with both federal and state law. As such, all they had shown was "the mere possibility of impossibility" or "a hypothetical or potential conflict" between federal and state law, which is insufficient to establish impossibility preemption. Thus, Justice Sotomayor would find impossibility only if there was evidence showing that (1) the FDA rejected a label change proposed by a generic manufacturer; (2) the FDA had not responded to a label change proposed by a generic manufacturer by the time the plaintiff was injured; or (3) the FDA had itself considered whether to request a label change by the brand-name manufacturer but had decided not to change the label.

The majority answered Justice Sotomayor's critique by noting that its decision did not conflict with Wyeth. While the result in this case was different from the result in Wyeth, the different outcomes were justified by the difference between the regulations applicable to generic manufacturers and brand-name manufacturers. Unlike generic manufacturers, brand-name manufacturers were permitted to make unilateral changes to a label—that is, without the FDA's prior approval. In that sense, brand-name manufacturers were able to comply with their state-law tort duties in a way that generic manufacturers could not.

120. Id. at 2581.
121. Id.
124. Id. at 2587-88.
125. Id. (quoting Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982)).
126. Id. at 2588-89.
127. Id. at 2581 (majority opinion) (citing Wyeth, 555 U.S. at 559-60).
128. Id. (citing Wyeth, 555 U.S. at 572-73).
129. Id.
130. Id.
The majority recognized that it may seem unfair to allow lawsuits against brand-name manufacturers but not against generic manufacturers, but "different federal statutes and regulations may, as here, lead to different pre-emption results."\textsuperscript{131} It is not the Supreme Court's function to decide whether a federal law is "'unusual or even bizarre,'"\textsuperscript{132} and so the majority refused to "distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme."\textsuperscript{132} Instead, "Congress and the FDA retain the authority to change the law and regulations if they so desire."\textsuperscript{133}

\subsection{Statute of Repose}

Because many product liability claims do not accrue until years after exposure to or use of the allegedly defective product, the statute of repose is an important defense for manufacturers. Unlike a statute of limitations, which does not begin to run until the cause of action accrues,\textsuperscript{134} "[a] statute of ultimate repose delineates a time period in which a right may accrue. If the injury occurs outside that period, it is not actionable."\textsuperscript{135} In other words, "a statute of limitations operates only on an existing cause of action, while a statute of repose may operate to extinguish or abolish a potential cause of action prior to its existence."\textsuperscript{136} Thus, a statute of repose stands as a substantial obstacle for plaintiffs because it can bar an action even before an injury occurs and before the statute of limitations begins to run.\textsuperscript{137} Similarly, a statute of repose can effectively shorten the limitations period if the cause of action accrues with less time remaining in the repose period than in the

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\bibitem{131} Id. at 2581-82.
\bibitem{132} Id. at 2582 (quoting Cuomo v. Clearing House Ass'n, 129 S. Ct. 2710, 2733 (2009)).
\bibitem{133} Id.
\bibitem{134} See, e.g., O.C.G.A. § 9-3-33 (2007) (providing that claims for personal injuries must be brought within two years after the cause of action accrues).
\bibitem{135} Hill v. Fordham, 186 Ga. App. 354, 357, 367 S.E.2d 128, 131 (1988); see also Gwinnett Place Assocs., L.P. v. Pharr Eng'g, Inc., 215 Ga. App. 53, 54 n.2, 449 S.E.2d 889, 890 n.2 (1994) ("A statute of ultimate repose limits absolutely the time during which a party may bring an action, regardless of when the cause of action accrues. It is distinguished from a statute of limitation, which is a procedural rule delineating a time period measured from the accrual of the right of action during which a party must bring an action.").
\bibitem{136} CHARLES R. ADAMS III, GEORGIA LAW OF TORTS § 25:9, at 547 (2011-2012 ed.).
\bibitem{137} Hatcher v. Allied Prods. Corp., 256 Ga. 100, 101, 344 S.E.2d 418, 420 (1986), superseded by statute on other grounds, O.C.G.A. § 51-1-11(c) (2000 & Supp. 2012); Hanna v. McWilliams, 213 Ga. App. 648, 651, 446 S.E.2d 741, 744 (1994) (en banc) ("Moreover, the eight-year repose limit applies regardless of when the injury occurs or, indeed, whether a cause of action has accrued at all prior to the expiration of the period.").
\end{thebibliography}
limitations period. For example, a cause of action that accrues one month before the repose period expires will be barred if a lawsuit is not filed within that month, even if the cause of action is subject to a two-year limitations period.

Georgia's statute of repose for product liability claims, which the Georgia Supreme Court has described as "an unyielding barrier to a plaintiff's right of action," bars strict liability claims brought more than ten years after "the date of the first sale for use or consumption of the personal property causing or otherwise bringing about the injury." The statute similarly bars negligence claims, except those based on injuries or damages arising out of (1) negligence in manufacturing a product that causes disease or birth defects; (2) conduct that "manifests a willful, reckless, or wanton disregard for life or property"; and (3) a negligent failure to warn. Most litigation involving the statute of repose has focused on determining when the repose period begins to run, which in turn has required the courts to interpret the meaning of the phrase "first sale for use or consumption." But with the meaning of that phrase having been clarified by the Georgia Supreme Court last year, there is little left to litigate with respect to when the repose period begins to run. Consequently, when a person is injured by a product that was first sold more than ten years before the injury occurred, he will find it difficult to argue that the repose period has not expired. Instead, he will be left to argue that an exception applies. The most important of these exceptions, and the one most likely to generate litigation, is the exception for willful, reckless, and wanton conduct.

139. Id. (Gregory, J., dissenting) ("If someone is injured by the use of personal property on the last day, or very near the end, of the ten year period commencing with the date of first sale, there is a great likelihood the injured person would have no opportunity to file suit within the ten year period.").
141. O.C.G.A. § 51-1-11(b)(2).
142. O.C.G.A. § 51-1-11(c).
145. O.C.G.A. § 51-1-11(c). The exception for cases involving a product that allegedly caused a disease or a birth defect is obviously quite narrow. Indeed, there are no reported appellate decisions involving the substance of this exception. The Georgia Supreme Court
As with other exceptions to a statute of repose, the plaintiff bears the burden of proving that the manufacturer's conduct was willful, reckless, and wanton.\textsuperscript{146} This is an exceedingly high standard that the Georgia Supreme Court has equated with actual intent to injure: "Wilful conduct is based on an actual intention to do harm or inflict injury; wanton conduct is that which is so reckless or so charged with indifference to the consequences . . . [as to be the] equivalent in spirit to actual intent."\textsuperscript{147} In\textit{ Watkins v. Ford Motor Co.},\textsuperscript{148} for example, the United States Court of Appeals for the Eleventh Circuit held that the plaintiffs had presented sufficient evidence of Ford's willful, reckless, and wanton conduct to defeat Ford's motion for summary judgment.\textsuperscript{149} The plaintiffs demonstrated that Ford knew about stability problems with the Bronco II but decided not to implement certain alterations to the vehicle's design that were recommended by its own engineers and that would have improved stability because doing so would have delayed production and diminished profits.\textsuperscript{150} Using\textit{ Watkins} as its benchmark, the Eleventh Circuit decided another case during the survey period in which the plaintiff argued that her claim for negligent design was not barred by the statute of repose because the manufacturer had acted willfully, recklessly, and wantonly.\textsuperscript{151} Coincidentally, this case also involved a vehicle manufactured by Ford.

In\textit{ Ivy v. Ford Motor Co.},\textsuperscript{152} the plaintiff was injured while driving a 1996 Ford Explorer when she swerved to avoid colliding with another vehicle, which caused her vehicle to roll over. The plaintiff's mother purchased the vehicle in September 1995, and the plaintiff filed the lawsuit on May 20, 2008. Among other allegations, the plaintiff alleged that the vehicle was defectively designed, and her expert opined that the vehicle was unreasonably dangerous due to inadequate rollover

\textsuperscript{148} 190 F.3d 1213 (11th Cir. 1999).
\textsuperscript{149} Id. at 1216-17.
\textsuperscript{150} Id.
\textsuperscript{151} Ivy v. Ford Motor Co., 646 F.3d 769 (11th Cir. 2011).
\textsuperscript{152} 646 F.3d 769 (11th Cir. 2011).
resistance, that there were technologically and economically feasible
design alternatives available at the time Ford designed the vehicle, that
Ford could have improved the vehicle's stability by lowering its center
of gravity and/or increasing its track width, and that these modifications
would not have diminished the vehicle's function or utility. The federal
district court granted Ford's motion for summary judgment on the
ground that this claim was barred by the statute of repose.\textsuperscript{153}

Because the plaintiff filed the lawsuit almost thirteen years after her
mother purchased the vehicle, the Eleventh Circuit noted that her claim
for negligent design was barred by the statute of repose unless she could
provide evidence of Ford's willful, reckless, or wanton conduct.\textsuperscript{154} To
evaluate Ford's knowledge of rollover problems with the Explorer, the
Eleventh Circuit examined "reputable mainstream sources."\textsuperscript{155} Most
notably, the Eleventh Circuit relied on rollover tests conducted by the
National Highway Traffic Safety Administration (NHTSA), which
showed that the Explorer performed very well compared to other sport-
utility vehicles.\textsuperscript{156} Moreover, when Ford first developed the Explorer
in the late 1980s, it used one of the two tests that NHTSA later
determined to be the most reliable, and the Explorer passed Ford's
internal tests.\textsuperscript{157} And when Ford first marketed the Explorer in 1990,
it passed a test conducted by the Consumers Union and was recommend-
ded by the Consumers Union in \textit{Consumer Reports} magazine.\textsuperscript{158} All of
this showed that "the Explorer performed well by all mainstream
standards reflected on this record at the time it was marketed, and
continued to perform well in testing done approximately five years after
its release."\textsuperscript{159}

The plaintiff relied on \textit{Watkins} to argue that she had presented
sufficient evidence of Ford's willful, reckless, or wanton conduct to
survive summary judgment.\textsuperscript{160} The Eleventh Circuit rejected this
argument because the Explorer rated better than the Bronco II from a
stability standpoint, a point conceded by the plaintiff's expert, and
because there was no evidence showing that Ford had chosen profits over
safety with respect to the Explorer, as there was with respect to the
Bronco II.\textsuperscript{161} In fact, Ford accepted and implemented the only two

\begin{itemize}
  \item \textsuperscript{153} \textit{Id.} at 771-72.
  \item \textsuperscript{154} \textit{Id.} at 773.
  \item \textsuperscript{155} \textit{Id.}
  \item \textsuperscript{156} \textit{Id.} at 773-74.
  \item \textsuperscript{157} \textit{Id.} at 774.
  \item \textsuperscript{158} \textit{Id.}
  \item \textsuperscript{159} \textit{Id.} at 774-75.
  \item \textsuperscript{160} \textit{Id.} at 775 (citing \textit{Watkins}, 190 F.3d at 1216-17).
  \item \textsuperscript{161} \textit{Id.}
\end{itemize}
stability-related changes to the Explorer's design that were recommend-
ed by its own engineers.\textsuperscript{162} In light of the Explorer's performance on both independent and internal tests, as well as the lack of evidence that had been so damning in Watkins, the Eleventh Circuit held that "a reasonable juror could not find the wanton and willful standard to be met."\textsuperscript{163} Regarding the testimony of the plaintiff's expert, the Eleventh Circuit held that "merely finding an after-the-fact expert to opine that a product is defective cannot be sufficient to create a jury question on the issue of wantonness . . . when the product satisfied the government and industry standards extant at the earlier relevant time."\textsuperscript{164} Accordingly, the Eleventh Circuit affirmed the district court's grant of summary judgment to Ford on the ground that the plaintiff's claim for negligent design was barred by the statute of repose.\textsuperscript{165}

C. Assumption of the Risk

"The affirmative defense of assumption of the risk bars recovery when it is established that a plaintiff, without coercion of circumstances, chooses a course of action with full knowledge of its danger and while exercising a free choice as to whether to engage in the act or not."\textsuperscript{166} In product liability cases, this defense bars both negligence claims and strict liability claims.\textsuperscript{167} To establish that a plaintiff assumed the risk, a defendant must show that "the plaintiff (1) had actual knowledge of the danger; (2) understood and appreciated the risks associated with such danger; and (3) voluntarily exposed himself to those risks."\textsuperscript{168} As this suggests, "the standard to be applied in assessing an assumption of the risk defense is a subjective one, geared to the particular plaintiff and his situation, rather than that of a reasonable person of ordinary prudence who appears in [the completely separate defense of] contributory negligence."\textsuperscript{169} Whether a plaintiff assumed the risk of injury is

\begin{itemize}
\item \textsuperscript{162} Id. at 776.
\item \textsuperscript{163} Id. at 777.
\item \textsuperscript{164} Id.
\item \textsuperscript{165} Id. at 778.
\item \textsuperscript{166} Muldovan v. McEachern, 271 Ga. 805, 807, 523 S.E.2d 566, 569 (1999) (internal quotation marks omitted).
\item \textsuperscript{167} Whirlpool Corp. v. Hurlbut, 166 Ga. App. 95, 100-01, 303 S.E.2d 284, 288-89 (1983).
\item \textsuperscript{168} Vaughn v. Plesant, 266 Ga. 862, 864, 471 S.E.2d 866, 868 (1996) (internal quotation marks omitted).
\item \textsuperscript{169} Muldovan, 271 Ga. at 808, 523 S.E.2d at 569 (alteration in original) (internal quotation marks omitted).
\end{itemize}
usually a question of fact for the jury, but the issue may be determined as a matter of law if the evidence is plain, palpable, and undisputed.\textsuperscript{170}

To assume a risk, a plaintiff must have subjective knowledge of "the specific, particular risk of harm associated with the activity or condition that proximately causes injury."\textsuperscript{171} A comprehension of "general, non-specific risks that might be associated with such conditions or activities" will not suffice.\textsuperscript{172} As with many rules, it is easy to articulate the rule but difficult to apply it to the facts of particular cases. Thus, while it is easy to say that a plaintiff assumes the risk of injury if he has specific knowledge of the danger but that he does not if he has only general knowledge, the cases that are litigated are those in which the specificity or generality of the plaintiff's knowledge lies somewhere along the middle of this spectrum. Of course, plaintiffs want to define the danger narrowly to make it more likely that their knowledge is not specific enough, whereas defendants want to define the danger broadly for the opposite purpose. Recent cases in Georgia have favored defendants by not requiring such specific knowledge.\textsuperscript{173}

The Georgia Court of Appeals decided one case during the survey period involving assumption of the risk. In \textit{Yamaha Motor Corp., USA v. McTaggart},\textsuperscript{174} the plaintiff was injured when his 2006 Yamaha Rhino 660 rolled over onto his left leg. The Rhino was a four-wheel, open-air (i.e., no doors or windows), off-road vehicle and had two bucket seats, a steel roof cage, a slip-resistant floor board, foot guards to help occupants keep their feet and legs inside, hip guards, handholds, and three-point seatbelts. It also had a warning sticker that instructed occupants to keep their arms and legs inside and warned users about the possibility of severe injury or death if they tried to prevent a rollover with their arms or legs. When the plaintiff purchased the Rhino, the salesman offered to sell him a flexible plastic weather enclosure, but he declined because he preferred open access so he could more easily get into and out of the Rhino. After using the Rhino for about seven months, the plaintiff was injured when he put it in gear and applied slight pressure to the gas pedal while turning slightly to the right. The Rhino traveled less than six feet and rolled over onto the plaintiff's leg,


\textsuperscript{171} Vaughn, 266 Ga. at 864, 471 S.E.2d at 866.

\textsuperscript{172} Id.


which he had involuntarily stuck out to prevent the rollover. The plaintiff sued Yamaha in negligence and strict liability, alleging that his injury was caused by a latent stability defect and the absence of doors on the Rhino. Shortly before trial, the plaintiff abandoned his claim based on a latent stability defect, which meant that his only theory of liability at trial was that the Rhino was defectively designed because it did not have doors. The jury returned a verdict for the plaintiff in the amount of $317,002.\textsuperscript{175}

Yamaha argued on appeal that the trial court erred in denying its motions for directed verdict and for judgment notwithstanding the verdict, both of which were based on Yamaha's argument that the plaintiff had assumed the risk of injury as a matter of law.\textsuperscript{176} The court of appeals agreed with Yamaha because the undisputed evidence at trial showed that the plaintiff knew about the specific danger presented by the lack of doors on the Rhino, appreciated the risks associated with that danger, and voluntarily exposed himself to those risks.\textsuperscript{177} According to the plaintiff's own testimony at trial, he wanted the Rhino precisely because it did not have doors, and he read and understood the warnings both on the Rhino and in the operator's manual about the dangers of not keeping his arms and legs inside.\textsuperscript{178} In fact, when the salesman reviewed these warnings with him, the plaintiff laughed and said that it was common sense to keep your arms and legs inside.\textsuperscript{179} Further, the plaintiff testified that he had substantial experience operating other off-road vehicles, that those vehicles presented a similar danger in the event of a rollover because they were not enclosed, and that operators of those vehicles were supposed to keep their arms and legs inside during a rollover.\textsuperscript{180}

The plaintiff argued that he did not know that he might involuntarily stick his leg out of the Rhino during a rollover, but the court of appeals found that this argument was belied by the plaintiff's own testimony.\textsuperscript{181} The plaintiff testified that if the Rhino started to roll over, the operator should brace his feet on the floorboard if he had time and should keep his arms and legs inside to the best of his ability.\textsuperscript{182} He further testified that the operator probably would not intentionally stick

\textsuperscript{175} Id. at 103-05, 720 S.E.2d at 218-19. The verdict included $25,000 allocated to the claim for loss of consortium for the plaintiff's wife. Id. at 105, 720 S.E.2d at 219.
\textsuperscript{176} Id. at 105, 720 S.E.2d at 219.
\textsuperscript{177} Id. at 106, 720 S.E.2d at 219.
\textsuperscript{178} Id. at 106, 720 S.E.2d at 219-20.
\textsuperscript{179} Id. at 107, 720 S.E.2d at 220.
\textsuperscript{180} Id. at 107-08, 720 S.E.2d at 220-21.
\textsuperscript{181} Id. at 108-09, 720 S.E.2d at 221.
\textsuperscript{182} Id.
his arms or legs out of the Rhino. These qualifications on the plaintiff's testimony showed that he knew an operator might not be able to keep his arms and legs inside the Rhino and that an operator's arms or legs might involuntarily extend outside the occupant compartment during a rollover. Based on the plaintiff's knowledge about the dangers to arms and legs presented by the doorless Rhino, the court of appeals held that he assumed the risk of injury. Accordingly, the court of appeals reversed the trial court's denial of Yamaha's motions for directed verdict and for judgment notwithstanding the verdict.

D. Learned Intermediary Doctrine

Generally, manufacturers and suppliers owe a duty to foreseeable users of their product to warn about foreseeable dangers in the product. The learned intermediary doctrine is an exception to this general rule that relieves manufacturers and suppliers of the duty to warn if there is a learned intermediary between them and the ultimate user. The classic example of a learned intermediary is a doctor, and this doctrine provides a defense to manufacturers and suppliers of prescription drugs and medical devices because doctors are in the best position to warn their patients about the risks of these products. Thus, Georgia's appellate courts and federal courts applying Georgia law have held that manufacturers and suppliers, such as pharmacists and pharmaceutical sales representatives, do not owe the patient a duty to warn. Instead, the duty to warn is owed to the doctor, and manufacturers and suppliers may be liable if the warning to the doctor is inadequate.

Although most litigation involving the learned intermediary doctrine arises in the context of healthcare, manufacturers and suppliers of prescription drugs and medical devices are not the only entities to which

183. Id. at 109, 720 S.E.2d at 221.
184. Id.
185. Id.
186. Id.
190. Id.
this doctrine applies, and doctors are not the only learned intermediaries. This doctrine also has been applied to a manufacturer of liquefied petroleum gas, the learned intermediary being the retail distributor of the gas,\textsuperscript{194} and to a manufacturer of a pesticide, the learned intermediary being the licensed pest control operator.\textsuperscript{195} However, this doctrine has been held not to apply to a company that refurbished a crane that was later purchased and used at a construction site by a crane operating company.\textsuperscript{196} Unfortunately, the courts have not articulated a clear standard for determining when this doctrine will apply, though at a minimum, the alleged intermediary must actually be learned about the danger associated with the product. This was the issue confronted by the Eleventh Circuit in one case decided during the survey period.

In \textit{Parker v. Schmiede Machine & Tool Corp.},\textsuperscript{197} the plaintiffs were employees and former employees of Lockheed Martin Corp. who were exposed to beryllium while working at Lockheed's facility in Marietta. Some of the plaintiffs contracted chronic beryllium disease, and others developed beryllium sensitization, allegedly due to sandblasting, polishing, drilling, and other types of high-velocity abrading of aircraft parts that contain beryllium, which created respirable particles. The plaintiffs sued Lockheed and several manufacturers of beryllium-containing parts, and after years of litigation, only four defendants remained, and the only surviving claim was for failure to warn. The remaining defendants filed motions for summary judgment, and after initially denying the motions, the federal district court reversed itself and granted the motions on the ground that the plaintiffs' claims were barred by the learned intermediary doctrine.\textsuperscript{198}

On appeal, the Eleventh Circuit reviewed Lockheed's experience with beryllium and concluded that it is "a sophisticated user of beryllium and a learned intermediary between its employees and the manufacturers of beryllium products."\textsuperscript{199} The plaintiffs did not dispute Lockheed's experience with beryllium but instead argued that the defendants had superior knowledge about the risks associated with it and failed to warn Lockheed about those risks.\textsuperscript{200} The Eleventh Circuit examined the evidence upon which the plaintiffs relied but determined that all such

\textsuperscript{196} Dozier Crane & Mach., Inc., 284 Ga. App. at 498-99, 644 S.E.2d at 335-36.
\textsuperscript{197} 445 F. App'x 231 (11th Cir. 2011) (per curiam).
\textsuperscript{198} Id. at 232-34.
\textsuperscript{199} Id. at 235.
\textsuperscript{200} Id.
evidence was either inadmissible or unrelated to the defendants.\textsuperscript{201} Thus, the Eleventh Circuit found that “the Plaintiffs fail[ed] to adduce evidence demonstrating knowledge of beryllium hazards that the Defendants had but failed to disclose to Lockheed.”\textsuperscript{202} More importantly, the Eleventh Circuit found that “the Plaintiffs also fail[ed] to demonstrate that Lockheed lacked actual knowledge regarding the hazards of beryllium.”\textsuperscript{203} The plaintiffs argued that Lockheed lacked knowledge of certain risks associated with beryllium, but the Eleventh Circuit determined that the evidence upon which the plaintiffs relied did not actually support their argument.\textsuperscript{204} To the contrary, the Eleventh Circuit held that there was “overwhelming” evidence showing that Lockheed was a learned and sophisticated user of beryllium and that its knowledge of the risks associated with beryllium was superior to the defendants’ knowledge.\textsuperscript{205} Accordingly, the Eleventh Circuit affirmed the trial court’s grant of summary judgment.\textsuperscript{206}

\begin{footnotesize}
\begin{enumerate}
\item \textit{Id.} at 235-36.
\item \textit{Id.} at 236.
\item \textit{Id.}
\item \textit{Id.} at 236-38.
\item \textit{Id.} at 238.
\item \textit{Id.}
\end{enumerate}
\end{footnotesize}