RECENT DEVELOPMENTS IN PRODUCTS, GENERAL LIABILITY, AND CONSUMER LAW

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I. PREEMPTION

The U.S. Supreme Court affirmed the decision of the Vermont Supreme Court in *Wyeth v. Levine*, holding that federal Food and Drug Administration (FDA) labeling requirements for prescription drugs do not preempt state negligence and strict liability claims asserting inadequate labeling of an antihistamine used to treat nausea under state law.[1] Diana Levine developed gangrene after being injected with Wyeth's antinausea drug Phenergan by the IV-push method to treat pain from a migraine headache, which resulted in doctors amputating her forearm.[2]

1. 129 S. Ct. 1187 (2009).
2. *Id.* at 1191.

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After settling claims against the health center and clinician, Levine brought action against Wyeth in Vermont state court for common law negligence and strict liability, alleging that Wyeth failed to adequately warn of significant risks of administering Phenergan by the IV-push method, rather than the IV-drip method.[3] Levine alleged that Phenergan's labeling was defective because, although it warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, it failed to instruct clinicians to use the IV-drip method instead of the higher-risk IV-push method.[4] Wyeth filed a motion for summary judgment, arguing that Levine's claims were preempted by federal law.[5] However, the trial court found no evidence that Wyeth attempted to strengthen the intra-arterial injection warning or that the FDA specifically disallowed stronger language.[6] Wyeth's motion for summary judgment was denied.[7] The jury found Wyeth negligent, and found that Phenergan was a defective product due to inadequate warnings and instructions.[8]

The Supreme Court of Vermont affirmed the jury's verdict, holding that it "did not conflict with the FDA's labeling requirements of Phenergan because [Wyeth] could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor, not a ceiling for state regulation."[9] Wyeth's petition for certiorari was granted by the U.S. Supreme Court, and Wyeth made two preemption arguments.[10] The first argument was that it was impossible for it to comply with the state law duty to modify Phenergan's labeling without violating federal law.[11] The second argument was that recognition of Levine's state tort action would obstruct the purposes and objectives of Congress by replacing the expert judgment of the FDA about drug labeling with a lay jury's decision.[12] The Court rejected Wyeth's arguments and affirmed the Supreme Court of Vermont's decision.[13]

The Court held that Wyeth failed to demonstrate that it was impossible for it to comply with both federal and state requirements.[14] Justice Stevens held that the FDA's "changes being effected" (CBE) permitted Wyeth to

3. *Id.*
4. *Id.* at 1191–92.
5. *Id.* at 1192.
6. *Id.*
7. *Id.* at 1193.
8. *Id.*
9. *Id.* (quoting Levine v. Wyeth, 944 A.2d 179, 184 (Vt. 2006)).
10. *Id.* at 1194.
11. *Id.*
12. *Id.*
13. *Id.* at 1204.
14. *Id.* at 1194–98.

independently strengthen its IV-push drug administration warning without waiting for FDA approval.[15] The responsibility of manufacturers for the content of its labels at all times is a central premise of federal drug regulation, and the FDA's approval of a label has no effect on a manufacturer's duty to ensure that its warnings were sufficient while the drug was on the market.[16]

In addition, the Court held that if Congress had believed state law posed an obstacle, it would have enacted an express preemption provision for labeling prescription drugs, similar to its provision that expressly preempted state and local requirements for medical devices.[17] The Court considered the silence of Congress on the preemption issue in the face of the prevalence of state tort litigation as powerful evidence that Congress did not intend the FDA to be the exclusive means of ensuring drug safety and effectiveness.[18] The Court also declined to give deference to the FDA's 2006 preamble, which addressed the content and format of prescription drug labels.[19] The preamble declared that the Food, Drug and Cosmetics Act (FDCA) established "both a 'floor' and a 'ceiling,' so that 'FDA approval of labeling . . . preempts conflicting or contrary State law.'"[20] The preamble reversed the FDA's long-standing position that federal labeling standards were cast as a floor upon which states could build, without providing any explanation or discussion of how state law interfered with the FDA's regulation of drug labeling.[21] Finally, the Court found that in the absence of delegation by Congress, agencies did not have special authority to make pronouncements on preemption.[22] Thus, the FDA traditionally regarded state law as a complementary, rather than conflicting, form of drug regulation, particularly in the face of the FDA's limited resources to monitor the thousands of drugs on the market and manufacturers' superior access to information about their own drugs.[23] Thus, Levine's state law failure-to-warn claims against Wyeth were not preempted by federal law.[24]

In *Stacel v. Teva Pharmaceuticals, USA*, plaintiff Melanie Stacel filed suit against Teva Pharmaceuticals, a generic drug manufacturer, alleging that she was afflicted with drug-induced lupus as a result of consuming a drug manufactured by Teva called minocycline, the generic form of the drug

15. *Id.*
16. *Id.*
17. *Id.* at 1199–1204.
18. *Id.*
19. *Id.* at 1200.
20. *Id.* (quoting 71 Fed. Reg. 3934–35 (2006)).
21. *Id.* at 1201–02.
22. *Id.* at 1201.
23. *Id.* at 1204.
24. *Id.*

Minocin.[25] Stacel brought claims under Illinois law for products liability, common law fraud, and violation of the Illinois Consumer Fraud and Deceptive Business Practices Act (ICFA).[26] Teva argued that Stacel's state law causes of action were preempted by the federal Food, Drug and Cosmetic Act (FDCA) and the entire complaint should be dismissed.[27] Teva argued that conflict preemption, where "state law is preempted to the extent that it actually conflicts with federal law,"[28] was the appropriate form of federal preemption because "Teva cannot comply with both the FDCA's and Illinois state law's labeling requirements."[29]

The Court rejected Teva's assertion and held that Stacel's claims were not preempted by the FDCA on the grounds that the labeling requirements of Illinois laws did not have a direct and positive conflict with the FDCA's labeling requirements for generic drugs.[30] Congress did not intend Food and Drug Administration oversight to be the exclusive means of ensuring drug safety and effectiveness, and since the manufacturer bears the responsibility for the contents of its labels at all times, Illinois laws provided appropriate relief for injured consumers.[31]

Bufford Furrow was in possession of at least seven illegally possessed firearms when he shot and injured or killed multiple children and adults on August 10, 1999.[32] In the resulting litigation, *Ileto v. Glock*, the shooting victims and their family members brought action under California common law tort statutes against the manufacturers, distributors, and dealers of firearms used and possessed by Furrow.[33] The plaintiffs alleged that the defendants intentionally produced, marketed, distributed, and sold more firearms than the market demanded in order to take advantage of resales to distributors that they knew would then sell to illegal buyers.[34] In 2002, the district court dismissed the case for failure to state a claim under California law, but in 2003 the Ninth Circuit reversed in part, holding that the plaintiffs stated cognizable negligence and public nuisance claims under California law with respect to the firearms actually used in the shootings.[35]

In 2005, Congress enacted the Protection of Lawful Commerce in Arms Act (PLCAA), which generally preempts claims against federally licensed

25. 620 F. Supp. 2d 899 (N.D. Ill. 2009).
26. *Id*. at 901.
27. *Id*.
28. *Id*. (citing English v. Gen. Elec. Co., 496 U.S. 72, 78 (1990)).
29. *Id*. at 903.
30. *Id*. at 906.
31. *Id*. at 905.
32. Ileto v. Glock, 565 F.3d 1126, 1130 (9th Cir. 2009).
33. *Id*.
34. *Id*.
35. *Id*. (citing Ileto v. Glock, Inc., 194 F. Supp. 2d 1040 (C.D. Cal. 2002), and Ileto v. Glock, Inc., 349 F.3d 1191 (9th Cir. 2003)).

manufacturers and sellers of firearms and ammunition resulting from the criminal use of those products.[36] The enactment of the PLCAA not only affected future lawsuits, but also required courts to immediately dismiss any pending lawsuits preempted by the PLCAA.[37] The district court halted discovery to hear briefing on the Act's effect on the case.[38] Subsequently, the district court dismissed the plaintiffs' claims against defendants Glock and RSR, but held that the PLCAA did not preempt plaintiffs' claims against China North because it is not a federal firearms licensee as required by the PLCAA.[39]

The Ninth Circuit affirmed both components of the district court's holding.[40] The court rejected the plaintiffs' claim that their allegations satisfy the requirements of the predicate exception to the PLCAA, in which the plaintiff "must allege a knowing violation of 'a State or Federal statute applicable to the sale or marketing of the product.' "[41] The court held that the plaintiffs' claims were not covered by the predicate exception because general tort theories of liability such as those pertaining to nuisance, public nuisance, and negligence, even in California where such causes of action are codified, are not applicable to the sale or marketing of firearms and were intended by Congress to be preempted.[42] The court also held that the PLCAA does not apply to defendant China North because it does not have a federal firearms license and thus cannot seek protection under the PLCAA.[43]

In *Miles v. Raymond Corporation*, personal representatives of a deceased forklift operator and the legal guardian of the deceased operator's children brought an action for wrongful death, negligence, and claims under the Ohio Products Liability Act (OPLA) against a manufacturer and marketer of a forklift.[44] Karla Grinder was killed when the stand-up forklift she operated traveled underneath a horizontal rack and crushed her between the operator's panel and the rack.[45] The defendants, forklift manufacturer Raymond Corporation and marketer Andersen & Associates, Inc., sought dismissal of the common law negligence and breach of warranties claims because they were products liability claims subject to preemption under the OPLA.[46] The OPLA applies to "recovery of compensatory damages

36. *Id*. at 1131.
37. *Id*.
38. *Id*.
39. *Id*.
40. *Id*. at 1146.
41. *Id*. at 1133 (quoting 15 U.S.C. § 7903(5)(a)(iii)).
42. *Id*. at 1136.
43. *Id*. at 1146.
44. 612 F. Supp. 2d 913 (N.D. Ohio 2009).
45. *Id*. at 916.
46. *Id*.

based on a product liability claim" and "[a]ny recovery of punitive or exemplary damages in connection with a product liability claim [. . .]."[47] Additionally, in a recent amendment to the statute, the Ohio legislature added the language "sections 2307.01 to 2307.80 are intended to abrogate all common law product liability causes of action."[48] Thus, if the plaintiffs' claims of common law negligence and breach of warranty are covered by the statutory language abrogating common law products liability cause of action, those claims would be extinguished.[49]

The plaintiffs attempted to analogize common law negligence with foreseeability of harm, thereby establishing the existence of duty, validating these claims independent of any product defect based upon the defendants' prior knowledge of the risk and their failure to warn.[50] However, the court held that any duties related exclusively to the forklift, which is a product, and any claims arising out of those factual allegations are products liability, not general negligence, claims.[51] Regarding the common law breach of warranty claims, the court held that the claims were "based upon allegations that a product, the forklift, failed to conform to relevant warranties. The complaint contains no allegation that Defendants issued any warranties unrelated to the product, or that the decedent was injured by the failure of some warranty not connected with the forklift."[52] Plaintiffs' common law negligence and breach of warranty claims could not be separated from the product, and therefore, they were preempted by the OPLA.[53]

The plaintiffs in *In re Mattel, Inc.*[54] were consumers who sued manufacturers and retailers of children's toys, alleging that the defendants produced and sold defective and unsafe toys.[55] In this multidistrict class action, the plaintiffs premised their claims on several theories, including the torts of strict liability and negligence.[56] The litigation involved several models of toys that allegedly contained high levels of unsafe lead or lead paint.[57] After the Consumer Product Safety Commission (CPSC) recalled the toys, the defendants provided replacement toys.[58] The U.S. District Court for

47. *Id.* at 917–18 (quoting Ohio Rev. Code § 2307.72(A) & (B)).
48. *Id.* at 918 (quoting Ohio Rev. Code § 2307.71(B)).
49. *Id.*
50. *Id.* at 921–22.
51. *Id.*
52. *Id.* at 923.
53. *Id.*
54. 588 F. Supp. 2d 1111 (C.D. Cal. 2008).
55. *Id.* at 1114.
56. *Id.*
57. *Id.*
58. *Id.*

the Central District of California reviewed the case on the defendants' motions to dismiss.[59]

In their motions to dismiss, the defendants raised the issue "that a voluntary products replacement pursuant to 16 C.F.R. § 1115.20 preempts state law remedies seeking reimbursement for an allegedly hazardous product."[60] The court noted that conflict preemption applies in cases in which it is impossible to comply with both state and federal requirements or in situations involving state laws that hinder Congress's ability to carry out its full objectives.[61] Moreover, the court explained that under the relevant CPSC regulations, actions taken pursuant to a voluntary corrective action plan are not legally binding, and the CPSC reserves the right to pursue remedies in addition to those that were voluntarily provided.[62]

In addition to considering the actual language of the CPSC regulations, the court discussed the regulatory record.[63] According to the court, the voluntary products replacement program was implemented to quickly correct potential hazards and to conserve resources.[64] Although requiring a company to comply with a state law remedy might make it less likely that the company would voluntarily replace the product, the court noted that nothing indicated that the CPSC considered that issue.[65] Because the regulatory record did not clearly disallow state law remedies, the court did not find that allowing the state law replacement remedy hindered Congress's ability to carry out its full objections of the CPSC voluntary recall program.[66] Thus, the court held that the voluntary replacement did not preempt state law remedies.[67]

In the U.S. Supreme Court case *Altria Group, Inc. v. Good*,[68] cigarette smokers sued tobacco products manufacturers, alleging that the manufacturers' advertising stating that their light cigarettes contained less tar and nicotine was fraudulent and in violation of the Maine Unfair Trade Practices Act (MUTPA).[69] The smokers acknowledged that a federally acceptable testing method of measuring the tar and nicotine content of cigarettes indicated that tar and nicotine levels in the light cigarettes were

59. *Id.*
60. *Id.* at 1115.
61. *Id.*
62. *Id.*
63. *Id.* at 1116.
64. *Id.*
65. *Id.*
66. *Id.*
67. *Id.*
68. 129 S. Ct. 538 (2008).
69. *Id.* at 541.

lower than the levels in regular cigarettes.[70] However, they argued that the manufacturers knew of the "compensatory behaviors" in which smokers unconsciously engaged, which resulted in the inhalation of as much tar and nicotine as they would inhale from a regular cigarette.[71] Thus, the smokers contended that light cigarettes are actually more harmful, and the manufacturers therefore violated the MUTPA by concealing that information and representing the light cigarettes as safer.[72]

The district court granted the manufacturers' motion for summary judgment, which argued that the Labeling Act[73] expressly preempted the state law claim because it was a failure-to-warn "neutralization claim" similar to one of the claims that the Supreme Court held was preempted in *Cipollone v. Liggett Group, Inc.*[74] Disputing the district court's characterization of the claim, the First Circuit reversed and noted that the claim was essentially a fraud claim.[75]

The Labeling Act, which requires that every package of cigarettes contain a warning about the health hazards, expressly preempts state law additions to the warning.[76] *Cipollone* noted that in determining if a claim is preempted, the question is "whether the legal duty that is the predicate of the common law damages action constitutes a 'requirement or prohibition based on smoking and health.'"[77] In that case, a plurality of the Court held that a claim that cigarette manufacturers fraudulently misrepresented a material fact was not preempted because the claim was not "based on" smoking and health.[78]

The U.S. Supreme Court stated that the smokers' claim was analogous to the nonpreempted *Cipollone* claim because it was based on deceptive statements regarding light cigarettes that induced them to buy the cigarettes.[79] Although the federal labeling requirements might relate to the materiality of the statements, the case was not based on the warnings.[80] Thus, the Court concluded that just as in *Cipollone*, "the phrase 'based on smoking and health'" did not entail a duty not to make fraudulent statements.[81] The Court also dismissed the manufacturers' argument that the claim was

70. *Id.*
71. *Id.*
72. *Id.* at 542.
73. 15 U.S.C. § 1334(b).
74. Altria Group, Inc. v. Good, 129 S. Ct. 538, 542 (2008) (citing Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992)).
75. *Id.*
76. *Id.* at 543.
77. *Id.* at 545 (quoting *Cipollone*, 505 U.S. at 524).
78. *Id.*
79. *Id.* at 546.
80. *Id.*
81. *Id.* at 549.

impliedly preempted because of its ability to hinder FTC policies to promote low tar cigarettes.[82] According to Justice Stevens, the FTC's decisions regarding statements of tar and nicotine levels did not justify a finding of preemption of state deceptive practices rules.[83] Thus, the Court affirmed the appellate court's judgment holding that neither the Labeling Act nor the FTC's actions preempted the smokers' MUTPA claim.[84]

The plaintiffs in *In re Medtronic, Inc.*[85] were patients with implantable cardiac defibrillators (ICDs) who brought suit against the manufacturer for alleged design defects of the ICDs.[86] In its motion to dismiss, the defendant argued that the preemption clause of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act preempted the plaintiffs' claims.[87] In response, the plaintiffs argued that the defendant's recall of the ICDs precluded its preemption argument.[88] Alternatively, they argued that their claims were "parallel" claims, and therefore constituted an exception to the preemption argument.[89]

The U.S. District Court for the District of Minnesota held that the recall did not preclude the defendant's preemption argument, and the plaintiffs' claims were not "parallel," and were thus preempted.[90] The court noted that the federal premarket approval for the ICDs was in place at the time the allegedly defective component parts of the ICDs were implanted in the plaintiffs.[91] As such, the plaintiffs' legal arguments were dependent on whether the component parts were defective at the time of implantation.[92] The court dismissed the plaintiffs' argument that their claims were "parallel" because they failed to allege in detail the defendant's purported violations of FDA regulations.[93] Concluding that Congress limited the liability of medical device manufacturers despite the fact that such devices may cause injury, the court noted that the plaintiffs needed to pursue a remedy through Congress.[94] Accordingly, the court granted the defendant's motion to dismiss.[95]

82. *Id.*
83. *Id.* at 551.
84. *Id.*
85. 592 F. Supp. 2d 1147 (D. Minn. 2009).
86. *Id.* at 1153, 1154.
87. *Id.* at 1155.
88. *Id.*
89. *Id.*
90. *Id.*
91. *Id.* at 1156.
92. *Id.*
93. *Id.* at 1158.
94. *Id.* at 1166.
95. *Id.*

In *Morris v. Wyeth, Inc.*,[96] the plaintiff brought several claims, including products liability, negligence, and breach of warranty, against generic manufacturers of metoclopramide, a prescription drug used to treat gastric reflux.[97] The plaintiff argued that the defendants failed to adequately warn him of the long-term effects of taking metoclopramide.[98] He took the drug for approximately fifteen years, and alleged that he developed tardive dyskinesia (TD), a neurological disease affecting the brain's chemistry, as a result.[99] The defendants moved to dismiss the claims on the basis of federal conflict preemption.[100]

The court noted that under federal regulations, a manufacturer of a generic drug must make the drug's label "the same as the labeling approved for the reference listed drug."[101] In order to comply with the federal regulations, a generic drug manufacturer is permitted to unilaterally change the label of its drug only to indicate an aspect of labeling protected by patent or differences in expiration date.[102] The court adopted the reasoning of a case from a federal district court that held that a generic drug manufacturer needs FDA approval to unilaterally strengthen a drug label.[103]

To prevent the defendants from prevailing on their motion to dismiss, the plaintiff advanced several arguments, all of which the court rejected.[104] For instance, the plaintiff argued that because federal law requires a generic drug manufacturer to update the FDA of adverse events and the defendants had information showing that long-term use of metoclopramide resulted in an increased risk of TD, the defendants' compliance with FDA regulations impacts a federal preemption conclusion.[105] In dismissing this argument, the court noted that the failure to notify the FDA about the effects of long-term use of the drug was irrelevant to a federal preemption determination because it is the proper role of the FDA to decide whether a generic drug manufacturer has failed to comply with reporting requirements.[106]

The court also rejected the plaintiff's public policy argument that if the defendants were successful on their preemption argument, they would be less likely to report adverse events.[107] Because Congress determined that the benefits of providing access to generic drugs are more important than

96. 582 F. Supp. 2d 861 (W.D. Ky. 2008).
97. *Id.* at 863.
98. *Id.*
99. *Id.*
100. *Id.* at 863–64.
101. *Id.* at 866.
102. *Id.*
103. *Id.* at 867 (citing Mensing v. Wyeth, Inc., 562 F. Supp. 2d 1056 (D. Minn. 2008)).
104. *Id.* at 868–69.
105. *Id.* at 869.
106. *Id.*
107. *Id.*

the potential risks, the court decided that Congress had already considered and rejected plaintiff's argument.[108] Accordingly, the court held that the plaintiff's claims were preempted, and therefore granted the defendants' motion to dismiss.[109]

II. EVIDENCE/DISCOVERY

A representative of the estate of Angela Plyler brought action against a tire manufacturer for negligence, breach of warranty, and strict liability in connection with an automobile rollover accident.[110] While driving with her three children, the tread from the left rear tire separated from the tire, allegedly causing the vehicle to overturn and collide with a tree, killing Angela and her son, and seriously injuring her two daughters.[111] The plaintiff alleged that Bridgestone used an inadequate tire design and failed to use proper manufacturing techniques, resulting in a defective tire.[112] Specifically, the plaintiff alleged that "Bridgestone failed to use sufficient antidegradants to protect the integrity of the tire," and sought to obtain information on the design and manufacturing processes for the tire.[113] Bridgestone objected to the plaintiff's discovery request for its steel belt skim stock formula and other information on the basis that it was protected as a trade secret of Bridgestone.[114]

After considering Bridgestone's experts' testimony, the trial court issued an order compelling the discovery, finding that the plaintiff met the prerequisites for discovery of trade secret information either under Rule 26(c) of the South Carolina Rules of Civil Procedure or under the South Carolina Trade Secrets Act.[115] The court found that the "composition of the ingredients, both actual and intended, and the method by which the rubber compound was made is [sic] relevant to the inquiry into why the subject tire failed."[116] Bridgestone appealed, and the Supreme Court of South Carolina reversed.

The state supreme court held that the plaintiff's experts' testimony did not establish that the trade secret formula for steel belt skim stock was necessary for the experts' analyses of the tire's defects.[117] The court also

108. *Id*.
109. *Id*.
110. Laffitte v. Bridgestone Corp., 674 S.E.2d 154, 157 (S.C. 2009).
111. *Id*.
112. *Id*.
113. *Id*.
114. *Id*.
115. *Id*. at 160 (citing S.C. Code Ann. § 39-8-10 (Supp. 2007)).
116. *Id*.
117. *Id*. at 163.

held that the skim stock formula was not essential to a defect inquiry, as a tire is a complex object made up of many components, and it would be inaccurate to gauge the performance of a tire by focusing on one isolated component.[118] Further, the court found that the trial court failed to analyze the "availability of reasonable alternatives to the discovery of the trade secret."[119] Thus, the plaintiff failed to meet the standard for discovery of the trade secret formula, and the court reversed the trial court's decision to compel discovery.[120]

In *In re Seroquel*, plaintiffs appealed the U.S. magistrate's ruling granting defendant AstraZeneca's motion excluding evidence and argument about foreign Seroquel labels and foreign regulatory actions.[121] The motion concerned regulatory actions in Japan, France, and Holland. AstraZeneca sought exclusion of the evidence on the grounds that it would confuse the jury, was irrelevant, and would be unfairly prejudicial.[122] Japanese regulatory actions regarded the requirement to add a diabetes contraindication to the Japanese label in 2002 and the requirement for AstraZeneca to send "Dear Doctor" letters informing Japanese physicians of the changes.[123] In 2005, the French regulatory authority denied AstraZeneca permission to market Seroquel in France.[124] The Dutch regulatory authority asked AstraZeneca to add language about hyperglycemia and diabetes to the Seroquel label in 2000–01.[125]

The plaintiffs argued that evidence of foreign regulatory actions was relevant to demonstrate AstraZeneca's knowledge and notice of hazards associated with Seroquel, and that they were not seeking to introduce Japanese, French, and Dutch legal or regulatory standards.[126] AstraZeneca, however, argued that if evidence of foreign regulations was allowed, AstraZeneca would have to be allowed to present evidence as to differences in the social, political, and medical landscapes of the foreign countries and the United States.[127] This would essentially amount to a mini-trial, and would be very time-consuming, confusing to the jury, and highly prejudicial.[128] AstraZeneca argued that the changes made in France, Japan, and Holland only showed that "a different regulatory authority, applying different standards

118. *Id.* at 165.
119. *Id.*
120. *Id.*
121. 601 F. Supp. 2d 1313, 1314 (M.D. Fla. 2009).
122. *Id.* at 1315.
123. *Id.* at 1314.
124. *Id.*
125. *Id.*
126. *Id.* at 1316.
127. *Id.* at 1315.
128. *Id.*

in a different social and medical landscape, reached a conclusion different than the conclusion reached by the FDA under the U.S. system."[129]

The court rejected plaintiffs' argument and held that "to admit evidence about the foreign regulators' actions regarding Seroquel without providing context concerning the regulatory schemes and decision-making processes involved would strip the jury of any framework within which to evaluate the meaning of that evidence," but to allow AstraZeneca to introduce this evidence would "confuse the jury and waste everyone's time."[130] Although the plaintiffs were not precluded from introducing evidence regarding the information the foreign regulators communicated to the drug manufacturer regarding the dangers of its drug, the court held that they were precluded from introducing evidence of the regulators' decisions and actions, including requiring label changes.[131]

The plaintiff in *Giles v. Wyeth, Inc.*, the widow of a man who committed suicide, sued Wyeth, claiming that Wyeth was strictly liable for failing to provide adequate warnings that the antidepressant drug Effexor potentially caused consumers to commit suicide.[132] After suffering a serious injury at his job as a coal miner, Jeff Giles experienced pain and decreased mobility, and was eventually laid off from his job.[133] Giles visited his primary care physician and told him that he was tired and depressed, and the doctor prescribed him Effexor.[134] Over the next two days, Giles took three Effexor pills, and two days after being prescribed Effexor, shot himself.[135] At the time Giles took Effexor, the drug had many labels, including a suicide precaution, but Wyeth eventually strengthened the suicide warnings after Giles' death.[136] Wyeth filed a motion in limine asking the district court to exclude suicide warnings that accompanied Effexor after Giles' death, as well as scientific data related to suicidality in pediatric patients taking antidepressants.[137]

The court granted Wyeth's motion in part, ruling that evidence of suicide-related warnings after Giles' death was not admissible, but rejected Wyeth's argument to exclude the scientific evidence.[138] The jury found in favor of Wyeth, and Giles' widow appealed, arguing that she should have been allowed to introduce warnings that accompanied Effexor in the years

129. *Id.* at 1316.
130. *Id.* at 1318.
131. *Id.* at 1318–19.
132. 556 F.3d 596, 597–98 (7th Cir. 2009).
133. *Id.* at 598.
134. *Id.*
135. *Id.*
136. *Id.* at 599.
137. *Id.*
138. *Id.*

following her husband's death.[139] The Seventh Circuit affirmed the district court's ruling that the evidence was inadmissible.[140] The court held that suicide warnings issued after forty-six-year-old Giles' death were focused on children and adults under twenty-five years old, and therefore their probative value was substantially outweighed by danger of unfair prejudice from jury confusion.[141] Further, whether Effexor's warnings were adequate was time dependent, and Illinois law only holds a manufacturer liable for failure to warn regarding dangers it knew or should have known about at the time it made the drug.[142]

III. FAILURE TO WARN

In *Rivera v. Philip Morris, Inc.*, Joe Rivera, a smoker's husband, brought a wrongful death suit against Philip Morris, the manufacturer of the cigarettes that he alleged killed his wife.[143] Pamela Rivera began smoking in 1969, before the federal government required warnings on cigarette labels about the health risks of smoking.[144] Until 1985, cigarette labels only warned of general health risks, rather than explicitly warning of smoking's connection to lung cancer, heart disease, and emphysema.[145] Rivera smoked until 1999, when she died of brain cancer, which her estate alleged was a result of lung cancer.[146] Joe Rivera filed suit alleging that by producing and selling cigarettes, Philip Morris breached its duty to Pamela not to manufacture and sell a product that was defective and unreasonably dangerous to her.[147]

The federal district court granted Philip Morris's motion for summary judgment, holding that the Federal Cigarette Labeling and Advertising Act of 1965 preempted the strict liability claim and the fraud claim, and additionally that there was a lack of evidence that Rivera would have stopped smoking even if Philip Morris had disclosed material information regarding smoking's health effects.[148] Rivera appealed to the Ninth Circuit, which affirmed summary judgment on the fraud claim.[149] However, the court reversed the district court on the strict products liability failure-to-warn

139. *Id.*
140. *Id.* at 602.
141. *Id.* at 601–02.
142. *Id.* at 602 (citing Smith v. Eli Lilly & Co., 560 N.E.2d 324, 344 (Ill. 1990)).
143. 209 P.3d 271 (Nev. 2009).
144. *Id.* at 273.
145. *Id.*
146. *Id.*
147. *Id.*
148. *Id.*
149. *Id.*

claim because the question of whether it was common knowledge when Pamela began smoking in 1969 that cigarette smoking caused lung cancer, or that cigarettes were addictive, were questions of fact for the jury.[150] On remand, Rivera filed a motion for partial summary judgment, and Philip Morris filed a cross-motion for summary judgment on the strict products liability failure-to-warn claim, arguing that Rivera could not prove that his wife would have acted differently had Philip Morris provided additional information or warnings.[151]

Rivera argued that the federal district court should apply a heeding presumption, which allows the fact finder to presume that the person injured by the product's use would have heeded an adequate warning, if given.[152] The court denied Philip Morris's motion for summary judgment, holding that the company failed to overcome the heeding presumption, and Philip Morris moved for clarification as to whether Nevada law recognizes a heeding presumption in strict liability failure-to-warn cases.[153] The federal district court denied Philip Morris's motions, and both parties joined in a motion to certify the question to the Nevada Supreme Court, which the federal district court granted.[154]

Whether Nevada law recognizes a heeding presumption was a matter of first impression for the Nevada Supreme Court, and the court recognized that its answer would determine whether Rivera would be able to prove causation.[155] The court held that Nevada does not recognize a heeding presumption in strict products liability failure-to-warn cases because it is contrary to both Nevada law and public policy.[156] The court held that a heeding presumption departs from established Nevada law by removing the plaintiff's responsibility to carry the initial burden of production as to the element of causation instead of requiring that the plaintiff prove each element of a strict products liability case.[157]

The issue before the Supreme Judicial Court of Maine in the case *Brown v. Crown Equipment Corporation*[158] was whether the law of Maine required a manufacturer to warn indirect purchasers about a hazardous defect in its product that developed after the time of sale.[159] The plaintiff, the wife of a man who was killed while using a forklift at work, sued the manufacturer

150. *Id.*
151. *Id.*
152. *Id.*
153. *Id.* at 274.
154. *Id.*
155. *Id.*
156. *Id.*
157. *Id.* at 275.
158. 960 A.2d 1188 (Me. 2008).
159. *Id.* at 1190.

of the forklift, alleging that the forklift was defective when designed and the manufacturer failed to warn her husband's employer once it became aware of the risk.[160] About six years after the manufacturer began making the forklift, it learned that a new warehouse shelf design exposed forklift operators to the risk of being struck by the shelving.[161] The manufacturer did not notify customers of this potential hazard until approximately four years later.[162]

Relying on prior precedent, the court noted several factors that supported a finding of a duty to warn.[163] First, the manufacturer knew of the forklift risks resulting from the new warehouse shelf designs, and it developed a way to reduce the risks.[164] In addition, the manufacturer had personal contact with the employer of the plaintiff's husband—an indirect purchaser—and evaluated the specific forklift involved in the accident.[165] For these reasons, the court concluded that the manufacturer owed the plaintiff's husband a duty as a known forklift operator, and it breached that duty in not warning the employer.[166] Thus, the court decided that Maine recognizes a duty to warn indirect and known purchasers of product hazards that become known to it after the sale of the product.[167]

In *Braaten v. Saberhagen Holdings*,[168] the plaintiff, a pipefitter who developed mesothelioma after working many years aboard navy ships, sued several manufacturers that sold pipes and valves to the navy.[169] The plaintiff alleged that the companies "failed to warn him of the danger of exposure to asbestos during routine maintenance of their equipment."[170] The defendant companies, however, never manufactured, sold, or supplied the asbestos insulation.[171] Rather, the navy had applied insulation containing asbestos to the valves and pumps after their installation on the ships.[172] The lower court granted the defendants' motion for summary judgment, and the Washington Court of Appeals reversed.[173]

The Washington Supreme Court framed the first issue as whether the defendants "had a duty to warn of the danger of exposure during mainte-

160. *Id.*
161. *Id.*
162. *Id.*
163. *Id.* at 1193.
164. *Id.*
165. *Id.*
166. *Id.*
167. *Id.* at 1193–94.
168. 198 P.3d 493 (Wash. 2008).
169. *Id.* at 495–96.
170. *Id.* at 495.
171. *Id.*
172. *Id.*
173. *Id.*

nance of their products to asbestos in insulation that the navy would foreseeably apply to their equipment."[174] The second issue involved the same duty to warn regarding replacement packing and gaskets that contained asbestos as originally sold but that the defendants did not manufacture or supply.[175]

The court considered *Simonetta v. Viad Corporation*,[176] a companion asbestos case, in which the court held that a manufacturer is not liable under principles of common law products liability or negligence for not warning of the dangers of exposure to asbestos arising from a different manufacturer's insulation applied to the manufacturer's products subsequent to its sale of the products.[177] In general, a manufacturer has no duty to gain expertise regarding another manufacturer's product, and the underlying policy for strict liability is inapplicable "when a manufacturer has not placed the product in stream of commerce."[178] With regard to the first issue, the court decided that its decision in *Simonetta* was determinative.[179] With regard to the second issue, the court decided that the defendants did not place the replacement packing or gaskets into the stream of commerce, nor did they require asbestos-containing materials for use with their valves and pumps.[180] Thus, the court held that the principles of products liability did not require the defendants to warn of the dangers of asbestos exposure arising from another manufacturer's products.[181]

IV. DEFECTIVE DESIGN

In *Bouher v. Aramark Services, Inc.*, plaintiff was severely burned when she dispensed hot water from a Food Equipment Technologies Company (FETCO) coffeemaker into a polystyrene cup from her work cafeteria.[182] Plaintiff alleged that she took the cup back to her desk with the intent of brewing tea, and after setting the cup down for a few minutes while talking to a coworker, she picked it back up and her thumb went through the softened polystyrene.[183] Plaintiff said she felt intense pain and shook the cup to free her thumb, which resulted in the lid popping off and the water inside the cup splashing on her body, causing second-degree burns.[184] Plaintiff

174. *Id.*
175. *Id.*
176. 197 P.3d 127 (Wash. Ct. App. 2008).
177. Braaten v. Saberhagen Holdings, 198 P.3d 493, 495 (Wash. 2008).
178. *Id.* at 498.
179. *Id.* at 495.
180. *Id.* at 495–96.
181. *Id.*
182. 910 N.E.2d 40, 42 (Ohio Ct. App. 2009).
183. *Id.*
184. *Id.*

and her husband alleged that the FETCO coffeemaker was defectively designed and that FETCO failed to give adequate warning of the coffee maker's "inherent danger."[185]

The trial court granted FETCO's motion for summary judgment, and plaintiff appealed the ruling.[186] The appellate court upheld the trial court's ruling, and held that the coffeemaker did exactly what any consumer would expect a coffeemaker to do—it produced water from a hot water spigot at a temperature hot enough to brew tea.[187] This decision overruled a prior case, *Nadel v. Burger King Corp*.,[188] in holding that the language in *Nadel* was "far too broad," and a manufacturer need not make its product "accident-proof or foolproof."[189] The court noted that, in fact, the water from the FETCO coffeemaker's water spigot was slightly cooler than the industry standard to brew tea.[190] Plaintiffs' claim of failure to warn was also not warranted because "burns from water hot enough to brew tea are an open and obvious risk," the red spigot informed the user that hot water came out, and the warning adequately put the user on notice of the risk of potential injury.[191] Thus, the plaintiff's injuries did not, by themselves, mean the coffeemaker was defective, and summary judgment was upheld.[192]

In *Walker v. George Koch Sons, Inc.*, plaintiff alleged that while standing on a fixed ladder manufactured and designed by George Koch Sons, Inc., he was injured at his place of employment (Howard Industries).[193] The ladder was designed to provide access to a surface preparation machine (SPM), and Walker alleged that he was standing on the top rung of the ladder when he slipped and fell while exiting the SPM.[194] Before falling, Walker leaned backward on the ladder in order to close the door to the SPM, and prior to the fall, Walker had entered and exited the SPM via the ladder "thousands of times."[195] Koch designed, manufactured, installed, and serviced the SPM and accompanying ladder, and the defendant provided a conditional warranty for the SPM that it be "free from defects" and "comply with Koch's interpretations of current OSHA regulations."[196]

John Walker and his wife Donna filed suit against Koch alleging that the fixed ladder should have had a platform or fixed stairs providing access

185. *Id.*
186. *Id.*
187. *Id.* at 44.
188. 695 N.E.2d 1185 (Ohio Ct. App. 1996).
189. Bouher v. Aramark Servs., Inc., 910 N.E.2d 40, 43 (Ohio Ct. App. 2009).
190. *Id.* at 42.
191. *Id.* at 44.
192. *Id.* at 46.
193. 610 F. Supp. 2d 551, 553 (S.D. Miss. 2009).
194. *Id.*
195. *Id.*
196. *Id.* at 554.

to it, or should have contained a notice warning of the danger posed, and therefore was defective and unreasonably dangerous under the provisions of the Mississippi Product Liability Act.[197] Although Koch conceded that a platform or stairs could have been part of the design for the SPM, Howard Industries did not request a platform or stairs because of space limitations involved.[198] Regarding plaintiffs' manufacturing defect claim, the court dismissed the claim because the plaintiffs did not produce evidence that the ladder deviated from Koch's specifications, malfunctioned, or contained inferior or defective materials.[199]

The court held that the plaintiffs' argument equivocated manufacturing specifications with a warranty of promise.[200] The court explained that, for example, there was no evidence that Koch had specifications that the ladder would contain a platform; but due to a manufacturer defect, the ladder was made without one.[201] Although Koch may have breached the contract by failing to design a ladder that was OSHA compliant, there was no evidence that the manufacturing process produced a ladder inconsistent with the manufacturing specifications, and therefore the ladder did not have a manufacturing defect.[202]

Betty Stalker, as the administrator of decedent George Stalker's estate, brought action against a tire manufacturer and a company that retreaded tires after their manufacture in *Stalker v. Goodyear Tire and Rubber Co*., alleging that Stalker was killed as a result of a defective tire.[203] The decedent was inflating a truck tire when a zipper rupture occurred, and the explosion propelled the decedent across the room, killing him.[204] The tire was manufactured by defendant Goodyear Tire and Rubber Company in 1993, and retreaded by defendant Rua & Sons, Inc. in 1996.[205] Defendants' summary judgment motion was granted, and the plaintiff appealed.[206]

The court stated that the defendants submitted ample proof that the explosion occurred as a result of poor maintenance and low air pressure, and not because of a defective design.[207] In order for summary judgment to be overturned, the court stated that the plaintiff must provide competent proof that the tire "as designed, was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the prod-

197. *Id*.
198. *Id*.
199. *Id*. at 556.
200. *Id*.
201. *Id*.
202. *Id*. at 557.
203. 874 N.Y.S.2d 632, 634 (N.Y. App. Div. 2009).
204. *Id*.
205. *Id*.
206. *Id*.
207. *Id*.

uct in a safer manner."[208] The plaintiff presented expert evidence from an engineer, who claimed without explanation and in a generalized manner that a proposed design in the 1994 Goodyear patent "cures the problem at the heart of this case."[209] The court held that a factual issue is not established regarding design defects by "merely pointing to efforts within the industry to make a safer product, without providing some detail as to how the current product is not reasonably safe and how a feasible alternative would be safer."[210] Thus, the defendants could not be held liable based on design defect, and the court affirmed the defendants' motion for summary judgment.[211]

In *Martinez v. Triad Controls, Inc.*,[212] the U.S. District Court for the Eastern District of Pennsylvania denied the defendant's motion for summary judgment, holding that the safety mechanisms on a mechanical power press were defectively designed and could be considered unreasonably dangerous.[213] The plaintiff sued the manufacturers of the power press and safety device for an injury that allegedly resulted from the power press descending onto his hand, which necessitated amputation of his fingers.[214]

The court noted that under Pennsylvania law, a plaintiff who brings a products liability claim for defective design must demonstrate "(1) that the product was defective, (2) that the defect existed when it left the hands of the defendant, and (3) that the defect caused the harm."[215] In this case, the plaintiff argued that the press's light curtains, which used infrared light to signal penetration of the work area around the press, were defective.[216] When the curtains detected penetration, they were supposed to prevent the press from continued operation.[217] The plaintiff alleged that the design of the curtains should have included a backup mechanism that would disable the press if the curtains malfunctioned.[218]

To support this argument, the plaintiff cited *Myers v. Triad Controls, Inc.*, an analogous case in which light curtains improperly illuminated a green light signaling a clear work area despite the fact that workers had disabled

208. *Id.* at 635 (quoting Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204, 208 (N.Y. 1983)).
209. *Id.*
210. *Id.*
211. *Id.*
212. 593 F. Supp. 2d 741 (E.D. Pa. 2009).
213. *Id.* at 761.
214. *Id.* at 748–49.
215. *Id.* at 756.
216. *Id.* at 748, 759.
217. *Id.* at 748.
218. *Id.* at 759.

the light curtain's connection.[219] The *Myers* court noted that "[w]here absent any warnings, a guard system can be disabled and yet continue to emit a green light," a jury should be able to consider whether the curtains had been defectively designed.[220] In this case, the court noted that similar to *Myers*, a jury could determine that the curtains were defective because they failed to prevent the press from operating, and thus protect the operator, even when part of the curtain's sensor malfunctioned.[221] After determining that the light curtains could be considered unreasonably dangerous, the court denied the defendant's motion for summary judgment.[222]

Adamo v. Brown & Williamson Tobacco Co.[223] involved a claim brought by a cigarette smoker and her husband against two cigarette manufacturers alleging that they negligently designed their product by failing to use lower levels of tar and nicotine.[224] The smoker, who died before the court reviewed the case, smoked more than one pack of regular cigarettes every day for over forty years.[225] Although she quit smoking in 1993, she was diagnosed in 1995 with lung cancer.[226] The Appellate Division of the New York Supreme Court reversed the jury's decision that the manufacturers negligently designed the cigarettes, and the plaintiffs appealed to the New York Court of Appeals.[227]

A plaintiff bringing a claim for negligent design must prove that "it was feasible to design the product in a safer manner."[228] The court noted that this burden requires the plaintiff to show that the safer product would also remain functional.[229] In applying these rules to the facts of the case, the court noted that although the plaintiffs showed that cigarettes containing less tar and nicotine are safer than regular cigarettes, they failed to show that the lighter cigarettes would remain "functional."[230] In particular, the plaintiffs failed to demonstrate that lighter cigarettes are as satisfying to the smoker as regular cigarettes.[231] Noting that the only function of a cigarette is to satisfy the consumer, the court concluded that the plaintiffs were

219. *Id.* at 759–60 (citing Myers v. Triad Controls, Inc., 720 A.2d 134 (Pa. Super. Ct. 1998)).
220. *Id.* at 760 (quoting *Myers*, 720 A.2d at 136).
221. *Id.* at 760.
222. *Id.* at 761.
223. 900 N.E.2d 966 (N.Y. 2008).
224. *Id.* at 968.
225. *Id.*
226. *Id.*
227. *Id.*
228. *Id.* (quoting Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204 (N.Y. 1983)).
229. *Id.*
230. *Id.*
231. *Id.*

required to show that the safer product would be as pleasurable to smokers as the regular product.[232]

Because a holding that each sale of regular cigarettes may result in tort liability for the manufacturer and have the practical effect of a judicial ban on regular cigarettes, the court affirmed the order of the Appellate Division.[233] One judge dissented, asserting that the plaintiffs met their burden.[234] The dissenting judge argued that the trial court erred in denying the defendants' motion to offer evidence showing that the safer cigarette design was not commercially viable.[235] Accordingly, that judge would have remitted the case for a new trial to allow the defendants to produce evidence of the "commercial unacceptability" of the safer cigarette.[236]

In *Bisbo v. GSW, Inc.*,[237] the plaintiff sued the manufacturer of a water heater safety control valve, alleging strict liability and negligence claims arising from burn injuries he sustained when the water heater's gas exploded.[238] Several theories, including design defect, formed the basis of the plaintiff's claims.[239] Both parties agreed that gas leaked from the water heater as a result of the failure of the gas safety valve.[240] The issue for consideration before the U.S. District Court for the District of Oregon was whether to adopt the magistrate judge's recommendation that the court grant the defendants' motion for summary judgment under a risk-benefit analysis.[241]

Applying California law, the court explained that the risk-benefit test is one of two ways a plaintiff may prove a design defect.[242] Under that test, the plaintiff has the initial burden of proving that the design proximately caused the injury.[243] The court noted, however, that after the plaintiff proves causation, the defendant has the burden to prove that the risks of using the product do not outweigh the benefits.[244] According to the court, this burden is a balancing test that considers several issues such as the gravity and likelihood of the danger, as well as the feasibility of a safer alternative.[245]

232. *Id.*
233. *Id.* at 969.
234. *Id.* (Pigott, J., dissenting).
235. *Id.* (Pigott, J., dissenting).
236. *Id.* (Pigott, J., dissenting).
237. 586 F. Supp. 2d 1226 (D. Or. 2008).
238. *Id.* at 1233.
239. *Id.* at 1236.
240. *Id.* at 1240.
241. *Id.* at 1230–31.
242. *Id.* at 1238.
243. *Id.* at 1240.
244. *Id.*
245. *Id.*

The court concluded that the benefits of the safety valve's design outweighed its risks.[246] In particular, the court decided that although an explosion caused by leaking gas is a severe danger, the likelihood of such an explosion occurring as a result of a safety valve failure was remote.[247] For example, the parties' experts were not able to replicate the failure or predict the circumstances that might result in a failure.[248] Because strict liability applies to a component manufacturer only for damages caused by a part that was defective upon its departure from the manufacturer's factory, the court dismissed the plaintiff's argument that the explosion may have been prevented if the defendant had installed a gas detector.[249] For these reasons, the court concluded that strict liability did not apply to the defendant.[250]

V. EXPERTS

In *Rose v. Truck Centers, Inc.*, plaintiff Robert Rose brought his single vehicle tractor-trailer in to Truck Centers to have maintenance performed on it due to a previous accident.[251] One of the repairs was the installation of a remanufactured steering gear produced by defendant TRW Automotive. In May 2006, Rose was driving the truck with his wife Barbara riding in the sleeper compartment when they allege that the steering of their vehicle "gave out" such that the wheels were not responding to the turning of the steering wheel. The plaintiffs brought an action against the steering gear manufacturer, bringing a claim under the Ohio Product Liability Act. Plaintiffs' expert, Philip Smith, testified that he had inspected the truck and steering gear at the plaintiff's home in Kentucky and believed that the cause of the accident was that the TRW-manufactured steering gear was defective. Smith was a truck mechanic who was a certified master technician and oversaw the repair and maintenance of the mechanical systems of automobile, heavy truck, and trailer fleets.

TRW filed a motion for summary judgment, claiming that Smith was not qualified to testify on issues of product defect and causation, and that Smith's opinions were unsupported by the facts of the case. The plaintiffs opposed the motion, claiming that Smith's testimony was admissible under Federal Rule of Evidence 702, but conceded that without admissible expert testimony from Smith, summary judgment would be appropriate for the defendant. The court granted TRW's motion for summary judgment,

246. *Id.*
247. *Id.*
248. *Id.* at 1240–41.
249. *Id.* at 1241.
250. *Id.*
251. 611 F. Supp. 2d 745 (N.D. Ohio 2009).

holding that the mechanic's testimony exceeded the field of maintenance, as he had not designed or manufactured a steering gear for a truck and did not demonstrate that he knew more about mechanical engineering principles than an average juror.[252] Additionally, the court found that Smith's testimony was unreliable because it was based on the erroneous assumption that the bolts were in the same place in November 2006, when he inspected them, as they were in May 2006, which was proved otherwise by a photograph taken of the steering gear in July 2006 that showed that the bolts were manipulated after the accident and before Smith's examination.[253] Consequently, Smith's testimony did not rest on a reliable foundation and was found to be inadmissible by the court.[254]

Robert C. Mracek brought action against Intuitive Surgical, Inc. for injuries from a prostatectomy performed with a "da Vinci" operative robot manufactured by Intuitive.[255] During the surgery, the robot began to display error messages, and attempts by the surgeon and a tech representative to reboot the robot failed multiple times.[256] Consequently, the surgical team abandoned its attempt to perform a robotic prostatectomy and finished the surgery laparoscopically, with forty-five minutes elapsing between the switch in procedures.[257] A week after the surgery, Mracek suffered a gross hematuria and was readmitted to the hospital, and Mracek contended that as a result of the delay and laparoscopic procedure he now suffers from total erectile dysfunction and severe abdominal pain.[258]

Mracek filed suit against the defendants for strict products liability, negligence, breach of warranty, and strict malfunction liability. Defendant Intuitive moved for summary judgment, asserting that since Mracek failed to submit any expert report that was critical of the da Vinci robot, he could not meet his burden of proof with respect to any of the theories of liability that he had asserted.[259] The court agreed with the defendant, holding that without an expert report, Mracek could not establish products liability claims where the asserted defect was not obvious enough to be ascertainable by the average juror without speculation.[260] Mracek could not demonstrate that the robot had a defect or that what occurred in the operating room with the robot caused his erectile dysfunction, and therefore the court granted Intuitive's summary judgment.[261]

252. *Id.* at 750.
253. *Id.* at 751.
254. *Id.* at 751–52.
255. Mracek v. Bryn Mawr Hosp., 610 F. Supp. 2d 401, 402 (E.D. Pa. 2009).
256. *Id.* at 403.
257. *Id.*
258. *Id.*
259. *Id.* at 404.
260. *Id.* at 405.
261. *Id.*

In *Henricksen v. ConocoPhillips Co*., a former gasoline tanker truck driver sued ConocoPhillips, alleging that his occupational exposure to the company's gasoline, which contained benzene and benzene-containing products, caused his acute myelogenous leukemia (AML).[262] Neil Henricksen worked as a gasoline truck driver from 1973 until 2003, and his job entailed loading petroleum fuels, including gasoline, refined and sold by ConocoPhillips.[263] It was alleged that Henricksen regularly spilled gasoline on his skin while filling the tank, and was exposed to fumes at a Conoco terminal that did not have a vapor recovery system to prevent exposure to gasoline fumes.[264] Henricksen was diagnosed with AML in 2003, and sued the gasoline company asserting products liability claims for negligence, strict liability, and breach of warranty.[265]

ConocoPhillips moved for exclusion of Henricksen's expert witnesses' testimony and for summary judgment, arguing that Henricksen could not reliably establish a medical or scientific link between exposure to gasoline and AML, nor could he demonstrate that his occupational exposure to benzene in gasoline was sufficient to cause his AML.[266] The court held that, while it did not question the scientific expertise of any of the experts, their testimony was unreliable because it was not supported by the predominant scientific literature.[267] Although the experts presented the theory that it was plausible that the benzene in gasoline led to his development of AML, plausible hypotheses are not " 'scientific knowledge,' but the building blocks and catalysts of such knowledge."[268] Thus, because a causal link between Henricksen's exposure and AML and ConocoPhillips' gasoline was not established, the court granted summary judgment for ConocoPhillips.[269]

In *Finke v. Hunter's View, Ltd*.,[270] the U.S. District Court for the District of Minnesota held that the opinion of the plaintiff's expert was not inadmissible merely because it conflicted with the plaintiff's testimony.[271] In *Finke*, the plaintiff and his wife brought claims for strict liability, negligence, and breach of warranty against a company that sold deer hunting stands.[272] According to the plaintiff, he climbed thirty feet up a tree with the tree stand, and while he adjusted the seat of the stand, a connection cable that attached the stand to the tree disengaged, causing him to lose

262. 605 F. Supp. 2d 1142, 1148 (E.D. Wash. 2009).
263. *Id*. at 1149.
264. *Id*.
265. *Id*. at 1148.
266. *Id*.
267. *Id*. at 1178.
268. *Id*.
269. *Id*.
270. 596 F. Supp. 2d 1254 (D. Minn. 2009).
271. *Id*. at 1266.
272. *Id*. at 1258–60.

his balance.[273] The plaintiff fell to the ground and suffered injuries that resulted in paraplegia from his chest down.[274]

The court reviewed the case on motions from all involved parties to exclude expert witnesses.[275] The defendants sought to exclude the opinion of one of the plaintiff's expert witnesses whose theory of how the accident happened conflicted with the plaintiff's deposition testimony recalling the event.[276] The expert believed that the plaintiff probably climbed the tree with the stand and, upon reaching the top, adjusted the cable that attached the seat to the tree by resetting the cable.[277] According to the expert, when the plaintiff reset the cable, he most likely improperly believed that the quick clip pin attaching the cable to the seat and the tree had locked through the loop on the cable.[278] The expert opined that because the pinlocking mechanism was not visible to the user, the tree stand was defective.[279] The plaintiff, on the other hand, testified that he remembered putting the pin in front of the swage fitting that formed a loop on the end of the cable.[280] According to the plaintiff's testimony, the pin wedged the swage fitting, supporting him until he reached the top of the tree, at which time it released, causing him to fall.[281]

Although the defendants argued that the opinion of the plaintiff's expert was inadmissible because it conflicted with the plaintiff's testimony, the court noted that an expert does not need to agree with the facts to which a party testifies.[282] In particular, the court suggested that the contradiction between the plaintiff and his expert's testimony demonstrated the independence of the expert's opinion.[283] Because the expert based his opinion on his knowledge, his examination of the stand, and his own testing, the court concluded that the jury could properly address the accuracy of the plaintiff's testimony.[284]

VI. DEFENSES

In *Mendez Montes De Oco v. Aventis Pharma*,[285] the plaintiffs, a husband, wife, and their children, sued the manufacturer of Lantus, an insulin prod-

273. *Id.*
274. *Id.* at 1259.
275. *Id.*
276. *Id.* at 1266.
277. *Id.* at 1265.
278. *Id.* at 1258, 1265.
279. *Id.* at 1265.
280. *Id.* at 1258–59.
281. *Id.* at 1265.
282. *Id.* at 1266.
283. *Id.*
284. *Id.*
285. 579 F. Supp. 2d 222 (D.P.R. 2008).

uct, alleging that the manufacturer failed to warn of the risks associated with the use of Lantus.[286] The suit arose out of the husband's development of a cancerous tumor, which resulted in his death.[287] The plaintiffs alleged that the use of Lantus in his left leg was the direct and proximate cause of the tumor.[288] The U.S. District Court for the District of Puerto Rico reviewed the case on the defendant's motion for summary judgment, which argued that the learned intermediary doctrine precluded the claims.[289]

The court noted that under the learned intermediary doctrine, prescription drug manufacturers are not liable for failing to warn customers if they properly warned the physicians who prescribe the medication.[290] The doctrine does not allow a manufacturer to escape providing adequate warnings of the risks of the drugs it sells; however, it does provide that the manufacturer has no duty to warn the patient—the ultimate consumer.[291] Several exceptions to the doctrine exist.[292] For example, an exception applies to mass immunizations and the prescription of oral contraceptives.[293]

Several facts supported the court's conclusion that the doctrine applied.[294] First, the parties did not contest that the warnings accompanying the drug complied with legal regulations and requirements.[295] Second, the plaintiffs' expert witness noted that even though the information provided to patients did not disclose the "carcinogenicity potential of the product," the information provided to physicians provided full disclosure of this risk.[296] Third, no evidence indicated that the plaintiffs sought prescription of Lantus on their own; rather, the evidence suggested that the plaintiffs' physician initially suggested the product.[297] Because none of the exceptions to the learned intermediary doctrine applied to the plaintiffs' situation, the court concluded that the doctrine applied, and it granted the defendant's motion for summary judgment.[298]

In *Marrone v. Greer & Polman Construction, Inc.*,[299] the Appellate Division of the New Jersey Superior Court held that the plaintiffs could not maintain a claim under the Products Liability Act (PLA) against the manufac-

286. *Id.* at 223.
287. *Id.*
288. *Id.*
289. *Id.*
290. *Id.* at 227.
291. *Id.*
292. *Id.* at 228.
293. *Id.*
294. *Id.* at 229–30.
295. *Id.* at 229.
296. *Id.*
297. *Id.* at 230.
298. *Id.* at 229–30.
299. 964 A.2d 330 (N.J. Super. Ct. App. Div. 2009).

turer and distributor of exterior insulation finish system (EIFS) cladding.[300] The plaintiffs' claims arose out of damage sustained to the cladding and the materials around the windows in plaintiffs' house as a result of the allegedly improper installation and poor design of the EIFS system.[301]

Under the PLA, a plaintiff may bring a claim for "harm" to property resulting from a product.[302] "Harm" is defined as "physical damage to property, other than to the product itself."[303] The motion judge dismissed the plaintiffs' claims on the theory of the economic loss doctrine.[304] In particular, the PLA claims failed because, under the doctrine, damage to an integrated product caused by a component of the product does not constitute separate property damage that removes the claim from "the realm of contract law into the field of tort law."[305]

In affirming the motion judge's dismissal, the court based its holding on two conclusions.[306] First, it concluded that under the PLA, the plaintiffs' house was a "product" that cannot be divided into its component parts.[307] Second, the court concluded that even if the plaintiffs purchased the cladding as a separate component, they could not recover the expenses incurred in replacing the cladding because defects in the cladding constituted "damage . . . to the product itself."[308] In other words, because the plaintiffs purchased a house and not the EIFS cladding, the appellate court concluded that the plaintiffs could not bring a claim under the PLA by subdividing the house into its component parts and suing for defects of the components.[309]

The facts of *International Flavors & Fragrances, Inc. v. McCormick & Co.*[310] involved the defendant's shipment of approximately 10,000 pounds of paprika to the plaintiff.[311] The plaintiff used some of the paprika to make barbeque seasoning for one of its customers.[312] The defendant later discovered that the paprika was infested with cigarette beetles.[313] After the defendant notified the plaintiff of this discovery, the plaintiff sued to recover the "significant expense" it incurred in trying to supply its customers with barbeque seasoning from an alternate source.[314]

300. *Id.* at 341.
301. *Id.* at 333.
302. *Id.* at 336.
303. *Id.*
304. *Id.* at 333.
305. *See id.*
306. *Id.* at 336.
307. *Id.*
308. *Id.*
309. *Id.* at 340.
310. 575 F. Supp. 2d 654 (D.N.J. 2008).
311. *Id.* at 655.
312. *Id.*
313. *Id.*
314. *Id.* at 655–56.

The issue before the U.S. District Court for the District of New Jersey was whether the economic loss doctrine precluded the plaintiff's products liability suit.[315] New Jersey state law limits claims premised on products liability theories to "damage to property other than the product itself."[316] The court noted that courts interpreting the "other property exception" have held that the exception does not apply when a defective component or ingredient damages the final product.[317] The court discussed *Sullivan Industries Inc. v. Double Seal Glass Co., Inc.*,[318] an analogous case in which a manufacturer of glass doors and windows sued suppliers of insulated glass units and polysulfide sealant, a component used in assembling the insulated glass units.[319] The manufacturer's tort and contract claims were based on its allegation that the defective sealant resulted in the failure of the insulated glass units, which caused significant monetary loss to the manufacturer.[320] That manufacturer sought to recover from the defendants damages caused to products in which the components had been incorporated.[321] The court in that case held that the trial court erred in finding damage to property other than the subject goods because the sealant damaged only the insulated glass units, which were the subject of the transaction.[322] The *International Flavors* court analogized to the *Sullivan* case as well as to several others from various jurisdictions and concluded that the relevant authority supported a finding that New Jersey law barred the plaintiff's damage claims.[323]

In *Technisand, Inc. v. Melton*,[324] the Supreme Court of Indiana held that a wrongful death claim that is premised on a products liability theory must comply with the Wrongful Death Act's (WDA) period of limitations.[325] The plaintiff in *Technisand* was the personal representative of the estate of his wife, who died in July 2002 from leukemia.[326] In October 2003, the plaintiff sued his deceased wife's employer after her doctor suggested that an exposure to carcinogenic fumes at work might have put her at a heightened risk for contracting the disease.[327] In February 2005, the trial court granted the plaintiff leave to add as a defendant the manufacturer of the

315. *Id.* at 656.
316. *Id.* at 658.
317. *Id.* at 662.
318. 480 N.W.2d 623 (Mich. Ct. App. 1991).
319. Int'l Flavors & Fragrances, Inc. v. McCormick & Co., 575 F. Supp. 2d 654, 663 (D.N.J. 2008).
320. *Id.*
321. *Id.*
322. *Id.*
323. *Id.* at 660–64.
324. 898 N.E.2d 303 (Ind. 2008).
325. *Id.* at 306.
326. *Id.* at 304.
327. *Id.*

product that caused the fumes.[328] The manufacturer filed a motion for summary judgment, arguing that the statute of limitations required the claim to be filed within two years of the wife's death, thus barring the plaintiff's claim against it.[329] The trial court and the Indiana Court of Appeals denied summary judgment, holding that the Indiana Products Liability Act (PLA), rather than the WDA, provided the statute of limitations period.[330]

Under the PLA, a plaintiff may bring a products liability action "within two years after the cause of action accrues."[331] Accrual is defined as the time at which a plaintiff's physician informs the plaintiff of the possibility that the injury resulted from an act or product.[332] The WDA, on the other hand, requires that a personal representative file a claim for wrongful death within two years of the death.[333] Indiana's Survival Statute also provides that a personal injury claim does not survive the death of the individual unless he or she dies from causes other than the personal injuries.[334]

After noting that the plaintiff's wife died from injuries allegedly caused by the defendant, and thus the plaintiff's claim was for wrongful death, the court discussed how legislative intent as evidenced in the Medical Malpractice Act (MMA) and Child Wrongful Death Act (CWDA) supported its conclusion that the WDA provided the limitations period.[335] The court noted that the MMA allows claims in which the victim is a small child to be brought before the child's eighth birthday, but under the CWDA, a claim must be brought within two years of death.[336] In a previous case, the court upheld a dismissal of a claim brought before the deceased child's eighth birthday but after the date provided in the CWDA.[337] Similarly, in this case, the court held that the legislature intended for the WDA to provide the outer limits for claims premised on products liability.[338]

328. *Id.*
329. *Id.*
330. *Id.*
331. *Id.*
332. *Id.*
333. *Id.*
334. *Id.* at 305.
335. *Id.* at 305–06.
336. *Id.*
337. *Id.*
338. *Id.* at 306.