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Article 2

Product Liability's Parallel Universe

FAULT-BASED LIABILITY THEORIES AND MODERN PRODUCTS LIABILITY LAW

Richard C. Ausness[†]

I. INTRODUCTION

Strict liability has always been the heart and soul of American products liability law. As early as 1963, Justice Roger Traynor in Greenman v. Yuba Power Products, Inc. stated that "[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it will be used without inspection for defects, proves to have a defect that causes injury to a human being." Shortly thereafter, the drafters of section 402A of the Restatement (Second) of Torts made it clear that the exercise of due care would not shield sellers from liability when their products caused injury.3 The new Products Liability Restatement continues to adhere to the concept of strict liability, at least in theory.⁴ Nevertheless, plaintiffs now commonly supplement or even replace strict liability with claims that rely on fault-based liability theories. These theories are attractive because they allow plaintiffs to avoid the Restatement's defect requirement and enable them to focus on a product seller's behavior instead of the condition of its product.

Part II examines some of these theories, including fraudulent misrepresentation, fraudulent concealment, civil conspiracy, negligent entrustment, negligent marketing, and negligence per se. Part III identifies some of the reasons why plaintiffs prefer fault-based liability theories instead of strict liability: these theories enable them to avoid the product defect requirement, to circumvent the preemptive effect of federal law on certain failure to warn claims, and to focus the jury's attention on the defendant's culpable misconduct. In addition, these theories allow plaintiffs to side-step risk-utility analysis in design defect cases and relieve them of the need to prove the existence of a reasonable alternative design. Theories such as fraud and negligent marketing may

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¹ 377 P.2d 897 (Cal. 1963). ² *Id.* at 900.

³ See RESTATEMENT (SECOND) OF TORTS § 402A (2)(a) (1965).

⁴ See Restatement (Third) of Torts: Prods. Liab. § 1 (1998).

prove useful in obvious hazard situations. Fault-based liability theories are also useful in suits against drug companies because they help plaintiffs to avoid the Restatement's special rules, which limit conventional design defect and failure to warn claims against manufacturers of prescription drugs and medical devices.⁵

Part IV concludes by predicting that strict liability will continue to lose ground in products liability law, except in manufacturing defect cases, because of the advantages that plaintiffs see in fault-based liability theories. While this trend may be beneficial because it helps to reorient products liability law toward a conduct-based liability regime, it also encourages litigants to expand existing liability doctrines beyond their traditional boundaries. Hence, courts must be wary of embracing extreme versions of these theories.

II. FAULT-BASED LIABILITY THEORIES

Injured consumers who are unlikely to be successful under traditional strict liability now rely on a variety of other liability theories to improve their chances of recovering. These theories include fraudulent misrepresentation and fraudulent concealment, civil conspiracy, negligent entrustment, negligent marketing, and negligence per se. Although some of these theories, such as misrepresentation and civil conspiracy, are subject to onerous requirements, and others, such as negligent entrustment and negligent marketing, have not completely gained judicial acceptance, it nevertheless appears that plaintiffs continue to invoke them in products liability litigation.

A. Fraudulent Misrepresentation and Fraudulent Concealment

Courts commonly classify fraud as either fraudulent misrepresentation or fraudulent concealment. "Fraudulent misrepresentation is defined as the false statement of a material fact made to induce another party to act in reliance thereon and resulting in damage to the party who so relies." In order to establish a cause of action for fraudulent misrepresentation, the plaintiff must prove: (1) that the defendant made a false representation of a material fact; (2) that the defendant was aware that the statement was false; (3) that the defendant intended to induce the plaintiff to rely on this false statement; and (4) that the plaintiff suffered harm as a result of his or her justifiable reliance on the defendant's false statement. In addition, the elements of a fraud claim must be pleaded with particularity.

⁶ See People ex rel. Hartigan v. E & E Hauling, Inc., 577 N.E.2d 1262, 1271 (Ill. App. Ct. 1991), aff'd in part, rev'd in part, 607 N.E.2d 165 (Ill. 1992).

See id. § 6.

⁷ See, e.g., Dallas Aerospace, Inc. v. CIS Air Corp., 352 F.3d 775, 784 (2d Cir. 2003) (listing requirements); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 549 (E.D. Pa. 2006) (same), aff'd, 521 F.3d 253, 276 (3d Cir. 2008), vacated, No. 08-437, 2009 WL 578682 (U.S. Mar. 9. 2009);

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These requirements are often difficult for plaintiffs to meet. For example, to satisfy the false statement requirement, the plaintiff must prove that the defendant made a false representation of material fact, as opposed to merely expressing an opinion or engaging in "sales talk." This caused the court to dismiss the plaintiffs' fraudulent misrepresentation claim in Boumelhem v. Bic Corp. 10 The plaintiffs were two young children who were injured when the older boy used a disposable lighter manufactured by the defendant to start a fire.¹¹ The plaintiffs argued that various marketing techniques, such as the slogan "Flick My Bic," the schoolboy logo on the lighter's packaging, or the pastel colors of the lighters amounted to a representation that these products were safe for children.¹² Affirming the lower court's ruling in favor of the defendant, a Michigan intermediate appellate court concluded that the defendant had made no assurances that its lighters could not be used by children to start fires.¹³

The estate of a deceased smoker fared somewhat better in *Estate* of Schwarz v. Philip Morris, Inc. 14 In that case, the decedent's personal representative alleged that the defendant made a number of false representations about the health effects of smoking, namely that no causal link between smoking and lung cancer had been established, that cigarettes were not addictive, and that "low tar" cigarettes were safer than regular cigarettes.¹⁵ On appeal, an Oregon court observed that a defendant who made a promise knowing that it would not be performed was guilty of fraudulent misrepresentation.¹⁶ The court found that the plaintiff had presented sufficient evidence at trial for the jury to find that the defendant knew during this period that tobacco smoke was carcinogenic, that nicotine was addictive, and that nicotine addiction was

Gerrity v. R.J. Reynolds Tobacco Co., 399 F. Supp. 2d 87, 93 (D. Conn. 2005) (same); Jeter ex rel. Estate of Smith v. Brown & Williamson Tobacco Corp., 294 F. Supp. 2d 681, 686 (W.D. Pa. 2003) (same); Chase v. Kawasaki Motors Corp., 140 F. Supp. 2d 1280, 1291 (M.D. Ala. 2001) (same); Staudt v. Artifex, Ltd., 16 F. Supp. 2d 1023, 1030 (E.D. Wis. 1998) (same); Mason v. Chrysler Corp., 653 So. 2d 951, 952 (Ala. 1995) (same); Khan v. Shiley, Inc., 266 Cal. Rptr. 106, 112 (Ct. App. 1990) (same); Lewis v. Lead Indus. Ass'n, Inc., 793 N.E.2d 869, 876 (III. Ct. App. 2003) (same); Flynn v. Am. Home Prods. Corp., 627 N.W.2d 342, 349 (Minn. Ct. App. 2001) (same); Freeman v. Hoffman-LaRoche, Inc., 618 N.W.2d 827, 844-45 (Neb. 2000) (same); Estate of Schwarz v. Philip Morris, Inc., 135 P.3d 409, 422 (Or. 2006) (same).

See Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 783-84 (4th Cir. 1999); Roney v. Gencorp, 431 F. Supp. 2d 622, 635 (S.D. W. Va. 2006); Wajda v. R.J. Reynolds Tobacco Co., 103 F. Supp. 2d 29, 32-33 (D. Mass. 2000); Bd. of Educ. of Chicago v. A, C & S, Inc., 546 N.E.2d 580, 593 (III. 1989).

See Mason v. Chrysler Corp., 653 So. 2d 951, 954 (Ala. 1995); McGowan v. Chrysler Corp., 631 So. 2d 842, 847 (Ala. 1993); Boumelhem v. Bic Corp., 535 N.W.2d 574, 579 (Mich. Ct. App. 1995).

⁵³⁵ N.W.2d 574 (Mich. Ct. App. 1995).

¹¹ *Id.* at 576.

¹² *Id.* at 579.

¹³ *Id*.

¹⁴ 135 P.3d 409 (Or. Ct. App. 2006).

¹⁵ *Id.* at 416.

¹⁶ *Id.* at 422.

the principal reason that smokers continued to smoke.¹⁷ Instead of making this research public, as it had pledged to do, the "defendant publicly denied" that there was any link between smoking and cancer and "suppressed the results of its [own] research."¹⁸ From this evidence, the court concluded that the defendant promised to conduct research on the health effects of smoking and to promptly and fully disclose the results of this research to the public, but, in fact, had no intention of carrying these promises out.¹⁹ Consequently, the court upheld the deceased smoker's fraud claim.²⁰

Reliance is another essential element of any fraudulent misrepresentation claim.²¹ This element is often difficult for a plaintiff to prove. However, as Ronev v. Gencorp²² illustrates, proving reliance is not an insurmountable burden. In Roney, the plaintiff died from liver cancer as the result of exposure at his workplace to vapor, steam, and fumes containing vinyl chloride monomer (VCM).²³ Roney's personal representative brought suit against various manufacturers and suppliers of VCM, alleging that they fraudulently misrepresented and concealed the dangers of exposure to this chemical.²⁴ According to the plaintiff, the defendants supplied the decedent's employer with a publication, DS-56, that contained the fraudulent statements.²⁵ The plaintiff in Roney had specifically alleged that the fraudulent misrepresentations contained in DS-56 were communicated to the decedent by his employer.²⁶ In fact, the plaintiffs claimed that the decedent's employer gave him a copy of DS-56 and that the decedent relied upon the information contained in that document.²⁷ For this reason, the court in *Ronev* refused to dismiss the plaintiff's fraudulent misrepresentation claim on grounds of lack of reliance.28

¹⁷ *Id.* at 418.

⁸ *Id*.

¹⁹ *Id.* at 423.

²⁰ *Id*.

²¹ See, e.g., Jeter ex rel. Estate of Smith v. Brown & Williamson Tobacco Corp., 294 F. Supp. 2d 681, 687 (W.D. Pa. 2003); Chase v. Kawasaki Motors Corp., 140 F. Supp. 2d 1280, 1293 (M.D. Ala. 2001); Wajda v. R.J. Reynolds Tobacco Co., 103 F. Supp. 2d 29, 32 (D. Mass. 2000); Boerner v. Brown & Williamson Tobacco Co., 126 F. Supp. 2d 1160, 1169 (E.D. Ark. 1999); Berres v. Artifex, Ltd., 21 F. Supp. 2d 909, 917 (E.D. Wis. 1998); Staudt v. Artifex, Ltd., 16 F. Supp. 2d 1023, 1030-31 (E.D. Wis. 1998); Lewis v. Lead Indus. Ass'n, Inc., 793 N.E.2d 869, 876 (Ill. App. Ct. 2003); Am. Tobacco Co., Inc. v. Grinnell, 951 S.W.2d 420, 437 (Tex. 1997); see also John C.P. Goldberg, Anthony J. Sebok & Benjamin C. Zipursky, The Place of Reliance in Fraud, 48 ARIZ. L. REV. 1001, 1004 (2006).

⁴³¹ F. Supp. 2d 622 (S.D. W. Va. 2006); see also Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728, 730 (Fla. Dist. Ct. App. 1991) (concluding that the plaintiff alleged reliance sufficiently in the pleadings to satisfy the reliance requirement).

²³ 431 F. Supp. 2d at 626-27.

²⁴ *Id.* at 634.

²⁵ *Id.* at 636.

²⁶ *Id.*

²⁷ *Id*.

²⁸ *Id.* at 637.

Fraudulent concealment involves the concealment of material facts by one who has knowledge of these facts and a duty to disclose when the purpose of this concealment is to mislead or defraud the plaintiff.²⁹ Most fraudulent concealment cases involve either a duty to disclose or the reliance requirement. When fraudulent concealment merely involves a failure to disclose information, as opposed to active concealment, the plaintiff must prove that the defendant had a duty to disclose the facts in question.³⁰ For example, in Estate of White ex rel. White v. R.J. Reynolds Tobacco Co., 31 the court declared that fraudulent concealment required the existence of "a separate duty of disclosure to plaintiff by defendant."32 According to the court, this duty to disclose would arise when the parties were in a fiduciary or confidential relationship with each other or when one party made a partial or incomplete statement of fact.³³ The court concluded that "the arms-length relationship between [the] defendant cigarette manufacturers" and the decedent smoker was not the sort of "special relationship" that would create a duty on the part of the defendants to divulge information to consumers about the dangers of smoking.³⁴

On the other hand, in the *Roney* case, the court refused to dismiss the plaintiff's fraudulent concealment claim against the defendant chemical supplier.³⁵ As noted, the plaintiff in that case alleged, inter alia, that the defendant had concealed information about the danger of workplace exposure to its product, VCM.³⁶ The court held that the manufacturer had a common law duty to warn and its breach of that duty was sufficient to support a claim for fraudulent concealment.³⁷ A court employed similar reasoning in *Falk v. General Motors Corp.*³⁸ In *Falk*, the plaintiffs claimed that General Motors placed defective speedometers in some of its trucks and sports utility vehicles and failed to disclose this information to consumers once it became aware of it.³⁹ The court concluded that the plaintiffs stated a claim for fraudulent concealment by alleging sufficient facts to establish that General Motors had a duty to warn purchasers of its products about the defective speedometers, a

²⁹ See Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 549 (E.D. Pa. 2006), aff^{*}d, 521 F.3d 253 (3d Cir. 2008), vacated, No. 08-437, 2009 WL 578682 (U.S. Mar. 9. 2009); Roney, 431 F. Supp. 2d at 637; Livingstone v. K-Mart Corp., 32 F. Supp. 2d 369, 374 (S.D. W. Va. 1998); Mason v. Chrysler Corp., 653 So. 2d 951, 954 (Ala. 1995).

³⁰ See, e.g., Estate of White ex. rel. White v. R.J. Reynold Tobacco Co., 109 F. Supp. 2d 424, 430 (D. Md. 2000); Chavers v. Gatke Corp., 132 Cal. Rptr. 2d 198, 203 (Ct. App. 2003); Viguers v. Philip Morris USA, Inc., 837 A.2d 534, 540 (Pa. Super. Ct. 2003).

³¹ 109 F. Supp. 2d 424 (D. Md. 2000).

³² *Id.* at 430 (internal citations omitted).

³³ *Id.* at 431.

³⁴ Id.

³⁵ 431 F. Supp. 2d 622 (S.D. W. Va. 2006).

³⁶ *Id.* at 637.

³⁷ *Id*.

³⁸ 496 F. Supp. 2d 1088 (N.D. Cal. 2007).

³⁹ *Id.* at 1092-93.

potential safety hazard, and instead withheld this information from them 40

The false representation and reliance requirements sometimes prevent plaintiffs from recovering in fraudulent misrepresentation cases. 41 However, others, particularly injured smokers, have been successful in bringing fraudulent misrepresentation claims against product manufacturers. 42 Likewise, the reliance requirement and the duty to disclose requirement have thwarted a number of fraudulent concealment claims, but some plaintiffs have overcome and prevailed, at least in the early stages of litigation.

Civil Conspiracy В.

A civil conspiracy exists when two or more persons engage in concerted action to achieve some unlawful objective (or to achieve a lawful objective by unlawful means).43 Thus, the plaintiff in a civil conspiracy case must prove: (1) the existence of an agreement to commit an unlawful act or to commit a lawful act by unlawful means; (2) the commission of an overt act or independent tort for the purpose of furthering the objectives of the conspiracy; and (3) damage to another caused by the conspiracy.44 These can be formidable requirements for plaintiffs in products liability cases.

For there to be a civil conspiracy, two or more persons must agree to commit a wrongful act.45 Thus, a person who is merely aware that others are engaged in a conspiracy⁴⁶ or becomes involved in one inadvertently, accidentally, or even negligently⁴⁷ will not be subject to liability for civil conspiracy. Furthermore, as illustrated by *Cousineau v*.

⁴⁰ *Id.* at 1099.

⁴¹ See Jeter ex rel. Estate of Smith v. Brown & Williamson Tobacco Corp., 294 F. Supp. 2d 681, 686 (W.D. Pa. 2003) (finding no proof of reliance); Boumelhem v. Bic Corp., 535 N.W.2d 574, 579 (Mich. Ct. App. 1995) (finding that the defendant had not made any false representations).

See, e.g., supra notes 14-20 and accompanying text.

See LaBelle ex rel. LaBelle v. Philip Morris, Inc., 243 F. Supp. 2d 508, 526 (D.S.C. 2001); In re N.D. Personal Injury Asbestos Litig. No. 1, 737 F. Supp. 1087, 1095 (D.N.D. 1990); Belkow v. Celotex Corp., 722 F. Supp. 1547, 1550 (N.D. Ill. 1989); Lewis v. Lead Indus. Ass'n. Inc., 793 N.E.2d 869, 878 (Ill. App. Ct. 2003); Fenestra, Inc. v. Gulf Am. Land Corp., 141 N.W.2d 36, 48 (Mich. 1966); Skipworth v. Lead Indus. Ass'n, 690 A.2d 169, 174 (Pa. 1997); Triplex Communications, Inc. v. Riley, 900 S.W.2d 716, 719 (Tex. 1995).

⁴⁴ See Boerner v. Brown & Williamson Tobacco Co., 126 F. Supp. 2d 1160, 1171 (E.D. Ark. 1999); Sonnenreich v. Philip Morris, Inc., 929 F. Supp. 416, 419 (S.D. Fla. 1996); Nicolet, Inc., v. Nutt, 525 A.2d 146, 149-50 (Del. 1987); Jay Edwards, Inc. v. Baker, 534 A.2d 706, 709 (N.H. 1987).

See In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig., 175 F. Supp. 2d 593, 634 (S.D.N.Y. 2001); Ryan v. Eli Lilly & Co., 514 F. Supp. 1004, 1012 (D.S.C. 1981); Wright v. Brooke Group Ltd., 652 N.W.2d 159, 172 (Iowa 2002).

See RESTATEMENT (SECOND) OF TORTS § 876 (1965) (requiring that the actor provide assistance or encouragement to the conspirators).

See Jones v. City of Chicago, 856 F.2d 985, 993 (7th Cir. 1988); In re Methyl Tertiary Butyl Ether, 175 F. Supp. 2d at 634.

Ford Motor Co.,⁴⁸ the agreement between the conspirators must involve an objective that is tortious or unlawful.⁴⁹ In Cousineau, the plaintiff's son was killed when a multi-rim truck wheel flew apart as he was removing it to repair the tire on his employer's truck.⁵⁰ Because the plaintiff was unable to identify the manufacturer of the truck wheel in question, she sued all of the manufacturers of multi-rim truck wheels, alleging that they conspired to make product identification more difficult.⁵¹ However, a Michigan appeals court held that the plaintiff's claim failed because she was unable to prove that the alleged industry-wide agreement was unlawful.⁵²

On the other hand, the plaintiffs in *In re Methyl Tertiary Butyl Ether (MTBE) Products Liability Litigation* successfully demonstrated that the agreement in question was unlawful.⁵³ In that class action suit, the plaintiffs alleged that the manufacturers of MTBE, a gasoline additive, formed a number of joint task forces and committees for the express purpose of suppressing information about MTBE's environmental and health hazards.⁵⁴ The plaintiffs also accused the defendant manufacturers of conspiring to deceive government regulators and the public about these hazards.⁵⁵ The court held that these charges, if proven, would support the plaintiffs' assertion that the defendants had entered into an unlawful agreement.⁵⁶

The plaintiff must also show that the defendants have actually committed an "overt act" or "independent tort." Although this requirement potentially includes a wide range of wrongful conduct, the overt acts alleged against the defendants in products liability cases have usually been either fraudulent misrepresentation. Or fraudulent concealment. In cases where the overt act alleged is fraudulent misrepresentation, plaintiffs have sometimes had difficulty satisfying the

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48 363 N.W.2d 721 (Mich. Ct. App. 1985).
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Id. at 730-31.

⁵⁰ *Id.* at 725.

⁵¹ *Id.* at 731.

⁵² Id

⁵³ 175 F. Supp. 2d 593 (S.D.N.Y. 2001).

⁵⁴ *Id.* at 634.

⁵⁵ *Id.*

⁵⁶ *Id.* at 635.

⁵⁷ See Roney v. Gencorp, 431 F. Supp. 2d 622, 637 (S.D. W. Va. 2006); Hays v. Bankers Trust Co. of Cal., 46 F. Supp. 2d 490, 497 (S.D. W. Va. 1999).

⁵⁸ See, e.g., Taylor v. Airco, Inc., 503 F. Supp. 2d 432, 445-47 (D. Mass. 2007); Johnson v. Brown & Williamson Tobacco Corp., 122 F. Supp. 2d 194, 207-08 (D. Mass. 2000); Estate of White ex rel. White v. R.J. Reynolds Tobacco Co., 109 F. Supp. 2d 424, 428 (D. Md. 2000); Ryan v. Eli Lilly & Co., 514 F. Supp. 1004, 1012 (D.S.C. 1981); Brenner v. American Cyanamid Co., 732 N.Y.S.2d 799, 801 (App. Div. 2001).

⁵⁹ See, e.g., Estate of White, 109 F. Supp. 2d at 430; Chavers v. Gatke Corp., 132 Cal. Rptr. 2d 198, 203 (Ct. App. 2003); Nicolet, Inc. v. Nutt, 525 A.2d 146, 150 (Del. 1987); In re Fifth Judicial Dist. Asbestos Litig., 784 N.Y.S.2d 829, 833 (Sup. Ct. 2004); Viguers v. Philip Morris USA, Inc., 837 A.2d 534, 540 (Pa. Super. Ct. 2003).

reliance requirement. 60 Plaintiffs have also relied on fraudulent concealment to satisfy the overt act in civil conspiracy cases. Thus, a court allowed the plaintiffs in Nicolet, Inc. v. Nutt⁶¹ to show that the defendant participated in a conspiracy to conceal information about the health risks of exposure to asbestos.⁶² The court concluded that a defendant who "actively conceal[ed] a material fact" would be guilty of fraudulent concealment regardless of whether there was a duty to speak.⁶³ Consequently, the court held that the plaintiffs could recover under a theory of civil conspiracy if they could prove that the defendant was involved in a conspiracy whose participants actively concealed information about the risks of asbestos.64

Despite its burdensome requirements, civil conspiracy is a useful theory for plaintiffs because it allows them to sue multiple parties and also enables them to show that an entire industry has acted wrongfully. 65 The imposition of large punitive damage awards in such cases suggests that juries have responded with outrage when plaintiffs presented evidence of concerted action by asbestos and tobacco companies to withhold information from consumers about the health risks associated with their products.⁶⁶

C. Negligent Entrustment

The doctrine of negligent entrustment ordinarily imposes liability on the owners of dangerous chattels, such as motor vehicles or firearms, when they knowingly place these objects in the hands of incompetent persons who harm themselves or others.⁶⁷ The defendant's duty of care arises from the fact that he or she has the ability to determine who may use the chattel.⁶⁸ Consequently, the negligent entrustment doctrine is not usually applicable to negligent acts that occur

See, e.g., Taylor v. Airco, Inc., 503 F. Supp. 2d 432, 447 (D. Mass. 2007); Estate of White, 109 F. Supp. 2d at 428-30.

^{61 525} A.2d 146 (Del. 1987).

⁶² *Id.* at 150.

⁶³ *Id.* at 149.

⁶⁴ *Id.* at 150.

See Formosa Plastics Corp. USA v. Presidio Eng'rs & Contractors, Inc., 960 S.W.2d 41, 47 (Tex. 1998).

See, e.g., Garza v. Asbestos Corp., 74 Cal. Rptr. 3d 359 (Ct. App. 2008) (\$10 million punitive damage award); Boeken v. Philip Morris, Inc., 26 Cal. Rptr. 3d 638 (Ct. App. 2005) (\$3 billion award reduced to \$50 million on appeal); Owens-Corning Fiberglas Corp. v. Malone, 972 S.W.2d 35 (Tex. 1998) (\$3.7 million punitive damage award upheld); see also DAVID G. OWEN, PRODUCTS LIABILITY § 18.2 at 1184 (2d ed. 2008).

See, e.g., Ireland v. Jefferson County Sheriff's Dept., 193 F. Supp. 2d 1201, 1229 (D. Colo. 2002); Brown v. Wal-Mart Stores, Inc., 976 F. Supp. 729, 734 (W.D. Tenn. 1997); Kitchen v. K-Mart Corp., 697 So. 2d 1200, 1202 (Fla. 1997); McBerry v. Ivie, 159 S.E.2d 108, 111 (Ga. Ct. App. 1967); Leone v. Doran, 292 N.E.2d 19 (Mass. 1973); Stoelting v. Hauck, 159 A.2d 385, 389 (N.J. 1960); Mazzilli v. Selger, 99 A.2d 417, 421 (N.J. 1953); LaFaso v. LaFaso, 223 A.2d 814, 819 (N.J. 1966).

See Sampson v. W.F. Enterprises, Inc., 611 S.W.2d 333, 338 (Mo. Ct. App. 1980).

after possession or control has passed to the transferee.⁶⁹ However, some courts have expanded the doctrine of negligent entrustment and applied it to cases where a defendant who has never had legal possession or control over the chattel assisted or enabled an unsuitable person to acquire possession or control over it.⁷⁰ For example, a number of courts have applied the negligent entrustment doctrine to impose liability on parents who donated or purchased automobiles for the use of their reckless or incompetent children.⁷¹

Recently, plaintiffs have tried to expand the concept of negligent entrustment even further by seeking to impose liability on manufacturers who sell or facilitate the sale of dangerous products to minors and other unsuitable persons.⁷² So far, these efforts have largely failed.⁷³ A leading example of this is Kyte v. Philip Morris, Inc., 74 where the plaintiffs tried to apply the concept of negligent entrustment to a cigarette manufacturer. The plaintiffs in that case were teenagers who suffered various injuries, including nicotine addiction, as the result of smoking cigarettes manufactured by the defendant, Philip Morris. 75 They alleged that they purchased cigarettes at various convenience stores in the area despite the fact that state law prohibited the sale of tobacco products to minors.⁷⁶ According to the plaintiffs, Philip Morris was guilty of negligent entrustment because it introduced cigarettes into the stream of commerce, knowing that retailers routinely sold cigarettes to minors in violation of the law.⁷⁷ The lower court denied the manufacturer's motion for summary judgment.78

On appeal, the Supreme Judicial Court acknowledged that Massachusetts recognized the validity of the negligent entrustment doctrine in its traditional form, but the court refused to extend liability to a manufacturer solely because its products might be dangerous when purchased by certain individuals.⁷⁹ Furthermore, the court ruled that since the defendant did not sell cigarettes directly to minors, it could only be held liable for their injuries if there were some sort of agreement between

⁶⁹ See Estes v. Gibson, 257 S.W.2d 604, 606-07 (Ky. 1953); Sikora v. Wade, 342 A.2d 580, 582 (N.J. Super. Ct. 1975); Brown v. Harkleroad, 287 S.W.2d 92, 96 (Tenn. Ct. App. 1955).

⁰ See Vince v. Wilson, 561 A.2d 103, 106 (Vt. 1989).

⁷¹ See, e.g., McCart v. Muir, 641 P.2d 384, 388 (Kan. 1982); Kahlenberg v. Goldstein, 431 A.2d 76, 81 (Md. 1981); Vince v. Wilson, 561 A.2d 103, 106 (Vt. 1989).

⁷² See Timothy D. Lytton, Halberstam v. Daniel and the Uncertain Future of Negligent Marketing Claims Against Firearms Manufacturers, 64 BROOK. L. REV. 681, 689 (1998).

See Kyte v. Philip Morris, Inc., 556 N.E.2d 1025, 1029 (Mass. 1990); Hamilton v. Beretta U.S.A. Corp., 750 N.E.2d 1055, 1064 (N.Y. 2001); Earsing v. Nelson, 629 N.Y.S. 2d 563, 565 (App. Div. 1995).

⁷⁴ 556 N.E.2d 1025 (Mass. 1990).

⁷⁵ *Id.* at 1026.

⁷⁶ *Id*.

⁷⁷ *Id.*

⁷⁸ *Id.* at 1027.

⁷⁹ *Id.* at 1029.

it and its retailers to engage in such sales.80 In the absence of such an agreement, the fact that retailers engaged in a pattern of selling cigarettes to minors was not enough to hold the manufacturer liable under a theory of negligent entrustment.81

A New York intermediate appellate court also refused to apply the doctrine of negligent entrustment to a product manufacturer. In Earsing v. Nelson,82 a teenaged boy who was hit by a BB pellet from a gun sued the manufacturer of the gun and the retail seller, alleging, inter alia, negligent entrustment.83 The retailer had sold the BB gun to a thirteen-year-old who gave it to a seventeen-year-old friend for safekeeping. 84 The friend accidentally shot the plaintiff, not knowing that the gun was loaded at the time of the accident.85 The trial court allowed the negligent entrustment claim against the retailer to stand but dismissed the claim against the manufacturer. 86 On appeal, the higher court noted that "[t]he tort of negligent entrustment is based on the degree of knowledge the supplier of a chattel had or should have concerning the entrustee's propensity to use the chattel in an improper or dangerous fashion."87 Unlike the retail seller, the BB gun manufacturer had no direct involvement in the sale and could not have known that the purchaser of the gun in question was only thirteen years old.88 Accordingly, the court upheld the trial court's decision.89

Obviously, it would be a huge boon to injured consumers if courts were to recognize the expanded version of negligent entrustment proposed by the plaintiffs in Kyte and Earsing. This form of negligent entrustment would be especially effective against manufacturers of inherently dangerous products such as handguns and cigarettes. Although courts have so far refused to extend negligent entrustment beyond its traditional boundaries, plaintiffs will no doubt continue to push for a change in the law.

D. Negligent Marketing

The theory of negligent marketing requires sellers to market their products in a manner that will not increase the products' inherent risks to consumers or third parties. 90 There are three categories of negligent

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⁶²⁹ N.Y.S. 2d 563 (App. Div. 1995).

⁸³ *Id.* at 564.

⁸⁵ Id.

⁸⁶ Id.

Id. at 565.

Id. at 564.

Id. at 565.

See Andrew Jay McClurg, The Tortious Marketing of Handguns: Strict Liability Is Dead, Long Live Negligence, 19 SETON HALL LEGIS. J. 777, 799 (1995).

marketing claims: "(1) product designs that make the product more attractive to criminals; (2) advertising and promotional activities that target inappropriate users; and (3) product distribution practices that [encourage or] facilitate retail sales of dangerous products to vulnerable or unsuitable users."91

Merrill v. Navegar, Inc. 92 provides a good example of a negligent marketing claim based on product design. Navegar, the defendant, manufactured two types of semiautomatic assault weapons, the TEC-9 and the TEC-DC9.93 A man named Gian Ferri used several of the defendant's products to kill eight persons and wound six others before killing himself.94 Although Ferri purchased the weapons from licensed gun dealers in a nearby state, the plaintiffs argued that the manufacturer should be held civilly liable because the weapons were designed to appeal to those who were likely to use them to commit criminal acts. 95 For example, the TEC-9 and TEC-DC9 were designed to accept largecapacity fifty-round magazines and were equipped with "barrel shroud[s]," which allowed the user to spray his fire. 6 In addition, the barrels were threaded to enable the user to attach a silencer or flash suppressor to the weapon. 97 Furthermore, the weapons were fitted with a sling device that allowed them to be fired rapidly from the hip. 98 Finally, the TEC-DC9s were compact and capable of being broken down for easy concealment, and they were compatible with a "Hell Fire" trigger mechanism, which enabled them to be fired at a faster rate than a normal semiautomatic weapon.⁹⁹ A TEC-DC9 so equipped could be easily modified to fire like a fully automatic submachine gun. 100 In spite of this, the trial court granted the defendant's motion for summary judgment on the plaintiffs' negligence claims, finding that they had failed to establish that Navegar had any duty to protect them against the criminal actions of Mr. Ferri. 101

On appeal, a California intermediate appellate court focused on duty and causation.¹⁰² In its analysis of the duty issue, the court acknowledged that the manufacturer of a non-defective product is not liable for merely placing it in the market. 103 However, the court declared

See Richard C. Ausness. Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing, 53 S.C. L. REV. 907, 909 (2002).

⁸⁹ Cal. Rptr. 2d 146 (Ct. App. 1999), rev'd, 28 P.3d 116 (Cal. 2001).

⁹³ *Id.* at 152.

Id

Id. at 152, 159-60.

Id. at 154.

Id.

Id.

Id. at 157.

See id. at 152.

Id. at 161.

Id. at 163.

that the defendant could be liable if it increased the risk of an activity beyond its inherent risks. 104 The court then considered a number of factors that might give rise to a duty to refrain from affirmatively increasing the risk of marketing firearms. These factors included the foreseeability of harm to the plaintiff, the public interest in preventing future harm, and the burden that imposing a duty would have on the defendant and the community. 105

Addressing the foreseeability issue, the court in Merrill stated that criminal acts, such as those committed by Ferri, were foreseeable, in part because many of the TEC-DC9's features were designed to appeal to criminal users. 106 Turning to the public interest issue, the court observed that gunshot-related crimes imposed substantial social costs on the community and that public policy, as expressed by courts and legislatures, provided strong support for reducing these costs by imposing a duty on handgun manufacturers to market their products more responsibly.¹⁰⁷ Finally, the court declared that the imposition of a duty to exercise due care in the marketing of its products would not be unduly burdensome for the defendant and that the costs to society of imposing such a duty would be slight since this type of weapon had such low social utility. 108 Therefore, the court concluded it should impose a duty on Navegar to avoid marketing the TEC-DC9 "in such a way as to increase the inherent risks posed by such a weapon." ¹⁰⁹ Unfortunately for the plaintiffs, the California Supreme Court reversed the intermediate appellate court, holding that the negligent marketing claim was actually a product category claim prohibited by state law. 110 In addition, the court concluded that the defendant's marketing choices did not actually cause the plaintiffs' injuries.¹¹¹

Another form of negligent marketing involves sales campaigns that are directed at consumers who are likely to harm themselves or others. 112 Pelman ex rel. Pelman v. McDonald's Corp. 113 is illustrative. In Pelman, the plaintiffs alleged that McDonald's was guilty of targeting much of its fast food advertising at young children.¹¹⁴ One promotion

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Id. at 163-64.
105
    Id. at 163-65.
    Id. at 166-67.
    Id. at 169-71.
<sup>108</sup> Id. at 171-72.
    Id. at 172.
110
    Merrill v. Navegar, Inc., 28 P.3d 116, 133 (Cal. 2001).
See generally Pelman ex rel. Pelman v. McDonald's Corp. (Pelman I), 237 F. Supp. 2d
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^{512 (}S.D.N.Y. 2003); Leslie v. United States, 986 F. Supp. 900 (D.N.J. 1997), aff'd, 178 F.3d 1279 (3d Cir. 1999); McCarthy v. Sturm, Ruger & Co., Inc., 916 F. Supp. 366 (S.D.N.Y. 1996), aff'd, McCarthy v. Olin Corp., 119 F.3d 148 (2d Cir. 1997); Merrill v. Navegar, Inc., 89 Cal. Rptr. 2d 146 (Ct. App. 1999), rev'd, 28 P.3d 116 (Cal. 2001); Moning v. Alfono, 254 N.W.2d 759 (Mich. 1977).

237 F. Supp. 2d 512 (S.D.N.Y. 2003).

¹¹⁴ *Id.* at 530.

featured "a plastic beef steak figure named 'Slugger" who was accompanied by a pamphlet that assured customers that eating two servings a day from the meat group would help them "climb higher and ride [their] bike[s] farther." The second promotion featured the "Mighty Kids Meal," a beefed-up version of the "Happy Meal." The plaintiffs contended that the phrase "Mightier Kids Meal" suggested to children that they would become "mightier" or more grown up if they consumed large quantities of this product.¹¹⁷

McDonald's moved to dismiss the complaint and the trial court agreed but granted the plaintiffs leave to file an amended complaint. 118 The court refused to consider the "Slugger" claim because it had not been mentioned in the original complaint. 119 However, the court declared that if the plaintiffs cited the "Slugger" example in their amended complaint, they would have to show that the pamphlet was deceptive and that they suffered injury as a consequence of this deceptive language. 120 The court also rejected the argument that the "Mightier Kids Meal" promotion constituted improper targeting, concluding instead that it was merely an example of sales talk or "puffery." The plaintiffs subsequently filed an amended complaint that dropped the targeting claim and focused on alleged violations of New York's Consumer Protection Act. 122 The trial court also dismissed this complaint, but portions of it were reinstated on appeal. 123

Plaintiffs have also brought negligent marketing claims against manufacturers who targeted unsuitable consumers. For example, the court in Merrill also found that Navegar directed its advertising and promotional activities toward a criminal clientele.¹²⁴ According to the court, the defendant advertised its firearms in magazines that were aimed at militarists and survivalists, "such as Soldier of Fortune, SWAT, Combat Handguns, Guns, Firepower, and Heavy Metal Weapons."125 In addition, Navegar highlighted the paramilitary character of its products in promotional materials that extolled their "military non-glare finish and combat-type sights."126 The court also observed that the defendant called

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   Id.
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¹¹⁶ *Id*.

¹¹⁷ *Id*.

¹¹⁸ Id. at 543.

¹¹⁹ *Id.* at 530.

¹²⁰ *Id*.

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See Richard C. Ausness, Tell Me What You Eat, and I Will Tell You Whom to Sue: Big Problems Ahead for "Big Food"?, 39 GA. L. REV. 839, 848 (2005).

See Pelman ex rel. Pelman v. McDonald's Corp. (Pelman III), 396 F.3d 508, 512

Merrill v. Navegar, Inc., 89 Cal. Rptr. 2d 146, 156 (Ct. App. 1999), rev'd, 28 P.3d 116 (Cal. 2001).

¹²⁶ *Id.* (internal quotation marks omitted).

attention to the fact that its firearms were equipped with combat slings and threaded barrels and were resistant to fingerprints. Finally, the court noted that Navegar displayed its products at the sort of gun shows that attracted violence-prone people and provided TEC-DC9s for use in violence-oriented movies and television shows. This was enough for the court to rule that this form of conduct could constitute negligent marketing. The product is supported by the court to rule that the form of conduct could constitute negligent marketing.

A more common form of negligent marketing involves distribution practices that facilitate retail sales of a dangerous product to unsuitable consumers. One of the leading cases is *Hamilton v. Accu-Tek*, where the plaintiffs alleged that the defendants shipped large numbers of firearms to southeastern states, which had relatively weak gun control regulations, knowing that these products would subsequently be transported to northeastern states, such as New York, where they would be sold illegally in black market transactions. The lower court allowed the case to go to trial and the jury found fifteen of the defendants liable. These defendants appealed to the Second Circuit Court of Appeals, which certified the following questions to the New York Court of Appeals: (1) Does New York impose a duty of care on those who market and distribute firearms? (2) Can damages in negligent marketing cases involving multiple defendants be apportioned according to principles of market share liability?

The New York court discussed the duty issue first, declaring that gun manufacturers did not owe a general duty of care to society at large; rather, their liability for negligent marketing had to be based on a specific duty owed to the injured plaintiff. According to the court, such a duty might arise from a relationship between the defendant and the plaintiff, as in the case of the duty of care owed by a common carrier to a passenger, or it might arise from a relationship between the defendant and the third party tortfeasor, such as employer and employee,

¹²⁷ *Id.* at 156-57.

¹²⁸ *Id.* at 157.

¹²⁹ Id. at 189.

See, e.g., Ileto v. Glock, Inc., 349 F.3d 1191, 1196 (9th Cir. 2003); Hamilton v. Accu-Tek, 62 F. Supp. 2d 802, 808 (E.D.N.Y. 1999), vacated, Hamilton v. Beretta U.S.A. Corp., 264 F.3d 21 (2d. Cir. 2001); District of Columbia v. Beretta, U.S.A. Corp., 872 A.2d 633, 644-45 (D.C. 2005) (en banc); Riordan v. Internat'l Armament Corp., 477 N.E.2d 1293, 1295 (Ill. Ct. App. 1985).

⁶² F. Supp. 2d 802.

¹³² *Id.* at 832.

¹³³ *Id.* at 808.

¹³⁴ See Hamilton v. Beretta U.S.A. Corp. (Beretta I), 222 F.3d 36 (2d Cir. 2000), certifying questions to 738 N.E.2d 360 (N.Y. 2000), certifying questions answered 750 N.E.2d 1055 (N.Y. 2001).

¹³⁵ *Id*. at 46

¹³⁶ See Hamilton v. Beretta U.S.A. Corp. (Beretta II), 750 N.E.2d 1055, 1061 (N.Y. 2001).

that enabled the defendant to exercise some control over the acts of the third party.¹³⁷

In this case, the court felt that both the connection between handgun manufacturers and criminals and between manufacturers and victims of handgun violence was extremely tenuous.¹³⁸ As the court pointed out, the typical chain of distribution for firearms would include the manufacturer, wholesalers and distributors, the first retailer, subsequent legal purchasers, and ultimately the person who injured the plaintiff.¹³⁹ Because of this attenuated connection between the manufacturer and either the victim or the criminal, the court determined that it was virtually impossible for the manufacturer to exercise any control over the conduct of others in the chain of distribution.¹⁴⁰ Consequently, the court concluded that it would be inappropriate to impose a duty on handgun manufacturers to protect victims against criminal acts by third parties.¹⁴¹ Upon receipt of the New York court's answers to these certified questions, the federal Circuit Court ordered the plaintiffs' lawsuit to be dismissed.¹⁴²

In sum, by focusing on the defendant's marketing practices, negligent marketing claims provide a way for plaintiffs to avoid troublesome issues with design defects and inherently dangerous products. In particular, negligent marketing can be used against manufacturers who target their products at underage or unsuitable consumers or who create distribution structures that facilitate illegal sales of their products at the retail level.

E. Negligence Per Se

According to the Restatement, "[a]n actor is negligent if, without excuse, the actor violates a statute that is designed to protect against the type of accident the actor's conduct causes, and if the accident victim is within the class of persons the statute is designed to protect." In effect, a court relies upon the statute to define the applicable standard of care in a negligence case. Thus, if the plaintiff can prove that the defendant violated the statute, the court will instruct the jury that the defendant has

¹³⁷ *Id*.

¹³⁸ *Id.* at 1061-62.

¹³⁹ *Id.* at 1062.

¹⁴⁰ *Id*.

 $^{^{141}}$ Id. The court also concluded that it was not proper under New York law to apply the principle of market share liability to negligent marketing cases such as this. Id. at 1066-68.

Hamilton v. Beretta U.S.A. Corp. (*Beretta III*), 264 F.3d 21, 32 (2d Cir. 2001).

RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM § 14 (Proposed Final Draft No. 1, 2005).

See Andrew E. Costa, Negligence Per Se Theories in Pharmaceutical & Medical

Device Litigation, 57 ME. L. REV. 51, 54 (2005); Christopher Scott D'Angelo, Effect of Compliance or Noncompliance with Applicable Governmental Product Safety Regulations on a Determination of Product Defect, 36 S. Tex. L. Rev. 453, 454, 456, 458 (1995).

failed to exercise the requisite standard of care and the defendant will be held liable if the plaintiff can prove causation and injury. Relying on the concept of negligence per se, plaintiffs have argued that product manufacturers who violate FDA regulations should be held liable in tort for any injuries that are proximately caused by such products, regardless of whether the products are defective or not. In addition, plaintiffs have urged courts to treat violations of consumer protection acts as negligence per se.

1. Violation of FDA Regulations

In Talley v. Danek Medical, Inc., 146 the plaintiff alleged that the defendant obtained FDA approval for its product as a Class II medical device and then promoted it as a pedicle screw fixation device.¹⁴⁷ If the manufacturer had sought formal FDA approval of the device for use in pedicle screw fixation procedures, it would have had to secure premarket approval for the product as a Class III device. 148 By seeking FDA approval of its device for use on long bones and then promoting its offlabel use for back surgery, the defendant avoided having to satisfy the FDA's requirements for premarket approval as a Class III device. The plaintiff in Talley suffered injuries when the defendant's device was used in her back surgeries and sued Danek, contending that by deliberately marketing its product for an unapproved use, the defendant had violated the FDCA and therefore was negligent as a matter of law. 149 The lower court granted the defendant's motion for summary judgment and the plaintiff appealed. 150 On appeal, the court declared that the requirement that medical devices receive FDA approval before being marketed did not embody a substantive standard of care. 151 Furthermore, the court determined that the plaintiff had failed to show that the defendant's failure to obtain proper FDA approval had proximately caused her injuries. 152 Consequently, the court upheld the dismissal of the plaintiff's negligence per se claim. 153

¹⁴⁵ See In re Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d 781, 790 (3d Cir. 1999).

¹⁷⁹ F.3d 154 (4th Cir. 1999).

¹⁴⁷ *Id.* at 160.

¹⁴⁸ *Id*.

¹⁴⁹ *Id*.

¹⁵⁰ See Talley v. Danek Med., Inc., 7 F. Supp. 2d 725, 727 (E.D. Va. 1998), aff'd, 179 F.3d 154 (4th Cir. 1999).

¹⁵¹ Talley, 179 F.3d at 161.

¹⁵² *Id*.

¹⁵³ *Id*.

2. Violation of State Consumer Protection Law as Negligence Per Se

Many states have enacted unfair trade and consumer protection statutes that are designed to protect consumers against false advertising and other unethical business practices. Although these statutes are concerned with fraud against consumers, they are often less restrictive than common law fraudulent misrepresentation.¹⁵⁴ Not surprisingly, consumers have often attempted to recover for personal injuries against defendants on the basis of their alleged violations of these statutes. In some cases, however, these lawsuits have failed because the statutes in question were only intended to protect against economic losses. 155 For example, in Gorran v. Atkins Nutritionals, Inc., 156 the plaintiff sued a promoter of the Atkins Diet, claiming that the low-carbohydrate diet caused heart problems that required angioplasty.¹⁵⁷ The plaintiff contended that the defendant violated the Florida Deceptive and Unfair Trade Practices Act (FDUTPA), 158 which prohibited "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce "159 According to the plaintiff, the defendant violated FDUTPA by:

(1) promoting the Diet and products as safe for all customers "when they well knew that, for at least a substantial minority of their customers, the [D]iet and their products carried potential serious risks," (2) failing to give adequate warnings about the adverse health consequences of the Diet, and (3) claiming that the Diet was "fool proof" and a guaranteed success "when they well knew that there would be people for whom the [D]iet would not be safe." 160

Notwithstanding these allegations, the court ruled that the plaintiff's FDUTPA claim must fail because the statute only applied to economic losses.¹⁶¹

Plaintiffs who have based their claims on violations of consumer protection statutes have encountered other problems as well. For example, in *LaBelle ex rel. LaBelle v. Philip Morris, Inc.*, ¹⁶² a federal district court granted a defendant's motion for summary judgment on a claim based on an alleged violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law because the plaintiff was unable

See Joseph M. Price & Rachel F. Bond, Litigation as a Tool in Food Advertising: Consumer Protection Statutes, 39 Loy. L.A. L. REV. 277, 279-80 (2006).

See, e.g., Gorran v. Atkins Nutritionals, Inc., 464 F. Supp. 2d 315, 329 (S.D.N.Y. 2006); Blowers v. Eli Lilly & Co., 100 F. Supp. 2d 1265, 1270 (D. Haw. 2000).

⁴⁶⁴ F. Supp. 2d 315 (S.D.N.Y. 2006), aff'd, 279 Fed. Appx. 40 (2d Cir. 2008).

¹⁵⁷ *Id.* at 321-22.

¹⁵⁸ *Id.* at 322.

¹⁵⁹ FLA. STAT. § 501.204(1) (2006).

¹⁶⁰ Gorran, 464 F. Supp. 2d at 328 (quoting complaint ¶ 78).

Id. at 329.

¹⁶² 243 F. Supp. 2d 508 (D.S.C. 2001).

to prove that the deceased smoker relied on any of the defendant's false statements about smoking and health. Similarly, a claim based on an alleged violation of the Virginia Consumer Protection Act failed in *McCauley v. Purdue Pharma L.P.* Health because the plaintiff was unable to prove causation. In that case, the plaintiffs alleged that the defendant's sales representatives falsely claimed that its product, OxyContin, was "safer, less addictive, and less prone to abuse than other oxycodone-based pain medications. However, it appeared that the plaintiffs were already addicted to pain medication long before their physicians first prescribed OxyContin. Furthermore, the plaintiffs continued to take other opioid pain medications at the same time that they were using OxyContin. This caused the court to conclude that the plaintiffs had failed to prove that OxyContin caused their injuries because there was "inadequate evidence to differentiate between the plaintiffs' use of OxyContin and the other medications taken by them."

However, other plaintiffs have achieved some success against product sellers based on alleged violations of state consumer protection statutes. For example, in the *Pelman* case, ¹⁷⁰ discussed earlier, ¹⁷¹ the parents of two overweight children sued McDonald's Corporation and two fast food restaurants, alleging, inter alia, that the defendants had violated sections 349 and 350 of the New York Consumer Protection From Deceptive Acts and Practices Act ("Consumer Protection Act"). 172 Section 349 of the Consumer Protection Act prohibited "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state . . . "173 Section 350 banned "[f]alse advertising in the conduct of any business."¹⁷⁴ The plaintiffs did not cite any particular practices or advertisements in their complaint that might have violated the Consumer Protection Act, but they later identified statements in McDonald's advertising campaigns that they claimed were deceptive. 175 One campaign contained the slogans "McChicken Everyday" and "Big N' Tasty Everyday," which suggested that

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<sup>163</sup> Id. at 525-26.
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¹⁶⁴ 331 F. Supp. 2d 449 (W.D. Va. 2004).

⁶⁵ *Id.* at 462.

⁶⁶ *Id.* at 451.

¹⁶⁷ *Id.* at 452-59.

¹⁰⁸ Id.

¹⁶⁹ Id. at 462; see also Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 551-52 (E.D. Pa. 2006), aff'd, 521 F.3d 253 (3d Cir. 2008) (holding that false advertising claim against drug company under N.Y. Consumer Protection Act was preempted by federal law), vacated, No. 08-437, 2009 WL 578682 (U.S. Mar. 9. 2009).

¹⁷⁰ Pelman ex rel. Pelman v. McDonald's Corp. (Pelman I), 237 F. Supp. 2d 512 (S.D.N.Y. 2003).

See supra notes 113-123 and accompanying text.

¹⁷² *Pelman I*, 237 F. Supp. 2d at 519, 524.

¹⁷³ N.Y. GEN. BUS. LAW § 349 (McKinney 2004).

¹⁷⁴ *Id.* § 350.

¹⁷⁵ *Pelman I*, 237 F. Supp. 2d at 527.

customers could safely consume McDonald's fast food products on an everyday basis. 176 In another campaign, the statement, "McDonald's can be part of any balanced diet and lifestyle," appeared on the defendant's website. 177 In addition, the plaintiffs argued that the defendant's failure to post nutritional information in its restaurants or on its product packaging was a deceptive practice within the meaning of the Act. 178

The trial court rejected all of these arguments. First, it declared that the exhortation to eat McDonald's products "everyday" made no specific health claims and was nothing more than "mere puffery." The court also determined that the statement on the defendant's website, which suggested that *moderate* consumption of McDonald's products could be part of a healthy diet and lifestyle, was not deceptive. 180 Finally, the court concluded that the Consumer Protection Act did not require McDonald's to provide nutritional information in its restaurants as long as this information was otherwise available online. 181

The plaintiffs subsequently filed an amended complaint that also alleged various violations of the Consumer Protection Act. 182 Specifically, the amended complaint stated that McDonald's advertising misled the plaintiffs by assuring them "that its fast food products were nutritious" and could be safely consumed on a daily basis. 183 The complaint also claimed that McDonald's failed to disclose the fact that its processing methods and use of artificial ingredients resulted in products that were less healthy than those depicted in its advertising. Finally, the complaint alleged that the defendant falsely stated that it provided nutritional information about its products in all of its restaurants. 184 The court agreed that the plaintiffs had properly pleaded that they had relied on McDonald's claims about the nutritional content and healthiness of its food¹⁸⁵ but dismissed the complaint again because the plaintiffs failed to show that consumption of McDonald's products was a significant cause of their health problems. 186

On appeal, the Second Circuit Court of Appeals determined that proof of actual reliance was not required to bring a deceptive practices

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    Id.
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¹⁷⁷ Id.

¹⁷⁸ Id. at 529.

Id. at 528.

Id. at 527-28.

See Pelman ex rel. Pelman v. McDonald's Corp. (Pelman II), No. 02 Civ. 7821 (RWS), 2003 WL 22052778, at *2 (S.D.N.Y. Sept. 3, 2003), vacated in part, 396 F.3d 508 (2d Cir. 2005).

¹⁸⁴ *Id*.

¹⁸⁵ *Id.* at *9.

¹⁸⁶ *Id.* at *11-12.

claim under section 349 of the Consumer Protection Act. ¹⁸⁷ However, the appellate court reversed the trial court's dismissal of the complaint, holding that the plaintiffs did not have to provide any specific information in their complaint alleging that the consumption of McDonald's products caused their obesity and resulting health problems. ¹⁸⁸ According to the court, information on the causation issue could best be obtained at a later stage in the proceedings through the discovery process. ¹⁸⁹

Although negligence per se may not be a viable theory when it is based upon alleged violations of FDA regulations, plaintiffs have successfully invoked it in connection with violations of state consumer protection laws. Negligence per se is often more advantageous for plaintiffs than fraudulent misrepresentation or fraudulent concealment because consumer protection statutes tend to be broader in scope than common law fraud doctrines.

III. ADVANTAGES OF FAULT-BASED LIABILITY THEORIES

At first blush, there would seem to be many disadvantages to using fault-based liability theories instead of traditional strict liability in tort. Thus, in theory, it would seem to be much easier to prove that a product is defective than to prove that the manufacturer or seller failed to exercise due care. As a matter of fact, one of the early arguments for strict liability was that it would be more consumer friendly than negligence. 190 To be sure, this was probably true in manufacturing defect cases, where strict liability relieves the plaintiff of the duty of proving by expert testimony that the producer's manufacturing and quality control processes were negligent. However, many plaintiffs now believe that the advantages of fault-based liability theories, at least in certain cases, outweigh their disadvantages. These advantages include avoiding the Restatement's requirement that a product be defective, avoiding federal preemption of certain types of common law tort claims, and enabling plaintiffs to focus attention on the conduct of the defendant instead of the condition of the product.

¹⁸⁷ See Pelman ex rel. Pelman v. McDonald's Corp. (Pelman III), 396 F.3d 508, 511 (2d Cir. 2005).

¹⁸⁸ Id. at 511-12.

¹⁸⁹ *Id.* at 512.

¹⁹⁰ See Thomas A. Cowan, Some Policy Bases of Products Liability, 17 STAN. L. REV. 1077, 1086-87 (1965); William L. Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 YALE L.J. 1099, 1122-23 (1960); William L. Prosser, The Fall of the Citadel (Strict Liability to the Consumer), 50 MINN. L. REV. 791, 799-800 (1966).

A. Avoiding the Defect Requirement

Defectiveness is a core concept in American products liability law. 191 However, the defectiveness requirement may cause difficulties for some plaintiffs. First of all, it is virtually impossible to prove that inherently dangerous products are defective under traditional tests for defectiveness. In addition, juries have trouble understanding the risk-utility test in design defect cases. Furthermore, the *Products Liability Restatement*'s alternative reasonable design requirement may create difficulties for plaintiffs in design defect cases. The existence of obvious hazards is a common pitfall for plaintiffs in failure to warn cases. Finally, in most states, the standard for defectiveness is narrower for prescription drugs and medical devices than for other products.

1. Inherently Dangerous Products

Inherently dangerous products are products whose danger cannot be eliminated without impairing their intended function. Neither section 402A nor the *Products Liability Restatement* treat inherently dangerous products as defective, at least when their risks are commonly known, and most courts have followed their lead. Consequently, consumers who cannot satisfy the defect requirement must rely on other liability theories. Some of these theories have been relatively successful, particularly when invoked against manufacturers of cigarettes and handguns. Fraud and civil conspiracy theories have been especially effective against tobacco companies. For example, in *Estate of Schwarz v. Philip Morris, Inc.*, an appellate court upheld a jury verdict in favor of the personal representative of a deceased smoker who alleged that the defendant cigarette manufacturer had made false statements about the health risks of smoking. Plaintiffs have also used negligent marketing in order to avoid having to prove defectiveness. In *Hamilton v. Accu-*

 $^{^{191}}$ See OWEN, supra note 66, § 6.1 at 342.

See Joseph A. Page, Generic Product Risks: The Case Against Comment k and for Strict Tort Liability, 58 N.Y.U. L. REV. 853, 857 (1983).
 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. c (1998); RESTATEMENT

See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. c (1998); RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965).

See, e.g., Jeter ex rel. Estate of Smith v. Brown & Williamson Tobacco Corp., 294 F.

See, e.g., Jeter ex rel. Estate of Smith v. Brown & Williamson Tobacco Corp., 294 F. Supp. 2d 681, 686 (W.D. Pa. 2003), aff'd on other grounds, 113 Fed. Appx. 465 (3d Cir. 2004) (cigarettes); Pelman ex rel. Pelman v. McDonald's Corp. (Pelman I), 237 F. Supp. 2d 512, 517-18 (S.D.N.Y. 2003) (fast food); LaBelle v. Philip Morris, Inc., 243 F. Supp. 2d 508, 517 (D.S.C. 2001) (cigarettes); Bruner v. Anheuser-Busch, Inc., 153 F. Supp. 2d 1358, 1361 (S.D. Fla. 2001), aff'd, 31 Fed. Appx. 932 (11th Cir. 2002) (alcoholic beverages); Little v. Brown & Williamson Tobacco Corp., 243 F. Supp. 2d 480, 491-92 (D.S.C. 2001) (cigarettes); Estate of White ex rel. White v. R.J. Reynolds Tobacco Co., 109 F. Supp. 2d 424, 434 (D. Md. 2000) (cigarettes); Miller v. Brown & Williamson Tobacco Corp., 679 F. Supp. 485, 488 (E.D. Pa. 1988), aff'd, 856 F.2d 184 (3d Cir. 1988); Downs v. R.T.S. Security, Inc., 670 So. 2d 434, 439 (La. Ct. App. 1996) (firearms); Lane v. R.J. Reynolds Tobacco Co., 853 So. 2d 1144, 1149 (Miss. 2003) (cigarettes); Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp., 596 A.2d 845, 849 (Pa. Super. Ct. 1991) (alcoholic beverages).

Tek¹⁹⁶ and Pelman ex rel. Pelman v. McDonald's Corp., ¹⁹⁷ for example, plaintiffs focused on the marketing practices of handgun and fast food sellers instead of basing their claims solely on the alleged defectiveness of their respective products.

2. The Risk-Utility Test and the Reasonable Alternative Design Requirement

The prevailing test for design defect is known as the risk-utility test. 198 Under this approach, a plaintiff must show that the utility of the product with a feasible safer alternative design (that is, with an additional safety feature) outweighs the utility of the product as actually designed. 199 The Restatement (Third) has adopted this version of the risk-utility test, declaring that a design is deemed to be defective if the foreseeable risks of the product, as designed, "could have been reduced or avoided by . . . a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe."200 Unfortunately, the risk-utility test is frequently confusing and difficult to apply.²⁰¹ To make matters worse, jurors are often hostile to the concept of balancing risks and benefits.²⁰² Consequently, plaintiffs sometimes prefer to utilize a fault-based theory that jurors can more easily understand and accept.

The reasonable alternative design requirement also presents difficulties for plaintiffs in design defect cases. According to the Products Liability Restatement formulation, a design is considered defective if the foreseeable risks of the product, as designed, "could have been reduced or avoided by . . . a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe."203 The Restatement's requirement of a "reasonable alternative design" is highly controversial and is not recognized in every state. 204

⁶² F. Supp. 2d 802, 808 (E.D.N.Y. 1999), vacated, Hamilton v. Beretta U.S.A. Corp., 264 F.3d 21 (2d. Cir. 2001). For a discussion of Accu-Tek, see supra notes 131-142 and accompanying text.

²³⁷ F. Supp. 2d 512 (S.D.N.Y. 2003) (discussing the complaint allegations). For a discussion of Pelman, see supra notes 113-123, notes 170-188, and accompanying text.

See OWEN, supra note 191, § 8.4 at 508.

¹⁹⁹ See Thibault v. Sears, Roebuck & Co., 395 A.2d 843, 846 (N.H. 1978); Wilson v. Piper Aircraft Corp., 577 P.2d 1322, 1327 (Or. 1978); see also David G. Owen, Toward a Proper Test for Design Defectiveness: "Micro-Balancing" Costs and Benefits, 75 Tex. L. Rev. 1661, 1690 (1997).

²⁰⁰ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (b) (1998).

See David G. Owen, Risk-Utility Balancing in Design Defect Cases, 30 U. MICH. J.L. REFORM 239, 243 (1997).

²⁰² See W. Kip Viscusi, Corporate Risk Analysis: A Reckless Act?, 52 STAN. L. REV. 547, 563 (2000).

203 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (b) (1998).

²⁰⁴ Compare Wankier v. Crown Equip. Corp., 353 F.3d 862, 867 (10th Cir. 2003) (requiring a reasonable alternative design); Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 83-84 (S.D.N.Y. 2001) (same); Hollister v. Dayton Hudson Corp., 5 F. Supp. 2d 530, 533 (E.D. Mich. 1998) (same), aff'd in part, rev'd in part, 201 F.3d 731 (6th Cir. 2000); Thornton v.

However, when a court does require proof of an alternative design, this can seriously compromise a plaintiff's case.²⁰⁵ For this reason, plaintiffs may find it advantageous to look for other liability theories in design defect cases in order to avoid the alternative design requirement.

The *Merrill* case, ²⁰⁶ discussed earlier, ²⁰⁷ provides a good example of this strategy. In *Merrill*, the plaintiffs objected to various aspects of an assault weapon's design. ²⁰⁸ If the plaintiffs had sued under a theory of defective design, they would have had to suggest alternatives to each of the offending design features. The resulting weapon would have borne no resemblance to the product that the defendant actually produced, and it is unlikely that a court would have regarded the plaintiffs' version of the defendant's product as a reasonable alternative design. The plaintiffs apparently tried to sidestep this problem by formulating their claim as a negligent marketing claim instead of a design defect claim. ²⁰⁹ Interestingly, on appeal, the California Supreme Court saw through the plaintiffs' ruse and declared that their negligent marketing case was really a design defect case in disguise. ²¹⁰

3. Obvious Hazards and the Duty to Warn

Many courts have concluded that product sellers have no duty to warn consumers about "open and obvious" hazards.²¹¹ To avoid the effect of this rule, plaintiffs have eschewed traditional failure to warn claims and relied instead on fraudulent misrepresentation or negligent marketing theories. In a fraudulent misrepresentation case, the issue is whether the defendant lulled consumers into a false sense of security by falsely assuring them that a known risk was not as great as they might otherwise expect. This was the issue in most of the fraudulent misrepresentation cases brought against the tobacco industry. In these cases, the focus was not on whether the health risks of smoking were open and obvious, but

Caterpillar, Inc., 951 F. Supp. 575, 579 (D.S.C. 1997) (same); Bagley v. Mazda Motor Corp., 864 So. 2d 301, 312 (Ala. 2003) (same); Green v. General Motors Corp., 709 A.2d 205, 210 (N.J. Super. Ct. App. Div. 1998) (same); Buonanno v. Colmar Belting Co., 733 A.2d 712, 717-18 (R.I. 1999) (same), with Potter v. Chicago Pneumatic Tool Co., 694 A.2d 1319, 1334 (Conn. 1997) (rejecting a reasonable alternative design requirement); Delaney v. Deere & Co., 999 P.2d 930, 944 (Kan. 2000) (same); Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178, 1183 (N.H. 2001) (same); McCathern v. Toyota Motor Corp., 23 P.3d 320, 331 (Or. 2001) (same).

²⁰⁵ See, e.g., Whitted v. General Motors Corp., 58 F.3d 1200, 1206 (7th Cir. 1995); Williams v. Bennett, 921 So. 2d 1269, 1274-77 (Miss. 2006); Smith v. Keller Ladder Co., 645 A.2d 1269, 1271-72 (N.J. Super. Ct., App. Div. 1994).

- ²⁰⁶ 89 Cal. Rptr. 2d 146 (Ct. App. 1999), rev'd, 28 P.3d 116 (Cal. 2001).
- See supra notes 92-111 and accompanying text.
- ²⁰⁸ *Id.* at 154-57.
- ²⁰⁹ *Id.* at 162.
- ²¹⁰ See Merrill v. Navegar, Inc., 28 P.3d 116, 126 (Cal. 2001).
- ²¹¹ See Hiner v. Deere & Co., 340 F.3d 1190, 1194 (10th Cir. 2003); Ahrens v. Ford Motor Co., 340 F.3d 1142, 1146 (10th Cir. 2003); Scheibe v. Fort James Corp., 276 F. Supp. 2d 246, 252 (D. Del. 2003); Mohr v. St. Paul Fire & Marine Ins. Co., 674 N.W.2d 576, 585 (Wis. Ct. App. 2003).

whether the plaintiff reasonably relied on the tobacco companies' assurances that smoking did not cause lung cancer or other diseases.²¹² Having vigorously denied that smoking was harmful for almost half a century, it was difficult for cigarette companies to argue that the hazards of smoking were matters of common knowledge or that smokers would not believe the industry's health claims.²¹³

Another response to the obvious hazard problem is to rely on negligent marketing instead of failure to warn. Negligent marketing might be especially effective when the defendant has targeted children or some other vulnerable group whose knowledge or judgment may not be as good as that of the general population.²¹⁴ The tobacco industry's use of cartoon characters like "Joe Camel" and other promotional efforts to encourage underage consumers to smoke is a good example of this type of negligent marketing.²¹⁵ There is also evidence that fast food purveyors have targeted children and teenagers, knowing that they are "notoriously capricious in their reasoning skills" and "much more likely to be motivated by mere emotion or peer pressure than are adults."²¹⁶ In fact, this very issue arose in the *Pelman* case. ²¹⁷ The court in *Pelman* rejected the plaintiffs' failure to warn claim, concluding that the health risks of consuming too much fast food were open and obvious to the general population.²¹⁸ However, the plaintiffs in Pelman also alleged that McDonald's advertising was targeted at small children.²¹⁹ The court also dismissed this claim, but only because the plaintiffs failed to provide any examples of this type of targeting in their complaint.²²⁰ Furthermore, the court suggested that a targeting claim might be successful if the plaintiffs referred to specific statements by the defendant and alleged that the plaintiffs relied upon them.²²¹

²¹² See Richard L. Cupp, Jr., A Morality Play's Third Act: Revisiting Addiction, Fraud and Consumer Choice in "Third Wave" Tobacco Litigation, 46 U. KAN. L. REV. 465, 494 (1998).

²¹³ Id. at 492. But see Horton v. American Tobacco Co., 667 So. 2d 1289, 1293 (Miss. 1995).

See Ausness, supra note 91, at 913.

See Jon D. Hanson & Douglas A. Kysar, Taking Behaviorism Seriously: Some Evidence of Market Manipulation, 112 Harv. L. Rev. 1420, 1481 (1999); Frank J. Vandall, Reallocating the Costs of Smoking: The Application of Absolute Liability to Cigarette Manufacturers, 52 Ohio St. L.J. 405, 419-20 (1991); Erica Sweeker, Note, Joe Camel: Will "Old Joe" Survive?, 36 WM. & MARY L. Rev. 1519, 1519 (1995).

See John Alan Cohan, Obesity, Public Policy, and Tort Claims Against Fast-Food Companies, 12 WIDENER L.J. 103, 112 (2003).

See supra notes 113-123, 170-189.

²¹⁸ See Pelman ex rel. Pelman v. McDonald's Corp. (*Pelman I*), 237 F. Supp. 2d 512, 541 (S.D.N.Y. 2003).

²¹⁹ *Id.* at 530.

²²⁰ *Id.*

²²¹ *Id.*

4. Special Rules for Pharmaceutical Products

Pharmaceutical products, such as prescription drugs and medical devices, received special treatment in section 402A.²²² For example, the drafters of section 402A created an exception to strict liability in comment k for "[u]navoidably unsafe" but useful products.²²³ Specifically, comment k provided that the manufacturer of "a product that is incapable of being made safe for its intended use" would not be subject to strict liability as long as the utility of the product "outweigh[ed] its apparent risks and an adequate warning [was] given."²²⁴ According to comment k, an unavoidably unsafe product was neither defective nor unreasonably dangerous even though it caused harm to consumers.²²⁵ Almost all courts agreed that comment k exempted prescription drugs and medical devices from strict liability, provided that they were properly prepared or manufactured and accompanied by adequate warnings.²²⁶

The *Products Liability Restatement* also creates a separate, and more restrictive, liability standard for pharmaceutical products.²²⁷ According to the Restatement, a prescription drug or medical device may be "not reasonably safe due to defective design if the foreseeable risks of harm . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers . . . would not prescribe the drug or medical device for *any* class of patients."²²⁸ This standard protects drug manufacturers against design defect liability, no matter how dangerous their products may be, as long as they have therapeutic value for at least one class of users.²²⁹

To avoid this limitation on manufacturer liability for prescription drugs and medical devices, plaintiffs have begun to abandon strict products liability in favor of fraudulent misrepresentation.²³⁰ While many

²²⁴ See Richard C. Ausness, Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?, 78 KY. L.J. 705, 712 (1989-1990).

See Marcia Anne Mobilia, Allergic Reactions to Prescription Drugs: A Proposal for Compensation, 48 ALB. L. REV. 343, 344 (1984).

²²⁶ See Transue v. Aesthetech Corp., 341 F.3d 911, 914 (9th Cir. 2003); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 744 (W.D. Pa. 2004); Brown v. Superior Court, 751 P.2d 470, 477 (Cal. 1988). But see Allison v. Merck & Co., 878 P.2d 948, 954 (Nev. 1994); Collins v. Eli Lilly Co., 342 N.W.2d 37, 52 (Wis. 1984).

²²⁷ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1998); see also James A. Henderson, Jr. & Aaron D. Twerski, Essay, Drug Designs Are Different, 111 YALE L.J. 151, 178 (2001).

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1998) (emphasis added).

²²⁹ See George W. Conk, Essay, Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?, 109 YALE L.J. 1087, 1102 (2000).

²³⁰ See, e.g., McCauley v. Purdue Pharma L.P., 331 F. Supp. 2d 449, 451 (W.D. Va. 2004) (OxyContin); Berres v. Artifex, Ltd., 21 F. Supp. 2d 909, 916-17 (E.D. Wis. 1998) (bone screw fixation device); Staudt v. Artifex, Ltd., 16 F. Supp. 2d 1023, 1030-31 (E.D. Wis. 1998) (bone

²²² See Restatement (Second) of Torts § 402A cmt. k (1965).

²²³ *Id*.

of these claims have failed because the injured plaintiff could not prove causation or reliance, 231 others have been more successful. 232 For example, in Freeman v. Hoffman-LaRoche, Inc., 233 the Nebraska Supreme Court upheld a fraudulent misrepresentation claim against the manufacturer of Accutane, an acne medication.²³⁴ The plaintiff in Freeman alleged that the defendant manufacturer falsely represented that Accutane was safe to use as directed when in fact it knew of the drug's danger and "misled the medical community with incomplete and inaccurate information about the safety of the drug."235 The plaintiff also alleged that she had relied on the defendant's assurances of safety. 236 The court concluded that the plaintiff had stated a claim for fraudulent misrepresentation and reversed the lower court's dismissal of her suit.²³⁷

В. Avoiding Federal Preemption of Tort Claims

The preemption doctrine, which is rooted in the Supremacy Clause of the United States Constitution, gives Congress the power to override state law.²³⁸ Courts and commentators traditionally divide preemption into two basic categories, express and implied, and further divide implied preemption into field and conflict preemption.²³⁹ Express preemption occurs when a federal statute or administrative regulation specifically excludes state regulation in a particular area.²⁴⁰ Congress may also enact a regulatory scheme that is so comprehensive that it completely "occupies the field" and excludes any form of state

screw fixation device); Khan v. Shiley, Inc., 266 Cal. Rptr. 106, 112 (Ct. App. 1990) (heart valve); Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728, 730 (Fla. Dist. Ct. App. 1991) (Cu-7 IUD); Freeman v. Hoffman-LaRoche, Inc., 618 N.W.2d 827, 844-45 (Neb. 2000) (Accutane). Plaintiffs have tried to base their claims against drug companies on negligent marketing practices. See, e.g., Yurcic v. Purdue Pharma, L.P., 343 F. Supp. 2d 386, 388 (M.D. Pa. 2004); Little v. Purdue Pharma, L.P., 227 F. Supp. 2d 838, 843 (S.D. Ohio 2002); Howland v. Purdue Pharma L.P., 821 N.E.2d 141, 143-44 (Ohio 2004).

See, e.g., McCauley v. Purdue Pharma L.P., 331 F. Supp. 2d 449, 462 (W.D. Va. 2004) (no causation); Berres v. Artifex, Ltd., 21 F. Supp. 2d 909, 917 (E.D. Wis. 1998) (no reliance); Staudt v. Artifex, Ltd., 16 F. Supp. 2d 1023, 1031 (E.D. Wis. 1998) (no reliance).

See, e.g., Khan v. Shiley, Inc., 266 Cal. Rptr. 106, 112 (Ct. App. 1990); Adams v.

G.D. Searle & Co., Inc., 576 So. 2d 728, 730 (Fla. Dist. Ct. App. 1991); Freeman v. Hoffman-LaRoche, Inc., 618 N.W.2d 827, 844-45 (Neb. 2000).

233 618 N.W.2d 827 (Neb. 2000).

²³⁴ *Id.* at 845.

²³⁵ *Id.* at 844.

²³⁶ *Id.*

²³⁷ *Id.* at 845-46.

²³⁸ See Mary J. Davis, On Preemption, Congressional Intent, and Conflict of Laws, 66 U.

PITT. L. REV. 181, 182-83 (2004).

239 See M. Stuart Madden, Federal Preemption of Inconsistent State Safety Obligations, 21 PACE L. REV. 103, 105-10 (2000).

²⁴⁰ See, e.g., Morales v. Trans World Airlines, Inc., 504 U.S. 374, 383 (1992); Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 106-08 (1983); Ry. Employees' Dep't v. Hanson, 351 U.S. 225, 232 (1956); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 236 (1947).

regulation.²⁴¹ Conflict preemption occurs when it is impossible to comply with both state and federal law²⁴² or where state law stands as an obstacle to the achievement of federal regulatory objectives.²⁴³

Federal statutes and administrative regulations not only preempt state statutes and local ordinances, they can also preempt state common law tort doctrines.²⁴⁴ In recent years, federal preemption has prevented injured smokers from recovering against cigarette companies who failed to warn them about the health risks of smoking. The leading case on this issue is Cipollone v. Liggett Group, Inc. 245 In Cipollone, the United States Supreme Court, in a plurality opinion, concluded that the 1969 Federal Cigarette Labeling and Advertising Act expressly preempted the plaintiff's failure-to-warn claims²⁴⁶ but did not necessarily preempt based on breach of express warranty, fraudulent claims misrepresentation, or conspiracy. 247 This, in turn, encouraged plaintiffs to transform their failure to warn claims into fraudulent misrepresentation or conspiracy claims. Although a few courts have concluded that the federal cigarette labeling statute preempted fraudulent misrepresentation claims, ²⁴⁸ most determined that such claims were not preempted. ²⁴⁹

Good v. Altria Group, Inc. 250 is a good example of the majority's reasoning. In that case, a group of smokers sued various cigarette manufacturers, arguing that the manufacturers' claims that their products were "light" and had "[l]owered [t]ar and [n]icotine" amounted to

See, e.g., Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 300 (1988); Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 700 (1984).

See McDermott v. Wisconsin, 228 U.S. 115, 133-34 (1913).

²⁴³ See Int'l Paper Co. v. Ouellette, 479 U.S. 481, 491 (1987); Mich. Canners & Freezers Ass'n v. Agric. Mktg. & Bargaining Bd., 467 U.S. 461, 478 (1984).

See generally Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008) (pacemaker); Geier v. American Honda Motor Co., 529 U.S. 861 (2000) (airbags); Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) (cigarettes).

²⁴⁵ 505 U.S. 504 (1992).

²⁴⁶ *Id.* at 524.

²⁴⁷ *Id.* at 525-30.

²⁴⁸ See Brown v. Brown & Williamson Tobacco Corp., 479 F.3d 383, 393 (5th Cir. 2007), abrogated by Altria Group, Inc. v. Good, 129 S. Ct. 538 (2008); Clinton v. Brown & Williamson Holdings, Inc., 498 F. Supp. 2d 639, 651-52 (S.D.N.Y. 2007); see also In re Tobacco Cases II, 163 P.3d 106, 116-17 (Cal. 2007) (preempting statutory claim based on cigarette's alleged targeting of underage consumers).

See Good v. Altria Group, Inc., 501 F.3d 29, 39 (1st Cir. 2007), aff'd, Altria Group,

Inc. v. Good, 129 S. Ct. 538 (2008); Spain v. Brown & Williamson Tobacco Corp., 363 F.3d 1183, 1202 (11th Cir. 2004); Mulford v. Altria Group, Inc., 506 F. Supp. 2d 733, 750-51 (D.N.M. 2007); Johnson v. Brown & Williamson Tobacco Corp., 122 F. Supp. 2d 194, 203 (D. Mass. 2000); Izzarelli v. R.J. Reynolds Tobacco Co., 117 F. Supp. 2d 167, 175 (D. Conn. 2000); Whiteley v. Philip Morris, Inc., 11 Cal. Rptr. 3d 807, 842 (Ct. App. 2004); Price v. Philip Morris, Inc., 848 N.E.2d 1, 33 (Ill. 2005); Dahl v. R.J. Reynolds Tobacco Co., 742 N.W.2d 186, 195 (Minn. Ct. App. 2007); Small v. Lorillard Tobacco Co., 679 N.Y.S.2d 593, 604 (App. Div. 1998), aff'd, 720 N.E.2d 892 (N.Y. 1999); Estate of Schwarz v. Philip Morris Inc., 135 P.3d 409, 421 (Or. Ct. App. 2006); Am. Tobacco Co. v. Grinnell, 951 S.W.2d 420, 440 (Tex. 1997); see also Rivera v. Philip Morris, Inc., 395 F.3d 1142, 1148-49 (9th Cir 2005) (holding that plaintiff's fraudulent concealment claim was preempted).

Good, 501 F.3d 29.

fraudulent misrepresentations.²⁵¹ The plaintiffs conceded that the defendants' light brands produced lower levels of tar and nicotine in a FTC-approved test, but alleged that persons who smoked these types of cigarettes "compensated" by taking longer puffs or smoking more cigarettes than they would if they smoked "full flavor" brands. 252 Consequently, the defendants' implicit claims about the relative safety of their products were deceptive.²⁵³ The lower court ruled that the plaintiffs' fraudulent misrepresentation claims were preempted by the Federal Cigarette Labeling and Advertising Act.²⁵⁴ However, on appeal, the First Circuit Court of Appeals concluded that the Supreme Court in Cipollone had distinguished between failure to warn, concealment, and dilution which expressly preempted, and were misrepresentations of fact, which were not preempted even if they were concerned with the health effects of smoking.²⁵⁵ Consequently, the court reversed the lower court and allowed the plaintiffs to proceed with their fraudulent misrepresentation claims.²⁵⁶

However, preemption has also caused problems for those who have been injured by prescription drugs. In such cases, plaintiffs have tended to rely on both failure to warn and fraudulent misrepresentation claims. In the past, a number of courts held that failure to warn claims based on FDA-approved labeling were impliedly preempted on actual conflict grounds. ²⁵⁷ However, the United States Supreme Court's recent decision in *Wyeth v. Levine* ²⁵⁸ has greatly reduced the chances that failure to warn claims against drug companies will be preempted in the future. In that case, the plaintiff's claim was based on an alleged failure to strengthen an FDA-approved warning in accordance with state law. In contrast to the courts above, the Supreme Court refused to find that the state regulation was impliedly preempted and allowed the plaintiff's claim. ²⁵⁹ On the other hand, the status of fraudulent misrepresentation in this area is somewhat unclear. So far, several courts have already held

²⁵¹ *Id.* at 30 (internal quotations omitted).

²⁵² *Id.* at 30-31.

²⁵³ *Id.* at 31.

²⁵⁴ See Good v. Altria Group, Inc., 436 F. Supp. 2d 132, 153 (D. Me. 2006).

²⁵⁵ Good, 501 F.3d at 39-44.

²⁵⁶ Id. at 58-59. The Supreme Court has granted certiorari and will rule on the preemption issue in 2009. See Altria Group, Inc. v. Good, 128 S. Ct. 1119 (2008).

^{See, e.g., Colacicco v. Apotex, Inc., 521 F.3d 253, 276 (3d Cir. 2008), vacated, No. 08-437, 2009 WL 578682 (U.S. Mar. 9. 2009); Horne v. Novartis Pharmaceuticals Corp., 541 F. Supp. 2d 768, 782 (W.D.N.C. 2008); Dobbs v. Wyeth Pharm., 530 F. Supp. 2d 1275, 1287-89 (W.D. Okla. 2008); Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 317 (E.D. Pa. 2007). But see In re Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 776, 788 (E.D. La. 2007); In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007); Weiss v. Fujisawa Phar. Co., 464 F. Supp. 2d 666, 674 (E.D. Ky. 2006); Perry v. Novartis Pharma. Corp., 456 F. Supp. 2d 678, 684 (E.D. Pa. 2006); Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964, 968 (D. Neb. 2006); McDarby v. Merck & Co., Inc., 949 A.2d 223, 251 (N.J. Super. Ct. App. Div. 2008), cert. granted in part and denied in part, 960 A.2d 393 (N.J. 2008).}

²⁵⁸ Wyeth v. Levine, 129 S. Ct. 1187 (2009).

²⁵⁹ *Id.* at 1204.

that fraudulent misrepresentation claims based on FDA-approved labeling are impliedly preempted, ²⁶⁰ although in an unreported New York trial court decision, one court has concluded that they are not.²⁶¹ In this latter case, Smith v. Johnson & Johnson Co., the court refused to grant a summary judgment motion by the defendant, the manufacturer of Propulsid, a drug used in the treatment of diabetes.²⁶² The plaintiff set forth a number of allegations against the defendant, including fraudulent misrepresentation and concealment, in connection with the risks of Propulsid use. 263 The court declared that it agreed with the federal district court's decision in Jones ex rel. Jones v. Lederle Laboratories, 264 which held that Congress did not intend for federal prescription drug regulations to preempt state tort law claims.²⁶⁵

C. Playing the "Blame Game"

Another advantage of fault-based theories is that they enable plaintiffs' lawyers to use the "hot" rhetoric of fault instead of the "cold" rhetoric of strict liability. 266 In addition, these theories reinforce claims for punitive damages.

Despite the fact that strict products liability was developed to make it easier for consumers to recover for their injuries, many lawyers prefer to rely on negligence instead of strict liability.²⁶⁷ As Paul Rheingold pointed out more than thirty years ago, "negligence is 'hot' and strict liability is 'cold.'"268 In other words, it was easier for a plaintiff to persuade jurors that the defendant did something wrong than it was to convince them that the product in question was defective in some way.²⁶⁹ Other commentators have agreed with this observation.²⁷⁰ This may explain why fault-based liability theories, like negligent entrustment, negligent marketing, and negligence per se, are popular with plaintiffs' lawyers. If jurors respond positively to fault-based claims against product sellers, one would expect them to be even more receptive to liability

²⁶⁰ See Horne v. Novartis Pharmaceuticals Corp., 541 F. Supp. 2d 768, 775, 782-83

⁽W.D.N.C. 2008); Colacicco 432 F. Supp. 2d at 525, 549.

²⁶¹ See Smith v. Johnson & Johnson Co., No. 108901/01, 2004 WL 2964419 (N.Y. Sup. Ct. 2004).

262 Id. at *1.

²⁶³ *Id.* at *2.

 $^{^{264}}$ $\,$ 695 F. Supp. 700, 710-12 (E.D.N.Y. 1988), $\it aff'd, 182$ F.2d 63 (2d Cir. 1992).

See infra text accompanying note 268.

²⁶⁷ See Richard L. Cupp, Jr. & Danielle Polage, The Rhetoric of Strict Products Liability Versus Negligence: An Empirical Analysis, 77 N.Y.U. L. REV. 874, 899 (2002).

See Paul D. Rheingold, The Expanding Liability of the Product Supplier: A Primer, 2 HOFSTRA L. REV. 521, 531 (1974).

²⁷⁰ See Anita Bernstein, How Can a Product Be Liable?, 45 DUKE L.J. 1, 10 (1995); Martin A. Kotler, Utility Autonomy and Motive: A Descriptive Model of the Development of Tort Doctrine, 58 U. CIN. L. REV. 1231, 1234 (1990).

theories, like fraudulent misrepresentation or fraudulent concealment, which involve serious wrongdoing. What jury could resist doing its part to ensure that good triumphs over evil? The moral high ground for plaintiffs is even greater when the several defendants conspire together to behave badly. Hence, the popularity of civil conspiracy claims.

Sadly, examples of blameworthy behavior on the part of product manufacturers are not hard to find. For example, the manufacturer of the Dalkon Shield IUD marketed its product without conducting adequate testing and ignored reports of septic abortions and other injuries that were caused by its intrauterine device.²⁷¹ Asbestos litigation revealed that asbestos manufacturers not only failed to disclose health risks associated with exposure to asbestos insulation products, but conspired to prevent information about these risks obtained by third parties from reaching workers, consumers, or the general public.²⁷² Even more shocking was the forty-year campaign by the tobacco industry to conceal the health risks of smoking from the medical community and the public. Beginning in 1953, tobacco companies, either individually or through industry trade associations, allegedly issued misleading press releases, disseminated false information in articles, destroyed or concealed evidence about the health risks of smoking, denied that nicotine was addictive, and targeted their advertising at underage consumers.²⁷³ It is also claimed that tobacco companies manipulated nicotine levels in cigarettes to keep smokers addicted to their products.²⁷⁴

More recently, manufacturers of lead paint and their trade associations have been accused of conspiring to suppress information about the health risks of exposure to lead-based paint.²⁷⁵ The marketing practices of handgun manufacturers, ²⁷⁶ pharmaceutical companies, ²⁷⁷ and

See Hillard v. A.H. Robins Co., 196 Cal. Rptr. 117, 132 (Ct. App. 1983); Palmer v. A.H. Robins Co., 684 P.2d 187, 197 (Colo. 1984); Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1218 (Kan. 1987).

See Jackson v. Johns-Manville Sales Corp., 750 F.2d 1314, 1317-18 (5th Cir. 1985); Hansen v. Johns-Manville Prods. Corp., 734 F.2d 1036, 1039-40 (5th Cir. 1984); Fischer v. Johns-Manville Corp., 472 A.2d 577, 580 (N.J. Super. App. Div. 1984), aff'd, 512 A.2d 466 (N.J. 1986).

²⁷³ See United States v. Philip Morris, Inc., 116 F. Supp. 2d 131, 136 (D.D.C. 2000).

274 See Tucker S. Player, Note, After the Fall: The Cigarette Papers, the Global Settlement, and the Future of Tobacco Litigation, 49 S.C. L. REV. 311, 325-26 (1998).

See Scott A. Smith, Turning Lead into Asbestos and Tobacco: Litigation Alchemy Gone Wrong, 71 DEF. COUNS. J. 119, 122 (2004); Amber E. Dean, Comment, Lead Paint Public Entity Lawsuits: Has the Broad Stroke of Tobacco and Firearms Litigation Painted a Troubling Picture for Lead Paint Manufacturers?, 28 PEPP. L. REV. 915, 933 (2001).

See generally Timothy D. Lytton, Tort Claims Against Gun Manufacturers for Crime-

Related Injuries: Defining a Suitable Role for the Tort System in Regulating the Firearms Industry, 65 Mo. L. REV. 1 (2000); see also Mark D. Polston, Civil Liability for High Risk Gun Sales: An Approach to Combat Gun Trafficking, 19 SETON HALL LEGIS. J. 821, 829-36 (1995).

See George S. Craft, Jr., Note, Promoting Off-Label in Pursuit of Profit: An Examination of a Fraudulent Business Model, 8 HOUS. J. HEALTH L. & POL'Y 103, 120-24 (2007); Joseph B. Prater, Comment, West Virginia's Painful Settlement: How the OxyContin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets, 100 Nw. U. L. REV. 1409, 1427-29 (2006).

fast food purveyors²⁷⁸ have come under fire as well. Therefore, it is not surprising that plaintiffs have been quick to discover the benefits of bringing fault-based claims against product manufacturers in lieu of those based on conventional strict liability theory in instances, such as those discussed above, where product sellers appear to have engaged in flagrant misconduct.

In addition, focusing on the defendant's misconduct also directs attention away from the role that the plaintiff or others may have played in causing the plaintiff's injury. This is illustrated by the history of tobacco litigation. In the early decades of this litigation, tobacco companies were able to persuade juries that smokers freely chose to smoke and were, therefore, responsible for their injuries.²⁷⁹ However, juries later began to sympathize more with smokers after they presented evidence of fraud and other misconduct by the tobacco industry.²⁸⁰ A similar result may eventually occur in fast food cases if plaintiffs continue to emphasize the questionable marketing practices of fast food companies.

Furthermore, basing claims for compensatory damages on fault-based liability theories may increase a plaintiff's chances of obtaining a generous punitive damage award. Punitive or exemplary damages constitute an award to an injured party in addition to that which is necessary to compensate for his or her actual loss.²⁸¹ The principal objectives of punitive damages are "(1) to punish the defendant for outrageous misconduct and (2) to deter the defendant and others from similarly misbehaving in the future."²⁸² However, in traditional products liability litigation, liability for compensatory damages is determined on a strict liability basis, while punitive damages are awarded on the basis of fault. Consequently, when the compensatory damage claim is fault-

²⁷⁸ See Dustin Frazier, Note, The Link Between Fast Food and the Obesity Epidemic, 17 HEALTH- MATRIX 291, 312 (2007); Glenna Novack, Note, Lawsuits in the Fast-Food Nation: Will Fast-Food Suits Succeed as Obesity Becomes an American Tradition?, 52 WAYNE L. REV. 1307, 1317-18 (2006); Samuel J. Romero, Comment, Obesity Liability: A Super-Sized Problem or a Small Fry in the Inevitable Development of Products Liability?, 7 CHAP. L. REV. 239, 277-78 (2004).

²⁷⁹ See Robert L. Rabin, A Sociolegal History of the Tobacco Tort Litigation, 44 STAN. L. REV. 853, 873 (1992).

²⁸⁰ See Cupp, supra note 212, at 489-90. Anti-smoking lawyers also sought out "blameless" parties, such as governmental entities, to serve as plaintiffs in lawsuits against tobacco companies. With the revelations of tobacco industry misconduct and the use of blameless plaintiffs, the moral balance shifted decisively against the cigarette companies. See Bryce A. Jensen, Note, From Tobacco to Health Care and Beyond—A Critique of Lawsuits Targeting Unpopular Industries, 86 CORNELL L. REV. 1334, 1343 (2001).

²⁸¹ See Richard C. Ausness, Retribution and Deterrence: The Role of Punitive Damages in Products Liability Litigation, 74 Ky. L.J. 1, 2 (1985-1986); OWEN, supra note 191, § 18.1, at 1173.

at 1173.

See M. Stuart Madden, Essay, Renegade Conduct and Punitive Damages in Tort, 53
S.C. L. REV. 1175, 1176 (2002); David G. Owen, A Punitive Damages Overview: Functions, Problems and Reform, 39 VILL. L. REV. 363, 364 (1994). See generally OWEN, supra note 66, § 18.4.

based, the plaintiff may be able to support both damage claims with the same fault-based narrative.

IV. CONCLUSION

This Article has examined some of the liability theories that plaintiffs have used to supplement or to substitute for more conventional strict liability claims in products liability cases. They include fraudulent misrepresentation and fraudulent concealment, civil conspiracy, negligent entrustment, negligent marketing, and negligence per se. Plaintiffs find these fault-based theories appealing because they allow them to avoid some of the doctrinal limitations and proof problems associated with strict liability. These theories are more likely to resonate with juries than the efficiency-based approach that defines strict products liability. Consequently, plaintiffs will almost certainly continue to use these fault-based theories in the future.

However, this increased reliance on alternative liability theories raises a number of concerns. The first is whether it is appropriate for juries to take account of the defendant's conduct when deciding product liability cases. The injection of fault-based liability theories would seem to threaten the doctrinal integrity of products liability law, which has traditionally been based on strict liability. Arguably, a liability regime that rests on two antithetical principles—fault and no fault—will not be able to retain its doctrinal integrity for long. In response, it must be acknowledged that conduct already plays an important role in products liability. For example, affirmative defenses such as assumption of risk, and, more recently, comparative fault, can reduce damage awards to victims in strict liability cases, or even prevent them from recovering any damages at all. In addition, jurors often focus on the defendant's conduct now that punitive damages have become an integral part of products liability law. Moreover, the Products Liability Restatement itself has incorporated negligence principles into its definition of design defects and inadequate warnings.²⁸³ With a number of fault-based principles already fully incorporated into modern products liability law, it is probably too late to worry about doctrinal coherence.

Another concern is whether incorporating fault-based liability doctrines into products liability law might result in excessive liability for product sellers. Some of these theories, such as fraudulent misrepresentation, fraudulent concealment, civil conspiracy, and negligence per se, are established doctrines with clear requirements that plaintiffs must satisfy in order to recover. As such, they are limited in scope and therefore do not present much risk of excessive liability in their present form. On the other hand, newer, undeveloped doctrines, like negligent marketing, pose a greater risk to product sellers if they are

See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §§ 2(b)-(c) (1998).

expanded to impose new obligations or restrictions on marketing practices. There is also a risk that plaintiffs will use fault-based theories in order to demonize unpopular defendants like tobacco companies or handgun manufacturers and thus increase the chances of large damage awards awarded by outraged juries. Another link between fault-based liability theories and the risk of excessive liability is that these theories may unfairly prejudice defendants when plaintiffs seek punitive damages.

To conclude, it appears that fault-based liability theories are here to stay and may ultimately be good for products liability law. However, courts should be cautious about embracing novel or expansive versions of these theories, especially when they are accompanied by claims for punitive damages.