

“Danger Is My Business”: The Right to Manufacture Unsafe Products

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I. INTRODUCTION

Danger Is My Business is the title of a book published in 1938 by Colonel John D. Craig, a twentieth-century explorer, adventurer, and military figure.¹ However, this phrase can also be applied to the activities of companies that manufacture dangerous or unsafe products. As judges² and commentators³ have observed, products liability law is supposed to encourage manufacturers to produce safe products by subjecting them to liability when their products fall below an acceptable level of safety. Nevertheless, products liability law sometimes operates to discourage the production of safe products by shielding manufacturers from liability when they place unsafe products on the market.

This is not necessarily a bad policy. While no one would dispute that safety is a desirable objective, it may not always be an absolute priority. Rather, in some cases, other societal interests such as personal autonomy, consumer choice, product cost, and performance may trump legitimate safety goals. This is reflected in some of the doctrines and defenses that have evolved to protect the producers of unsafe products against tort liability. Some of these doctrines, such as those determining liability for the producers of optional safety equipment, inherently dangerous products, products with obvious hazards, and prescription drugs

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1. See JOHN D. CRAIG, *DANGER IS MY BUSINESS* (1938).

2. See *Wood v. General Motors Corp.*, 865 F.2d 395, 425 (1st Cir. 1988) (Selya, J., dissenting); *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440-41 (Cal. 1944) (Traynor, J., concurring); *Barrett v. Superior Court*, 272 Cal. Rptr. 304, 314 n.7 (Ct. App. 1990); *Bewers v. Am. Home Prods. Corp.*, 459 N.Y.S.2d 666, 678 (Sup. Ct. 1982), *rev'd*, 472 N.Y.S.2d 637 (App. Div. 1984), *aff'd*, 474 N.E.2d 247 (N.Y. 1984).

3. See Derek W. Black, *A Framework for the Next Civil Rights Act: What Tort Concepts Reveal About Goals, Results, and Standards*, 60 RUTGERS L. REV. 259, 322 (2008).

and medical devices, are part of the law of products liability. Other doctrines, such as the regulatory compliance defense and the contract specification defense, are aspects of the broader law of torts. Finally, a few of these doctrines, such as federal preemption and the government contractor defense, are rooted in principles of federal supremacy.

Part II of this article begins with an examination of the relationship between defectiveness and safety. It observes that liability is based on the sale of a “defective” product rather than on the sale of an unsafe one.⁴ In other words, the fact that a product is not particularly safe does not necessarily mean that it is defective.

Part III identifies a number of doctrines and defenses that potentially shield manufacturers of unsafe products from liability. These include federal preemption, the regulatory compliance defense, the contract specification defense, and the government contractor defense. Part III also observes that current products liability law often allows manufacturers to offer safety equipment on an optional basis, thereby enabling consumers to purchase products that may not be optimally safe. Likewise, manufacturers of inherently dangerous products, such as cigarettes, alcoholic beverages, and fast food, are generally immune from liability as long as they warn about product risks that might not be matters of common knowledge. Furthermore, under the obvious hazard rule, the duty to warn does not extend to hazards that should be known to the average consumer. In addition, the Products Liability Restatement, along with most courts, has declined to impose strict liability on the sellers of used products. Finally, certain potentially dangerous products, such as prescription drugs, vaccines, and medical devices, receive special treatment in products liability law because of their high social value.

Part IV examines a number of societal interests that may sometimes prevail over safety goals. Personal autonomy and consumer choice are two closely related interests. The principle of personal autonomy respects the right of individuals to engage

4. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998) (“One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.”).

in risky activities and to purchase dangerous products.⁵ In addition, public policy supports the proposition that consumers should have access to a wide range of options when they purchase products, including ones that are cheaper, but less safe.⁶ Product cost and performance are also important considerations that must be balanced against product safety. Additional safety features often increase product cost and, consequently, may price some consumers out of the market. In addition, as anyone who has struggled with child-proof caps knows, safety features sometimes adversely affect convenience and product performance.⁷ Safety must sometimes be compromised in order to protect governmental interests such as military procurement or agency decision-making. Finally, sub-optimal safety is sometimes tolerated in order to protect sellers from liability, as was the case when airbags were phased in gradually instead of being required all at once.

II. HOW SAFE DOES A PRODUCT HAVE TO BE?

A. Is Product Safety Really “Job One?”

Undoubtedly, safety is a popular and important societal goal. For example, the term “safety” appears prominently in the names of federal agencies such as the Consumer Product Safety Commission and the National Highway Traffic Safety Administration. In addition, Congress has placed the words “safe” or “safety” in the titles of various pieces of federal legislation. These include the Safe Drinking Water Act,⁸ the Keeping Children and Families Safe Act of 2003,⁹ the Consumer Product Safety Improvement Act,¹⁰ the Occupational Safety and Health Act of 1970,¹¹ the Virginia Graeme Baker Pool and Spa

5. See Peter L. Berger, *Furtive Smokers—and What They Tell Us About America*, COMMENTARY, June 1994, at 21, 26 (“[A] strong tradition of individual autonomy has existed in America . . .”).

6. See Richard J. Pierce, Jr., *Encouraging Safety: The Limits of Tort Law and Government Regulation*, 33 VAND. L. REV. 1281, 1283-84 (1980).

7. See J.M. Balkin, *Media Filters, the V-Chip, and the Foundations of Broadcast Regulation*, 45 DUKE L.J. 1131, 1154 (1996).

8. Safe Drinking Water Act, 42 U.S.C. §§ 300f to 300j-26 (2012).

9. Keeping Children and Families Safe Act of 2003, Pub. L. No. 108-36 (codified as amended in scattered sections of 42 U.S.C.).

10. Consumer Product Safety Improvement Act, 15 U.S.C. §§ 2051–2089 (2012).

11. Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651–678 (2012).

Safety Act,¹² the Federal Railroad Safety Authorization Act of 1994,¹³ the FDA Food Safety Modernization Act,¹⁴ and the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011,¹⁵ just to name a few.

Consequently, one would expect product manufacturers to embrace the idea of safety as well, and indeed they have. For years, product sellers have gone to great lengths to assure the public of the safety and reliability of their products. Some have even included the words “safe” or “safety” as part of a product’s name,¹⁶ or even as part of the company’s name,¹⁷ to suggest that these products are benign and pose no threat to life or limb. Unfortunately, product manufacturers do not always practice what they preach.¹⁸ Despite all this talk of safety, many products currently on the market are not particularly safe, and some are downright dangerous. Nevertheless, manufacturers continue to produce and sell these dangerous products with impunity.

B. What Do We Mean by “Safety”?

The term safety has a number of different meanings. For example, the dictionary defines safety as “the condition of being safe from undergoing or causing hurt, injury, or loss.”¹⁹ However, other definitions of safety may be more appropriate to products liability law. One such definition focuses on technological feasibility. To satisfy a feasibility standard, manufacturers must produce products that are as safe as they

12. Virginia Graeme Baker Pool and Spa Safety Act, 15 U.S.C. §§ 8001–8007 (2012).

13. Federal Railroad Safety Authorization Act of 1994, Pub. L. No. 103-440 (codified as amended in scattered sections of 49 U.S.C.).

14. FDA Food Safety Modernization Act, Pub. L. No. 111-353 (codified as amended at 7 U.S.C. § 7625, 42 U.S.C. § 280g-16, and in scattered sections of 21 U.S.C.).

15. Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011, 49 U.S.C. §§ 60138-60140 (2012).

16. *See, e.g.*, *Maize v. Atl. Ref. Co.*, 41 A.2d 850, 851 (Pa. 1945) (noting cleaning fluid named “Safety-Kleen” produced deadly tetrachloride fumes).

17. *See, e.g.*, GARDEN SAFE PRODUCTS, <http://www.gardensafe.com> (last visited Oct. 3, 2014); SAFE HOME PRODUCTS, <http://www.safehomeproducts.com> (last visited Oct. 3, 2014); SAFETY-KLEEN, <http://www.safety-kleen.com> (last visited Oct. 3, 2014); SKATE SAFE PRODUCTS, <http://www.skatesafeproducts.com> (last visited Oct. 3, 2014).

18. *See, e.g.*, *Baxter v. Ford Motor Co.*, 12 P.2d 409, 412 (Wash. 1932) (holding manufacturer’s claim that the glass in its windshield was “so made that it will not fly or shatter under the hardest impact” was false and constituted a breach of express warranty).

19. *See* WEBSTER’S NINTH NEW COLLEGIATE DICTIONARY 1036 (1983).

could be in light of current technology.²⁰ Some federal statutes also mandate safety levels based on a feasibility standard.²¹ Although this standard is commonly embodied in statutory safety standards, only a few state courts have endorsed it for purposes of products liability.²² A more popular standard is optimal safety. This efficiency-based standard, discussed in more detail below, requires manufacturers to make cost-effective investments in product safety. It should be noted that the level of safety necessary to satisfy an optimality standard may be less than the level of safety required by the feasibility standard since a safety feature that is feasible may not necessarily be cost-effective. Finally, a level of safety may be legally sufficient even though it is less than optimal. These sorts of sub-optimally safe products are the principal focus of this article.

C. Safety and Tort Liability

The relationship between product safety, however defined, and products liability has always been somewhat obscure. For example, when the Restatement (Second) of Torts was first promulgated by the American Law Institute in 1965, it imposed strict liability in tort on the sellers of “defective” and “unreasonably dangerous” products.²³ However, comments suggested that these terms were the same, or nearly the same, by defining both as products that were more dangerous than an ordinary consumer would expect them to be.²⁴ This “consumer expectation” test was derived from warranty law and seemed to

20. *Cf.* *Robinson v. Brandtjen & Kluge, Inc.*, 500 F.3d 691, 696 (8th Cir. 2007) (“While a manufacturer has a duty to design a product that is reasonably safe for its foreseeable use, it is not required to design the ‘best possible product,’ and ‘proof that technology existed, which if implemented could feasibly have avoided a dangerous condition, does not alone establish a defect.’” (quoting *Sexton ex rel Sexton v. Bell Helmets, Inc.*, 926 F.2d 331, 336 (4th Cir. 1991))).

21. *See* Mark Geistfeld, *Reconciling Cost-Benefit Analysis with the Principle That Safety Matters More Than Money*, 76 N.Y.U. L. REV. 114, 118 (2001) (discussing Occupational Health and Safety Act safety standards).

22. *See, e.g.*, *Gosewisch v. Am. Honda Motor Co.*, 737 P.2d 365, 370 (Ariz. Ct. App. 1985), *vacated in part*, 737 P.2d 376 (Ariz. 1987); *Indianapolis Athletic Club v. Alco Standard Corp.*, 709 N.E.2d 1070, 1074 (Ind. Ct. App. 1999); *Falada v. Trinity Indus., Inc.*, 642 N.W.2d 247, 251 (Iowa 2002); *AC&S, Inc. v. Asner*, 686 A.2d 250, 254 (Md. 1996); *Wiska v. St. Stanislaus Soc. Club*, 390 N.E.2d 1133, 1138 n.8 (Mass. App. Ct. 1979); *Johnson v. Salem Corp.*, 477 A.2d 1246, 1251-52 (N.J. 1984); *Lenhardt v. Ford Motor Co.*, 683 P.2d 1097, 1099 (Wash. 1984).

23. *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965).

24. *See id.* § 402A cmts. g, i.

indicate that liability should be based on deception of consumers rather than upon a manufacturer's failure to meet a particular standard of product safety.²⁵ Furthermore, by imposing liability only upon manufacturers whose products were "unreasonably dangerous," the drafters of the Restatement (Second) of Torts seemed to imply that manufacturers and others who produced or sold *reasonably* dangerous products would not be subject to tort liability.

It is clear from the foregoing discussion that liability under the Restatement (Second) of Torts was not based on whether a product was safe or unsafe in any sort of absolute sense. Instead, liability depended upon whether a product was *reasonably* safe. But what does reasonably safe mean in this context? One possibility is that it is equivalent to technological feasibility, at least in design defect cases. Under this definition, in order to avoid liability, a manufacturer would have to make a product as safe as current technology permits. Although some "state-of-the-art" cases seemed to have taken this position,²⁶ reasonable safety eventually became identified more with optimality than with feasibility.

Influenced by law and economics theorists, courts and legal scholars in the 1980s began to view product safety in resource-allocation terms and concluded that manufacturers should spend money on risk-reduction measures only up to the point where the marginal cost of achieving further risk reduction would equal or exceed the marginal benefits of such reduction.²⁷ Imposing liability on the party in the best position to make this

25. The concept of an unreasonably dangerous product, as defined by the consumer expectation test, was replaced by the deviation-from-the-norm test in manufacturing defect cases. *See, e.g.,* McKenzie v. S K Hand Tool Corp., 650 N.E.2d 612, 615-20 (Ill. App. Ct. 1995). Under this approach, a product is considered to be defective if it deviates from the manufacturer's intended design. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(a) (1998). Of course, there is no guarantee that the design in question will not be unreasonably dangerous, but that question will not arise in a manufacturing defect case.

26. *See, e.g.,* Indianapolis Athletic Club, 709 N.E.2d at 1074; AC&S, Inc., 686 A.2d at 254; O'Brien v. Muskin Corp., 463 A.2d 298, 305 (N.J. 1983).

27. *See* James A. Henderson, Jr., *Product Liability and the Passage of Time: The Imprisonment of Corporate Rationality*, 58 N.Y.U. L. REV. 765, 768 (1983); David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 849, 865 (1984).

determination would ensure that an “efficient” or “optimal” level of product safety would be achieved.²⁸

For the most part, this approach has been retained by the drafters of the Products Liability Restatement. For example, section 2(b) declares that a product “is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design.”²⁹ In addition, comment a expressly adopts optimal safety as a goal by pointing out that in subsections (b) and (c), which deal with design defect and failure-to-warn claims, respectively, “[t]he emphasis is on creating incentives for manufacturers to achieve optimal levels of safety in designing and marketing products.”³⁰ The comment continues, “[s]ociety does not benefit from products that are excessively safe . . . any more than it benefits from products that are too risky.”³¹ Rather, “[s]ociety benefits most when the right, or optimal, amount of product safety is achieved.”³²

All of this suggests the “reasonable alternative design” or the “reasonable instructions or warnings” are designs or warnings that are optimal, or sufficient, to achieve a marginal level of accident cost reduction that exceeds their marginal cost. This means that manufacturers need not make their products as safe as current technology permits; instead, they are merely required to spend money on product safety so long as the marginal cost of additional safety measures is less than the expected reduction of product-related accident costs.³³

Nevertheless, having identified an optimal level of product safety as the standard for avoiding tort liability, the drafters of the Products Liability Restatement seem to have retreated from this position. Comment f to section 2, which identifies various factors relevant to determining whether an alternative design is reasonable, mentions a number of factors unrelated to safety.

28. See Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163, 1176 n.42 (1998) (“[E]fficiently safe products,’ [are] products for which manufacturers have made all cost-justified investments in safety. ‘Inefficiently unsafe products’ are those for which not all such investments have been made.”).

29. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998).

30. *Id.* § 2 cmt. a.

31. *Id.*

32. *Id.*

33. See Henderson, *supra* note 27, at 768.

These include the likely effects of the alternative design on product maintenance, repair, and aesthetics, as well as the range of consumer choice among products.³⁴ In theory, these considerations could trump safety concerns and allow a less safe design to pass muster, even if a safer design was both feasible and cost effective.

More importantly, the Products Liability Restatement also retains a number of doctrines that potentially allow manufacturers to escape tort liability despite the fact that their products are not optimally safe. These include provisions for optional safety equipment,³⁵ protection for inherently dangerous products,³⁶ and reduced liability for manufacturers and sellers of prescription drugs and medical devices.³⁷ In addition, a number of other common-law doctrines and defenses, not expressly mentioned in the Products Liability Restatement, also allow for the production and sale of products that are less than optimally safe.

III. DOCTRINES AND DEFENSES ALLOWING FOR SUB-OPTIMAL SAFETY

Manufacturers may invoke a number of specific doctrines and defenses to escape liability for injuries to consumers caused by products with sub-optimal levels of safety. These doctrines involve such concepts as federal preemption, compliance with state-of-the-art, optional safety equipment, and obvious hazards. In addition, special rules applicable to inherently dangerous products and prescription drugs arguably permit manufacturers to produce and sell products that are not optimally safe.

A. Federal Preemption

Although the states are considered to be sovereign entities under the United States Constitution,³⁸ Congress has the authority to preempt state law in the exercise of its constitutional powers when it chooses to do so.³⁹ This power to preempt state law derives from the Supremacy Clause of the United States

34. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. f (1998).

35. *See id.* § 2 cmt. f, illus. 10.

36. *See id.* § 2 cmt. d.

37. *Id.* § 6.

38. *See Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991).

39. *See id.* at 460.

Constitution.⁴⁰ The federal power to preempt not only applies to state statutes;⁴¹ it extends to local ordinances as well.⁴² Furthermore, in recent decades, product manufacturers have successfully invoked principles of federal preemption in order to negate the effect of state products liability doctrines.⁴³

Courts⁴⁴ and commentators⁴⁵ usually distinguish between express and implied preemption. Express preemption occurs when a federal statute specifically excludes state regulation in a particular area.⁴⁶ A number of federal statutes contain express preemption provisions.⁴⁷ In addition, federal agencies, when acting within the scope of their delegated authority, may expressly preempt state law by regulation.⁴⁸ Furthermore, Congress may impliedly preempt state law. One form of implied preemption occurs when a state attempts to regulate in an area that involves a dominant federal interest such as foreign affairs,⁴⁹ or when a federal regulatory scheme is so pervasive that it

40. See *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *Hines v. Davidowitz*, 312 U.S. 52, 63 (1941); see also U.S. CONST. art VI, cl. 2 (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).

41. See, e.g., *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 99 (1992); *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 300 (1988); *Mich. Canners & Freezers Ass’n v. Agric. Mktg. & Bargaining Bd.*, 467 U.S. 461, 478 (1984).

42. See, e.g., *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 633 (1973).

43. See, e.g., *Geier v. Am. Honda Motor Co. Inc.*, 529 U.S. 861, 874 (2000).

44. See *English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990); *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-13 (1985).

45. See Robert R. Gasaway, *The Problem of Federal Preemption: Reformulating the Black Letter Rules*, 33 PEPP. L. REV. 25, 25 (2005); David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 414 (2003).

46. See *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. Employes’ Dep’t v. Hanson*, 351 U.S. 225, 232 (1956); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 233-34 (1947).

47. See, e.g., 49 U.S.C. § 30103 (2012) (preempting certain state motor vehicle standards).

48. See *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 700 (1984) (granting the Federal Communications Commission broad authority to regulate cable communications systems); *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 170 (1982) (preempting state restrictions on due-on-sale clauses in loan agreements); *Free v. Bland*, 369 U.S. 663, 667-68 (1962) (holding a savings bond right of survivorship is enforceable regardless of state law); *Pub. Utils. Comm’n of Cal. v. United States*, 355 U.S. 534, 544-45 (1958) (ruling federal policy governing shipping rates for common carriers expressly preempted conflicting state policy).

49. See *Hines v. Davidowitz*, 312 U.S. 52, 62-63 (1941).

occupies the field and leaves no room for state regulation.⁵⁰ Another form of preemption, known as conflict preemption, occurs either when it is impossible to comply with conflicting state and federal laws,⁵¹ or when state law stands as an obstacle to the achievement of federal regulatory objectives.⁵²

Legal scholars agree that preemption analysis requires a court to ascertain congressional intent.⁵³ However, this is easier said than done. When a federal statute contains an express preemption provision, it is clear that Congress intended to preempt state law to some extent, and the court's job is to determine the scope of the statute's preemptive language.⁵⁴ Determining congressional intent is more difficult in implied preemption situations where there is no specific preemptive language to examine. Thus, the court must examine the statute's regulatory structure and purpose to determine whether Congress intended for the federal regulatory scheme to co-exist with state regulatory provisions.⁵⁵

If state law requires manufacturers to achieve an optimal level of safety and federal law allows them to get away with a lower, sub-optimal level of safety, the doctrine of federal preemption, if applicable, will ensure that the lower level of safety prevails. One might ask why Congress would permit, or even mandate, the manufacture of products that were not optimally safe. In most cases, the answer is that Congress has subordinated product safety to the achievement of a more important federal objective.

This conflict between product safety and other congressional objectives is nicely illustrated by *Cipollone v. Liggett Group, Inc.*⁵⁶ In *Cipollone*, the personal representative of a deceased

50. See *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 300 (1988).

51. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011); *McDermott v. Wisconsin*, 228 U.S. 115, 137 (1913).

52. See *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 491-92 (1987); *Mich. Canners & Freezers Ass'n v. Agric. Mktg. & Bargaining Bd.*, 467 U.S. 461, 478 (1984); *Ark. La. Gas Co. v. Hall*, 453 U.S. 571, 584 (1981).

53. See Jonathan V. O'Steen & Van O'Steen, *The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 70 (2006); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 455 (2008).

54. See Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 970 (2002).

55. See Mary J. Davis, *On Restating Products Liability Preemption*, 74 BROOK. L. REV. 759, 761-62 (2009).

56. 505 U.S. 504 (1992).

smoker brought suit against a tobacco company, claiming that its products caused her death from lung cancer.⁵⁷ The plaintiff alleged, *inter alia*, that the warnings on cigarette labels did not adequately inform consumers about the health risks of smoking.⁵⁸ However, the United States Supreme Court concluded that the express provisions of the Federal Cigarette Labeling and Advertising Act of 1969, but not its predecessor enacted in 1965, barred tort claims against tobacco companies based on their failure to provide stronger warnings about the health risks of smoking.⁵⁹

Given the knowledge at the time about the health risks of smoking, particularly the risk of lung cancer, the warnings mandated by the federal statutes were manifestly inadequate.⁶⁰ Therefore, preempting failure-to-warn claims immunized cigarette companies from liability and allowed them to manufacture products with sub-optimal health warnings. Why would Congress allow cigarette companies to market such products? As the Court observed, Congress had objectives, other than protecting public health, in mind when it enacted the cigarette labeling legislation.⁶¹ To be sure, one objective was to warn the public about the health risks of smoking.⁶² However, another objective was to “protect[] the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations.”⁶³ This goal of uniformity was presumably intended to protect the economic interests of the tobacco industry against stricter state regulation. Ostensibly, these same considerations motivated Congress to enact a revised cigarette labeling law when the original Act expired in 1969.

57. *Id.* at 508. The smoker and her husband originally brought the action, and it was continued after their deaths by their son on behalf of both estates. *Id.* at 509.

58. *Id.* at 508.

59. *Id.* at 530-31. However, the Court held that the 1969 Act did not preempt claims based on breach of express warranty, misrepresentation, or conspiracy. *Id.* at 531. Nor were any claims preempted based on the defendant’s failure to provide any health warnings prior to 1965. *Id.* at 518-20.

60. See Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 SYRACUSE L. REV. 897, 908-09 (1988); Lars Noah, *The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 304 (1994).

61. See *Cipollone*, 505 U.S. at 514.

62. *Id.* (stating statute sought to “adequately inform[] the public that cigarette smoking may be hazardous to health”).

63. *Id.*

*Geier v. American Honda Motor Co.*⁶⁴ also illustrates the tension between safety and non-safety objectives. The plaintiff in *Geier* was injured when her 1987 Honda Accord struck a tree.⁶⁵ She brought suit against the manufacturer, alleging that the vehicle was defectively designed because it was not equipped with an airbag on the driver's side.⁶⁶ In response, the manufacturer contended that the National Traffic and Motor Vehicle Safety Act⁶⁷ and Federal Motor Vehicle Safety Standard 208 ("FMVSS 208"), promulgated by the Department of Transportation under the authority of the Act, preempted the plaintiff's "no airbag" claim.⁶⁸ The manufacturer maintained that the plaintiff's automobile complied with the requirements of FMVSS 208, which did not require it to install airbags.⁶⁹

Although the federal statute contained an express-preemption provision, it did not specifically apply to state-law tort claims.⁷⁰ In addition, it contained a savings clause that appeared to preserve common-law remedies.⁷¹ Consequently, the Court concluded that it should interpret the preemption provision narrowly⁷² and ruled that the Act did not expressly preempt the plaintiff's tort claim against the manufacturer.⁷³ Having rejected the defendant's express-preemption argument, the Court then considered the argument that the plaintiff's claim was impliedly preempted on conflict grounds.⁷⁴ Addressing this issue, the Court declared that FMVSS 208 "deliberately sought a *gradual* phase-in of passive restraints" in annual increments over a three-year period.⁷⁵ This phase-in process was supposed to allow more time for manufacturers to improve airbag technology or to develop other passive restraint systems.⁷⁶ In the Court's view, the plaintiff's lawsuit was predicated on the notion that the defendant

64. 529 U.S. 861 (2000).

65. *Id.* at 865.

66. *Id.*

67. See National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. §§ 1381–1431 (1988) (repealed 1994). The Act was later recodified. See 49 U.S.C. §§ 30101–30183 (2012).

68. *Geier*, 529 U.S. at 865–66.

69. *Id.* at 865.

70. See 15 U.S.C. § 1392(d) (1988) (repealed 1994).

71. See 15 U.S.C. § 1397(k) (1988) (repealed 1994).

72. *Geier*, 529 U.S. at 868.

73. *Id.* at 867–68.

74. *Id.* at 869.

75. *Id.* at 879.

76. *Id.*

had a duty to equip all of its 1987 vehicles with airbags.⁷⁷ However, the Court concluded that holding the defendant liable on this basis “would have stood as an obstacle to the gradual passive restraint phase-in that the federal regulation deliberately imposed.”⁷⁸

In two recent cases, the Court held that certain provisions of the Federal Food, Drug, and Cosmetic Act⁷⁹ relating to the licensing of generic drugs impliedly preempted common-law claims.⁸⁰ The first, *PLIVA, Inc. v. Mensing*,⁸¹ involved the generic drug metoclopramide, which is commonly used to treat certain digestive tract problems.⁸² The FDA approved the drug in 1980 under the brand name Reglan, and the other manufacturers began generic production five years later.⁸³ However, as early as 1985, the FDA and the drug manufacturers became aware that long-term use of metoclopramide could cause tardive dyskinesia, a severe neurological disorder.⁸⁴

The plaintiffs in *Mensing* developed tardive dyskinesia after taking a generic version of metoclopramide for several years.⁸⁵ They alleged that warnings provided by the manufacturers of metoclopramide failed to adequately warn about the danger of contracting tardive dyskinesia from long-term use of the drug.⁸⁶ In response, the defendant manufacturers argued that the plaintiffs’ claims were preempted by federal law.⁸⁷

The defendants’ preemption claim relied on the provisions of the Hatch-Waxman Amendments, which governed FDA licensing of generic drugs.⁸⁸ The Act allowed drug manufacturers to secure approval of generic drugs simply by showing that their product was equivalent to a “listed” drug that had already been

77. *Geier*, 529 U.S. at 881.

78. *Id.*

79. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301–399f (2012).

80. The Federal Food, Drug and Cosmetic Act does not contain a generally applicable express preemption provision. See Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1092 (2007).

81. 131 S. Ct. 2567 (2011).

82. *Id.* at 2572.

83. *Id.*

84. *Id.*

85. *Id.* at 2573.

86. *Mensing*, 131 S. Ct. at 2573.

87. *Id.*

88. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

approved by the FDA.⁸⁹ The Court stated this meant that the generic drug's chemical ingredients and labeling had to be identical to that of the listed drug.⁹⁰ This requirement sought to enable manufacturers to inexpensively market generic drugs by exempting them from the costly process of conducting duplicative clinical trials or other drug testing before seeking FDA approval.⁹¹

The defendants and the FDA argued that generic drug manufacturers were not permitted to unilaterally strengthen the warnings that had been approved by the FDA for the listed drug.⁹² The Court agreed and declared that it was impossible for the drug companies to comply with both the federal labeling requirements and the duty to warn under the state law about newly discovered product risks.⁹³ Accordingly, the Court held that the plaintiffs' failure-to-warn claims were impliedly preempted.⁹⁴

The Court reached a similar result in *Mutual Pharmaceutical Co. v. Bartlett*.⁹⁵ This case involved sulindac, a pain reliever approved by the FDA in 1978 under the brand name Clinoril.⁹⁶ Unfortunately, sulindac caused serious hypersensitivity skin reactions in a small number of users.⁹⁷ In December 2004, the plaintiff took sulindac for shoulder pain and developed toxic epidermal necrolysis, which resulted in disfigurement, a number of physical disabilities, and near blindness.⁹⁸ At the time, the drug's label warned that the drug could cause skin reactions or death but it did not state that it could cause specific conditions such as toxic epidermal necrolysis.⁹⁹ The plaintiff brought suit against a generic manufacturer of sulindac, alleging failure to warn and defective design.¹⁰⁰ The failure-to-warn claim was dismissed on causation grounds, but the plaintiff ultimately

89. See 21 U.S.C. § 355(j)(2)(A) (2012).

90. *Mensing*, 131 S. Ct. at 2574; see also 21 U.S.C. § 355(j)(A) (2012) (relevant statutory provision).

91. *Mensing*, 131 S. Ct. at 2574.

92. *Id.* at 2574-75.

93. *Id.* at 2577-78.

94. *Id.* at 2581.

95. 133 S. Ct. 2466 (2013).

96. *Id.* at 2471.

97. *Id.* at 2471-72.

98. *Id.* at 2472.

99. *Id.* However, toxic epidermal necrolysis was listed as a "potential adverse reaction" on the drug's package insert. *Id.*

100. *Bartlett*, 133 S. Ct. at 2472.

prevailed on the design defect claim.¹⁰¹ However, on appeal, the United States Supreme Court relied on the reasoning of *Mensing* to conclude that the plaintiff's design defect claim was also preempted.¹⁰²

The Court observed that under state law, a drug manufacturer had a duty to reduce the risk of danger from a drug's side effects either by changing the chemical composition of the drug or by altering the drug's labeling.¹⁰³ Since it was not possible to change sulindac's chemical composition, the only way for the manufacturer to reduce the risk of its side effects was to strengthen the drug's warnings.¹⁰⁴ However, because sulindac was a generic drug, the manufacturer could not change its labeling either.¹⁰⁵ Therefore, because it was impossible for the manufacturer to comply with both state and federal law requirements, state law was necessarily preempted.¹⁰⁶

By preempting the plaintiffs' tort claims in *Mensing* and *Bartlett*, the Court enabled the generic drug companies to market their products without fear of liability, even though the warnings they provided might have been inadequate. Apparently, the Court believed that it was more important to uphold the FDA's uniform labeling policy for generic drugs than it was to encourage manufacturers of these products to improve their warnings.

B. The Contract Specification Defense

The contract specification defense provides that a manufacturer will not be held liable for a design defect when it manufactures a product in accordance with the buyer's plans and specifications.¹⁰⁷ "As the contract specification defense is grounded on the theory of reasonable reliance, the contractor is not protected by the defense if he follows specifications that" are obviously dangerous.¹⁰⁸ However, since the "average contractor cannot be expected to possess the expertise needed to examine

101. *Id.*

102. *See id.* at 2478-80.

103. *Id.* at 2474.

104. *Id.*

105. *Bartlett*, 133 S. Ct. at 2476.

106. *Id.* at 2477.

107. *See* David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 3 (2005).

108. *See* Charles E. Cantu & Randy W. Young, *The Government Contractor Defense: Breaking the Boyle Barrier*, 62 ALB. L. REV. 403, 409 (1998).

every design” that is proposed by a potential customer, a contractor should ordinarily be able to “rely on a third-party’s design specifications without fear of liability.”¹⁰⁹

Although the contract specification doctrine first appeared in negligence cases,¹¹⁰ it has also been applied with some frequency in products liability cases.¹¹¹ *Moon v. Winger Boss Co.*¹¹² is illustrative. In *Moon*, a worker was injured when his arm became

109. *Id.* at 410; *see also* *Burgess v. Colo. Serum Co.*, 772 F.2d 844, 846-47 (11th Cir. 1985) (affirming judgment for vaccine manufacturer whose product met detailed specifications of government contract); *Johnston v. United States*, 568 F. Supp. 351, 355 (D. Kan. 1983) (denying summary judgment in negligence claim because essential facts to the contract specification defense remained controverted); *Davis v. Henderlong Lumber Co.*, 221 F. Supp. 129, 134-35 (N.D. Ind. 1963) (allowing defense where contractor was not negligent and merely carried out contract plans and specifications in building chemical exhaust apparatus).

110. *See, e.g.*, *Spangler v. Kranco, Inc.*, 481 F.2d 373, 374-75 (4th Cir. 1973) (affirming summary judgment in favor of defendant crane manufacturer on negligence claim where manufacturer followed industrial buyer’s plans and specifications); *Moran v. Pittsburgh-Des Moines Steel Co.*, 166 F.2d 908, 914-17 (3d Cir. 1948) (allowing trier of fact to determine liability where manufacturer planned the construction of a structure that later caused damage to plaintiff); *Md. Cas. Co. v. Indep. Metal Prods. Co.*, 99 F. Supp. 862, 868 (D. Neb. 1951) (noting that the defendant did not fail to exercise reasonable care in planning a product where a third party determined the product’s design and specifications), *aff’d*, 203 F.2d 838 (8th Cir. 1953); *Wright v. Holland Furnace Co.*, 243 N.W. 387, 387-88 (Minn. 1932) (discussing whether a buyer’s reliance on a seller’s “more expert and dependable knowledge” of stove construction details shielded the buyer from contributory negligence); *Szatkowski v. Turner & Harrison, Inc.*, 584 N.Y.S.2d 170, 171-72 (App. Div. 1992) (affirming summary judgment in favor of defendant who complied with purchaser’s design specifications).

111. *See, e.g.*, *Garrison v. Rohm & Haas Co.*, 492 F.2d 346, 351 (6th Cir. 1974) (refusing to hold a manufacturer liable for defective design in products liability case where manufacturer was not the designer); *Housand v. Bra-Con Indus.*, 751 F. Supp. 541, 544-45 (D. Md. 1990) (barring products liability claim where none of the defendants designed or engineered the automobile assembly line where plaintiff was injured); *Lesnefsky v. Fischer & Porter Co.*, 527 F. Supp. 951, 953-56 (E.D. Pa. 1981) (finding manufacturer of brewery cooking device not liable for injury caused by design defect where manufacturer followed experienced purchaser’s specifications); *Orion Ins. Co. v. United Techs. Corp.*, 502 F. Supp. 173, 174 (E.D. Pa. 1980) (addressing manufacturer’s defense in products liability case where helicopter component part was made to the specifications of a third party); *McCabe Powers Body Co. v. Sharp*, 594 S.W.2d 592, 593-94 (Ky. 1980) (allowing defense to products liability claim where defendant constructed “cherry picker” in accordance with buyer’s detailed specifications); *Bloemer v. Art Welding Co. Inc.*, 884 S.W.2d 55, 56 (Mo. Ct. App. 1994) (holding “a contractor’s compliance with its customer’s plans and specifications is . . . a complete defense to strict liability and negligence claims based on defective design”). *But see, e.g.*, *Challoner v. Day & Zimmermann, Inc.*, 512 F.2d 77, 82-83 (5th Cir. 1975) (refusing to allow defense in products liability case where manufacturer was not in control of design but followed government buyer’s design specifications), *vacated*, 423 U.S. 3 (1975); *Hendricks v. Comerio Ercole*, 763 F. Supp. 505, 512-13 (D. Kan. 1991) (refusing to shield manufacturer from liability for design defects where manufacturer followed buyer’s plans and specifications).

112. 287 N.W.2d 430 (Neb. 1980).

entangled in the sprocket and chain of a moving breaking table.¹¹³ The specifications provided by the plaintiff's employer did not provide for protective guards, which left the chain mechanism exposed.¹¹⁴ The plaintiff alleged that the machine was defectively designed,¹¹⁵ but the court concluded that the manufacturer was not liable if it manufactured the product in accordance with the employer's plans and specifications, assuming they were not "obviously, patently, or glaringly dangerous."¹¹⁶

A Missouri appellate court reached a similar result in *Bloemer v. Art Welding Co.*¹¹⁷ In the case, two employees were injured while they were cleaning a three-story-tall cylindrical tank known as a "cyclone."¹¹⁸ The defendant constructed the machine according to specifications provided by the plaintiffs' employer.¹¹⁹ The plaintiffs claimed that various design defects caused them to be burned by hot water trapped inside the cyclone when they attempted to open its access door.¹²⁰ Affirming the lower court's judgment for the manufacturer, the court applied the contract specification doctrine to shield the product manufacturer from liability.¹²¹

Although the contract specification defense is based on the notion that it is unfair to hold a manufacturer liable for a product's defective design when the manufacturer had no role in designing the product,¹²² by immunizing a manufacturer from liability in all but the most egregious cases, the doctrine arguably reduces incentives to produce a safe product.

C. Government Contractor Defense

The government contractor defense protects a manufacturer from liability when its product complies with design specifications set forth in a government procurement contract.¹²³ The defense was originally invoked by public-works contractors

113. *Id.* at 431.

114. *Id.* at 431-32.

115. *Id.* at 432.

116. *Id.* at 434.

117. 884 S.W.2d 55 (Mo. Ct. App. 1994).

118. *Id.* at 56-57 (internal quotation marks omitted).

119. *Id.* at 57.

120. *Id.*

121. *Id.* at 59.

122. *See Garrison v. Rohm & Haas Co.*, 492 F.2d 346, 351 (6th Cir. 1974).

123. *See Koutsoubos v. Boeing Vertol*, 553 F. Supp. 340, 342 (E.D. Pa. 1982), *aff'd*, 755 F.2d 352 (3d Cir. 1985).

to bar negligence claims against them for damage to land and other property.¹²⁴ Later, defense contractors began to rely on this defense to defeat claims brought against them by third parties for injuries caused by defectively designed products supplied to the military.¹²⁵ Prior to 1988, there was some uncertainty about the nature and scope of the government contractor defense.¹²⁶ However, these issues were resolved that year by the United States Supreme Court's decision in *Boyle v. United Technologies Corp.*¹²⁷

The decedent in *Boyle*, a United States Marine Corps pilot, drowned when his helicopter crashed into the Atlantic Ocean during a training exercise.¹²⁸ The pilot's personal representative brought suit against Sikorsky, the manufacturer of the aircraft, alleging that its emergency escape hatch system was defectively designed.¹²⁹ The plaintiff claimed that the hatch door was defective because it was designed to open outward and, therefore, could not be opened because of water pressure if the helicopter crashed at sea.¹³⁰ The plaintiff also claimed that when one of the control sticks was pulled fully up, it interfered with the pilot's access to the escape hatch.¹³¹ A jury awarded damages to the plaintiff, but the judgment was reversed on appeal.¹³² The Fourth Circuit Court of Appeals concluded that the plaintiff's claim was barred by what it called the "military contractor defense."¹³³

After granting certiorari, the United States Supreme Court first considered whether federal law would relieve a government

124. See, e.g., *Yearsley v. W.A. Ross Constr. Co.*, 309 U.S. 18, 19 (1940); *Green v. ICI Am., Inc.*, 362 F. Supp. 1263, 1264 (E.D. Tenn. 1973); *Dolphin Gardens, Inc. v. United States*, 243 F. Supp. 824, 827 (D. Conn. 1965).

125. See *Tozer v. LTV Corp.*, 792 F.2d 403, 404 (4th Cir. 1986); *Shaw v. Grumman Aerospace Corp.*, 778 F.2d 736, 738 (11th Cir. 1985); *Burgess v. Colo. Serum Co.*, 772 F.2d 844, 844-45 (11th Cir. 1985); *Bynum v. FMC Corp.*, 770 F.2d 556, 558 (5th Cir. 1985); *Tillett v. J.I. Case Co.*, 756 F.2d 591, 598-600 (7th Cir. 1985); *Koutsoubos*, 755 F.2d at 353; *McKay v. Rockwell Int'l Corp.*, 704 F.2d 444, 448 (9th Cir. 1983).

126. See Richard Ausness, *Surrogate Immunity: The Government Contract Defense and Products Liability*, 47 OHIO ST. L.J. 985, 1014 (1986) ("[A] number of issues must still be resolved before the specific dimensions of the government contract defense are fully revealed.").

127. 487 U.S. 500 (1988).

128. *Id.* at 502.

129. *Id.* at 503.

130. *Id.*

131. See *id.*

132. See *Boyle v. United Techs. Corp.*, 792 F.2d 413 (4th Cir. 1986).

133. *Id.* at 415.

contractor of any state-law duty regarding product design.¹³⁴ The Court determined that procurement decisions by the federal government were discretionary functions under the Federal Tort Claims Act.¹³⁵ Further, the Court held that the procurement of products and services by the federal government was a unique federal interest and, therefore, those who contracted with the federal government to supply these goods and services should also be exempt from liability.¹³⁶ Without such protection, when state standards and federal product-design requirements differed, federal contractors would be forced to choose between complying with the requirements of state law or designing their products according to the specifications provided by the federal government.¹³⁷ This conflict would adversely affect the procurement process because if government contractors were subject to liability under state law, they might decline to manufacture a product according to the design specified by the government, or they might raise the price for such products in order to pay prospective design defect claims.¹³⁸

Having concluded that federal contractors should receive some protection from liability under state tort law, the Court adopted the test formulated by the Fourth and Ninth Circuits.¹³⁹ Under this approach, a court should not impose tort liability for design defects in military equipment if: (1) the United States approved reasonably precise specifications for the product; (2) the equipment in question conformed to these specifications; and (3) the military contractor warned procurement officers about any product-related risks known to the supplier but not known to government officials.¹⁴⁰

Safety may not be the primary concern of designers of military hardware. Often, cost is an important consideration, and, therefore, government procurement officers must forego expensive safety features in order to stay within budget. In addition, it is sometimes necessary to reject a safer alternative

134. See *Boyle*, 487 U.S. at 507.

135. *Id.* at 511.

136. *Id.* at 504-06.

137. See *id.* at 509.

138. *Id.* at 507.

139. *Boyle*, 487 U.S. at 512; see also *Boyle v. United Techs. Corp.* 792 F.2d 413, 414 (4th Cir. 1986) (articulating Fourth Circuit test); *McKay v. Rockwell Int'l Corp.*, 704 F.2d 444, 451 (9th Cir. 1983) (articulating Ninth Circuit test).

140. See *Boyle*, 487 U.S. at 512.

because it will adversely affect the performance of the product's military mission. *Sanner v. Ford Motor Co.*¹⁴¹ provides a good illustration of this trade-off between safety and performance. In *Sanner*, the plaintiff was injured when a military jeep in which he was riding was struck by another vehicle.¹⁴² The jeep did not overturn, but the plaintiff was thrown out of the vehicle because it was not equipped with seat belts.¹⁴³ The plaintiff alleged that the jeep was defective because it was manufactured without seatbelts or other restraints.¹⁴⁴ Although the United States Army considered equipping its jeeps with seat belts, it eventually rejected the idea because "when used in certain tactical situations they could compromise the occupants by deterring immediate egress and escape from the vehicle."¹⁴⁵ A New Jersey court ruled in favor of the manufacturer, even though the installation of seat belts would have made the vehicle much safer in most accident situations.¹⁴⁶

The government contractor defense validates the government's decision to accept greater product risk than necessary in order to achieve other objectives. Unfortunately, it also shifts the risk of product-related injuries from those who design and manufacture dangerous products to those who are injured by them.

D. Optional Safety Equipment

The legal rules governing optional safety equipment also allow manufacturers to design and sell products that are not as safe as they could be. Courts and commentators have offered several reasons for allowing manufacturers to provide safety equipment to consumers on an optional basis.¹⁴⁷ First, as a matter of personal autonomy, consumers who have a higher tolerance for risk should be able to purchase products with fewer safety features if they choose, just as they are allowed to engage in

141. 364 A.2d 43 (N.J. Super. Ct. Law Div. 1976).

142. *Id.* at 43-44.

143. *Id.* at 44.

144. *Id.* at 43-44.

145. *Id.* at 44.

146. *See Sanner*, 364 A.2d at 45.

147. *See generally* Richard C. Ausness, *Risky Business: Liability of Product Sellers Who Offer Safety Devices as Optional Equipment*, 39 HOFSTRA L. REV. 807 (2011); James A. Henderson, Jr. & Aaron D. Twerski, *Optional Safety Devices: Delegating Product Design Responsibility to the Market*, 45 ARIZ. ST. L.J. 1399 (2013).

unavoidably risky activities. It follows that consumers should also be able to purchase cheaper versions of a product in order to save money for other purposes. In addition, some consumers may be better risk bearers because they are more intelligent or more skilled, or because they have a greater capacity to spread the risk of injury through insurance. Finally, when a product is designed for multiple uses, the consumer, rather than the manufacturer, will be better able to determine which safety devices are necessary for the consumer's intended use.

Over the years, courts have applied various approaches to decide when a manufacturer should be allowed to offer safety equipment to consumers on an optional basis. A number of early cases avoided any direct consideration of the issue and instead focused on whether the product was defective as sold.¹⁴⁸ *Miller v. Dvornik*¹⁴⁹ illustrates this approach. In *Miller*, the plaintiff was injured when his motorcycle was struck by an automobile.¹⁵⁰ The plaintiff alleged that the motorcycle was defective because it was not equipped with safety crash bars.¹⁵¹ The manufacturer apparently offered crash bars as an option.¹⁵² Affirming the lower court's dismissal of the strict liability claim against the retail seller of the motorcycle, the court declared that the mere availability of optional safety equipment was not relevant to whether the product, as sold, was unreasonably dangerous.¹⁵³

However, other courts have recognized that the availability of optional safety equipment constitutes a defense in some circumstances. For example, in *Rainbow v. Albert Elia Building Co.*,¹⁵⁴ a New York court determined that the purchaser of a motorcycle was in the best position to decide whether to purchase optional side crash bars.¹⁵⁵ The plaintiff, who was injured when he struck a parked car, argued that the motorcycle was defectively

148. See *Pahuta v. Massey-Ferguson, Inc.*, 170 F.3d 125, 135 (2d Cir. 1999); *Nettles v. Electrolux Motor AB*, 784 F.2d 1574, 1578-80 (11th Cir. 1986); *Tannenbaum v. Yale Materials Handling Corp.*, 38 F. Supp. 2d 425, 433 (D. Md. 1999); *Beron v. Kramer-Trenton Co.*, 402 F. Supp. 1268, 1270-71 (E.D. Pa. 1975); *Caterpillar Tractor Co. v. Ford*, 406 So. 2d 854, 857 (Ala. 1981); *Pigliavento v. Tyler Equip. Corp.*, 669 N.Y.S.2d 747, 748-49 (App. Div. 1998); *Coleman v. Cintas Sales Corp.*, 40 S.W.3d 544, 548-49 (Tex. App. 2001).

149. 501 N.E.2d 160 (Ill. App. Ct. 1986).

150. *Id.* at 161-62.

151. *Id.* at 162.

152. *Id.*

153. *Id.* at 163-64.

154. 436 N.Y.S.2d 480 (App. Div. 1981), *aff'd*, 434 N.E.2d 1345 (N.Y. 1982).

155. *Id.* at 483.

designed because the manufacturer failed to provide side crash bars as standard equipment.¹⁵⁶ The court, however, concluded that the consumer's knowledge of the risk was an important factor in determining whether a product is unreasonably dangerous due to its lack of optional, as opposed to standard, safety equipment.¹⁵⁷

Other courts distinguish between single-purpose and multi-purpose products, allowing manufacturers to offer safety devices as options for multi-purpose products, but not for single-purpose products.¹⁵⁸ One of the first cases to adopt this approach was *Turney v. Ford Motor Co.*¹⁵⁹ In *Turney*, the plaintiff, who was injured after being ejected from a tractor, alleged that the tractor was unreasonably dangerous because it was not equipped with a "roll-over protection system," which usually consists of a roll bar and seatbelt.¹⁶⁰ The court observed that the tractor was multi-functional and was sold for use in a variety of workplace environments, some of which had low clearances not suitable for tractors with roll bars.¹⁶¹ Accordingly, the court held that it was proper for the lower court to allow the manufacturer to introduce evidence of the tractor's multi-purpose nature as a factor for the jury to consider in determining whether it was unreasonably dangerous.¹⁶²

A Texas court applied the same approach in *Sears, Roebuck & Co. v. Kunze*.¹⁶³ Therein, the purchaser of a ten-inch radial power saw contended that the saw was defectively designed because it was not equipped with a lower blade guard.¹⁶⁴ The manufacturer claimed that because consumers used the saw to make many different kinds of cuts, it was difficult to design a

156. *Id.* at 481.

157. *Id.* at 482-83.

158. *See, e.g.,* *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 624 (Minn. 1984). This should be distinguished from the situation in which a manufacturer is allowed to sell a multi-purpose product without any safety devices, thereby shifting the responsibility to the buyer to purchase safety devices from another vendor that are appropriate for the product's intended use. *See* *Gordon v. Niagara Mach. & Tool Works*, 574 F.2d 1182, 1190 (5th Cir. 1978); *Bautista v. Verson Allsteel Press Co.*, 504 N.E.2d 772, 775-76 (Ill. App. Ct. 1987). *But see* *Bexiga v. Havir Mfg. Corp.*, 290 A.2d 281, 284-85 (N.J. 1972).

159. 418 N.E.2d 1079 (Ill. App. Ct. 1981).

160. *Id.* at 1082 (internal quotation marks omitted).

161. *Id.* at 1083.

162. *Id.*

163. 996 S.W.2d 416 (Tex. App. 1999).

164. *Id.* at 421-22.

lower blade guard that would protect all users in every case.¹⁶⁵ However, the court was not persuaded by this argument and affirmed the lower court's judgment for the plaintiff.¹⁶⁶

Finally, some courts may opt for the multi-factor analysis first articulated by the New York Court of Appeals in *Scarangella v. Thomas Built Buses, Inc.*¹⁶⁷ and subsequently followed in several other cases.¹⁶⁸ In *Scarangella*, a school bus driver was struck by another school bus that was backing up.¹⁶⁹ The plaintiff maintained that the bus was defectively designed because it was not equipped with a back-up alarm system.¹⁷⁰ The school bus manufacturer offered this device as optional equipment, but the plaintiff's employer declined to purchase it.¹⁷¹ Affirming a lower court judgment in favor of the defendant, the court declared that three factors must be shown to exist before a manufacturer can shift responsibility for making safety decisions to a purchaser: (1) the buyer is knowledgeable about the product and is aware of available safety features; (2) there are some uses for which it is not unreasonably dangerous without the optional safety equipment; and (3) the buyer can balance the risks and benefits of not purchasing the safety device in question, given the buyer's contemplated use of the product.¹⁷² The court found that all of these factors were present and, therefore, held that the bus was not defective.¹⁷³

It is obvious that allowing manufacturers to offer safety devices as optional equipment may lead to a sub-optimal level of product safety for some purchasers. First, consumers may decline to purchase optional safety equipment because they erroneously believe that they can safely encounter the risk. Second, many products are purchased by employers or others who will not

165. *Id.* at 422.

166. *Id.* at 420.

167. 717 N.E.2d 679 (N.Y. 1999).

168. *See, e.g.,* Passante v. Agway Consumer Prods. Inc., 909 N.E.2d 563, 566-67 (N.Y. 2009); Campbell v. Int'l Truck & Engine Corp., 822 N.Y.S.2d 188, 189 (App. Div. 2006); Beemer v. Deere & Co., 794 N.Y.S.2d 253, 254 (App. Div. 2005); Bova v. Caterpillar, Inc., 761 N.Y.S.2d 85, 86-87 (App. Div. 2003); Geddes v. Crown Equip. Corp., 709 N.Y.S.2d 770, 771 (App. Div. 2000).

169. *Scarangella*, 717 N.E.2d at 680.

170. *Id.* at 681.

171. *Id.* at 680.

172. *Id.* at 683.

173. *Id.* at 683-84.

actually use them.¹⁷⁴ By refusing to purchase optional safety equipment, buyers benefit by saving money, but the increased risk of injury falls upon employees or other users.¹⁷⁵

E. Inherently Dangerous Products

Virtually all products are capable of causing harm if they are not used properly.¹⁷⁶ However, there are products that are “inherently hazardous,” even when used properly, “because of their inescapable, generic risks.”¹⁷⁷ Some of these products are dangerous in their natural state, like certain types of mushrooms,¹⁷⁸ or Dasheen root, which is poisonous in its uncooked state.¹⁷⁹ Others, such as butter, bacon, cigarettes, alcoholic beverages, or hamburgers, come from natural products that are processed before being sold to consumers.¹⁸⁰ Finally, there are manufactured products, such as all-terrain vehicles, above-ground swimming pools, and explosives or firearms, which also pose a serious risk of injury to users and bystanders.¹⁸¹

In general, manufacturers are not liable under strict liability principles for selling inherently dangerous products to the public as long as they provide adequate warnings about latent inherent risks.¹⁸² The traditional rationale for this lenient treatment was that inherently dangerous products, when accompanied by appropriate warnings, were not unreasonably dangerous or defective.¹⁸³ This can be traced back to comment i in section 402A of the Restatement (Second) of Torts, which declared that such inherently dangerous products as “[g]ood whiskey,” “[g]ood tobacco,” and “[g]ood butter” were not unreasonably dangerous

174. See James A. Henderson, Jr., *The Constitutive Dimensions of Tort: Promoting Private Solutions to Risk-Management Problems*, 40 FLA. ST. U. L. REV. 221, 252 n.169 (2013).

175. See James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect*, 66 N.Y.U. L. REV. 1263, 1274-75 (1991).

176. David G. Owen, *Inherent Product Hazards*, 93 KY. L.J. 377, 377 (2004).

177. *Id.* at 378.

178. See *Winter v. G.P. Putnam’s Sons*, 938 F.2d 1033, 1033 (9th Cir. 1991).

179. See *Cardozo v. True*, 342 So. 2d 1053, 1054-55 (Fla. Dist. Ct. App. 1977).

180. See Owen, *supra* note 176, at 379.

181. See *id.* at 404 (providing firearms as an example of such a manufactured product).

182. See *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1090 (5th Cir. 1973).

On the other hand, there is no duty to warn about obvious risks or matters of common knowledge. See *Bruner v. Anheuser-Busch, Inc.*, 153 F. Supp. 2d 1358, 1360 (S.D. Fla. 2001); *Pemberton v. Am. Distilled Spirits Co.*, 664 S.W.2d 690, 693 (Tenn. 1984).

183. See Owen, *supra* note 176, at 383-84.

under the Restatement's ordinary consumer expectation test.¹⁸⁴ The Products Liability Restatement has reiterated this approach. For example, comment d to section 2 declares that "[c]ommon and widely distributed products such as alcoholic beverages, firearms, and above-ground swimming pools may be found to be defective only upon proof of the requisite conditions in Subsection (a), (b), or (c)."¹⁸⁵ The comment further states that in the absence of such proof, courts have not imposed liability upon the sellers of such products "even if they pose substantial risks of harm."¹⁸⁶ According to the Products Liability Restatement, this more lenient treatment is justified because legislatures and administrative agencies are better equipped to determine whether any of these inherently dangerous products should be sold to the public.¹⁸⁷

Although most courts have accepted the Restatement's approach, some plaintiffs' lawyers and legal commentators have advocated that the manufacturers of inherently dangerous products be held liable to injured consumers even though their products are not defective. One of the more popular liability theories is known as product category liability.¹⁸⁸ According to this concept, manufacturers can be held liable, even in the absence of a conventional defect, if the accident costs that they generate outweigh the benefits that the public derives from their use or

184. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965).

185. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. d (1998).

186. *Id.*

187. *Id.*

188. See generally Carl T. Bogus, *War on the Common Law: The Struggle at the Center of Products Liability*, 60 MO. L. REV. (1995); John L. Diamond, *Eliminating the "Defect" in Design Strict Products Liability Theory*, 34 HASTINGS L.J. 529 (1983); Ellen Wertheimer, *The Smoke Gets in Their Eyes: Product Category Liability and Alternative Feasible Designs in the Third Restatement*, 61 TENN. L. REV. 1429 (1994); Franklin E. Crawford, Note, *Fit for Its Ordinary Purpose? Tobacco, Fast Food, and the Implied Warranty of Merchantability*, 63 OHIO ST. L.J. 1165 (2002); Michael J. Toke, Note, *Categorical Liability for Manifestly Unreasonable Designs: Why the Comment D Caveat Should Be Removed from the Restatement (Third)*, 81 CORNELL L. REV. 1181 (1996). Several commentators are critical of the theory. See generally Richard C. Ausness, *Product Category Liability: A Critical Analysis*, 24 N. KY. L. REV. 423 (1997); Harvey M. Grossman, *Categorical Liability: Why the Gates Should Be Kept Closed*, 36 S. TEX. L. REV. 385 (1995); Henderson & Twerski, *supra* note 175.

consumption.¹⁸⁹ Although a few courts have endorsed product category liability,¹⁹⁰ most have rejected it.¹⁹¹

By definition, a specific inherently dangerous product has dangerous attributes that cannot be reduced by a safer design or by additional warnings.¹⁹² Therefore, a manufacturer cannot make an inherently dangerous product safer by installing additional safety devices.¹⁹³ Nevertheless, there is another way to reduce the costs to society of such a product. In theory, the imposition of tort liability would increase the price of an inherently dangerous product and, therefore, reduce consumption.¹⁹⁴ Less consumption, in turn, would result in fewer accident costs associated with the products.¹⁹⁵ On the other hand, the present approach, which immunizes the manufacturers of inherently dangerous products, causes the products to be cheaper, increasing consumption and, therefore, increasing product-related injuries.¹⁹⁶ Thus, from a public-policy perspective, relieving the manufacturer of liability for the sale of an inherently dangerous product is analogous to relieving it of the duty to install a safety device.

189. See Toke, *supra* note 188, at 1185.

190. See Halphen v. Johns-Manville Sales Corp., 484 So. 2d 110, 114 (La. 1986) (discussing asbestos); Kelley v. R.G. Indus., 497 A.2d 1143, 1159 (Md. 1985) (discussing handguns); O'Brien v. Muskin Corp., 463 A.2d 298, 306 (N.J. 1983) (discussing above-ground swimming pools).

191. See Kotler v. Am. Tobacco Co., 926 F.2d 1217, 1225 (1st Cir. 1990) (discussing cigarettes), *vacated*, 505 U.S. 1215, *reaff'd on remand*, 981 F.2d 7 (1st Cir. 1992); Roysdon v. R.J. Reynolds Tobacco Co., 849 F.2d 230, 236 (6th Cir. 1988) (discussing cigarettes); Shipman v. Jennings Firearms, Inc., 791 F.2d 1532, 1533-34 (11th Cir. 1986) (discussing firearms); Perkins v. F.I.E. Corp., 762 F.2d 1250, 1274 (5th Cir. 1985) (discussing firearms); Gianitsis v. Am. Brands, Inc., 685 F. Supp. 853, 859 (D.N.H. 1988) (discussing cigarettes); Miller v. Brown & Williamson Tobacco Corp., 679 F. Supp. 485, 489 (E.D. Pa. 1988) (discussing cigarettes), *aff'd*, 856 F.2d 184 (3d Cir. 1988); Gunsalus v. Celotex Corp., 674 F. Supp. 1149, 1159 (E.D. Pa. 1987) (discussing cigarettes); Armijo v. Ex Cam, Inc., 656 F. Supp. 771, 773 (D.N.M. 1987) (discussing firearms), *aff'd*, 843 F.2d 406 (10th Cir. 1988); Richardson v. Holland, 741 S.W.2d 751, 754 (Mo. Ct. App. 1987) (discussing firearms); Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp., 596 A.2d 845, 849 (Pa. Super. Ct. 1991) (discussing alcoholic beverages).

192. Owen, *supra* note 176, at 380.

193. *Id.*

194. See Henderson & Twerski, *supra* note 175, at 1273.

195. James A. Henderson, Jr., *Extending the Boundaries of Strict Products Liability: Implications of the Theory of the Second Best*, 128 U. PA. L. REV. 1036, 1040 (1980).

196. See Raymond E. Gangarosa et al., *Suits by Public Hospitals to Recover Expenditures for the Treatment of Disease, Injury and Disability Caused by Tobacco and Alcohol*, 22 FORDHAM URB. L.J. 81, 104 (1994).

F. Products with Obvious Hazards

At one time, consumers who exposed themselves to obvious product-related risks did so at their own peril.¹⁹⁷ According to the patent danger rule, manufacturers had no duty to eliminate obvious hazards by improving the design of their products.¹⁹⁸ However, some courts criticized the patent danger rule as it related to design defect claims,¹⁹⁹ and it eventually fell out of favor.²⁰⁰ Today, the obviousness of the danger is no longer conclusive in design defect cases; instead, it serves simply as a factor that the jury may take into account in evaluating a product's design.²⁰¹

On the other hand, the vast majority of courts have concluded that there is no duty to warn consumers about risks that are open, obvious, or commonly known.²⁰² Courts have offered various justifications for this rule. In the first place, if a user or consumer of a product is already aware of the risk, a warning would be redundant and serve no useful purpose.²⁰³ In addition, when a risk is obvious, it should follow that failure to warn about it cannot be a cause-in-fact of any injury that results from exposure to the hazard in question. Finally, requiring unnecessary warnings might vitiate the effectiveness of warnings about non-obvious hazards.²⁰⁴

*Glittenberg v. Doughboy Recreational Industries*²⁰⁵ provides a good illustration of how the obvious danger rule affects a manufacturer's duty to warn. In the case, the plaintiffs were severely injured when they dove headfirst into a shallow, above-

197. See *Campo v. Scofield*, 95 N.E.2d 802, 804 (N.Y. 1950); *Bartkewich v. Billinger*, 247 A.2d 603, 605 (Pa. 1968).

198. See 2 DAVID G. OWEN & MARY J. DAVIS, OWEN & DAVIS ON PRODUCTS LIABILITY § 10.2 (4th ed. 2014) (describing the "patent danger" rule).

199. See, e.g., *Pike v. Frank G. Hough Co.*, 467 P.2d 229, 235 (Cal. 1970) (en banc); *Micallef v. Miehle Co.*, 348 N.E.2d 571, 576-77 (N.Y. 1976); *Palmer v. Massey-Ferguson, Inc.*, 476 P.2d 713, 718-19 (Wash. Ct. App. 1970).

200. 2 OWEN & DAVIS, *supra* note 198, § 10.3.

201. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. d (1998).

202. See, e.g., *Abney v. Crosman Corp.*, 919 So. 2d 289, 296 (Ala. 2005); *Johnson v. Am. Standard, Inc.*, 179 P.3d 905, 911-12 (Cal. 2008); *Greene v. A.P. Prods., Ltd.*, 717 N.W.2d 855, 863 (Mich. 2006); *Fitzgerald v. Fed. Signal Corp.*, 883 N.Y.S.2d 67, 67 (App. Div. 2009); see also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. j (1998) (noting the rule).

203. See *First Nat'l Bank & Trust v. Am. Eurocopter Corp.*, 378 F.3d 682, 690 (7th Cir. 2004).

204. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. j (1998).

205. 491 N.W.2d 208 (Mich. 1992).

ground swimming pool.²⁰⁶ Each plaintiff claimed that the product was defective because the manufacturer failed to warn about the risk of paralysis from diving into a shallow pool.²⁰⁷ The court rejected the claims, declaring that the obvious nature of the product's danger served the same function as a warning and, therefore, made an express warning unnecessary.²⁰⁸ Consequently, the plaintiffs could not complain that the manufacturer had failed to warn about this particular danger.²⁰⁹

Despite this reasoning, the obvious danger rule, as it relates to the duty to warn, may lead to a sub-optimal level of safety in some cases. That is because a hazard that is obvious to an ordinary consumer may not be obvious to all consumers. Young children and persons with mental disabilities may not be able to appreciate risks to the same extent as people of greater experience or intelligence. However, these individuals might respond to a warning about such "obvious" risks. By removing any incentive to provide a warning in such cases, the obvious danger rule enables a manufacturer to place a product on the market that is not optimally safe.

G. Used Products

Generally speaking, used products are less safe than new ones. One reason for this is that advances in safety technology virtually ensure that older products will not be designed as well as newer ones. In addition, older products will be less safe than newer ones because of wear and tear and other forms of deterioration.²¹⁰ The effect of aging and obsolescent design is particularly serious in the case of products such as motor vehicles, airplanes, farm equipment, and industrial products like punch presses, which are dangerous even when they are new. Given the fact that used products are likely to be inherently less safe than new products, one might expect courts to encourage accident cost avoidance measures by product sellers by subjecting them to strict liability. However, the opposite is true. Most states have rejected

206. *Id.* at 210.

207. *Id.* at 223.

208. *See id.* at 217-219.

209. *See id.*

210. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 8 cmt. b (1998).

strict liability and instead have subjected product sellers to a less rigorous liability standard such as negligence.²¹¹

*Peterson v. Lou Bachrodt Chevrolet Co.*²¹² exemplifies the majority approach. In the case, two children were struck by a six-year-old motor vehicle while walking home from school.²¹³ One child was killed, and the other was severely injured.²¹⁴ The car was a used vehicle purchased a few months earlier from the defendant car dealer.²¹⁵ The plaintiff alleged that the vehicle was defective for three reasons: (1) “[a] spring or springs in the left front wheel braking system was missing at the time of its sale”; (2) “[o]ne of the left rear brake shoes was completely worn out at the time of the sale”; and (3) “[a] part of the cylinder braking system in the left rear wheel was missing at the time of the sale.”²¹⁶ The trial court dismissed the plaintiff’s strict liability claims, but an intermediate appellate court reversed.²¹⁷

On appeal, the Illinois Supreme Court held that strict liability is not applicable to the sellers of used products when they are outside of the original production and marketing chain.²¹⁸ The court distinguished those who are part of the original marketing chain, such as wholesalers and retailers, from used product sellers.²¹⁹ Unlike wholesalers and retailers, the court reasoned that the sellers of used products had no ability to exert pressure upon manufacturers to increase the safety of their products.²²⁰ Furthermore, the court declared that since the used car dealer in this case did not create the risk, imposing strict liability upon the dealer would make it an insurer for any risks that arose after the

211. See, e.g., *Harber v. Altec Indus., Inc.*, 812 F. Supp. 954, 965 (W.D. Mo. 1993), *aff’d*, 5 F.3d 339 (8th Cir. 1993); *Keith v. Russell T. Bundy & Assocs.*, 495 So. 2d 1223, 1228 (Fla. Dist. Ct. App. 1986); *Grimes v. Axtell Ford Lincoln-Mercury*, 403 N.W.2d 781, 785 (Iowa 1987); *Tillman v. Vance Equip. Co.*, 596 P.2d 1299, 1304 (Or. 1979). But see *Jordan v. Sunnyslope Appliance Propane & Plumbing Supplies Co.*, 660 P.2d 1236, 1241 (Ariz. Ct. App. 1983); *Turner v. Int’l Harvester Co.*, 336 A.2d 62, 70 (N.J. Super. Ct. Law Div. 1975); *Crandell v. Larkin & Jones Appliance Co.*, 334 N.W.2d 31, 34 (S.D. 1983); *Hibbard ex rel Nelson v. Nelson Hardware, Inc.*, 467 N.W.2d 518, 524 (Wis. 1991).

212. 329 N.E.2d 785 (Ill. 1975).

213. *Id.* at 786.

214. *Id.*

215. *Id.*

216. *Id.*

217. See *Peterson v. Lou Backrodt Chevrolet Co.*, 307 N.E.2d 729, 734-35 (Ill. App. Ct. 1974), *rev’d*, 329 N.E.2d 785 (Ill. 1975).

218. See *Peterson*, 329 N.E.2d at 787.

219. *Id.*

220. See *id.*

vehicle left the manufacturer's possession and while it was under the control of one or more consumers.²²¹ The court also rejected the plaintiff's contention that it should impose a duty on used car dealers to inspect their vehicles for defects and to insure against any defects that were not discoverable through a reasonable inspection.²²²

For the most part, the Products Liability Restatement adopts the majority position on this issue.²²³ The drafters set forth a negligence standard as the general liability rule applicable to the sale of used products.²²⁴ Strict liability is imposed only in cases where the seller represents that the product is as safe as a new product,²²⁵ where the product is remanufactured,²²⁶ or where the seller has failed to comply with applicable governmental safety standards.²²⁷

Assuming that a negligence standard does not provide the same safety incentive to merchants that strict liability does, sellers of used products will probably devote fewer resources to inspections and maintenance under a negligence regime. This may very well create a market for used products that are not optimally safe. As Justice Goldenhersh pointed out in his dissent in *Peterson*, the defects in the motor vehicle's braking system probably could have been discovered upon reasonable inspection.²²⁸ Presumably, the used car dealer in the case would have inspected the vehicle more carefully if he were subject to strict liability.

H. Pharmaceutical Products

Pharmaceutical products include chemical drugs, biologics, and medical devices. Chemical drugs are chemical compounds that affect the human body through chemical means.²²⁹ The FDA's regulatory scheme distinguishes between prescription

221. *Id.*

222. *Id.*

223. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 8 (1998).

224. *See id.* § 8(a).

225. *Id.* § 8(b).

226. *Id.* § 8(c).

227. *See id.* § 8(d).

228. *Peterson v. Lou Bachrodt Chevrolet Co.*, 329 N.E.2d 785, 788 (Ill. 1975) (Goldenhersh, J., dissenting).

229. *See* Bryan A. Liang, *Regulating Follow-On Biologics*, 44 HARV. J. ON LEGIS. 363, 367 (2007).

drugs and “over-the-counter” products.²³⁰ As might be expected, prescription drugs are more strictly regulated and may only be sold to patients who have obtained a prescription from their physician.²³¹ Over-the-counter drugs are considered to be less dangerous, but they are still subject to regulation by the FDA.²³² Biologics, such as vaccines and antibiotics, affect the body through biological rather than chemical processes.²³³ They are regulated by the FDA in much the same way as prescription drugs.²³⁴ Medical devices are also subject to regulation by the FDA, which distinguishes between three classes of devices based on the degree of danger posed to the public.²³⁵

From the earliest days of modern products liability, special liability rules have been applied to pharmaceutical products. Various reasons explain this special treatment: (1) the chemical composition of drugs cannot be changed to provide greater safety; (2) their adverse effects cannot always be discovered prior to marketing; (3) they are subject to strict regulation by the FDA; (4) they have very high social utility; and (5) medical practitioners, not ordinary consumers, decide which drugs their patients should take.²³⁶

When the Restatement (Second) of Torts was first promulgated, the drafters declared in comment k to section 402A that “unavoidably unsafe” products were neither unreasonably dangerous nor defective, even though they caused harm, as long as their apparent utility outweighed their apparent risks and proper warnings were given.²³⁷ Although the term “unavoidably unsafe” was left undefined, the drafters provided several

230. See *Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/Resourcesforyou/consumers/QuestionsAnswers/ucm100101.htm> (last updated Sept. 3, 2013).

231. *Id.*

232. *See id.*

233. See Kyle Barrett, Note, *Implementing the Biologics Price Competition and Innovation Act: Why Legal Principles Justify a Broad Definition of Biosimilarity*, 85 S. CAL. L. REV. 1597, 1600-01 (2012).

234. *See id.* at 1608.

235. Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 912 (1994).

236. See Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 210-11 (1999) (noting these justifications).

237. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

examples, all of which involved pharmaceutical products.²³⁸ Most courts and commentators accepted, at least to some degree, this concept of limited liability for pharmaceutical products.²³⁹ However, some courts ruled that all prescription drugs were entitled to automatic class-wide protection from claims of defective design,²⁴⁰ while others were willing to consider whether a drug came within the “unavoidably unsafe” description of comment k on a case-by-case basis.²⁴¹ A few jurisdictions refused to adopt the approach at all.²⁴² However, over the years, courts have characterized a variety of pharmaceutical products as “unavoidably unsafe” and have applied comment k’s provisions to most types of pharmaceutical products, including chemical drugs, antibiotics, vaccines, blood, and medical devices.²⁴³ At the same time, judges refused to extend the principle articulated in comment k to non-medical products such as golf carts or concrete mix.²⁴⁴

In 1998, the drafters of the Products Liability Restatement included a provision that specifically addressed the issue of liability for the manufacturers of pharmaceutical products.²⁴⁵ Section 6(d) subjects pharmaceutical manufacturers to liability for inadequate warnings only if: (1) reasonable warnings are not provided to prescribing physicians or other health care providers who are in a position to reduce the risk of harm or (2) the warnings

238. *See id.*

239. *See* Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Reasoning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1141 (1985).

240. *See, e.g.,* *Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991).

241. *See, e.g.,* *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989); *Toner v. Lederle Labs.*, 732 P.2d 297, 309 (Idaho 1987); *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988).

242. *See, e.g.,* *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 659 (1st Cir. 1981).

243. *See, e.g.,* *Plummer v. Lederle Labs.*, 819 F.2d 349, 356 (2d Cir. 1987) (discussing vaccines); *Swayze v. McNeil Labs., Inc.*, 807 F.2d 464, 468 (5th Cir. 1987) (discussing prescription drugs); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1337-1339 (9th Cir. 1985) (discussing an intrauterine device); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (discussing a cardiac pacemaker); *DeLuryea v. Winthrop Labs.*, 697 F.2d 222, 229 (8th Cir. 1983) (discussing prescription drugs); *Belle Bonfils Memorial Blood Bank v. Hansen*, 665 P.2d 118, 125-26 (Colo. 1983) (en banc) (discussing blood); *Feldman*, 479 A.2d at 383 (discussing antibiotics).

244. *See* *Blevins v. Cushman Motors*, 551 S.W.2d 602, 608 (Mo. 1977) (en banc); *Netzel v. State Sand & Gravel Co.*, 186 N.W.2d 258, 264 (Wis. 1971).

245. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998). The Products Liability Restatement treats manufacturing defects for prescription drugs and medical devices in the same manner as it treats other products. *See* Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 841 (2009).

are not provided to the patient when the manufacturer knows or should know that a health-care provider will not be available to reduce the risk to the patient.²⁴⁶ Section 6(c) declares that a prescription drug or medical device is defectively designed only if its foreseeable risks “are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for *any class of patients*.”²⁴⁷

Comment b to section 6 declares that under section 6(c), “a drug is defectively designed *only* when it provides *no* net benefit to any class of patients.”²⁴⁸ Comment b goes on to state that defective design will be found when “the drug or device ha[s] so little merit compared with its risks that reasonable health-care providers, possessing knowledge of risks that were known or reasonably should have been known, would not have prescribed the drug or device for any class of patients.”²⁴⁹ The comment continues, “a prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients.”²⁵⁰

Needless to say, this approach has proved to be very controversial.²⁵¹ Under this formulation, an injured party cannot prove that a prescription drug or medical device is defectively designed by showing that a safer alternative was available.²⁵² Drug A would not be considered defective even though a competitor, Drug B, was available and had the same therapeutic benefits but had fewer adverse side effects. Under the Products Liability Restatement’s approach, the fact that Drug B was a better product would not mean that Drug A should not also be marketed.

Only a few cases have ruled on this provision, and the results have been mixed. A small number of courts have either expressly

246. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d).

247. *Id.* § 6(c) (emphasis added).

248. *Id.* § 6 cmt. b (emphasis added).

249. *Id.*

250. *Id.*

251. See generally George W. Conk, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market*, 49 UCLA L. REV. 737 (2002).

252. See George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1089 (2000).

adopted section 6(c) or have mentioned it favorably in passing.²⁵³ For example, a federal district court, in *Madsen v. American Home Products Corp.*,²⁵⁴ concluded that Iowa courts would apply section 6(c) in a prescription drug design defect case.²⁵⁵ In the case, the plaintiff alleged that she had contracted valvular heart disease as a result of taking fen-phen for five months.²⁵⁶ She claimed, *inter alia*, that the drug was defectively designed.²⁵⁷ Granting the defendant's motion for summary judgment, the court concluded that the plaintiff had failed to show that no reasonable health-care provider would prescribe the drug for any class of patients.²⁵⁸

In contrast, several courts have rejected the approach of section 6(c) and instead have elected to retain section 402A's comment k formula. *Freeman v. Hoffman-La Roche, Inc.*²⁵⁹ reflects this view. The plaintiff in *Freeman* developed multiple health problems after taking the drug Accutane to treat chronic acne.²⁶⁰ She brought suit against the drug's manufacturer, relying on various theories of recovery.²⁶¹ Her design defect claim alleged that the risks inherent in the drug's design outweighed its benefits.²⁶² A lower court dismissed her suit, and she appealed.²⁶³ In deciding whether to reinstate the plaintiff's design defect claim, the Nebraska Supreme Court had to choose between the comment k and section 6(c) approaches.²⁶⁴ After reviewing some of the criticisms that had been made against section 6(c), the Nebraska court concluded that "recovery would be nearly impossible" under the Product Liability Restatement's approach.²⁶⁵ Instead, the court determined that comment k

253. See, e.g., *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999) (discussing anti-reflux prosthesis); *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1361 n.11 (N.D. Ga. 1999) (discussing a bone-screw device); *Sita v. Danek Med. Inc.*, 43 F. Supp. 2d 245, 256 n.9 (E.D.N.Y. 1999) (discussing a bone-screw device).

254. 477 F. Supp. 2d 1025 (E.D. Mo 2004).

255. *Id.* at 1037.

256. *Id.* at 1028-29.

257. *Id.* at 1029.

258. *Id.* at 1037.

259. 618 N.W.2d 827 (Neb. 2000).

260. *Id.* at 832.

261. *Id.*

262. *Id.* at 833.

263. *Id.* at 832.

264. *Freeman*, 618 N.W.2d at 840.

265. *Id.*

applied to drug-related design defects and held that the plaintiff's design defect claim should go forward on that theory.²⁶⁶

The Products Liability Restatement's approach represents a tradeoff between drug safety and other concerns. One such concern is the need to protect licensing decisions by the FDA from collateral attacks in the form of lawsuits against pharmaceutical companies.²⁶⁷ In addition, it is necessary that new drugs be developed as quickly as possible so they may be made available to the public.²⁶⁸ Although there is some debate about the effectiveness of the FDA's licensing process, there is no doubt that the agency has a high degree of expertise in the area of drug safety.²⁶⁹ For this reason, the courts have shown considerable willingness to shield the FDA's licensing decisions and regulatory policies by preempting certain types of design defect and failure-to-warn suits against drug manufacturers.²⁷⁰ Regulatory compliance statutes in some states also protect FDA decision making—albeit less effectively than federal preemption.²⁷¹

IV. TRADEOFFS BETWEEN PRODUCT SAFETY AND OTHER SOCIETAL OBJECTIVES

As the foregoing discussion suggests, the Product Liability Restatement's risk-utility balancing test allows courts and juries to make tradeoffs between product safety and other considerations, particularly where product design is at issue. In addition, there are a number of specific doctrines that protect manufacturers against liability for the marketing of products that may not be optimally safe. This portion of the article identifies some of the societal objectives that compete with, and sometimes trump, product safety. These social goals include personal autonomy and consumer choice, product cost and performance,

266. *Id.* at 840-41.

267. See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2165 (2000).

268. See Steven Goldberg, *Technology Unbound: Will Funded Libertarianism Dominate the Future?*, 18 STAN. L. & POL'Y REV. 21, 26 (2007) (“[F]aster access to new drugs has been an increasingly popular position for decades.”).

269. See James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151, 162 n.41 (2001).

270. See *Mut. Pharma. Co. v. Bartlett*, 133 S. Ct. 2466, 2476-77 (2013).

271. See 2 OWEN & DAVIS, *supra* note 198, § 14.6.

the protection of product sellers, and the protection of third parties.

A. Personal Autonomy and Consumer Choice

1. *Personal Autonomy*

The principle of personal autonomy assumes that individuals should have the power to make meaningful choices without having to justify them to others.²⁷² The moral right to make such choices is grounded on the unique capacity of human beings to reason and to act according to normative principles.²⁷³ Respect for the right of personal autonomy is deeply rooted in American culture, as well as in American political and legal institutions.²⁷⁴

Risk-taking is an important aspect of the exercise of personal autonomy.²⁷⁵ Risk-seekers are likely to engage in dangerous activities such as hang gliding, bungee jumping, skydiving, or mountain climbing. They also prefer to ride motorcycles without a helmet in states where this is permitted. Risk-avoiders, on the other hand, prefer to live more sedated, and possibly longer, lives. It is important to note, however, that a high tolerance for risk is not necessarily based on emotion alone. In many cases, a risk-seeker may have a well-founded belief that he or she is better able to deal with a particular risk than the average person.²⁷⁶

Product liability law's approach to optional safety equipment is consistent with consumers' autonomy-based right to voluntarily encounter risks.²⁷⁷ Safety equipment adds to a product's cost and may adversely affect its performance or functionality.²⁷⁸ This is particularly true of some of the annoying gadgets found on modern automobiles. It is not surprising, therefore, that some consumers would prefer to do without these features, even though the resulting product is more dangerous

272. See Stephen Gardbaum, *Liberalism, Autonomy, and Moral Conflict*, 48 STAN. L. REV. 385, 395 (1996).

273. See DAVID A.J. RICHARDS, *SEX, DRUGS, DEATH, AND THE LAW* 8 (1982).

274. See Berger, *supra* note 5, at 26.

275. See Mark A. Geistfeld, *The Value of Consumer Choice in Products Liability*, 74 BROOK. L. REV. 781, 782 (2009); see also Christine Hurt, *Regulating Public Morals and Private Markets: Online Securities Trading, Internet Gambling, and the Speculation Paradox*, 86 B.U. L. REV. 371, 372 (2006).

276. See Henderson & Twerski, *supra* note 175, at 1321.

277. Ausness, *supra* note 147, at 823.

278. Geistfeld, *supra* note 275, at 786.

than it would otherwise be.²⁷⁹ Safety is literally optional to the extent that manufacturers are allowed to offer safety features as optional, rather than as standard equipment. In the case of ordinary consumer products, the primary justifications for this rule are personal autonomy and consumer choice.²⁸⁰ Just as individuals are permitted to engage in risky activities, within reason they are allowed to embrace danger by declining to purchase safer products. Personal autonomy is an important interest and the rules concerning optional equipment support this interest by permitting manufacturers to make safety optional as long as they fully disclose to consumers the risks and choices that are available.

The principle of personal autonomy also guides the law's treatment of inherently dangerous products. Many of these products such as cigarettes, fast food, alcoholic beverages, trampolines, all-terrain vehicles, hang-gliders, and above-ground swimming pools are not essential to human welfare. Nevertheless, despite their dangerous character, the principle of personal autonomy suggests that people should be free to purchase them and manufacturers should not be held liable for placing these products into the stream of commerce.²⁸¹ Clearly, society values, or at least tolerates, the public's right to consume or utilize inherently dangerous products and thereby expose themselves to the unavoidable risks associated with them.

Finally, personal autonomy may also support imposing a negligence standard on used product sellers instead of subjecting them to strict liability. If strict liability were imposed on used product sellers, their products would be safer, but more expensive, because of the additional measures the seller would have to take in order to avoid liability.²⁸² On the other hand, imposing a negligence standard on these sellers allows them to sell their goods more cheaply.²⁸³ This in turn enables those consumers who are willing to accept greater risk to purchase a used product instead of paying more for a new, safer one. In other

279. *See id.* at 797.

280. *See id.* at 798.

281. Of course, manufacturers may be liable to injured consumers if they are guilty of fraud or failure to warn, or if they engage in unethical marketing practices.

282. *See* Antonio J. Senagore, *The Benefits of Limiting Strict Liability for Used-Product Sellers*, 30 N. ILL. U. L. REV. 349, 373 (2010).

283. *Id.* at 378.

words, consumers can subject themselves to a greater risk of injury in order to have more money to spend on other things.

2. Consumer Choice

Consumer choice is closely related to personal autonomy because the right to make choices is illusory if there are no meaningful choices available.²⁸⁴ However, consumer choice can also be justified on utilitarian grounds. In order for individuals to allocate resources in a way that maximizes their utility, they must be able to choose from a wide variety of goods and services.²⁸⁵ Producers respond to this demand from consumers by offering a range of products that vary significantly in terms of quality, appearance, performance, convenience, and safety. It follows, therefore, that some products will be safer than others. Motor vehicles provide a good example of this phenomenon. Low-end vehicles typically have fewer safety features than more expensive ones, yet consumers still choose to purchase them.²⁸⁶ On the other hand, risk-adverse individuals are free to purchase a more expensive model that is equipped with such safety devices as anti-lock brakes, rearview cameras, side airbags, blind-spot monitors, and the like.²⁸⁷

Consumer choice may also support the view that consumers should have access to inherently dangerous products, even when safer alternatives are available. An obvious example of this is food and drink. Consumers can choose to eat healthy foods, such as lean meats, whole-grain products, and fruits and vegetables, or they can choose to consume tasty, but less healthy, fare, such as hamburgers, chili dogs, pizza, and sugary soft drinks. Perhaps the same is true of alcoholic beverages, although some might say that iced tea is a poor substitute for a dry martini. In any event, the consumer-choice rationale supports consumers' right to choose

284. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. f (1998) (noting the drafters of the Products Liability Restatement approved of consumer choice in considering the defective design of products).

285. See Richard J. Pierce, Jr., *Encouraging Safety: The Limits of Tort Law and Government Regulation*, 33 VAND. L. REV. 1281, 1283 (1980).

286. See Geistfeld, *supra* note 21, at 123.

287. See Pierce, *supra* note 285, at 1283. By the same token, risk-adverse consumers may prefer to pay for safety features that are not cost-effective from a risk-utility point of view. In the case of big-ticket items like automobiles, there may be a niche market for ultra-safe models for this class of consumers. Wealthy, older consumers are likely a prime demographic for this apparent over-investment in product safety.

whatever products they want, not just products that are good for them.

The practice of allowing manufacturers to offer some forms of safety equipment on an optional basis also ensures that products will be available to a wide range of consumers. Many of these consumers consider some safety features to be unnecessary, inconvenient, or too expensive. Providing safety features as optional, rather than standard, equipment allows consumers to decide which safety features they want or do not want, depending upon their intended use of the product. Finally, the imposition of a negligence standard, instead of strict liability, on the sellers of used products, enables them to sell their goods more cheaply. This provides consumers with more choices by enabling them to purchase cheaper, but less safe, used products if they prefer to do so.

B. Product Cost and Performance

Many of the doctrines discussed above subordinate product safety to some degree in order to achieve lower product cost or better product performance. Product “cost,” in this context, refers to the price that a retail consumer must pay to purchase a particular product. If manufacturers try to achieve greater product safety by equipping their products with safety devices, either because they are required to do so by government regulation or to avoid potential tort liability, they will have to charge more for these products.

Although public policy may support higher prices, in order to lower consumption of some products, such as cigarettes, in most cases it is preferable that prices of consumer goods be lower rather than higher. There are several reasons that society prefers lower-cost goods. First, if product prices are relatively high, poorer consumers will not be able to afford them. Excessively high prices for food and other necessities can cause serious social unrest. Second, in a consumption-oriented economy, the nation’s economic prosperity is dependent on maintaining a healthy level of public consumption. Finally, if safety costs increase the price of a product, consumers may turn to cheaper, but more dangerous, substitutes.²⁸⁸

288. See Henderson, *supra* note 195, at 1040 (noting this tendency).

Increased safety may also affect product availability. When a certain level of safety is required by government regulation or by tort law, manufacturers may simply get out of the market and turn to the production of other products. This apparently occurred some years ago with childhood vaccines²⁸⁹ and general aviation aircraft.²⁹⁰ In both cases, Congress felt compelled to pass legislation encouraging manufacturers to produce these products again.²⁹¹

Sometimes tradeoffs must also be made between product safety and product performance. Product performance is concerned with how well a product performs its intended function. It includes such considerations as efficiency of operation, costs of maintenance and operation, reliability, durability, convenience, and even aesthetics. However, some safety devices significantly impair product performance, such as safety guards on punch presses, radial power saws, or similar products. Likewise, roll-over protection devices and seat belts may also adversely affect the performance and versatility of products such as forklifts, tractors, and farm equipment.

The contract specification defense encourages better product performance by enabling purchasers to obtain custom-designed products without having to accept features, including safety features, they do not want. This not only increases the number of possible options available to purchasers, but it also allows them to decide how much safety they want. Thus, the appropriate level of safety, at least in the case of custom-designed products, is left to the discretion of consumers rather than this being imposed upon them by others. Economic efficiency may also provide some support for the contract specification doctrine because it enables purchasers with superior risk-avoidance skills to avoid having to pay for safety devices that they do not need.

289. See Betsy J. Grey, *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 HARV. J. ON LEGIS. 343, 351 (2011).

290. See Scott David Smith, Note, *The General Aviation Revitalization Act of 1994: The Initial Necessity for, Outright Success of, and Continued Need for the Act to Maintain American General Aviation Predominance Throughout the World*, 34 OKLA. CITY U. L. REV. 75, 77-78 (2009).

291. See National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-2 to -33 (2012); General Aviation Revitalization Act of 1994, 49 U.S.C. § 40101 (1994) (amended 1997).

C. The Protection of Significant Governmental Policies and Interests

In some instances, product safety must be balanced against important governmental policies and interests. These policies and interests are typically expressed or implied in either federal statutes or agency regulations. For example, statutes and regulations may be enacted in order to impose a uniform regulatory standard throughout the country. This approach often reflects a view by Congress or a federal regulatory agency that the economic or administrative benefits of uniform regulatory standards outweigh the marginal benefits of any stricter safety requirements that may be imposed under state law. For example, in *Cipollone*,²⁹² the United States Supreme Court declared that one of the objectives of the 1965 Federal Cigarette Labeling and Advertising Act was to “protect[] the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations.”²⁹³ Thus, the Court concluded that the states could not impose stricter labeling requirements, either by direct regulation or by judicial decision, on cigarette manufacturers.²⁹⁴

Another important regulatory goal is the protection of agency decision-making from second-guessing by juries. This issue has arisen on several occasions in connection with the FDA’s approval of particular warning language on prescription drug labeling. For example, in *Wyeth v. Levine*,²⁹⁵ the defendant drug company argued that the plaintiff’s failure-to-warn claim should be preempted on actual conflict grounds because Congress intended “to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives.”²⁹⁶ Although the Court rejected this argument in *Wyeth*, it has shown a greater willingness to protect the FDA’s decision-making process in other cases.²⁹⁷

The courts have also acknowledged the need to protect the federal government’s design decisions against collateral attacks

292. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

293. *Id.* at 514.

294. *See id.* at 524.

295. 555 U.S. 555 (2009).

296. *Id.* at 573.

297. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011).

by injured military personnel and others. Thus, in *Boyle*,²⁹⁸ the Court invoked the government contractor defense to shield the manufacturer of a helicopter from tort liability when its design had been dictated by procurement officials to meet specific military needs, even though a safer design was possible.²⁹⁹ In the case, the Court expressed concern that manufacturers of military hardware might be deterred from contracting with the government out of fear that they would be subject to damage claims from injured military personnel.³⁰⁰

A fourth federal interest is that of protecting particular economic activities or geographic areas of the country from the adverse effects of aggressive state regulatory action, including the imposition of tort liability on product sellers. This principle was reflected in the Federal Cigarette Labeling and Advertising Act, with which the *Cipollone* majority balanced the public-health objectives against the goal of protecting the tobacco industry and the economic interests of tobacco-producing states from stricter regulation of cigarette labeling by other jurisdictions.³⁰¹ Congress was evidently motivated by similar concerns, as the Court noted in *Geier*,³⁰² when it concluded that a DOT regulation that mandated the gradual introduction of airbags preempted a “no airbag” claim against a car manufacturer by an injured consumer.³⁰³

Finally, the federal government may need to protect its own financial interests at the expense of greater product safety. At least one doctrine, although nominally aimed at protecting product sellers, is actually intended to protect the interests of the federal government, albeit indirectly. The doctrine in question is the government contractor defense. When the government formulates designs and specifications for a product, it is usually not liable to injured parties because of its sovereign immunity.³⁰⁴ However, as the United States Supreme Court pointed out in *Boyle*, the government will be indirectly liable if an accident

298. *Boyle v. United Techs. Corp.*, 487 U.S. 500 (1988).

299. *Id.* at 503, 512. The Court remanded the case to the appellate court for a clarification as to whether the evidence would support a verdict in favor of the defendant since the government contractor defense applied. *Id.* at 513-14.

300. *See id.* at 507.

301. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513-14 (1992).

302. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000).

303. *Id.* at 886.

304. *See Boyle*, 487 U.S. at 511.

victim can sue its contractor, since the contractor will take its potential tort liability into account when it bids on a contract.³⁰⁵ The government contractor defense enables the government to sacrifice safety for other objectives without having to pay more for the products that it orders from private contractors.³⁰⁶ This is particularly significant in military procurement cases because the federal government must often balance safety against cost or military effectiveness when it develops designs for products to meet its military needs.³⁰⁷

D. Protection of Product Sellers

A number of doctrines are intended to provide manufacturers and other product sellers with a safe harbor against claims that their products are not optimally safe. These include federal preemption, the contract specification doctrine, and the regulatory compliance doctrine. One reason to protect product sellers is that massive tort liability may bankrupt them, causing harm to employees, shareholders, creditors, and the communities where these products were produced. The experience of the asbestos industry showed that this risk is not illusory.³⁰⁸ The economic influence of other industries makes them “too big to fail” and, therefore, arguably justifies the creation of doctrines that limit their liability for the sale of products that may be sub-optimally safe. Cigarette companies, firearms manufacturers, and purveyors of fast food are examples of such industries. Finally, courts or legislatures may want to protect product sellers to ensure the availability of essential and highly beneficial products. The special treatment accorded by the Products Liability Restatement to vaccines and prescription drugs reflects this policy.³⁰⁹

305. *Id.* at 511-12.

306. See Mary J. Davis, *The Supreme Court and Our Culture of Irresponsibility*, 31 WAKE FOREST L. REV. 1075, 1093 (1996).

307. See, e.g., *Sanner v. Ford Motor Co.*, 364 A.2d 43, 47 (N.J. Super. Ct. Law Div. 1976) (deferring to the Army’s judgment that seat belts on a vehicle would interfere with its combat effectiveness).

308. See Richard L. Cupp, Jr., *Asbestos Litigation and Bankruptcy: A Case Study for Ad Hoc Public Policy Limitations on Joint and Several Liability*, 31 PEPP. L. REV. 203, 210 (2003).

309. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998).

V. CONCLUSION

The aforementioned doctrines and defenses reflect compromises between optional safety and other interests. In most cases, these compromises appear to be fully justified. Nevertheless, sometimes it might be possible to tweak them a bit to improve the level of product safety without interfering with other important societal interests. For example, if the courts wish to shift the balance in favor of product safety in the case of federal preemption, they could treat the “presumption against preemption”³¹⁰ as a clear-statement rule and refuse to find preemption unless Congress makes its intent to preempt clear.³¹¹ This would lead to fewer products liability cases being preempted, thereby arguably increasing product safety.

By protecting a manufacturer from liability, the contract specification defense provides more leeway to the purchaser to obtain the design features he or she wants.³¹² However, it also creates an externality problem when others, such as employees of the purchaser, are forced to bear the risks associated with unsafe designs. One solution would be to modify the exclusive-remedy rule of workers’ compensation law and allow injured workers to recover against their employers in cases where design specifications provided by the employer are substantially unsafe. A similar negative externality problem exists when employers purchase off-the-shelf equipment for commercial use. When safety equipment is optional, employers may be tempted to save money by declining to purchase safety equipment because they are not exposed to risks associated with placing dangerous products in the workplace. Yet again, the solution may be to restrict the exclusive-remedy rule in such cases.

Turning to the government contractor defense, the requirements set forth in *Boyle* for that doctrine provide a fair degree of assurance that government officials will consciously

310. The presumption against preemption states that the states’ historic police powers should not be superseded by federal legislation unless Congress expresses a clear and manifest purpose to do so. See Mary J. Davis, *The “New” Presumption Against Preemption*, 61 HASTINGS L.J. 1217, 1219 (2010).

311. See Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone*, 92 KY. L.J. 913, 971 (2004); Susan Raeker-Jordan, *The Pre-emption Presumption that Never Was: Pre-emption Doctrine Swallows the Rule*, 40 ARIZ. L. REV. 1379, 1429 (1998).

312. See *Davis v. Henderlong Lumber Co.*, 221 F. Supp. 129, 133-34 (N.D. Ind. 1963).

balance safety considerations against other national interests.³¹³ Nevertheless, a higher level of safety might be achieved if the defense was limited to the procurement of military equipment and not applied to products that are not specifically designed for military use. Of course, this would require the United States Supreme Court to reconsider the *Boyle* decision and shift the rationale of the government contractor defense from the discretionary function doctrine to the *Feres* rule.³¹⁴

In addition, courts could change the obvious hazard rule from a “no duty” rule to one that raises a presumption that a warning is not required in obvious hazard situations. Plaintiffs could then overcome this presumption by proving the existence of special circumstances. In the case of used products, it would be useful for state legislatures or administrative agencies to impose a duty to inspect safety equipment, such as brakes, on certain products.

Due to the heavily regulated nature of prescription drugs and medical devices, tort law can probably do little to increase the safety of these products without unduly infringing upon the FDA’s regulatory authority. However, it may be possible to increase product safety by expediting and simplifying the process of strengthening warning labels in response to new information about product risks that arises after a drug or medical device is approved for marketing by the FDA. In addition, the FDA could require the producers of generic drugs to update their labeling in response to new information about side effects or other product-related risks.

In conclusion, various doctrines and defenses protect manufacturers from liability even though their products are not particularly safe. While this state of affairs would seem to be at odds with the safety goals of modern products liability law, it may in fact be defensible. Safety is a desirable objective, but it is not necessarily an absolute priority. Instead, other values and objectives, such as personal autonomy and consumer choice, product cost, and product performance may trump safety goals.

313. See *Boyle v. United Techs. Corp.*, 487 U.S. 500, 512 (1988).

314. See *Feres v. United States*, 340 U.S. 135, 146 (1950). The Court in *Feres* held that military personnel could not sue the federal government under the Federal Tort Claims Act for service-related injuries. *Id.*; see also Ausness, *supra* note 126, at 990-91 (discussing the rule).

Nevertheless, it may be possible to adjust some of these doctrines and defenses slightly to enhance consumer protection.