
PRESCRIPTION DRUGS AND DESIGN DEFECT LIABILITY: BLANKET IMMUNITY APPROACH TO THE INCREASED COSTS AND UNAVAILABILITY OF PRESCRIPTION MEDICATION

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ABSTRACT

District judges apply three approaches to Section 402A of the Second Restatement of Torts in dealing with prescription drugs and design defect liability: the case-by-case approach, the blanket immunity approach, and the Third Restatement's approach. Given the fundamental disagreements between these three approaches, this Article argues that the blanket immunity approach—employed by the minority of the courts—offers the most consistency, is the most equitable, and is socially and economically beneficial. In doing so, this Article examines the role of the FDA regulatory process in approving prescription drug designs, as well as the proper role of courts in reviewing claims of defectively designed pharmaceutical products. Additionally, this Article argues that the U.S. Supreme Court's growing skepticism of the current state of state tort liability and the recent trend of preempting all state court tort claims, indicates the need for state courts employing the case-by-case approach to adopt the blanket immunity approach instead.

Under the blanket immunity approach, the tort system does not unduly interfere with the FDA's regulatory scheme, and still serves its compensatory role in pharmaceutical liability by allowing for negligence claims. Decisions regarding whether a drug's benefits outweigh its risks are essentially left to those who are better equipped to make those decisions. The blanket immunity approach's preclusion of strict liability also keeps costs associated with litigation at a minimum—leading to lower costs of medication and a greater incentive to innovate.

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Research indicates that the cost of prescription medications in the United States is among the highest in the world—leaving many patients without drugs that they desperately need.¹ Partially due to the increased costs of product liability lawsuits and inconsistent strict liability standards employed by state courts, pharmaceutical companies are progressively raising their prices, pulling products from shelves, or refusing to produce and innovate new and cutting-edge products.² While the U.S. Supreme Court has

1. See Nadia Kounang, *Why Pharmaceuticals Are Cheaper Abroad*, CNN (Sept. 28, 2015), <http://www.cnn.com/2015/09/28/health/us-pays-more-for-drugs/>; Valerie Paris, *Why Do Americans Spend so Much on Pharmaceuticals?*, PBS: NEWSHOUR (Feb. 7, 2014), <http://www.pbs.org/newshour/updates/americans-spend-much-pharmaceuticals/>.

2. See H.R. REP. NO. 104-63, at 9 (1995), <http://www.gpo.gov/fdsys/pkg/CRPT-104hrpt63/html/CRPT-104hrpt63-pt1.htm> (“[B]ecause of liability costs, 36% of American manufacturers have withdrawn products from the world market, 47% have withdrawn products from the domestic market, 39% have decided not to introduce new products, and 25% have discontinued new product research.”); Tomas J. Philipson &

expressed its growing skepticism of state strict liability standards in the form of the preemption,³ most states still allow for strict liability as a common law avenue of redress for design defect products liability claims.⁴ Not only are these standards inconsistent among the states,⁵ but given the adequacy of the FDA review processes for new products,⁶ strict liability does nothing more than serve as a costly and duplicative process adding to the already enormous costs associated with pharmaceutical production.

This Article proceeds in five parts. Part I explains the early history and evolution of strict liability for mass-manufactured products. This Part explores the manner in which courts grapple with the concepts of equity, distribution of costs, and fairness. Part II explores in depth Section 402A of the Second Restatement of Torts and the way that its drafters codified the growing trend by courts to apply strict liability for defectively designed, mass-manufactured products. This Article explains standards adopted by the American Law Institute (ALI) in determining precisely what makes a product “defective,”⁷ as well as comment *k* of that section, which provides a safe harbor from strict liability for “unavoidably unsafe” products.⁸ Part III then offers an overview of the competing theories of what makes a product unavoidably unsafe. While most jurisdictions agree that the unavoidably unsafe exception to strict liability applies only to prescription drugs, courts disagree over whether the safe harbor offers blanket immunity to all prescription drugs, or if it should only protect a select few on a case-by-case basis.⁹ This Article also briefly discusses an alternate approach of the Third Restatement of Torts.¹⁰

Having established the fundamental disagreements between the competing approaches, Part IV argues that the blanket immunity approach—employed by the minority of the courts—offers the most consistency, is the most equitable, and is socially and economically beneficial. In doing so, this Article examines the role of the FDA regulatory

Eric Sun, *Is the Food and Drug Administration Safe and Effective?*, 22 J. ECON. PERSP. 85, 90–93 (2008).

3. See discussion *infra* Part IV.C.
4. See discussion *infra* Part III.
5. See discussion *infra* Part III.
6. See discussion *infra* Part IV.A.
7. See discussion *infra* Part II.A.
8. See discussion *infra* Part II.B.
9. See discussion *infra* Part III.A–B.
10. See discussion *infra* Part III.C.

process in approving prescription drug designs,¹¹ as well as the proper role of courts in reviewing claims of defectively designed pharmaceutical products.¹² Additionally, this Article argues that the Supreme Court's growing skepticism of state tort liability, and its recent trend of preempting all state court tort claims,¹³ indicate the need for state courts employing the case-by-case approach to adopt the blanket immunity approach instead. Part V briefly concludes.

I. EVOLUTION AND HISTORY OF STRICT LIABILITY

The American court system has offered redress for harms done since at the least the nineteenth century. Prior to this, early common law actions such as trespass and trespass on the case offered recovery for the plaintiff and protection from direct invasion to person and property.¹⁴ A showing of negligence was not required, and besides certain immunities and restrictions, people were liable as long as it could be shown that they caused an injury.¹⁵ Negligence, as a distinct basis for recovery of unintentional wrongs, began to develop by the beginning of the nineteenth century, stimulated by the Industrial Revolution and the desire to "limit the scope of liability to some manageable proportions, while at the same time providing a remedy more easily accessible to those harmed."¹⁶

By the mid-nineteenth century, there was a shift back towards the no-fault, strict liability standard, but only for those consumers injured by consumer or industrial products.¹⁷ Plaintiffs were given the opportunity to

11. See discussion *infra* Part IV.A.

12. See discussion *infra* Part IV.B.

13. See discussion *infra* Part IV.C.

14. See PROSSER AND KEETON ON THE LAW OF TORTS 28–30 (W. Page Keeton et al. eds., 5th ed. 1984) [hereinafter PROSSER AND KEETON]. Trespass was a form of action brought to get compensation for the harm done to person, property or relationship with another, while trespass on the case was for injuries resulting out of less direct force. *Id.* at 29; see also BLACK'S LAW DICTIONARY 1642–43 (Bryan A. Garner et al. eds., 9th ed. 2009).

15. See PROSSER AND KEETON, *supra* note 14, at 29–30.

16. Lee S. Kreindler et al., *Development of Negligence Law in the United States*, in 14 N.Y. PRAC. SERIES NEW YORK LAW OF TORTS § 6:2, at 225 (1997); accord PROSSER AND KEETON, *supra* note 14, at 30–31; see also Adam F. Trupp, Comment, *A Step Backwards in Products Liability Law: The Utah Supreme Court and Comment k*, 1992 UTAH L. REV. 101, 101–02 (1992).

17. Alex Grant, *The Evolution of Massachusetts Products Liability Law and the Conundrum of Strict Liability*, 33 W. N. ENG. L. REV. 1, 13–14 (2011).

sue under a strict liability standard based on a contract theory of warranty.¹⁸ Under this “breach of warranty theory,” a seller providing goods warranted that the goods would be suitable and safe for use.¹⁹ However, these plaintiffs were immediately confronted with the privity requirement, which required that the plaintiff show a contractual relationship with the defendant.²⁰ Stemming from the case of *Winterbottom v. Wright*,²¹ this rule effectively shielded contractors, manufacturers, and vendors from actions by ultimate consumers or remote third parties because of the lack of privity.²²

Courts began to establish exceptions to the privity requirement if a manufacturer failed to give notice when it knew a product to be imminently dangerous to life and limb.²³ Inherently dangerous products, such as gunpowder, nitroglycerine, and poisonous drugs were also excepted from the privity requirement, and third parties were able to sue manufacturers for negligently made products.²⁴ Yet, it was not until the beginning of the nineteenth century that courts realized a need for a totally new standard of liability in products liability cases. In 1916, The New York Court of Appeals in *MacPherson v. Buick Motor Corp.*²⁵ was the first to terminate the privity requirement entirely.²⁶ Judge Cardozo, writing for the court, broadened the privity exception to encompass not only products that were inherently or imminently dangerous, but to any product which “[wa]s reasonably certain to place life and limb in peril when negligently made.”²⁷ In effect, “The MacPherson case caused the exception to swallow the asserted general rule

18. *Id.*

19. PROSSER AND KEETON, *supra* note 14, at 690; *see also* Trupp, *supra* note 16, at 102–03.

20. Trupp, *supra* note 16, at 103.

21. *See* *Winterbottom v. Wright* (1842) 152 Eng. Rep. 402, 405.

22. Kennard Neal, *Development of Georgia Product Liability Law*, in GA. PRODUCTS LIABILITY LAW § 1:1, at 1 (4th ed.).

23. *See, e.g.*, *Huset v. J.I. Case Threshing Mach. Co.*, 120 F. 865, 872–73 (8th Cir. 1903) (holding that a manufacturer who has knowledge that an article is imminently dangerous to life and limb but fails to give notice of such qualities is liable to third parties who are injured, even though not in privity with the purchaser); *Thomas v. Winchester*, 6 N.Y. 397, 409–10 (1852) (establishing exception to the privity requirement if negligence produces an article imminently dangerous to human life or health); *see also* Trupp, *supra* note 16, at 103–04.

24. *See, e.g.*, *Lebourdais v. Vitrified Wheel Co.*, 80 N.E. 482, 483 (Mass. 1907); *Curtin v. Somerset*, 21 A. 244, 245 (Pa. 1891).

25. *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916).

26. *See* *Grant*, *supra* note 17, at 6–7.

27. *MacPherson*, 111 N.E. at 1053.

of non-liability, leaving nothing upon which that rule would operate.”²⁸ Other high-level courts soon took notice of the New York standard and terminated the privity requirement altogether as an essential component in a negligence cause of action.²⁹

Although negligence remained the primary standard in cases involving defective products, evidentiary problems of proving actual negligence lingered.³⁰ In an attempt to address these issues, implied warranties became the primary basis for recovery in products liability actions.³¹ Initially limited to cases of food or drink,³² and subsequently expanded to automobiles in *Henningsen v. Bloomfield Motors, Inc.*,³³ the breach of these implied warranties ensured that sellers “would be strictly liable for the safety of his product even though he had exercised all reasonable care.”³⁴ Nevertheless, significant obstacles remained for plaintiffs, who were required to prove that they relied on a warranty, that they were injured as a direct result of that reliance, and that they gave notice of the defect within a reasonable time.³⁵ Even without the privity requirement, “consumers continued to lose cases that—based on the equities—they should have won.”³⁶

Differing trends eventually culminated in the 1963 decision of *Greenman v. Yuba Power Products, Inc.*, in which Justice Traynor, writing for the California Supreme Court, held that strict liability—and not contract theory—would, from now on, govern products liability cases.³⁷ The

28. PROSSER AND KEETON, *supra* note 14, § 96, at 683 (quoting *Carter v. Yardley & Co.*, 64 N.E.2d 693, 700 (Mass. 1946)).

29. Grant, *supra* note 17, at 7; Trupp, *supra* note 16, at 104.

30. See PROSSER AND KEETON, *supra* note 14, at 681–89 (discussing negligence as it applied to product liability cases).

31. See *id.* at 690–91. Subsequent to 1913 courts used many different theories in products liability cases. See *id.* Negligence, express warranties, and fraud were often used, but were ultimately not helpful to plaintiffs. See *id.*

32. See *Mazetti v. Armour & Co.*, 135 P. 631, 632–33 (1913).

33. See *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 84 (N.J. 1960).

34. Neal, *supra* note 22, at 3.

35. Trupp, *supra* note 16, at 104.

36. *Id.* (citing F. VANDALL, STRICT LIABILITY 8 (1989)).

37. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900–01 (Cal. 1963); see also Eric Lindenfeld & Jasper L. Tran, *Strict Liability and 3D-Printed Medical Devices*, YALE J.L. & TECH. BLOG (2015), <http://yjolt.org/blog/2015/12/11/strict-liability-and-3d-printed-medical-devices> (discussing strict liability for 3D printing as envisioned by Justice Traynor). For more discussion on 3D printing, see Jasper L. Tran, *Press Clause and 3D Printing*, 14 NW. J. TECH & INTELL. PROP. 75, 78 (2016); Jasper L. Tran, *To*

Greenman court held that “[t]o establish the manufacturer’s liability it was sufficient that plaintiff proved that he was injured while using the [product] in a way it was intended to be used as a result of a defect in design and manufacture of which plaintiff was not aware that made the [product] unsafe for its intended use.”³⁸ This ruling gained widespread acceptance and was echoed in section 402A of the Second Restatement of Torts only two years later.³⁹

II. SECTION 402A OF THE SECOND RESTATEMENT OF TORTS

Section 402A of the Second Restatement of Torts⁴⁰ codified the modern rule of strict product liability and was eventually adopted by many state courts in the country.⁴¹ It is now the standard.⁴² In relevant part, Section 402A provides that a seller is strictly liable for physical harm to person or property caused by a “product in defective condition unreasonably dangerous to the user or consumer or to his property.”⁴³ These sellers can be held liable as long as they “engaged in the business of selling such a product” and the product reached the consumer “without substantial changes in the condition in which it [was] sold.”⁴⁴ This rule applies even though the seller has exercised all reasonable care.⁴⁵ However, like the negligence cause of

Bioprint or Not to Bioprint, 17 N.C. J.L. & TECH. 123, 133–35 (2015); Jasper L. Tran, *The Law and 3D Printing*, 31 J. MARSHALL J. INFO. TECH. & PRIVACY L. 505, 505–08 (2015); Jasper L. Tran, *Patenting Bioprinting*, HARV. J.L. & TECH. DIG. (2015), <http://jolt.law.harvard.edu/digest/patent/patenting-bioprinting>.

38. *Id.* at 901.

39. See RESTATEMENT (SECOND) OF TORTS § 402A (1965); see also Richard W. Wright, *The Principles of Product Liability*, 26 REV. LITIG. 1067, 1068 (2007) (“Almost twenty years later, in 1963, Traynor’s rationales and position were ratified and adopted in an opinion that he wrote for a unanimous court in *Greenman v. Yuba Power Products, Inc.* The *Greenman* opinion was a catalyst for the adoption of strict product liability, based on the same rationales, in Restatement Second section 402A . . .”).

40. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

41. See, e.g., *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425 (2d Cir. 1969) (noting the Connecticut Supreme Court had adopted § 402A as the standard for strict liability); *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966) (adopting the § 402A standard); see also PROSSER AND KEETON, *supra* note 14, at 694 (noting most jurisdictions recognize some form of strict liability in product liability cases); Wright, *supra* note 39 (“[Section 402A] was rapidly adopted by most states in the United States and greatly influenced the adoption of product liability laws in other countries.”).

42. See Wright, *supra* note 39, at 1068.

43. RESTATEMENT (SECOND) OF TORTS: STRICT LIABILITY § 402A(1) (1965).

44. *Id.* § 402A(1)(a)–(b).

45. *Id.* § 402A(2)(a).

action, causation is still an essential element that the plaintiff must prove under the strict liability regime.⁴⁶

A. What Is a Defect?

Initially, courts struggled over what constituted a “defect,”⁴⁷ but eventually, the courts acknowledged three types of product defects: manufacturing flaws,⁴⁸ inadequate warnings,⁴⁹ and design defects.⁵⁰ Manufacturing flaws are those that result from an error in the manufacturing processes that make a product more dangerous than it was designed to be.⁵¹ Liability is imposed on products sellers for manufacturing flaws even in the exercise of due care because they are in the best position to control production flaws.⁵² Inadequate warnings are defects that the manufacturer failed to warn of in a product “whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product.”⁵³ For design defects, courts generally use one of two basic standards, or some combination of them. There is the “consumer expectations” test, which assesses “whether the design meets the safety expectations of users and consumers,” and the “risk-utility” test, which assesses “whether the safety benefits of designing away a foreseeable danger

46. See, e.g., *Bockrath v. Aldrich Chem. Co.*, 74 Cal. Rptr. 2d 774, 779 (Cal. Ct. App. 1998) (citations omitted) (plaintiff must prove there is a “connection between injuries and a defendant’s conduct” under any tort theory), *rev’d on other grounds*, 980 P.2d 398 (Cal. 1999); *Lovick v. Wil-Rich*, 588 N.W.2d 688, 700 (Iowa 1999) (citing *Spaur v. Owens-Corning Fiberglass Corp.*, 510 N.W.2d 854, 858 (Iowa 1994)) (noting a plaintiff in a products liability action is required to establish causation between negligence and injury); *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 107 (Nev. 1998) (citing *Price v. Blaine Kern Artista, Inc.*, 893 P.2d 367, 369 (Nev. 1995)) (a plaintiff must establish causation both under negligence and strict liability).

47. See *Wright*, *supra* note 39, at 1068–69.

48. See, e.g., *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 672 (Ga. 1994) (naming manufacturing defects as one of three general categories of product defect).

49. See, e.g., *Greiner v. Volkswagenwerk Aktiengesellschaft*, 540 F.2d 85, 90–92 (3d Cir. 1976) (recognizing strict liability for failure to warn as an independent avenue to impose liability, distinct from liability for design defect, manufacturing defect, or negligence).

50. See, e.g., *Banks*, 450 S.E.2d at 672 (identifying design defects as one of the three categories of product defect).

51. See *Wright*, *supra* note 39, at 1072–73 (discussing construction defects).

52. John Riper, Note, *Strict Liability in Hybrid Cases*, 32 STAN. L. REV. 391, 394–95 (1980).

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

exceed the resulting costs.”⁵⁴

B. Comment k and the Safe Harbor for “Unavoidably Unsafe” Products

Section 402A reflects the drafters’ desire to eliminate the plaintiff’s burden of showing negligence in design, recognizing that industries manufacturing these products are better able to bear the costs of these injuries.⁵⁵ However, comment *k* to the section reflects the drafters’ alternative desire to “insulate . . . products that ought not be subject to such sweeping liability because their unique utility justifies their availability, even in the face of recognized dangers.”⁵⁶ Essentially, comment *k* recognizes the vulnerabilities that Section 402A imposes upon the pharmaceutical industry: namely, that it will prevent the industry from adequately providing beneficial products for harmful ailments, out of fear of lawsuits and risky liability.⁵⁷ Comment *k*, in relevant part, states that there are certain products that are “unavoidably unsafe,” and that strict liability will not apply to the sale of these products so long as its utility outweighs its apparent risks and a proper warning is given.⁵⁸ “Since all of the examples enumerated in comment *k* involve pharmaceutical products, one may reasonably conclude that the drafters [were concerned primarily of the harmful consequences on the pharmaceutical companies producing] drugs, vaccines, and similar products.”⁵⁹ Additionally, since the comment speaks of products that are “properly prepared” with “proper directions and warning,”⁶⁰ courts have interpreted the comment as applying only to allegations of design defect and not manufacturing and warning defects.⁶¹

While comment *k* does not define the term “unavoidably unsafe,” it does give a number of examples, which courts have used as guidance.⁶² The

54. See David G. Owen, *Design Defects*, 73 MO. L. REV. 291, 299 (2008).

55. David S. Torborg, Comment, *Design Defect Liability and Prescription Drugs: Who’s in Charge?*, 59 OHIO ST. L.J. 633, 634 (1998).

56. *Id.* at 635.

57. *Id.*

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

59. Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?* 78 KY. L.J. 705, 713–14 (1990).

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

61. See *Toner v. Lederle Labs.*, 732 P.2d 297, 309–10 (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, 781–83 (R.I. 1988).

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

first example is the Pasteur vaccine, which is a vaccine that ensures protection against contracting rabies, a “disease . . . which invariably leads to a dreadful death.”⁶³ Even in the face of “high degree of risk” of “very serious and damaging consequences” of injection of the vaccine, the comment acknowledges that the marketing and use of the vaccines, like “many other drugs, vaccines, and the like,” are fully justified.⁶⁴ The comment acknowledges “new or experimental” drugs are potentially dangerous because “lack of time and opportunity for sufficient medical experience” prevent the manufacturer from providing any assurance of safety.⁶⁵ The comment indicates that in both these examples, the seller of the “useful and desirable product[s]” should not be held strictly liable for “unfortunate consequences attending their use.”⁶⁶

III. COMPETING APPLICATIONS OF COMMENT *K*

While most courts have accepted the general reasoning behind comment *k*,⁶⁷ there is disagreement as to which pharmaceutical products actually deserve the characterization of being an “unavoidably unsafe product.” Courts have employed one of three tests in determining the scope of comment *k* application. First is the “case-by-case” approach, which holds that protection for prescription drugs must be determined on a case-by-case basis, so that some prescription drugs deserve protection from strict liability, while others do not.⁶⁸ The second is the “blanket immunity” approach, which holds that all drugs that are approved by the FDA are immune from the strict liability regime of Section 402A.⁶⁹ Finally, the Third Restatement approach allows strict liability only if no reasonable health care provider, knowing all

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *See supra* note 41 and accompanying text.

68. *See, e.g.,* Hill v. Searle Labs., 884 F.2d 1064, 1068–69 (8th Cir. 1989) (holding that comment *k* is best supported by a case-by-case approach); Weiss v. Fujisawa Pharm. Co., No. 5:05-527-JMH, 2006 WL 3533072, at *3 (E.D. Ky. Dec. 7, 2006) (agreeing with the majority position that the case-by-case analysis is better supported by the language of comment *k*); Freeman v. Hoffman–La Roche, Inc., 618 N.W.2d 827, 836, 840 (Neb. 2000) (“The majority of jurisdictions that have adopted comment *k* apply it on a case-by-case basis . . .”).

69. *See, e.g.,* Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 90 (2d Cir. 1980); Brown v. Superior Court, 751 P.2d 470, 482–83 (Cal. 1988); McKee v. Moore, 648 P.2d 21, 24 (Okla. 1982); Grundberg v. Upjohn Co., 813 P.2d 89, 95 (Utah 1991); Young v. Key Pharm., Inc., 922 P.2d 59, 64 (Wash. 1996).

the foreseeable therapeutic risks and benefits, would prescribe them to any class.⁷⁰

A. *The Case-by-Case Approach*

The earliest case that cites the case-by-case approach is *Kearl v. Lederle Laboratories*.⁷¹ In *Kearl*, a four-month-old developed paralysis due to an adverse reaction from a polio vaccine.⁷² The court, in addressing the strict liability claims made by the plaintiffs, concluded that a drug would be considered “unavoidably unsafe” under the comment *k* exception so long as

(1) . . . the product was intended to provide an exceptionally important benefit that made its availability highly desirable; (2) . . . the then-existing risk posed by the product was both “substantial” and “unavoidable”; and (3) . . . the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability⁷³

If so, the product was deemed unavoidably dangerous and exempted from strict products liability design defect analysis.⁷⁴ Two years later, in *Toner v. Lederle Laboratories*, Idaho proposed a more refined version of the *Kearl* test when it held that a drug manufacturer was required to prove at trial on a case-by-case basis that: (1) the benefits of the drug outweighed the risks at the time of marketing, (2) no feasible alternative with a lesser risk was available, and (3) the drug was accompanied by adequate warnings.⁷⁵ *Toner* points to the language of comment *k*, indicating that it was not intended to apply to all drugs.⁷⁶ Rather, it was intended “when the situation calls for it.”⁷⁷ To imply that all drugs are “unavoidably unsafe” under the meaning of comment *k* would imply that “all drugs are so perfectly designed that they cannot be made more pure or more safe . . . [and that] the benefits of all drugs necessarily outweigh their risks.”⁷⁸

These courts assert that comment *k* was meant to distinguish “between

70. RESTATEMENT (THIRD) OF TORTS § 6(c) (1998).

71. See *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463–64 (Cal. Ct. App. 1985).

72. *Id.* at 456.

73. *Id.* at 464.

74. *Id.*

75. *Toner v. Lederle Labs.*, 732 P.2d 297, 305–06 (Idaho 1987).

76. See *id.* at 308.

77. *Id.* at n.11 (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965)).

78. *Id.* (citations omitted).

drugs which have an enormously profound impact on society's health and drugs which merely make life more convenient."⁷⁹ Furthermore, proponents point to the defeated proposal to provide a blanket immunity approach to all pharmaceuticals at the ALI meeting when Section 402A and comment *k* were adopted.⁸⁰

Currently, this is the most preferred approach to comment *k*, and most courts have chosen to evaluate each pharmaceutical product on a case-by-case basis.⁸¹ In most jurisdictions today, comment *k* immunity will only apply if the risks posed by the drug were unavoidable,⁸² and if the benefits of the drugs outweighed the known risks.⁸³ Additionally, the product seller also must warn about known risks and will be held strictly liable if it fails to do so.⁸⁴ It is important to note, however, that there are almost as many different standards for applying these elements in the case-by-case approach as there are jurisdictions that employ this approach.⁸⁵

B. The "Blanket Immunity" Approach

A small minority of courts, fearing the lack of uniformity and predictability to the case-by-case approach, have employed the "blanket immunity" approach, establishing blanket immunity for pharmaceutical products so long as the FDA has approved them.⁸⁶ The courts that employ this approach maintain that providing blanket immunity to all pharmaceutical drugs will lessen the exposure of pharmaceutical companies to large-scale judgments, which cause disincentives to research and develop

79. *Id.* at 640–41.

80. *See Hill v. Searle Lab.*, 884 F.2d 1064, 1069 (8th Cir. 1989) ("The drafters of comment *k* did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability. Such an exception was proposed at the American Law Institute meeting where section 402A and comment *k* were adopted, but this proposal was defeated." (citing 38 AM. LAW INST. PROC. 19, 90–98 (1961))).

81. *See Torborg*, *supra* note 55, at 639.

82. *See* Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Reasoning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1140–41 (1985) (discussing unavoidability requirement of comment *k*).

83. *See Toner*, 732 P.2d at 306 (articulating that comment *k* contemplates the risk/benefit analysis).

84. *See, e.g., Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 654 (1st Cir. 1981); *Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290 (7th Cir. 1972) (noting that comment *k* limits the duty to warn to risks that were scientifically knowable when the product was sold).

85. *See infra* note 115 and accompanying text.

86. *See Torborg*, *supra* note 55, at 641.

new drugs.⁸⁷ Additionally, these courts have argued that the FDA regulatory scheme, rather than the courts, provides a better arena for determining whether a drug's benefits outweigh its risks.⁸⁸ Essentially, these courts hold that the public interest in the development of prescription drug products requires the consumer of the product to bear all the costs of injury associated with the drug product.⁸⁹ Interestingly, the courts that employ this approach concede that the blanket immunity approach runs directly against the language of comment *k*, but runs parallel to its overall policy goals.⁹⁰

California, in *Brown v. Superior Court*, was the first jurisdiction to formally adopt the blanket immunity approach.⁹¹ In *Brown*, mothers were injured after consuming diethylstilbestrol (DES), marketed as a morning sickness cure, while pregnant.⁹² They sued for the injuries they incurred.⁹³ In its ruling, the court found that the public interest of discovery and marketing of medications would be gravely affected with the imposition of a strict liability regime.⁹⁴ Instead, they deferred to negligence as the most appropriate forum to seek damages.⁹⁵ The court in *Brown* addressed the case-by-case approach employed by other jurisdictions, ultimately finding that it would create a degree of uncertainty amongst manufacturers, lead to inconsistent results, and increase costs of doing business.⁹⁶ These increased costs would come in the form of additional expenses of defending against lawsuits and increasing insurance prices,⁹⁷ which would subsequently be passed on to consumers, harming the public interest in obtaining life-saving products by "plac[ing] the cost of medication beyond the reach of people who need it the most."⁹⁸

87. See, e.g., *Brown v. Superior Court*, 751 P.2d 470, 479 (Cal. 1988).

88. See, e.g., *Grundberg v. Upjohn Co.*, 813 P.2d 89, 97 (Utah 1991).

89. See *id.* at 96.

90. *Id.* at 95.

91. *Brown*, 751 P.2d at 477; *Torborg*, *supra* note 55, at 641.

92. *Brown*, 751 P.2d at 473.

93. *Id.*

94. *Id.* at 477, 479.

95. See *id.* at 477.

96. *Id.* at 479, 481–82.

97. *Id.* at 479.

98. *Id.* The court's argument that extreme liability exposure for vaccines leads to high costs of litigation and difficulty in obtaining adequate insurance has been the bedrock of many state blood shield statutes. See, e.g., *Glass v. Ingalls Mem'l Hosp.*, 336 N.E.2d 495, 498 (Ill. Ct. App. 1975). This is because many blood disorders are rare, but the people afflicted with them require constant infusions. See, e.g., *Rogers v. Miles Labs.*,

Utah's *Grundberg v. Upjohn Co.*, decided only three years after the *Brown* decision,⁹⁹ remains the bedrock upon which all subsequent jurisdictions refer when justifying their blanket immunity approach.¹⁰⁰ *Grundberg* involved a woman who, in a stupor, killed her mother after ingesting Halcion, a drug marketed for depression, anxiety, and insomnia.¹⁰¹ The plaintiff sued in part based on defective design, alleging that the drug was unreasonably dangerous under the meaning of Section 402A.¹⁰² The court ruled that the drug was protected by "the principle" of comment *k*, "that manufacturers of unavoidably dangerous products should not be liable for a claim of design defect."¹⁰³ The court acknowledged certain reasons for adopting blanket immunity from strict liability for all prescription medications.¹⁰⁴ First, it addressed not only the issue of increased costs of drugs passed onto consumers as a result of litigation,¹⁰⁵ but the increased costs of health care generally if those drugs fail to be manufactured.¹⁰⁶ "A ten-dollar prescription is frequently a substitute for \$2,000 worth of hospital services—a substitute that produces a positive outcome with much higher frequency than hospital care. . . . If we are serious about minimizing costs, our best bet is to increase the number of drug innovations."¹⁰⁷ Second, the

802 P.2d 1346, 1351 (Wash. 1991) ("It would be unrealistic to expect such a small number of hemophiliacs to be able efficiently to spread the costs associated with liability insurance.").

99. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 91–94 (Utah 1991).

100. See, e.g., *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002); see also Torborg, *supra* note 55, at 642.

101. *Grundberg*, 813 P.2d at 90.

102. *Id.*

103. *Id.* at 95.

104. *Id.* ("[A]ll prescription drugs should be classified as unavoidably dangerous in design because of their unique nature and value, the elaborate regulatory system overseen by the FDA, the difficulties of relying on individual lawsuits as a forum in which to review a prescription drug's design, and the significant public policy considerations noted in *Brown*.").

105. *Id.* at 96. For a discussion on pharmaceutical litigation, see Jasper L. Tran, *Timing Matters: Prior Art's Age Infers Patent Nonobviousness*, 50 GONZ. L. REV. 189, 207–08 (2015); compare Jasper L. Tran, *Software Patents: A One-Year Review of Alice v. CLS Bank*, 97 J. PAT. & TRADEMARK OFF. SOC'Y 532, 539–42 (2015) (discussing the current landscape for software patents). For a discussion of FDA's regulation of drugs, see generally Jasper L. Tran & Derek Tri Tran, *(De)Regulating Neuroenhancement*, 37 U. LA VERNE L. REV. 179, 186–91 (2015).

106. *Grundberg*, 813 P.2d at 95–96.

107. *Id.* at 96 (quoting Yale Brozen, *Statements, in DRUGS AND HEALTH: ECONOMIC ISSUE AND POLICY OBJECTIVES* 305 (Robert B. Helms ed., 1981)).

court pointed to the extensive screening process that the FDA employs to protect consumers from harmful and dangerous products.¹⁰⁸ Third, the court addressed the fact that the FDA approval process, and not the court, is the proper forum to ascertain whether the risks inherent in a drug outweigh its benefits.¹⁰⁹

Pennsylvania has also adopted the view that strict liability should not apply to design defect claims for prescription medications.¹¹⁰ Although recent Pennsylvania decisions echo the policy considerations of Utah's *Grundberg* decision,¹¹¹ the state is not short, historically, in its hesitance to hold drug manufacturers strictly liable for drug design.¹¹² Early on in pharmaceutical liability, the court demonstrated this reluctance by holding that “the making and selling” of prescription drugs “would be a most pecuniarily hazardous enterprise” if liability attached any time a drug caused “harmful results.”¹¹³ Other courts cautioned that expanding liability to drug manufacturers would “fatally choke the industry in its marketing and development procedures.”¹¹⁴ One court noted that “[i]t is illusory to believe the public does not pay for tort recoveries, or that resources for such are limitless.”¹¹⁵ Courts and litigants have relied on the guidance of these courts for years; as a result, there has been no strict liability prescription drug design defect claim litigated in the Pennsylvania appellate courts.¹¹⁶ Washington is also among those courts concluding that comment *k* applies to all prescription medications.¹¹⁷

108. *Id.*

109. *Id.* at 97.

110. *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996).

111. *See, e.g., Hahn v. Richter*, 628 A.2d 860, 870–71 (Pa. Super. Ct. 1993) (Cavanaugh, J., concurring).

112. *See, e.g., Henderson v. Nat'l Drug Co.*, 23 A.2d 743, 748 (Pa. 1942); *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 458 (Pa. Super. Ct. 1973).

113. *Henderson*, 23 A.2d at 743.

114. *Leibowitz*, 307 A.2d at 458.

115. *White v. Weiner*, 562 A.2d 378, 385 (Pa. Super. Ct. 1989) (quoting *Steiner v. Bell Tel. Co.*, 517 A.2d 1348, 1357 (Pa. Super. Ct. 1986) (en banc)).

116. The most recent court cases in Pennsylvania have grappled with the question as to whether comment *k* blanket immunity should bar claims of negligence as well. *Lance v. Wyeth*, 85 A.3d 434, 450–53, 461–62 (Pa. 2014) (holding comment *k* does not protect manufacturers under a negligent theory of liability).

117. *See, e.g., Ruiz-Guzman v. Amvac Chem. Corp.*, 7 P.3d 795, 803 (Wash. 2000); *see also Young v. Key Pharm., Inc.* 922 P.2d 59, 64 (Wash. 1996) (“[A] separate determination of whether a product is unavoidably unsafe need not be made on a case-by-case basis if that product is a prescription drug.” (citing *Pollard v. Ashby*, 793 S.W.2d

C. *The Third Restatement's Approach*

The American Law Institute, mindful of the split among the courts, sought to address the issue in the Third Restatement of Torts.¹¹⁸ Unlike the Second Restatement, the drafters of the Third Restatement included a separate section that expressly addresses the liability imposed upon the sellers of pharmaceutical and medical products in Section 6(c).¹¹⁹ The Third Restatement's position allows liability for defective design only if no reasonable health care provider knowing all the foreseeable therapeutic risks and benefits would prescribe the drugs to any class of practices.¹²⁰ Specifically:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device 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.¹²¹

Although facially similar to the case-by-case, risk and utility approach, 6(c) is actually significantly more restrictive.¹²² Instead of an overall assessment of whether the product's risks outweigh its overall benefits to all potential patients, courts are to look to whether the drug has therapeutic benefits that outweigh the dangers for any class of patients.¹²³ Interestingly, this "near immunity" standard essentially precludes liability for drug manufacturers, because there is hardly a circumstance where a drug has no net benefit to at least some class of patients.¹²⁴ Under the Third Restatement, a prescription drug that would seriously injure a large class of patients, but confer a sufficient benefit to minority class of patients, would not be defective.¹²⁵

This "near-immunity" approach of the Third Restatement is strikingly

394 (Mo. App. 1990); *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989)).

118. See Torborg, *supra* note 55, at 644.

119. See RESTATEMENT (THIRD) OF TORTS § 6(c) (AM. LAW INST. 1998).

120. *Id.*

121. *Id.*

122. See Torborg, *supra* note 55, at 646.

123. See RESTATEMENT (THIRD) OF TORTS § 6(c) (AM. LAW INST. 1998); Torborg, *supra* note 55, at 646.

124. Torborg, *supra* note 55, at 646.

125. See *id.*

similar to the blanket immunity approach in that both place profound reliance on the FDA regulatory process to review adequately for defective and dangerous designs.¹²⁶ While the Third Restatement contains no explicit exemption from FDA approval, one would be hard-pressed to find a scenario in which the FDA approves a prescription medicine that does not have some net benefit for a class of patients.¹²⁷ A plaintiff injured by a prescription medicine has the burden to prove that despite FDA approval, no health care provider, knowing all foreseeable risks and benefits, would prescribe that particular drug for any class of patients.¹²⁸

IV. WHY STATES SHOULD ADOPT THE BLANKET IMMUNITY APPROACH

A. The FDA Regulatory Scheme is an Adequate Gatekeeper

While the case-by-case approach may seem more appealing because it appears to offer a more individualized determination of each drug's utility versus its dangers, juries are the improper forum to make that determination.¹²⁹ Juries are often exposed to only the narrow focus of the trial and are unable to process the larger picture of "public health questions, such as whether the benefits of the medication to a broad class of people outweigh its risks."¹³⁰ Indeed, many studies and scholarly articles point to the inherent weaknesses of juries in dealing with scientific evidence.¹³¹ In contrast, the FDA *is* equipped to handle exactly that type of analysis and those types of balancing questions.¹³² The FDA approval process is significant, with rigorous testing done over the course of many years, and

126. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b.

127. See Torborg, *supra* note 55, at 646.

128. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c).

129. See, e.g., *Lance v. Wyeth*, 85 A.3d 434, 444 (Pa. 2014); Torborg, *supra* note 55, at 655 ("[J]ury verdicts in DPT cases illustrate[] the contention . . . that juries are not the appropriate forum to make design defect determinations.").

130. Brief of Amicus Curiae the Product Liability Advisory Council, Inc. In Support of Appellant Wyeth at 19, *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014) (Nos. 17 EAP 2011, 18 EAP 2011), 2011 WL 6987088.

131. See, e.g., generally KENNETH R. FOSTER & PETER W. HUBER, *JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS* 207–24 (MIT Press, 1997); PETER W. HUBER, *GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM* 3 (Basic Books, 1991).

132. See Veronica S. Jae, Note, *Simplifying FDASIA: The "Fast Track" to Expedited Drug Approval Efficiency*, 66 ADMIN. L. REV. 173, 177–79 (2014); Torborg, *supra* note 55, at 650.

some taking up to a decade.¹³³

Currently, as of 2014, the process is as follows: A company that is seeking to gain FDA approval for a new drug must first file an investigational new drug application (IND) with the FDA.¹³⁴ The IND is required to contain extremely detailed information and reports regarding all animal and non-clinical testing performed on the drug.¹³⁵ Physicians, pharmacologists, chemists, microbiologists, and statisticians review all laboratory testing, including pharmacology and toxicology reports.¹³⁶ Only once the FDA sees and approves this report can clinical trials on human begin.¹³⁷ Even passing this part of the approval process is extremely difficult.¹³⁸ In fact, estimates suggest “for every five thousand [active pharmaceutical ingredients] screened, only five will proceed to clinical testing, and only one will eventually be approved by the FDA.”¹³⁹ Once trials on humans begin, the process is split into three phases—each phase often taking several years.¹⁴⁰ Each phase involves an increased number of human subjects, and only after all phases are completed may a New Drug Application (NDA) be submitted to the FDA for final review.¹⁴¹ This process can also take several years, and many drugs are often denied in this stage of approval.¹⁴² Essentially, the

133. See Jae, *supra* note 132 (“When a new chemical entity is discovered, it must go through the FDA approval process to reach the public. This highly expensive process can take well over a decade due to the rigorous standards a new drug must meet.” (citing PETER BARTON HUTT, ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 577 (3d ed. 2007))); Torborg, *supra* note 55, at 650–52; SUSAN THAUL, CONG. RESEARCH SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 2–8 (2012) (explaining FDA processes and procedures).

134. *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA.GOV, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm> (last updated Nov. 06, 2014) [hereinafter *The FDA’s Drug Review Process*].

135. See 21 U.S.C.A. § 355(b)(1) (West 2015); *Investigational New Drug (IND) Application*, FDA.GOV, <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm> (last updated Oct. 27, 2014).

136. See 21 U.S.C.A. § 355(n)(3)(b) (West 2015); 21 C.F.R. § 56.107 (2015); see also THAUL, *supra* note 133, at 5.

137. Jae, *supra* note 132, at 177; *The FDA’s Drug Review Process*, *supra* note 134.

138. Jae, *supra* note 132, at 178.

139. *Id.*

140. *Id.*; *The FDA’s Drug Review Process*, *supra* note 134.

141. Jae, *supra* note 132, at 178; *The FDA’s Drug Review Process*, *supra* note 134.

142. See Torborg, *supra* note 55, at 652 (citing Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: The Need for Reform*, 17 AM. J.L. & MED. 363, 378 n.90 (1991)).

FDA decides whether the potential risks associated with the drug outweigh the potential benefits.¹⁴³ Of course, this information is unavoidably incomplete, as some adverse reactions are unable to be discovered until it has been on the market for many years.¹⁴⁴ Thus, the FDA maintains postmarket regulations even after approval.¹⁴⁵ Under these regulations, the manufacturer must report all instances of adverse drug reactions to the FDA, regardless of whether the physician, the manufacturer, or others believe the reaction to be drug-related.¹⁴⁶ Furthermore, the FDA retains “the ability to revoke approval upon new evidence of risks, to request changes in labeling, and to issue a risk evaluation and mitigation strategy, all in the interest of consumer safety.”¹⁴⁷

Critics of the blanket immunity approach pose that drug manufacturers are “profit-seeking corporations. Strong monetary incentives have, on occasion, led to falsifying test results and lying to the FDA regarding potential adverse side effects.”¹⁴⁸ These critics assert the state tort system offers the ability for injured consumers to access alternate methods of analysis.¹⁴⁹ However, with the large amount of money at stake in the pharmaceutical business, there will always be risks associated with bribery and corruption.¹⁵⁰ This also holds true with any judge or jury, who are not immune from the lure of large financial compensation for their

143. See *New Drug Application (NDA)*, FDA.GOV, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalsApplications/NewDrugApplicationNDA/> (last updated Feb. 03, 2015).

144. Bruce N. Kuhlik et al., *The Adverse Effects of Standardless Punitive Damage Awards on Pharmaceutical Development and Availability*, 45 FOOD DRUG COSM. L.J. 693, 696 (1990).

145. See Jae, *supra* note 132, at 179 (citing 21 U.S.C.A. § 355(e), (o) (West 2015)); THAUL, *supra* note 133, at 8.

146. See 21 C.F.R. § 314.80(c) (2015). Applicants must report any “adverse drug experience.” *Id.* An adverse drug experience is “[a]ny adverse event . . . whether or not considered drug related.” *Id.* § 314.80(a).

147. Jae, *supra* note 133, at 179.

148. See Yvonne M. Driessen, Note, *A Case-by-Case Approach to Determining Strict Liability in Prescription Drug Cases*, 67 TEMP. L. REV. 883, 898 (1994) (footnotes omitted).

149. See, e.g., Janet Fairchild, Annotation, *Liability of Manufacturer or Seller for Injury or Death Allegedly Caused by Failure to Warn Regarding Danger in use of Vaccine or Prescription Drug*, 94 A.L.R.3d 748, § 2(a) (West 2015).

150. See Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), www.bbc.com/news/business-28212223 (noting five pharmaceutical companies made a profit margin of 20 percent or more in 2013).

cooperation.¹⁵¹ Furthermore, “the incidents of fraud on the FDA are, on any view, few and far between.”¹⁵² The remote possibility of fraud occurring during the FDA approval process should not be the reason to undermine an FDA regulatory scheme, which is most capable and equipped to analyze the totality of risks and benefits of a drug.¹⁵³ On the other hand, a jury “sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”¹⁵⁴ Furthermore, the assertion by many courts that “tort liability encourages manufacturers to make safer products,”¹⁵⁵ is certainly untrue. As evidenced from the extensive FDA review process, the design of a particular drug is already as safe as can possibly be while retaining maximum effectiveness.¹⁵⁶

B. *Imposition of Strict Liability Causes Increased Prices and Dissuades Innovation*

Like the case-by-case, risk and utility approach employed by the majority of courts,¹⁵⁷ all companies within the pharmaceutical industry undergo a risk versus benefit analysis of their own when deciding to procure a product or to keep it on the market.¹⁵⁸ The possibility of facing multiple

151. See Martha Neil, *Ex-Judge Gives up Law License After Taking Plea in Federal Bribery Case over Jury Verdict*, ABA J. (Apr. 17, 2105), http://www.abajournal.com/mobile/article/ex_judge_gives_up_law_license_after_taking_plea_in_bribe_case_over_jury_ver; Ann W. O’Neill, *Bribed Jurors Get 5 Years In Prison*, SUN SENTINEL (Jan. 15, 2004), http://articles.sun-sentinel.com/2004-01-15/news/0401141376_1_jurors-gloria-alba-bribe-prison.

152. Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT L. 5, 13 (2006).

153. See *Grundburg v. Upjohn Co.*, 813 P.2d 89, 97 (Utah 1991).

154. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008).

155. Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus A Negligence Approach*, 63 GEO. WASH. L. REV. 76, 104 (1994) (citing *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1177 (5th Cir. 1988)).

156. *The FDA’s Drug Review Process*, *supra* note 134; see also *How Drugs are Developed and Approved*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm> (last updated Aug. 18, 2015).

157. See Richard L. Cupp Jr., *Preemption’s Rise (and a Bit of a Fall) as Products Liability Reform: Wyeth, Riegel, Altria, and the Restatement (Third)’s Prescription Product Design Defect Standard*, 74 BROOK. L. REV. 727, 741–42 (2009) [hereinafter Cupp, *Preemption’s Rise*].

158. Brett Hauber et al., *Risk-Benefit Analysis Methods for Pharmaceutical Decision-Making-where are we now?*, ISPOR CONNECTIONS 3–4 (Dec. 15, 2006).

claims under a variety of jurisdictions employing different legal standards is factored into the analysis, and as a result, the product will be procured and sold at a higher price to offset costs of potential litigation, or they will choose not to market it at all.¹⁵⁹

There is no question that the rising prices of pharmaceuticals in the United States is leaving a significant portion of the population without access to pharmaceutical drugs that they need.¹⁶⁰ Additionally, in response to the high prices of drugs, many of these people are increasingly importing cheaper medications from foreign sources, which are not subject to the same regulations and review process as medications sold in the United States.¹⁶¹ The safety of these drugs is questionable, as they are not subject to any form of FDA approval.¹⁶² In fact, a 2001 Congressional study found that the large amounts of drugs that had been re-imported into the United States have created health and safety risks to American consumers.¹⁶³

Comparisons between the U.S. and Canadian tort systems and the respective prices of pharmaceutical products within those countries indicate a clear need for jurisdictions to employ a blanket immunity approach in an attempt to remedy this disparity. Canada does not have strict liability for pharmaceutical products and relies on a negligence standard instead.¹⁶⁴ Recently, a sample of 121 of the most commonly prescribed drugs in the United States found that they are on average “43 percent higher in [the U.S.] than in Canada.”¹⁶⁵ Although there are other distinctions between both

159. STEVEN GARBER, RAND CORPORATION, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS xi, 6–7 (2013), <http://www.rand.org/pubs/monographs/MG1259.html>.

160. See, e.g., Elizabeth Rosenthal, *The Soaring Cost of a Single Breath*, N.Y. TIMES, http://www.nytimes.com/2013/10/13/us/the-soaring-cost-of-a-simple-breath.html?_r=0 (finding the high costs of asthma medication causes patients to go without).

161. Natalie J. Tanner, Note, *Understanding the Disparity in Availability of Prescription Drugs in the United States: Compromise May Be the Answer*, 2 IND. HEALTH L. REV. 267, 279 (2005) (citing Jennifer Rak, Note, *An Rx for Reform: A Medicare Prescription Drug Benefit*, 12 HEALTH MATRIX 449, 449 (2002)).

162. *Id.*; see also HHS TASK FORCE ON DRUG IMPORTATION, DEP’T. OF HEALTH AND HUM. SERVICES, REPORT ON PRESCRIPTION DRUG IMPORTATION 11 (2004), <http://archive.hhs.gov/importtaskforce/Report1220.pdf>.

163. See HHS TASK FORCE, *supra* note 162, at 13–14.

164. See Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & ECON. 203, 207–08 (1997).

165. *Id.* at 204.

countries' health care systems, experts believe that liability costs are the most important factor for the price differences.¹⁶⁶ This should come as no surprise. A well-known wave of lawsuits in the 1980s regarding diphtheria-pertussis-tetanus and polio vaccines directly led to a price increase of more than 6,000 percent, prompting many producers to pull the product from the market,¹⁶⁷ and Congress to pass the National Childhood Vaccine Injury Act of 1986.¹⁶⁸ Another less-known example is the case of the anti-nauseant Benedictin.¹⁶⁹ While the FDA continues to regard the drug as safe, and highly effective in treating nausea for pregnant women, the producer pulled it from the market entirely rather than defend the safety of the product in state tort suits.¹⁷⁰ Benedictin is not alone. "The sole manufacturer of Wydase, a treatment for I.V. infiltration, stopped production and left patients without a comparable alternative treatment."¹⁷¹ Similarly, patients who relied on the drug Oculinum to treat eye muscle spasms are now without its benefits after the drug's clinical testing stopped because of difficulty of obtaining affordable liability insurance.¹⁷² Indeed, excessive tort liability not only leads to increased prices for consumers, but also to increased private costs for manufacturers, driving individual manufacturers of multi-source drugs, and entire product lines, out of the market.¹⁷³ This often leads to the unavailability of drugs for classes of patients in dire need of them.¹⁷⁴

166. *Id.* at 206 ("Removing the effects of liability risk . . . reduce[d] the mean and median to 35.5 and 32.6 percent, respectively.").

167. Keith N. Hylton, *The Law and Economics of Products Liability*, 88 NOTRE DAME L. REV. 2457, 2481 n.100 (2013) (citing Richard L. Manning, *Changing Rules in Tort Law and the Market for Childhood Vaccines*, 37 J.L. & ECON. 247, 273 (1994)).

168. See James R. Copland, *Administrative Compensation for Pharmaceutical- and Vaccine-Related Injuries*, 8 IND. HEALTH L. REV. 275, 284 (2011).

169. Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 760–61 (2003).

170. See *id.*; see also *Brown v. Superior Court*, 751 P.2d 470, 479 (Cal. 1988) ("Bendectin, the only antinauseant drug available for pregnant women, was withdrawn from sale in 1983 because the cost of insurance almost equalled [sic] the entire income from sale of the drug. Before it was withdrawn, the price of Bendectin increased by over 300 percent." (citing 132 CHEMICAL WEEK 14 (June 12, 1983))).

171. See Paula Jacobi, *Pharmaceutical Tort Liability: A Justifiable Nemesis to Drug Innovation and Access?*, 38 J. MARSHALL L. REV. 987, 991 (2005).

172. *Id.*

173. See Noah, *supra* note 169, at 760.

174. See *id.* at 760–61 (noting Bendectin as the example of how a drug's withdrawal from the marketplace left an "unmet therapeutic need for pregnant women suffering from severe nausea, which could result in weight loss and dehydration that sometimes necessitated hospitalization").

Jurisdictions employing the case-by-case approach run the risk of stifling innovation for new, state-of-the-art products for classes of patients who are in dire need of new solutions.¹⁷⁵ Instead of investing over a billion dollars into research for new products, pharmaceutical companies often decide that it is unprofitable, and that it is better to avoid the uncertainty of litigation than to run the risk of enormous losses.¹⁷⁶ This holds true especially in cases where the drug is designed to benefit a healthy class of patients, such as children or pregnant women.¹⁷⁷ This is because those patients can easily blame “future ailment, regardless of actual cause, on the use of the drug.”¹⁷⁸ Indeed, the president of a major pharmaceutical company once commented: “Who in his right mind . . . would work on a product today that would be used by pregnant women?”¹⁷⁹

*C. Recent Trend of Preemption Causes Uncertainty and Inconsistency
Within States Applying Case-by-Case Approach*

Most importantly, the Supreme Court’s recent trend of upholding federal preemption of state common law doctrines on strict liability and pharmaceuticals indicates the futility of continuing with the case-by-case approach. Upholding federal preemption, especially with regard to generic drug products, indicates a clear desire of the Supreme Court to return to a more restrictive approach to prescription product design defect claims.¹⁸⁰ A finding of liability after expensive litigation and lengthy jury deliberations using the risk and utility approach chances on eventually being preempted by federal law.¹⁸¹ For example, in the recent case of *Mutual Pharmaceutical Co. Inc. v Bartlett*, the Supreme Court ruled that a federal law that prevented the ability of the defendant to limit its risk of liability should preempt the risk and utility, case-by-case balancing inquiry.¹⁸² In that case, a woman was severely disfigured and nearly blinded by a generic form of an anti-

175. Joseph F. Petros III, *The Other War on Drugs: Federal Preemption, the FDA, and Prescription Drugs After Wyeth v. Levine*, 25 NOTRE DAME J.L. ETHICS & PUB. POL’Y 637, 661 (2011).

176. *Id.*

177. *Id.*

178. *Id.* (citing PETER W. HUBNER, *LIABILITY THE LEGAL REVOLUTION AND ITS CONSEQUENCES* 155 (1990)).

179. *Id.* (quoting HUBNER, *supra* note 178, at 155).

180. See Cupp, *Preemption’s Rise*, *supra* note 157, at 756.

181. See *id.*; see also *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013).

182. *Mut. Pharm. Co.*, 133 S. Ct. at 2480.

inflammatory drug.¹⁸³ In its deliberations of design defect, the jury engaged in the risk and utility approach employed by New Hampshire.¹⁸⁴ In New Hampshire's risk and utility analysis for design defect,¹⁸⁵ the court balances the drug's usefulness, feasibility of alternative design, and presence and efficacy of a warning.¹⁸⁶ Because the possibility of a safer, alternative design was unfeasible, the allegations that the defendant's warning label was inadequate "featured prominently at trial."¹⁸⁷ However, federal law prohibited the pharmaceutical company from independently changing their labels, and as such, Mutual Pharmaceutical Company (the defendant) claimed that it was unable to take remedial action required to avoid liability under New Hampshire state law.¹⁸⁸ Justice Alito, writing for the Court, ruled that New Hampshire's common law duty of making sure one's product is on the positive side of the balancing inquiry, is preempted by the federal provision disallowing the changing of the label on a generic drug.¹⁸⁹

183. *Id.* at 2472.

184. *See id.* at 2490 (Sotomayor, J., dissenting).

185. "[T]he case-by-case approaches followed by courts are themselves divergent. 'There are almost as many different standards for applying comment *k* as there are jurisdictions that take this approach.'" Michael J. Wagner & Laura L. Peterson, *The New Restatement (Third) of Torts—Shelter from the Product Liability Storm for Pharmaceutical Companies and Medical Device Manufacturers?*, 53 *FOOD & DRUG L.J.* 225, 232 (1998) (quoting Carla Powers Herron & Kelli L. DeGeeter, *Can Texas Escape the Unavoidably Unsafe Medicine of Comment *k* by Adopting Section 8 of the Proposed Restatement of Torts?*, 49 *BAYLOR L. REV.* 73 (1997)).

186. *Mut. Pharm. Co. Inc.*, 133 S. Ct. at 2475.

187. *Id.*

188. *Id.* at 2476.

189. *Id.* Following the lead of the Supreme Court, many district courts have also asserted that design defect claims are often preempted by the FDCA. *See, e.g.,* *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1104 (D. Or. 2013); *see also* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011) (holding state law imposed duties which are prohibited by federal law are preempted under the FDCA); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 186 (5th Cir. 2012) (citations omitted) ("Post-*Mensing*, however, a seeming majority of federal district courts to consider other state-law tort claims have found them to be preempted based on the fact that the plaintiffs' claims are failure-to-warn claims under different names. In addition, other [district] courts have specifically held plaintiffs' design defect claims against generic metoclopramide manufacturers to be preempted based on *Mensing*."). It is also quite possible that we should see in coming years the beginning of preemption by brand-name manufacturers, as courts have not yet delineated the FDCA's precise preemptive scope. *See* Caitlin Sawyer, *Duty of "Sameness"? Bartlett Preserves Generic Drug Consumers' Design Defect Claims*, 54 *B.C. L. REV. E-SUPP.* 1, 3–8 (2013).

Bartlett is not alone, as similar analysis had been applied in earlier court cases involving preemption of state common law duties on design defects.¹⁹⁰ In *Riegel v. Medtronic*, a similar situation involving design defects of medical devices, the Supreme Court affirmed that a state's common law duty regarding design defects was expressly preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetics Act.¹⁹¹ Justice Scalia, writing for the court, was forthright with his growing skepticism of the reliability of American tort law when he "argue[d] that tort liability under negligence or strict liability is 'less deserving of preservation' in the presence of federal regulation than are state statutes or state regulations."¹⁹² It has been suggested that this very skepticism is an important factor in preemption's rise, and "even when courts are using the language of preemption doctrine, they may, to some extent, be seeking to reform products liability litigation."¹⁹³

The growing trend by the Supreme Court and the lower federal courts to preempt state common law doctrines relating to strict liability in design defects implicates a high degree of inconsistency and uncertainty for drug manufacturers within case-by-case jurisdictions.¹⁹⁴ This also holds true with plaintiffs—who do not always work within a contingency agreement with their attorney and who personally invest significant amounts of money in products liability cases.¹⁹⁵ A blanket immunity approach for all jurisdictions would ensure that pharmaceutical companies—along with injured litigants—can to some extent, predict the verdict of a case and better prepare for the costs of litigation or otherwise.

190. See, e.g., *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008).

191. *Id.* at 330.

192. Cupp, *Preemption's Rise*, *supra* note 157, at 741; accord *Riegel*, 552 U.S. at 325.

193. Cupp, *Preemption's Rise*, *supra* note 157, at 729.

194. See Stacey Allen Carroll, *Federal Preemption of State Products Liability Claims: Adding Clarity and Respect for State Sovereignty to the Analysis of Federal Preemption Defenses*, 36 GA. L. REV. 797, 798–99 (2002) (citations omitted) ("In recent years, the Supreme Court altered its analysis on several occasions, yielding many split and plurality opinions. The Court's most recent venture into the area [of federal law preemption] indicates that it remains sharply divided on the issue. Furthermore, defendants arguing a state tort claim is preempted by a federal statute have varying degrees of success depending on which state or federal court hears their case. Some of these lower courts have expressly noted their difficulty and confusion in applying the somewhat inconsistent and abstruse precedent handed down by the high Court.").

195. See J. Michael Robinson et al., *Impact of Product Liability Issues on Innovation* 32 CAN.-U.S. L.J. 263, 264 (2006).

D. *The Third Restatement Goes Too Far*

As previously discussed, Section 6(c) of the Third Restatement allows for liability for drug and prescription device designs only if a reasonable prescription health care provider, knowing the therapeutic risks and benefits would not prescribe them to *any* class of patients.¹⁹⁶ Additionally, under the Third Restatement, the burden of proving that a medical device is not reasonably safe lies with the plaintiff.¹⁹⁷ Indeed, this is a “very demanding objective standard,” in which “liability is likely to be imposed only under unusual circumstances.”¹⁹⁸ Like the blanket immunity approach, the Third Restatement effectively prevents most plaintiffs from being successful in strict liability design defect claims, because one would be hard-pressed to find a scenario in which the FDA approves a prescription medicine that does not have some net benefit for a class of patients.¹⁹⁹ Additionally, like the blanket immunity standard, the Third Restatement places great faith on the FDA regulatory scheme, and not the courts, to prevent dangerous and defective pharmaceutical products from reaching consumers.²⁰⁰ Commentators have indicated that the Third Restatement is less of a “restatement” of the current state of the common law as it is an endorsement of the blanket immunity approach employed by a minority of the courts.²⁰¹

The Third Restatement’s approach is undoubtedly a step up from the case-by-case approach in that it dissuades much of the duplicative litigation and protects pharmaceutical companies from many of the costs associated with that litigation. However, the Third Restatement’s approach is even more restrictive than the blanket immunity approach in that it excludes negligence as a distinct and available avenue of liability.²⁰² Indeed, notes

196. See discussion *supra* Part III.C.

197. Wagner & Peterson, *supra* note 185, at 229.

198. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f (AM. LAW INST. 1998).

199. See Torborg, *supra* note 55, at 646; Cupp, *Preemption’s Rise*, *supra* note 155, at 733.

200. Cupp, *Preemption’s Rise*, *supra* note 157, at 757 (citing RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmts. b, f (AM. LAW INST. 1998)).

201. See Mark D. Shifton, *The Restatement (Third) of Torts: Products Liability - the ALI’s Cure for Prescription Drug Design Liability*, 29 FORDHAM URB. L.J. 2343, 2347 (2002).

202. Compare *Lance v. Wyeth*, 85 A.3d 434, 451–52 (Pa. 2014) (employing blanket immunity approach and allowing a claim of negligent design), and *Toner v. Lederle Labs.*, 732 P.2d 297, 310 (Idaho 1987) (employing the case-by-case approach, the court held that even when exception from strict liability for unavoidably unsafe products

confirm that Section 6(c) provides the new Restatement's "exclusive basis" for a cause of action based on objective drug design.²⁰³ In other words, "whether the case is brought under negligence or strict liability, a plaintiff would be successful only if it could make out the elements set forth in [Section] 6(c)."²⁰⁴ In their eagerness to promote the laudable public policy goals of cheap medication and the stimulation of innovation, the drafters of the Third Restatement effectively preclude any injured litigant who has been adversely affected by a drug from receiving compensation.

The drafters of the Third Restatement should be commended for recognizing the inconsistency of the case-by-case approach and for attempting to reform pharmaceutical liability. However, by essentially barring all avenues of redress for injured litigants, the Third Restatement is unfaithful to the values of equity and fairness upon which the tort system is founded. Recently, the Pennsylvania Supreme Court echoed a similar sentiment when it refused to extend blanket immunity to pharmaceutical manufacturers for the negligence cause of action.²⁰⁵ Pennsylvania, one of the few jurisdictions that employs the blanket immunity approach,²⁰⁶ still recognizes the inherent unfairness of precluding plaintiffs from pleading negligence: "We appreciate that negligent design-defect claims implicate policies favoring access to beneficial medicines and guarding against unduly deterring prescription-drug manufacturers from developing new drugs. This, of course, must be balanced against the right to a remedy . . ."²⁰⁷ In other words, by barring all avenues of redress, the Third Restatement goes too far. The blanket immunity approach employed by the Pennsylvania Supreme Court is a good middle ground between the strict liability available in the case-by-case approach and the Third Restatement's "near immunity" standard for prescription product designs. The blanket immunity approach

applies, plaintiff may still allege negligence), *and* *Brown v. Yamaha Motor Corp.*, U.S.A., 691 P.2d 577, 579–80 (Wash. Ct. App. 1984) (employing blanket immunity approach, court acknowledges that rejection of strict liability theory does not foreclose a finding of negligence), *with* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f (AM. LAW INST. 1998).

203. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f (AM. LAW INST. 1998).

204. *Id.*

205. *See Wyeth*, 85 A.3d at 455.

206. *Id.* at 443 n.11 (citing *Torborg*, *supra* note 55, at 638–43).

207. *Id.* at 455 (citing PA. CONST. art. I, § 11); *cf.* Jasper L. Tran, *A Primer on Digital Rights Management Technologies*, in *DIGITAL RIGHTS MANAGEMENT* (Catherine Lemmer & Carla Wade eds., 2016) (discussing remedy in digital rights management).

allows for negligence liability when there is a failure to exercise due care, but does not tolerate strict liability because it imposes too high of a cost upon society in the form of increased prices and lack of innovation.

V. CONCLUSION

Long-departed Chief Justice Roger Traynor of the California Supreme Court, a fierce proponent of strict liability as the appropriate mechanism to balance the interests of consumers and manufacturers,²⁰⁸ could not have possibly envisioned the present state of pharmaceutical litigation. In many areas, strict liability, as a mechanism for redressing those adversely affected by manufactured products, has positive effects on public welfare and safety. However, holding pharmaceutical manufacturers strictly liable for injuries allegedly caused by their products distributes costs of anticipated or actual litigation in the form of increased prices and lack of innovation. Not only are the high prices of drugs leaving significant portions of the population without access to essential medication, but drug companies are choosing to leave the market or declining to innovate new and cutting edge products altogether, all out of fear of expensive and duplicative litigation.

This is particularly troublesome in light of the adequacy of the FDA regulatory scheme already in place. FDA regulations and approval processes are quite significant, with rigorous testing done over the course of a decade by top professionals in all fields. Ultimately, the FDA approves only a fraction of the safest and most useful drugs. Contrastingly, juries are less able to make similar types of risk-against-utility-analysis, and are an improper forum to second-guess the extensive balancing inquiries the FDA has already made. Furthermore, studies have shown that juries struggle with scientific evidence, and are often unable to look beyond the narrow scope of the trial in determining a drug's usefulness. Given the adequacy of FDA regulation, there is no reason to assume that the case-by-case approach does much more than serve as an expensive, duplicative, and inefficient means of disproportionately compensating greedy attorneys.

Significantly, the Supreme Court has indicated their growing skepticism of the case-by-case approach in its recent decisions preempting state law tort doctrines with FDA regulations. Not only does the threat of preemption cause increased uncertainty within jurisdictions that employ the case-by-case approach, but these jurisdictions should take heed of the Supreme Court's willingness to completely upend pharmaceutical liability

208. See John W. Wade, *Chief Justice Traynor and Strict Liability for Products*, 2 HOFSTRA L. REV. 455, 462 (1974).

unless they make concerted efforts to begin limiting tort liability for prescription products.

The method employed by the Third Restatement makes a commendable attempt to reform tort liability. However, its approach is too restrictive in that it essentially bars all possible claims made by injured plaintiffs in design defect cases in both negligence and strict liability. Policies that encourage the production of cheap, beneficial medicines and guard against deterring prescription drug manufacturers from developing new drugs must also be balanced against the right to a remedy.

In light of the aforementioned, the blanket immunity approach, employed by the minority of the courts, clearly offers the most consistency, is the most equitable, and is socially and economically beneficial. Under the blanket immunity approach, the tort system does not unduly interfere with the regulatory scheme of the FDA and is still able to serve its compensatory role in pharmaceutical liability by allowing for claims of negligence. Decisions regarding whether a drug's benefits outweigh its risks are left to those who are better equipped to make those decisions. The blanket immunity approach's preclusion of strict liability also keeps costs associated with litigation at a minimum, leading to lower costs of medication and a greater incentive to innovate.