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## The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals

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# PACE LAW REVIEW

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## Article

### **The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals**

**M. Stuart Madden\***

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## I. Introduction

The law of civil liability in money damages for the sale of defective or mislabeled prescription pharmaceuticals has long presented a policy paradox. On the one hand, and from the earliest judicial consideration of the risks associated with dangerous pharmaceuticals, courts endeavored to bring to bear the fullest liability exposure upon manufacturers and sellers. The logic then was, as it has remained, that the subtle dangers of defective drugs can often be lethal, and that such dangers will almost invariably be inscrutable to the untutored eye of the consumer or patient. On the other hand, particularly following the 1963 American Law Institute publication of *Restatement (Second) of Torts* § 402A and the influential comment *k* thereto, courts and legislatures have taken an extraordinarily solicitous and protective approach in crafting liability rules associated with the sale of prescription products. In most states, this legal solicitude has taken the form of a negligence safe harbor (from the nominal strict liability applied to other products) for manufacturers that have developed and marketed a drug that has been produced and sold in as safe a condition as then-extant scientific and medical knowledge permits.

At common law, the consumer's right of action for an injury caused by a defective product, including a defective or contaminated pharmaceutical or medicinal preparation, might be barred for lack of privity unless by fortuity plaintiff purchased

the preparation directly from the manufacturer.<sup>1</sup> In recognition that the extraordinary risks posed by defective or mislabeled drugs commended a greater flexibility for personal injury money damage suits, an early exception to the privity bar to the negligence cause of action for the remote vendee was fashioned for the purchaser of a mislabeled or contaminated drug.<sup>2</sup> The rationale for this departure from the venerable requirement of privity was explained in a widely-noted decision of the New York Court of Appeals, which noted that the sale of a mislabeled or contaminated drug to a consumer created the risk of "death or great bodily harm of some person[,] [as] the natural[,] and almost inevitable[,] consequence of the sale . . . by means of the false label."<sup>3</sup>

Thus, personal injury claims involving impure pharmaceuticals, together with adulterated foodstuffs and products intended for intimate bodily application, came to represent the earliest categories of claims in which an injured consumer could proceed against the manufacturer even without seller-consumer privity.<sup>4</sup> Additional public policy reasons bore upon conclusions

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1. See generally *Huset v. J.I. Case Threshing Mach. Co.*, 120 F. 865 (8th Cir. 1903).

[F]or the reason that in the cases of the character which have been mentioned[,] the natural and probable effect of the negligence of the contractor or manufacturer will generally be limited to the party for whom the article is constructed, or to whom it is sold, and, perhaps more than all this, for the reason that a wise and conservative public policy has impressed the courts with the view that there must be a fixed and definite limitation to the liability of manufacturers and vendors for negligence in the construction and sale of complicated [products] which are to be operated or used by the intelligent and the ignorant, the skillful and the incompetent, the watchful and the careless, parties that cannot be known to the manufacturers or vendors, and who use the articles all over the country hundreds of miles distant from the place of their manufacture or original sale[.]

*Id.* at 867.

2. See *Thomas v. Winchester*, 6 N.Y. 397, 397 (N.Y. 1852). The New York Court of Appeals distinguished the sale of such products from most transactions. See *id.*

3. *Id.* (involving an action "to recover damages from the defendant for negligently putting up, labeling[,] and selling[,] . . . extract of dandelion[,] . . . a simple and harmless medicine, [and] a jar of the extract of belladonna which is a deadly poison . . .").

4. See *Halloran v. Parke, Davis, & Co.*, 280 N.Y.S. 58, 58 (N.Y. App. Div. 1935) (holding pharmaceutical manufacturer liable for failure to warn). For a discussion, see *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 873 n.3 (E.D. Mich. 1985).

of many state courts that design, formulation and informational duties and potential liability should be imposed upon pharmaceutical sellers, be the claimant in privity with the seller or otherwise. These reasons included, and continue to contemplate today, the manufacturers' highly specialized knowledge of the safety, efficacy and appropriate means of the production of pharmaceutical products; as well as the not invariable, but nevertheless commonplace, ignorance of the consuming public (i.e., the patient) about the risks and efficacy of such prescription products.<sup>5</sup>

The special rules that have developed governing personal injury caused by prescription (or "ethical") pharmaceuticals are applied similarly to other medical products available only pursuant to a prescription by a health care professional.<sup>6</sup> In general terms, sales of both prescription blood and biological products, as well as prescription medical devices, are subject to the same (and usually more seller-forgiving) solicitous liability rules as are sales of prescription pharmaceuticals. The policy favoring access to such therapeutically important and frequently life-saving blood and biological products for which achievement of complete safety is frequently unattainable has resulted in certain rules, exceptions, and interpretations that create extraordinarily high hurdles for litigants seeking money damage remedies.<sup>7</sup>

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5. See *Hruska v. Parke, Davis & Co.*, 6 F.2d 536, 538 (8th Cir. 1925), which stated:

The defendant deals with the public to be treated with its preparations and drugs, not on an equal footing, but with an understanding the public will trust to the superior intelligence and general knowledge of defendant, its agents and employees, in the manufacture and preparation of its products; also, when its compounds, drugs, and preparations are placed on the market, that they are safe, harmless, and beneficial in use. In other words, the public relies on the truth of such statements employed in advertising by the defendant, and does not seek expert advice from others regarding the propriety of the use of the commodities defendant has manufactured and placed on the market.

*Id.*

6. See *id.*

7. See generally 2 DAVID G. OWEN, M. STUART MADDEN & MARY J. DAVIS, MADDEN & OWEN ON PRODUCTS LIABILITY §§ 22:3, 22:6, 22:15 (3d ed. 2000).

## II. *Restatement Second, Torts* § 402A and *Restatement Third, Torts: Products Liability*

### A. *Approaches Generally*

Liability for bodily harm caused by the ingestion of prescription drugs may be imposed in several ways: (1) upon the physician who prescribes it;<sup>8</sup> (2) upon the druggist who sells it;<sup>9</sup> or; (3) upon the manufacturer.<sup>10</sup> While the degree of care exercised by a physician, health care professional, or the pharmacist may affect the potential liability of a prescription product seller,<sup>11</sup> the potential liability of health care professionals is not grounded in products liability, but is instead liability for professional malpractice. The full array of compensatory damages is available to the person suffering injury due to the exposure to or the ingestion of a defective pharmaceutical.<sup>12</sup> Upon a showing of extreme, willful, or outrageous seller conduct, but subject to variations in the law from state to state, the plaintiff may also recover punitive damages.<sup>13</sup>

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8. See *id.* § 22:14 (applying the traditional rules of professional malpractice to pharmacists).

9. See *id.* Chapter 2 (pursuant to the rules of negligence), Chapter 4 (pursuant to the rules of warranty), Chapter 6 (pursuant to the rules of strict tort liability). Compare RESTATEMENT (THIRD) OF TORTS § 6 cmt. *h* (1998). See also RESTATEMENT (THIRD) OF TORTS § 6 cmt. *h*. In general terms, retailers of prescription drugs and medical devices are liable for harm caused by such products only if the retailers are negligent or if the drug contains a manufacturing defect. (The RESTATEMENT (THIRD) OF TORTS may be referred to as the *Products Liability Restatement*, herein-after, throughout the text.).

10. See OWEN ET AL., *supra* note 7, CHAPTER 2 (pursuant to the rules of negligence), Chapter 4 (pursuant to the rules of warranty), Chapter 6 (pursuant to the rules of strict tort liability). Compare RESTATEMENT (THIRD) OF TORTS § 6 cmt. *h* (1998). See also RESTATEMENT (THIRD) OF TORTS § 6 cmt. *f*.

11. See OWEN ET AL., *supra* note 7, § 22:16.

12. For a discussion on compensatory damages, see OWEN ET AL., *supra* note 7, §17.

13. See *id.*, §18. For example, liability for punitive damages was imposed upon one pharmaceutical manufacturer upon evidence that the defendant “knew or should have known that its course of conduct was about to inflict injury and yet continued its activities with conscious indifference to the consequences.” *Mulligan v. Lederle Labs.*, 786 F.2d 859, 864 (8th Cir. 1986). In *Mulligan*, punitive damages were levied against a manufacturer of a drug that was developed for the treatment of inflammation. See *id.* The plaintiff patient adduced evidence that, even during the initial testing, the drug was shown to have pyrogenicity and purity problems, and to trigger febrile reactions as well as potential circulatory collapse. See *id.* Notwithstanding notice of both these potential problems, the evidence further showed that defendant responded to a written inquiry from plaintiff’s physician

The *Restatement Second, Torts* § 402A does not differentiate between prescription products and the universe of all other products. Accordingly, with exclusive resort to the language of § 402A, a seller of a prescription product that is "in a defective condition unreasonably dangerous to the user or consumer" should be liable in strict tort even if the seller "exercised all possible care in the preparation and sale of the product[.]"<sup>14</sup>

It is readily apparent that application of the black letter strict products liability § 402A to prescription pharmaceuticals would create several troublesome health and liability policy tensions. First, there is general societal recognition of the public health benefits of bringing potentially life-saving prescriptions to market as promptly as possible, giving due consideration to relative safety. This policy premium on development and marketing of new pharmaceuticals, including drugs of which the use is attended by an irreducible element of known or knowable risks, might be, in some degree, thwarted by a strict liability rule that could have the consequence of making pharmaceutical manufacturers less likely to push for early introduction and marketing of important new drugs.<sup>15</sup> Second, a strict liability rule, creating as it would a potentially greater breadth of liability exposure than would a fault-based liability, could reasonably be foreseen to have an immediate and deleterious effect on the ability of pharmaceutical manufacturers to secure affordable third-party liability insurance coverage.<sup>16</sup> A third reason, militating in favor of a departure from a strict liability rule for prescription products speaks in terms both of what (1) precautionary measures a manufacturer might undertake to reduce the risks of liability; and (2) the plaintiff's conventional *prima facie* showing of an alternative feasible design, is that while manufacturers of many other products can evaluate the engineering efficacy and the financial viability of alternative and potentially safer product designs, the same does not go for manufacturers of pharmaceuticals. A prescription pharmaceu-

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listing some of these very side effects, only to be told that defendant "did not believe that Varidase could cause the symptoms that had been listed in the letter." *Id.* at 865.

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

15. See *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (employing DES as an example).

16. See *id.*

tical, i.e., chloromycetin, is, if differently designed, no longer chloromycetin, but rather a new pharmaceutical.<sup>17</sup>

As developed in the sections to follow, the official comments to *Restatement Second, Torts* § 402A implicitly addresses such concerns. First, comment *j* thereto makes clear that the pharmaceutical manufacturer is not required to warn of unknown or unknowable product risks.<sup>18</sup> Rather, adequate prescription product warnings or instructions need only address risks of which the seller “has knowledge, or by application of reasonable, developed human skill and foresight should have knowledge . . . .”<sup>19</sup> Secondly, many prescription products holding the promise of major health benefits, “are quite incapable of being made safe for their intended use . . . .”<sup>20</sup> *Restatement Second, Torts* § 402A comment *k* provides that for such products, “both the marketing and the use of [the pharmaceutical] are fully justified, notwithstanding the unavoidable high degree of risk which they involve.”<sup>21</sup> “Such a product[,]” comment *k* continues, “properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.”<sup>22</sup>

In jurisdictions that follow the conventional doctrinal approach to the products liability complainant’s claim, the interplay of negligence, warranty and strict tort liability may affect the liability of pharmaceutical manufacturers. Ordinarily, however, the effect of any doctrinal differentiation will be formally identifiable but substantively insignificant.<sup>23</sup> In negligence, the manufacturer’s duty of ordinary care under the circumstances is to sell a drug that by its packaging, labeling, warnings and instructions does not create an unreasonable risk of injury to users. Under the implied warranty of merchantability, a non-defective drug that is otherwise deficient in one or more of the

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17. See *id.* at 478. “While the defective equipment in *Barker* and other cases involving mechanical devices might be ‘redesigned’ by the addition of safety devices, there is no possibility for an alternative design for a drug like DES, which is a scientific constant compounded in accordance with a required formula.” *Id.* As the court in *Brown* explained, a pharmaceutical simply cannot be ‘redesigned.’ See *id.*

18. See *id.*

19. *Id.*

20. *Brown*, 751 P.2d at 478.

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

22. *Id.*

23. See *id.*



above safety-related characteristics is unfit for its ordinary purpose. Likewise, under *Restatement Second, Torts* § 402A, a prescription product with inadequate packaging, labeling, warnings or instructions is considered unsuited to the limited protections of *Restatement Second, Torts* § 402A comment *k* (the operation of which is discussed in the section to follow) and, therefore, constitutes a defective and unreasonably dangerous product.<sup>24</sup>

For liability claims associated with prescription products, the *Restatement Third, Torts: Products Liability* § 6 takes the functional approach adopted by § 2(a) - (c) to that *Restatement* for manufacturing, design, and informational defects; subjecting these claims to special rules.<sup>25</sup> A manufacturer of a prescription drug will be liable for harm caused by (1) a defect arising in the manufacturing process; (2) a defective design that renders the product not reasonably safe; or (3) inadequate warnings or instructions that make the product's use not reasonably safe.<sup>26</sup>

*Products Liability Restatement* §§ 6(d)(1) & (2) separates seller warning obligations into two settings: (1) the prescription of a drug or medical device chosen and prescribed pursuant to conventional means; and (2) other circumstances in which the manufacturer knows or has reason to know that the health care provider may not have sufficient individualized contact with the patient "to reduce the risks of harm in accordance with the instructions or warnings."<sup>27</sup> In the former situation, the *Products Liability Restatement* preserves the "learned intermediary" rule that permits the seller to discharge its warnings duties by providing adequate warnings or instructions to the appropriate health-care intermediaries.<sup>28</sup> When recognized, this exception to the "learned intermediary" rule has often been associated with (1) mass immunizations; and (2) certain limited physician-patient contact scenarios, such as prescriptions for birth control medicines (which may trigger a manufacturer's obligation to

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24. See *infra* Part III.

25. See RESTATEMENT (THIRD) OF TORTS § 6 (1998).

26. See *id.*

27. RESTATEMENT (THIRD) OF TORTS §§ 6(d)(1),(2) (1998). *Restatement Third, Torts: Products Liability* § 6 places in black letter the rule in *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968).

28. See *Davis*, 399 F.2d at 131.

provide warnings and instructional information directly to the patient.)<sup>29</sup>

III. *Restatement Second, Torts* § 402A comment *k*—  
*Unavoidably Unsafe Products*

The great majority of courts, as well as most commentators, considering the issue of applying a strict liability standard to the manufacturer of ethical pharmaceuticals, have concluded that applying such a standard would have a socially detrimental effect of inhibiting the contributions to public health made by the manufacturers of many life-saving drugs.<sup>30</sup> In *Kearl v. Lederle Laboratories*, plaintiff, who had been administered a polio vaccine manufactured by the defendant, brought a products liability action when she later contracted polio and limited paralysis.<sup>31</sup> The appellate court reversed the lower court's approval of a strict liability standard, commenting that application of strict liability to the pharmaceutical manufacturer could delay the marketing of beneficial products, and deter the research and development of others.<sup>32</sup> The strict liability standard, arguably suited to the "vast majority of products cases," the court suggested, "might not be appropriate with regard to some special products that are extremely beneficial to society and yet pose an inherent and substantial risk that is unavoidable at the time of distribution."<sup>33</sup>

Under *Restatement Second, Torts* § 402A comment *k*, the manufacturer of a valuable, efficacious, but concededly dangerous drug should not be found strictly liable if it has provided

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29. *See id.*

30. *See, e.g., Kearl v. Lederle Labs.*, 172 Cal. App. 3d 812, 823-25 (1985) *rev'd on other grounds* 751 P.2d 470 (1988). *See also* RESTATEMENT (THIRD) OF TORTS § 6(d)(1) cmt *b*.

31. *See Kearl*, 172 Cal. App.3d at 823-25.

32. *See id.* at 824-25. *Accord* RESTATEMENT (THIRD) OF TORTS § 6 cmt *b*.

33. *Brown*, 751 P.2d at 475. The court in *Brown* explained:

During a rather confusing discussion of a draft that was to become [§] 402A, a member of the [American Law Institute] proposed that drugs should be exempted from strict liability on the ground that it would be "against the public interest" to apply the doctrine to such products because of "the very serious tendency to stifle medical research and testing." Dean Prosser, who was the reporter for the Restatement Second of Torts, responded that the problem was a real one, and that he had it in mind in drafting [§] 402A.

*Id.*

adequate warning of all potential adverse reactions which the manufacturer, presumed to have the knowledge of an expert in the field, knew or should have known to exist at the time of marketing.<sup>34</sup>

#### A. *Prescription Pharmaceuticals*

One particular decision of the Ohio Supreme Court is illustrative of the application of *Restatement Second, Torts* comment *k* to prescription pharmaceuticals.<sup>35</sup> In *White v. Wyeth Laboratories, Inc.*, the Ohio Supreme Court did not hold the manufacturer of a whooping cough vaccine strictly liable for a seizure disorder that developed in a child as a result of the vaccination because the court found that the vaccine was "unavoidably unsafe."<sup>36</sup> Evidence in that action showed that there was no effective alternative to the vaccination at the time of its administration to plaintiff, and that adequate warnings of side effects and adverse reactions were provided. Comment *k*'s safe harbor from liability is a limited one, however. No matter how beneficial a pharmaceutical is when properly administered, if the seller's failure to provide adequate warnings as to known or

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34. See, e.g., *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 836 (Ohio 1981); see also *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 545-46 (Ind. Ct. App. 1979). Comment *k* provides more fully:

*k. Unavoidably Unsafe Products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use . . . .

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

35. See *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748 (Ohio 1988).

36. See *id.* at 748.

knowable risks, and this proximately causes personal injury—manufacturer liability will follow.<sup>37</sup>

In another influential decision, *Brown v. Superior Court*,<sup>38</sup> the California Supreme Court emphasized that comment *k* suggests the necessity of a finding of blameworthiness or negligence on the part of the pharmaceutical manufacturer before liability may be imposed.<sup>39</sup> In that DES action, the California Supreme Court concluded that “comment *k*, by focusing on the blameworthiness of the manufacturer, sets forth a test which sounds in negligence, while imposition of liability for failure to warn without regard to the reason for such failure is consistent with strict liability . . . .”<sup>40</sup> The state high court concluded that prescription pharmaceuticals are presumptively “unavoidably unsafe,” and therefore entitled to comment *k* treatment, thereby obviating a case-by-case analysis of either the public health benefits or the therapeutic attributes of each ethical drug. Naturally, such a presumption would operate only in circumstances in which the drug’s manufacturer provided warnings, instructions, and packaging consistent with the then-existing limits of medical and scientific knowledge.<sup>41</sup>

Not all jurisdictions have adopted the presumption of comment *k*’s applicability to all prescription drugs.<sup>42</sup> For example,

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37. See *Hamilton v. Hardy*, 549 P.2d 1099, 1099 (Colo. Ct. App. 1976) *rev’d on other grounds* State Bd. of Med. Exam’rs v. McCroskey, 880 P.2d 1188 (Colo. 1994).

38. 751 P.2d 470 (Cal. 1988).

39. See *id.*

40. *Id.* at 476 n.4. The court explained:

The test stated in comment *k* is to be distinguished from strict liability for failure to warn. Although both concepts identify failure to warn as the basis of liability, comment *k* imposes liability only if the manufacturer knew or should have known of the defect at the time the product was sold or distributed. Under strict liability, the reason why the warning was not issued is irrelevant, and the manufacturer is liable even if it neither knew nor could have known of the defect about which the warning was required.

*Id.*

41. See generally *Tansy v. Dacomed Corp.*, 890 P.2d 881 (Okla. 1994). *Tansy* was a penile implant action, in which the plaintiff alleged that the device failed due to the rubbing together of its internal metal cables. See *id.* The Oklahoma high court held that the evidence supported the finding that the device was an “unavoidably unsafe” product. See *id.*

42. See, e.g., *Shanks v. Upjohn Co.* 835 P.2d 1189 (Alaska 1992) (involving a suit brought by an estate on behalf of a patient who committed suicide shortly after beginning treatment with Xanax).

in *Shanks v. Upjohn Co.*,<sup>43</sup> the Alaska Supreme Court declined to follow the comment *k* approach of California and the majority of other jurisdictions. Instead, the court held that a prescription drug may be found to be defectively designed, and its manufacturer strictly liable, when the drug fails to perform as safely as an ordinary physician would expect, and the patient thereby suffers injury.<sup>44</sup>

### B. *Blood or Biological Products*

Contaminated blood and blood derivative products represent a persistent dilemma for sellers of such products as well as for the health care providers involved in the administration. Differentiable from most other areas of products liability law, states have responded not so much by decisional law, but by statute. All but a handful of states have enacted legislation establishing a negligence standard for evaluating liability of persons or institutions providing blood products.<sup>45</sup> This legislation was enacted in response to arguments of health care providers that the application of the strict liability remedy to the providers of crucial prescription blood, blood-related, and biological products will subject those sellers to debilitating liability.<sup>46</sup>

Most jurisdictions have enacted so-called "blood shield" statutes which limit the claims that may be brought against suppliers of blood and biological products. In general terms, "blood shield" statutes state that claims against sellers may only proceed upon a negligence theory, rather than in warranty or strict tort liability.<sup>47</sup> In *Zichichi v. Middlesex Memorial Hospital*,<sup>48</sup> the Connecticut Supreme Court elaborated upon the policy underpinnings of such statutes:

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43. 835 P.2d 1189 (Alaska 1992).

44. *See id.* at 1193.

45. For a listing of states that have not enacted such statutes, see Jay M. Zitter, Annotation, *Liability for Injury or Death From Blood Transfusion*, 20 A.L.R. 4th 136 (2000).

46. *See id.*

47. For a discussion on negligence, see OWEN ET AL., *supra* note 7, ch. 2. For a discussion on warranties, see OWEN ET AL., *supra* note 7, ch. 2. For a discussion on strict liability under the *Restatement Second* and *Third*, see OWEN ET AL., *supra* note 7, § 22.7.

48. 528 A.2d 805 (Conn. 1987).

"[T]he public policy represented by these statutes is not difficult to discern: blood transfusions are essential in the medical area and there are not now, and realistically there may never be, tests that can guarantee with absolute certainty that donated blood is uncontaminated with certain viruses." These statutes reflect a legislative judgment that to require providers to serve as insurers of the safety of these materials might impose such an overwhelming burden as to discourage the gathering and [sale] of blood.<sup>49</sup>

While there exists a consensus as to the goal of blood shield statutes, their language and application vary from state to state.<sup>50</sup> One prevalent means of avoiding strict tort and warranty liability for transactions in blood, blood products, or plasma has been to characterize such transactions as the rendition of a service rather than a sale. Illustrative is Arizona's statute, Ariz. Rev. Stat. § 36-1151, which provides:

The procurement, processing, distribution, or use of whole human blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing them into the human body shall be construed as to the transmission of serum hepatitis to be the rendition of a service by every person participating therein and shall not be construed to be a sale.<sup>51</sup>

The second means adopted by state legislatures has been to provide a "grant of immunity" to sellers of blood and other biological products from actions in strict products liability or im-

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49. *Id.* at 810 (citations omitted).

50. *See* *Weishorn v. Miles-Cutter, Inc.*, 721 A.2d 811, 814 (Pa. Super. Ct. 1998) (affirming a grant of summary judgment for provider of blood platelets, the Pennsylvania Superior Court referenced decisions that have interpreted the blood shield states of a cluster of jurisdictions). The decisions referenced by the *Weishorn* court are as follows:

*Coffee v. Cutter Biological*, 809 F.2d 191, 194 (2d Cir. 1987); *Roe v. Miles Labs., Inc.*, 740 F. Supp. 740, 742 (D. Alas. 1989); *Doe v. Travenol Labs., Inc.*, 698 F. Supp. 780, 783 (D. Minn. 1988); *Doe v. Cutter Labs.*, 703 F. Supp. 573, 575 (N.D. Tex. 1988); *McKee v. Miles Labs.*, 675 F. Supp. 1060, 1063 (E.D. Ky. 1987); *Smith v. Cutter Biological, Inc.*, 823 P.2d 717, 722 (Haw. 1991).

*Id.*

To be contrasted, the *Weishorn* court continues by noting decisions in two jurisdictions, Maryland and Louisiana, approving application of strict products liability claims to commercial suppliers of blood or biological products; *Doe v. Miles Labs., Inc.*, 675 F. Supp. 1466, 1478 (D. Md. 1987); *Shortess v. Touro Infirmary*, 520 So.2d 389, 391 (La. 1988). *See id.*

51. Ariz. Rev. Stat. § 36-1151 (2000).

plied warranty.<sup>52</sup> The applicable Pennsylvania statute provides:

No person shall be liable for death, disease or injury resulting from the lawful transfusion of blood, blood components or plasma derivatives, or for the lawful transplantation or insertion of tissue, bone or organs, except upon a showing of negligence on the part of such person. Specifically excluded hereunder is any liability by reason of any rule of strict liability or implied warranty or any other warranty not expressly undertaken by the party to be charged.<sup>53</sup>

It is seen readily that this prophylaxis against supplier liability, albeit with limitations, is the most supplier-protective in all of accident law. This approach has been tailored to the benefit of suppliers of a special subcategory of prescription in which the provision of adulterated, contaminated, or mislabeled products can be expected almost invariably to cause death or serious bodily injury. In the face of the gravest risks to patients, and operating independently of either the Second or the Third Restatements, these blood shield statutes impose the highest barriers to supplier liability. Stepping back from what may at first be viewed as a harsh irony, the blood shield protections for blood, blood products, and biological products can be seen as representing the products liability policy high wire at its most taut and highest elevation. The majority of the products at issue here are employed in life saving surgery. The risks posed by contamination are usually devastating. With no seeming alternative for such products, and with time exigencies and testing limitations arrayed against complete safety, the state legislatures have taken the steps thought necessary to preserve suppliers from potentially ruinous liability exposure.

#### IV. *Restatement Third, Torts: Products Liability* § 6

Pursuant to *Products Liability Restatement* § 6,<sup>54</sup> sellers of prescription drugs, as well as other prescription products, in-

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52. See, e.g., 42 Pa. C.S.A. § 8333(a) (1998).

53. *Id.*

54. Section 6, entitled "Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices," states:

(a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability

cluding biological products and certain medical devices, receive a measure of legal solicitude that can be harmonized with the decisional law.<sup>55</sup>

Most of these decisions have been reached with the guidance of *Restatement Second, Torts* § 402A and comment *j*.<sup>56</sup>

Similar to the liability that follows sale of any product with a manufacturing defect that causes harm, the provisions of § 6 propose that manufacturers of prescription products that contain a manufacturing defect will also be strictly liable for such flaws. However, prescription pharmaceuticals that are claimed

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for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.

(b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:

(1) contains a manufacturing defect as defined in § 2(a); or

(2) is not reasonably safe due to defective design as defined in Subsection (c); or

(3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).

(c) 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 such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

(e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:

(1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or

(2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

*Id.*

55. For its congruence with existing decisional law reached under *Restatement Second, Torts* § 402A, many state courts may be expected to continue their adherence to a *Restatement Second, Torts* § 402A cmt. *k*. approach. *Cf.*, *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827 (Neb. 2000).

56. See generally OWEN ET AL., *supra* note 7, § 22:3.



to have a design or formulation defect are treated differently. A claim of manufacturer liability arising from the design or formulation of a prescription drug will prevail only upon a showing that the product would be unduly dangerous for any class of patients, or specifically, when "reasonable health care providers, knowing of foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients."<sup>57</sup>

#### A. *Warnings and Instructions—Generally*

The manufacturer of a non-defective drug is obligated to provide such warnings of risks and instructions of reasonably safe use as to permit the patient to make an informed decision whether or not to follow the therapy the drug provides. The obligations to provide warnings as to pertinent risks and instructions as to duly safe use have been imposed consistently under the *Second Restatement* and are carried forward without material change in the *Products Liability Restatement*.

In the frequently cited Eleventh Circuit Court of Appeals decision of *Wells v. Ortho Pharmaceutical Corp.*,<sup>58</sup> the court affirmed judgment for the plaintiffs. In *Wells*, a child had been born with birth defects causally associated with her parents' use of the manufacturer's contraceptive spermicide.<sup>59</sup> The parents sued and presented evidence that showed the defendant knew or should have known of studies indicating that the use of spermicides might increase the risk of birth defects several years prior to plaintiff's use of the product.<sup>60</sup> Similarly, another court reversed a lower court's decision and denied summary judgment based upon its conclusion that plaintiffs raised material issues of fact whether the defendant manufacturer of Depo-Provera had a duty to warn of incidents of cancer in humans associated with use of the drug.<sup>61</sup>

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57. RESTATEMENT (THIRD) OF TORTS § 6 C (1998).

58. 788 F.2d 741 (11th Cir.1986).

59. *See id.* at 746.

60. *See id.*

61. *See Popham v. Reyner*, 503 N.Y.S.2d 645, 645 (N.Y. App. Div. 1986). *See also Tenuto v. Lederle Laboratories, Inc.*, 695 N.Y.S.2d 259 (N.Y. Sup. Ct. 1999) (held: fact issue of warning adequacy existed as to manufacturer's package insert that did not contain information concerning risks to third persons who would come into contact with patient).

Courts are virtually uniform in imposing warning duties only as they apply to adverse reactions or side effects of which the manufacturer knew or should have known at the time of manufacture.<sup>62</sup> Thus, courts in all jurisdictions adhere to a rule imposing a high standard of care for the manufacturers' preparation and testing of drugs.<sup>63</sup> However, the standard is interpreted in terms of reasonable, not hypothetical, scientific and medical foreseeability.<sup>64</sup> Illustrative is the decision in *McElhane v. Eli Lilly & Co.*,<sup>65</sup> in which the court, interpreting *Restatement Second, Torts* § 402A comment *j* emphasized that warning duties are confined to such subjects as to which it "has knowledge, or by the application of reasonably developed human skill and foresight, should have knowledge."<sup>66</sup> The court ultimately held that a manufacturer of DES had a duty to warn of possible adverse side effects "of which it knew, or reasonably should have known, at the time plaintiff's mother ingested the drug."<sup>67</sup>

Where the plaintiff's evidence suggests that the prescribing physician would not have prescribed the drug if he had read a package insert containing a warning of the type proposed as adequate by plaintiff, plaintiff's claim of warning inadequacy should be permitted to go to the jury.<sup>68</sup> Similarly, if the evidence suggests that the prescribing physician would have, in all probability, prescribed another drug, plaintiff's claim of warning inadequacy should also be permitted to go to the jury.<sup>69</sup>

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62. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. *j* (1965). See also RESTATEMENT (THIRD) OF TORTS § 6 cmt *b* (standard for proving design defect includes assessment of "risks that were known or reasonably should have been known" to a "reasonable health care provider.").

63. See W. PROSSER, THE LAW OF TORTS, § 99, 661 (4th ed. 1971). See also W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS, § 96, 688 (5th ed. 1984).

64. See W. Prosser, *The Law of Torts*, § 99, 661 (4th ed. 1971). See also W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS, § 96, 688 (5th ed. 1984).

65. 575 F. Supp. 228 (D.S.D. 1983).

66. *Id.* at page 231 (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. *j* (1965)).

67. *Id.* at 231-32 (finding no duty to warn for want of constructive knowledge).

68. See *Reeder v. Hammond*, 336 N.W.2d 3, 6 (Mich. Ct. App. 1983).

69. See *id.* In contrast, compare *Reeder* with *Bealer v. Hoffman-La Roche, Inc.*, 729 F. Supp. 43 (E.D. La. 1990) (woman pregnant while taking dermatological drug underwent therapeutic abortion due to high risk of birth defects associated with use during pregnancy; held that a manufacturer discharged duty to warn by providing adequate warnings to the plaintiff's physician).

An otherwise suitable warning may be vitiated by the conduct of the manufacturer or those acting at the direction of the manufacturer if they promote the product in such a fashion as to obscure or lessen the cautionary impact of the seller's warnings. For example, it has been held that a physician's receipt of the seller's desk calendar promoting the ethical pharmaceutical, together with a package sample containing a warning concerning the drug, could permit a jury to infer "that the absence of a warning on an advertisement for the use of a drug as potentially dangerous as chloromycetin was a form of overpromotion which [weakened] the effect of even a valid warning on the package."<sup>70</sup>

### 1. *To Whom Warnings Must be Given—Generally*

The duty of a pharmaceutical manufacturer to provide adequate warnings and instructions is interpreted as providing that, except in limited circumstances,<sup>71</sup> the pharmaceutical seller satisfies its duty to warn by providing timely and adequate information regarding the product to the medical profession, with the individual physician taking the role as the "learned intermediary" between the product seller and the individual patient.<sup>72</sup> As expressed by one court, "manufacturers of

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70. *Salmon v. Parke Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975) (citations omitted). In *Salmon*, the 4<sup>th</sup> Circuit stated that "[t]he likelihood of overpromotion by advertisements that lack a warning is increased when a physician writes a prescription without having either the package or its insert at hand and the patient obtains the drug from a pharmacist." *Id.* at 1364. See also *Incollingo v. Ewing*, 282 A.2d 206, 221 (Pa. 1971).

71. By way of an example, the exception to the rule that the pharmaceutical manufacturer's duty to warn is satisfied by a timely and adequate warning to the medical community. See *Davis*, 399 F.2d at 131. The role of the physician as the learned intermediary between the seller and the individual patient is recognized where the seller has no reason to believe that the pharmaceutical will be administered in a setting in which there will be the typical, binary, physician-patient relationship, i.e., where the pharmaceutical is to be administered by means of mass immunization. See *id.*

72. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b (1998). See *Pumphrey v. C.R. Bard, Inc.*, 906 F. Supp. 334 (N.D.W. Va. 1995). *Pumphrey* involved a medical device designed for repeated delivery of pharmaceuticals to the patient's blood system. See *id.* Plaintiff's claim was that the manufacturer failed to provide adequate warnings as to the risks of a "pinch-off syndrome" associated with the use of the port and catheter. See *id.* at 336, 339. The court held that (1) under West Virginia law, the manufacturer had a duty to warn the patient's physicians of potential complications, but did not have a duty to warn the patient di-

prescription drugs need only warn the prescribing physician and not the patient of risks and contraindications associated with a prescription drug.”<sup>73</sup> The California Supreme Court has explained that defining the manufacturer’s duty as an obligation to provide pertinent cautionary information to the appropriate health care community is supported by a characterization of the “consumer expectation” standard of § 402A as meaning “a patient’s expectations regarding the effects of such a drug [as] related to him by his physician, to whom the manufacturer directs the warnings regarding the drug’s properties.”<sup>74</sup> While the *Second Restatement* did not address in either its black letter or its commentary any rarified rule for warnings as related to prescription products, courts following *Restatement Second of Torts* § 402A adopted the “learned intermediary” rule, and the *Products Liability Restatement* has rendered it in the black letter.

This general rule that the person to be warned is the prescribing physician or other health care professional has been followed in a large number of cases.<sup>75</sup> In *McEwen v. Ortho*

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rectly; and (2) the manufacturer’s warnings to the physicians was adequate. See *id.* at 339.

A leading early decision reaching this conclusion is *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966), in which the court stated: “[I]n this case we are dealing with a prescription drug rather than a normal consumer item. In such a case, the purchaser’s doctor is a learned intermediary between the purchaser and the manufacturer.” *Sterling Drug*, 370 F.2d at 85.

73. *Nasios v. Pennwalt Corp.*, Prod. Liab. Rep. (CCH) ¶ 12,479, 37,047 (D. Md. 1990) (applying Maryland law to action brought by patient who suffered partial paralysis following injection of anesthetic in the subarachnoid space of the spinal column). See, e.g., *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 462 (Tex. Ct. App. 2000). The court in *Morgan* acknowledged that:

According to this [learned intermediary] doctrine, the manufacturer of a prescription drug has a duty to adequately warn the prescribing physician of the drug’s dangers. The physician, relying on his medical training, experience, and knowledge of the individual patient, then chooses the type and quantity of the drug to be prescribed. The physician assumes the duty to warn the patient of the dangers associated with a particular prescribed drug.

*Id.* (internal citations omitted) (relying upon *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. Ct. App. 1993).

74. *Brown*, 751 P.2d at 477 (citations omitted).

75. See, e.g., *Walker v. Merck & Co., Inc.*, 648 F. Supp. 931, 934 (M.D. Ga. 1986) (learned intermediary doctrine applied). See also *Buckner v. Allergan Pharm., Inc.*, 400 So.2d 820, 822 (Fla. Dist. Ct. App. 1981). (“[The] manufacturer of a dangerous commodity . . . does have a duty to warn[,] but when the commodity

*Pharmaceuticals Corp.*,<sup>76</sup> the court simply stated: “[i]t is well settled that the manufacturer of ethical drugs bears the duty of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs[.]”<sup>77</sup> *Ortho Pharmaceutical Corp. v. Chapman*,<sup>78</sup> also followed the general rule, with respect to most prescription drugs, that although the failure to warn adequately of the inherent dangers of the drug may give rise to the manufacturer’s liability to the ultimate user, the target of the warning is not the patient but rather the physician or other equivalently positioned health care provider.<sup>79</sup> The court stated that a proper warning by a manufacturer of a prescription drug communicates risks associated with the uses of the product, as are known or reasonably knowable to experts in the field during the period in which the product is used, and need only be directed at physicians—not to patients who are the ultimate “users.”<sup>80</sup>

Applying a harmonious analysis, in *Leibowitz v. Ortho Pharmaceuticals, Inc.*,<sup>81</sup> the court could not conclude, as a matter of law, that the insert on the package of contraceptive pills was misleading or inadequate. In that case, the insert cautioned against prescribing the pills to patients having recent cases of thrombophlebitis, and the warning stated that there were cases of thrombophlebitis reported from the use of the pills, and that there were studies being conducted into the causal connection, but that no evidence had established such a connection.<sup>82</sup>

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is a prescription drug . . . this duty to warn is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense, and administer drugs.”).

76. 528 P.2d 522 (Or. 1974).

77. *Id.* at 528.

78. 388 N.E.2d 541 (Ind. Ct. App. 1979).

79. *See id.* at 548. *Cf. Hasler v. United States*, 517 F. Supp. 1262, 1268-69 (E.D. Mich. 1981) (dispenser of a swine flu injection did not adequately warn the patient of the risks involved, and the consent form did not adequately advise the patient).

80. *See Chapman*, 388 N.E.2d at 548.

81. 307 A.2d 449 (Pa. Super. Ct. 1973); *but see generally* Teresa Moran Schwartz, *Consumer Warnings for Oral Contraceptives: A New Exception to the Prescription Drug Rule*, 41 FOOD DRUG COSM. L.J. 241 (1986).

82. *See Leibowitz*, 307 A.2d at 457.

With respect to vaccines, a manufacturer's duty to warn extends to the health care professional performing the inoculation, whose responsibility it is then to inform the patient of the risks inherent in its use.<sup>83</sup> In *White v. Wyeth Laboratories*<sup>84</sup> and *Niemiera by Niemiera v. Schneider*,<sup>85</sup> plaintiffs were infants who suffered brain damage and other injuries after being injected with the DPT vaccine. In each case, the court held that the 'learned intermediary' doctrine applied and that liability did not extend to the manufacturer.<sup>86</sup> In some circumstances, medical professionals other than physicians may be considered "learned intermediaries" for the purposes of this interpretation of the manufacturer's informational obligations. For example, the rule has been found applicable to nurses.<sup>87</sup>

Quite apart from the considerations afoot in application of the "learned intermediary" doctrine, the defendant manufacturer should prevail on a claim of failure to warn adequately where it can show that the prescribing physician, by virtue of defendant's product information or otherwise, was aware of the risks involved in prescribing the drug.<sup>88</sup> The court reached the same conclusion in *Wooten v. Johnson and Johnson Products*,

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83. See *White*, 533 N.E.2d at 748; see also *Niemiera by Niemiera v. Schneider*, 555 A.2d 1112 (N.J. 1989).

84. 533 N.E.2d 748 (Ohio 1988).

85. 555 A.2d 1112 (N.J. 1989).

86. Compare *White*, 533 N.E.2d at 748 with *Niemiera by Niemiera v. Schneider*, 555 A.2d 1112 (N.J. 1989).

87. See *Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 254 (E.D. Pa. 1990) (In context of measles epidemic, nurse's administration of vaccination to students; claimants suffered subacute sclerosing panencephalitis, a disease of the central nervous system; held that it is a triable issue of fact whether manufacturer of measles, mumps and rubella vaccination adequately warned the nurse).

88. See, e.g., *Goodson v. Searle Labs.*, 471 F. Supp. 546, 548 (D. Conn. 1978). Whereby the manufacturer's failure to adequately warn of the risk of cerebral thrombosis for patients prescribed oral contraceptives. See *id.* Upon the manufacturer's submission of PDR excerpts and the affidavit of the prescribing physician affirming his familiarity with the pertinent risk through several sources, including PDR, the court granted summary judgment, stating:

[T]here is no issue of material fact that the defendant warned the medical profession and the prescribing doctor prior to the plaintiff's use of the risk of cerebral thrombosis associated with the use of [the drug]. Even were the warning found to be inadequate as to the medical profession as a whole, it is clear that the physician who prescribed [the drug] for the plaintiff had been adequately warned of the increased risk of thromboembolic disease associated with its use.

See *id.*

*Inc.*,<sup>89</sup> an action arising out of decedent's fatal allergic reaction to several drugs, including defendant's Zomax. In that action, the prescribing physician testified that through the drug's package inserts, the PDR (Physician's Desk Reference), his training and experience, and through various other sources, he understood the risks of each of the medications prescribed to the decedent.<sup>90</sup> On this basis, the court granted summary judgment for defendant, finding that, as a matter of law, the pharmaceutical company had fulfilled its duty to warn the administering physician of the risks associated with use of the product.<sup>91</sup>

The court in *Ortho Pharmaceutical Corp. v. Chapman*<sup>92</sup> found that the duty to warn extends only to the medical profession and not to the ultimate users. It reasoned that a contraceptive is a complex "esoteric medicine available only through prescription by physicians who act as 'learned intermediaries' in balancing benefits and risks."<sup>93</sup> It is worth noting that the same "learned intermediary" approach to a manufacturer's informational obligations has been applied to manufacturers of medical devices.<sup>94</sup> For example, in *Terhune v. A.H. Robins Co.*, the Washington Supreme Court found that the manufacturer of the intrauterine device, Dalkon Shield, adequately fulfilled its duty to warn by providing a warning solely to the medical community.<sup>95</sup> In contrast with *Terhune*, the growing phenomenon of direct advertising to patients prompted the New Jersey Supreme Court in *Perez v. Wyeth Laboratories, Inc.*,<sup>96</sup> a suit brought against the manufacturer of surgically implantable contraceptive capsule, to hold that the "learned intermediary" doctrine ought not apply to a manufacturer's informational obligations when its marketing effort is targeted to the consumers themselves.

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89. 635 F. Supp. 799 (N.D. Ill. 1986).

90. *See id.* at 802.

91. *See id.* at 804. *See also* Cobb v. Syntax Labs., Inc., 444 So.2d 203, 206 (La. Ct. App. 1983).

92. 388 N.E.2d 541. *See generally* Rosalind M. Kendellen, *The Food and Drug Administration Retreats From Patient Package Inserts for Prescription Drugs*, 40 FOOD DRUG COSM. L.J. 172, 184 (1985).

93. *Chapman*, 388 N.E.2d at 549.

94. *See Terhune v. A.H. Robins Co.*, 577 P.2d 975 (Wash. 1978).

95. *See id.* For a discussion on a seller's warning obligations under the *Restatement Second and Third*, see OWEN ET AL., *supra* note 7, § 23:4.

96. 734 A.2d 1245 (N.J. 1999).

In some jurisdictions an exception to the “learned intermediary” rule has been recognized when vaccines are administered in a mass inoculation setting.<sup>97</sup> One of the earliest characterizations of the mass immunization exception to the “learned intermediary” rule was pronounced in the decision of *Davis v. Wyeth Laboratories, Inc.*<sup>98</sup> That case arose from an illness and injury suffered by an adult recipient of the manufacturer’s Type III polio vaccine at a mass immunization clinic.<sup>99</sup> Within thirty days of the vaccination, Davis suffered symptoms of polio and was eventually paralyzed from the waist down.<sup>100</sup> The manufacturer argued that it had satisfied its informational duties by a general dissemination of pertinent information to members of the medical profession, and indeed the court confirmed that, “[o]rordinarily in the case of prescription drugs warning to the prescribing physician is sufficient.”<sup>101</sup> However, the court explained that where the drug is administered in circumstances not permitting the ordinary patient-physician relation, a setting that does not allow “an individualized balancing” of the risks involved by a physician, the manufacturer does not meet its duty to warn simply by providing information to the medical community.<sup>102</sup> The court suggested that such information might be effectively conveyed to the clinical patient by means of

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97. See, e.g., *Davis*, 399 F.2d at 130-31.

98. 399 F.2d 121 (9th Cir. 1968).

99. See *id.* at 122.

100. See *id.*

101. *Id.* at 130 (citing *Sterling*, 370 F.2d at 82).

The *Davis* court added its observation that in such cases:

[T]he choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician’s knowledge of his patient’s needs and susceptibilities. Further, it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning. A warning to the medical profession is in such cases the only effective means by which a warning could help the patient . . . .

*Davis*, 399 F.2d at 130.

102. See *id.* at 131.

The decision (that on balance and in the public interest the personal risk to the individual was worth taking) may well have been that of the medical society and not that of appellee. But just as the responsibility for choice is not one that the manufacturer can assume for all comers, neither is it one that he can allow his immediate purchaser to assume.

*Id.*



"advertisements, posters, releases to be read and signed by recipients of the vaccine, or oral warnings . . . ." <sup>103</sup>

The lead of *Davis v. Wyeth Laboratories* was followed in *Reyes v. Wyeth Laboratories*.<sup>104</sup> In *Reyes*, an infant was taken by her mother to a polio immunization clinic, where she was administered an oral polio vaccine by an eyedropper.<sup>105</sup> No cautionary information was given to plaintiff's mother, although the mother was requested to, and in fact, executed a release.<sup>106</sup> The child, thereafter, was paralyzed from the waist down as a result of paralytic poliomyelitis.<sup>107</sup> Thus, where a titularly prescription drug was marketed by the manufacturer for administration in "assembly line fashion," precluding the ability of a physician to offer "individualized medical judgment," the court found, "Wyeth was under a duty to warn Anita Reyes's parents of the danger inherent in its vaccine."<sup>108</sup>

In the limited context of prescription oral contraceptives, Massachusetts has countenanced a significant departure from the "learned intermediary" rule, suggesting that manufacturers of such products may have a duty to warn the patient-consumer, directly, of possible adverse effects associated with the drug's use. In distinguishing the role of the intermediary in prescribing this drug, the Massachusetts Supreme Judicial Court reasoned that the consumer of oral contraceptives is more actively involved in the decision to use the drug, as it requires a choice between that form of contraception and others.<sup>109</sup> Accordingly, in *MacDonald v. Ortho Pharmaceutical Corp.*,<sup>110</sup> the state high court held that the manufacturer of oral contraceptives had a duty to warn the patient, directly, of any potentially serious adverse effects of the drug's use.<sup>111</sup> The duty adopted in

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103. *Id.*

104. 498 F.2d 1264 (5th Cir. 1974).

105. *See id.* at 1270.

106. *See id.*

107. *See id.*

108. *Id.* at 1277.

109. *See MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69 (Mass. 1985).

110. 475 N.E.2d 65 (Mass. 1985).

111. *See id.* at 69. Additional reference to the policy rationale and the decisional adherence to the informed intermediary rule may be found in numerous scholarly writings. *See generally* Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633 (1986).

*MacDonald* has gained no significant adherence in other jurisdictions.<sup>112</sup>

Of further significance to the warning obligations imposed upon manufacturers of injectable or oral contraceptives, important regulatory exceptions to the “learned intermediary” rule also require attention. The FDA has mandated that the pharmaceutical manufacturer do more than provide warnings to the medical profession, as the informed intermediary between the manufacturer and the recipient of the drug. With specific respect to certain injectable contraceptives and oral contraceptives, the FDA has issued detailed requirements for the warnings and precautions to accompany the product actually received by the user.<sup>113</sup> The FDA has promulgated comparable warnings standards for intrauterine devices.<sup>114</sup>

B. *Products Liability Restatement* § 6(d)(1) and (2)

*Products Liability Restatement* § 6(d)(1) and (2) separates seller warning obligations into two settings: (1) the prescription of a drug or medical device by means of the conventional health care provider-patient relationship; and (2) other circumstances in which the manufacturer knows or has reason to know that the health care provider may not be circumstanced in relation to the patient “to reduce the risks of harm in accordance with the instructions or warnings.”<sup>115</sup> In the former situation, the *Products Liability Restatement* preserves the “learned intermediary” rule that permits the seller to discharge its warnings duties by providing adequate warnings or instructions to the appropriate health-care providers. In the latter setting, identified to date in connection with (1) mass immunizations; (2) a limited number of direct manufacturer to consumer advertising scenarios; and (3) certain limited physician-patient contact sce-

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112. See, e.g., *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 424 (D.D.C. 1991). See generally James L. Rigelhaupt Jr., Annotation, *Contraceptive Causing Injury or Death: Liability of Manufacturer*, 70 A.L.R.3d 315, § 6 (1976).

113. See 21 C.F.R. § 310.501 (2000) which states that the package inserts for oral contraceptives must contain specific cautionary and directory narratives under subheadings such as: “Who Should Not Take (Name of Drug)”; “How (Name of Drug) Prevents Pregnancy”; “Important Risks”; “Common Adverse Reactions”; “Other Considerations”; and “Precautions You Should Take.” See *id.*

114. See *id.*

115. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(1), (2) (1998).

narios (such as prescriptions for birth control medicines), the manufacturer may have an obligation to provide warning and instruction information directly to the patient.<sup>116</sup> It is perceived that Section 6(d)(2) notes an important exception to the “learned intermediary” rule. Essentially, the *Products Liability Restatement* proposes that courts follow the limited decisional law suggesting that a pharmaceutical manufacturer may have a duty to provide adequate warnings and instructions directly to the patient “when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”<sup>117</sup> *Products Liability Restatement* § 6(d)(2) comment *e* provides one conspicuous example of such a duty to provide direct warnings: that of mass immunizations.<sup>118</sup>

Comment *e* notes also that the FDA in some circumstances, such as the sale of prescription birth control pills, requires that warning and instruction information be contained in the product package. Recognizing the widespread phenomenon of direct advertising to patients of the attributes of numerous prescription products, the American Law Institute concluded that it should “leav[e] to developing case law” whether other exceptions should come to be recognized.<sup>119</sup>

Where statutory schemes have established mandatory immunization for school-age children, neither the existence of such programs nor other statutory provisions shielding injured persons from liability will serve to protect the manufacturer of a

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116. *See id.* § 6(d)(2).

117. *Id.*

118. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2) (1998) cmt. *e* (1998).

“Subsection (d)(2) recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed to patients without the personal intervention or evaluation of a health-care provider. An example is the administration of a vaccine in clinics where mass inoculations are performed. In many such programs, health-care providers are not in a position to evaluate the risks attendant upon use of the drug or device or to relate them to patients. When a manufacturer supplies prescription drugs for distribution in this type of unsupervised environment, if a direct warning to patients is feasible and can be effective, the law requires measures to that effect.”

*Id.*

119. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2) cmt. *e* (1998).

pharmaceutical from potential liability in negligence or strict liability.<sup>120</sup> In these limited circumstances, a prescription drug manufacturer may be required to provide warnings not only to the health care provider, but also to a general or target population. A prominent example of drugs of this type is the polio vaccine, which has been given in mass inoculations to large numbers of children.<sup>121</sup> Some courts have held that in circumstances in which there is no informed intermediary who can communicate warnings to the recipients of the vaccine, the manufacturer may need to adopt means of informing patients or their guardians directly.<sup>122</sup> *Givens v. Lederle* provides an example of the manufacturer's duty to warn the general public when there is an expectation that the drug will be administered to large numbers of people without the direct intervention of prescribing physicians. In that case, suit was brought against the manufacturer by the parents after the mother contracted polio when the child was given oral polio vaccine by a pediatrician.<sup>123</sup> There was evidence that the vaccine was administered more in a manner like that "at a small county health clinic . . . than by prescription."<sup>124</sup> The court ruled that the jury could find the manufacturer responsible for taking definite steps to warn the consumer, directly, that exposure to oral polio vaccine could induce an active polio case.<sup>125</sup>

As is true of the seller's informational obligation for products other than pharmaceuticals, a manufacturer's conduct may satisfy a regulatory standard, and yet be inadequate under state tort law.<sup>126</sup> In *Wells v. Ortho Pharmaceutical Corp.*,<sup>127</sup> an

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120. See *Flood v. Wyeth Labs., Inc.*, 228 Cal. Rptr. 700, 704 (Cal. Dist. Ct. App. 1986). With reference to the statutory use of the word "administration" the court stated that, "[t]he term administration has several meanings. When used with respect to medicine, it clearly has a meaning close to the one suggested by appellant—the meting out, or the application, or dosage. None of the dictionary meanings can be said to include manufacturing." *Id.* at 703.

121. See *Reyes*, 498 F.2d at 1294; see also *Davis*, 399 F.2d at 131.

122. See, e.g., *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977).

123. See *id.*

124. *Id.* at 1345.

125. See *id.*

126. See *Dorsey v. Honda Motor Co.*, 655 F.2d 650, 656 (5th Cir. 1981) ("compliance with regulatory standards may be admissible on the issue of care[,] but does not require a jury to find a defendant's conduct reasonable.") and RESTATEMENT (THIRD) OF TORTS § 6 (d)(1)(2) cmt *b* (recognizing potential "common-law causes of action for defective drug design and for failure to provide reasonable

action arising out of the birth defects of a child whose parents had used defendant's contraceptive spermicide, the appellate court commented upon the manufacturer's protestation that the FDA had decided that no warning was necessary for non-ionic surfactant spermicides.<sup>128</sup> The court held that the finder of fact was not required to accept the agency's decision as conclusive.<sup>129</sup>

### C. *The Adequacy of Warnings and Instructions*

In pharmaceutical product liability, the manufacturer has a duty to warn persons who might use, consume or be affected by use of the drug, of any cognizable risk of injury, or adverse reaction occasioned thereby. What constitutes a risk requiring warnings or instructions is the subject of the preceding section. Where there is a duty to warn, and the manufacturer does give some warning, plaintiff's claim of failure to warn requires the factual-legal evaluation of what constitutes an adequate warning.

The adequacy of the manufacturer's warning is ordinarily a question for the finder of fact.<sup>130</sup> The sufficiency of the seller's discharge of its informational obligation is measured in terms of whether the cautionary information sufficiently conveys the nature, the scope, and the severity of the risk, together with a plain statement of how the user may avoid such risks and safely use the product.<sup>131</sup> If the adequacy issue is determined favorably to the manufacturer, that finding will preclude liability even where "the plaintiff's use of the drug was, in fact, causally connected to the plaintiff's injury."<sup>132</sup>

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warnings or instructions, even though the manufacturer complied with governmental standards.").

127. 788 F.2d 741 (11<sup>th</sup> Cir. 1986).

128. *See id.* at 746.

129. *See id.* ("An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes.").

130. *See* Tatum v. Schering Corp., 795 F.2d 925, 927 (11<sup>th</sup> Cir. 1986); Lawson v. G.D. Searle & Co., 356 N.E.2d 779, 783 (Ill. 1976) (warning adequacy central to determination of unreasonable danger under *Restatement (Second) of Torts* § 402A).

131. For a discussion on warnings, see 1 OWEN ET AL., *supra* note 7, § 9:10.

132. *Seley*, 423 N.E.2d at 836.

The necessary warning may be given through any avenue of communication open between the manufacturer and the physician. However, advertising in the numerous medical periodicals is obviously one such method on which the drug industry relies heavily. It is a method rarely used for the transmission of warnings. In communicating warnings, drug manufacturers have instead placed their principal reliance on the “package insert.” The package insert is precisely what its name suggests: a paper or pamphlet inserted in the container in which the drug is marketed. However, what is important here is that it is contained in the package received by the pharmacist or physician, and not (except in cases where direct warning to the user is required by the FDA) in the package received by the user when he has the prescription filled. The package insert is intended to explain the drug—its chemical structure, its pharmacological actions and effects, its approved, suggested or recommended uses, indications for its appropriate use, any contraindications to that use, and precautions to be taken in its prescription and usage. Warnings of potential adverse effects are included among contradictions and precautions.

Further, warnings may be labeled as such by the word “warning” used in a separate part of the insert. In many circumstances, the package insert will reach a physician prescribing the drug, and will often be through the manufacturer’s “detail man” who familiarizes him with its company’s products. Irrespective of any direct or delegated manufacturer communication with the health-care professional, pertinent product information is available to the physician in the form of a copy reproduced verbatim in the *Physician’s Desk Reference*.<sup>133</sup> The PDR is an annual publication, a compendium of information about all ethical drugs, which reproduces the information from the package inserts of all of them. The PDR is found in the offices of most United States physicians.

Both the form and content of a prescription pharmaceutical package insert are subject to approval by the FDA. It may approve warnings written by the manufacturer or it may require different or additional warnings. Compliance with FDA re-

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133. See generally PHYSICIAN’S DESK REFERENCE (2000).

quirements is a condition of obtaining its approval of the package insert, which is a prerequisite of the marketing of the drug.

As the package insert is required to accompany the pharmaceutical and to contain appropriate warnings, the typical warning claim before a court focuses upon whether the warnings and instructions were adequate. This means of warning, when taken in conjunction with the manufacturer's statement in the PDR, has generally been held to be a suitable mechanism for informing the health care profession.<sup>134</sup> Significantly, a contrary conclusion may be reached where the impact of the manufacturer's package insert information is diluted by other promotional efforts.<sup>135</sup>

Once the warning, however communicated, has reached the physician, there frequently arises a further question as to the adequacy of its content. The rule has been stated succinctly: "[i]t is incumbent upon the manufacturer to bring the warning home to the doctor[,]"<sup>136</sup> and such a warning should be "sufficient to [apprise] a general practitioner . . . of the dangerous propensities of the drug."<sup>137</sup> An "adequate warning" has been

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134. See, e.g., *Johnston v. Upjohn Co.*, 442 S.W.2d 93 (Mo. Ct. App. 1969).

135. See *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 163 (D.S.D. 1967). The court in *Yarrow v. Sterling Drug, Inc.* concluded:

Where the doctor is inundated with literature and product cards of the various manufacturers, as shown here by the facts, a change in the literature or an additional letter intended to present new information on drugs to the doctor is insufficient. The most effective method employed by the drug company in the promotion of new drugs is shown to be the use of detail men; thus, the Court feels that this would also present the most effective method of warning the doctor about recent developments in drugs already employed by the doctor, at no great additional expense. The detail men visit the doctors at frequent intervals and could make an effective oral warning, accompanied by literature on the development, that would affirmatively notify the doctor of side effects such as shown in the facts in this case.

*Id.*

136. *Id.* at 163. Paul D. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 993 (1964). The Rheingold article has been relied upon as authoritative by numerous courts in many scholarly writings. See, e.g., *Martin v. Hacker*, 550 N.Y.S.2d 130 (N.Y. App. Div. 1989); *Kearl v. Lederle Labs.*, 172 Cal. App. 3d 812 (1985) *rev'd on other grounds* 751 P.2d 470 (1988).

137. *Wooderson v. Ortho Pharms. Corp.*, 681 P.2d 1038, 1058 (Kan. 1984) (quoting *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390, 1400 (8th Cir. 1969)).

defined by the New Mexico Supreme Court in *Michael v. Warner/Chilcott*:<sup>138</sup>

What is an adequate warning on a drug label? "Adequate" is defined to mean "sufficient for a specific requirement." . . . The word "sufficient" is defined to mean adequate, enough, equal to the end proposed, and that which may be necessary to accomplish an object[,] it embraces no more than that which, when done, suffices to accomplish the purpose intended in light of present conditions and viewed through the eyes of practical and cautious men . . . . "Warning" is defined to mean previous notice; caution against danger. The purpose of a "warning" is to apprise a party of the existence of danger of which he is not aware to enable him to protect himself against it . . . .<sup>139</sup>

In *Richards v. The Upjohn Co.*,<sup>140</sup> a New Mexico court of appeals offered this quite orderly and appropriate protocol:

Five relevant standards concerning the adequacy of warnings about a dangerous drug are enumerated [in our precedents]: 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from a misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failing to follow it[;] and . . . 5. the means to convey the warning must be adequate.<sup>141</sup>

#### D. *Inadequate Warnings or Instructions and Causation*

As is true for all warnings liability, the plaintiff asserting a drug-related warnings claim must show that the manufacturer's failure to accompany its product with adequate warnings or instructions proximately caused the injury.<sup>142</sup> Comment *j* to *Restatement Second, Torts* § 402A establishes a presumption that a warning, where adequate, would be read and

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138. 579 P.2d 183 (N.M. Ct. App. 1978).

139. *Id.* at 186-87 (affirming denial of motion for summary judgment for non-prescription drug manufacturers of "Sinutab.")

140. 625 P.2d 1192 (N.M. Ct. App. 1980).

141. *Id.* at 1196.

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



heeded.<sup>143</sup> The presumption is two-edged. It aids the defendant manufacturer where an arguably adequate warning has been given. However, where an inadequate warning has been given, or no warning has been given at all, the presumption works in the favor of the plaintiff. In the latter situation, an application of comment *j* raises "a rebuttable presumption beneficial to the plaintiff, that the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug" and of the consequent injury.<sup>144</sup>

Upon plaintiff's proof of injury and the presence of an inadequate warning, or the absence of a warning in the first instance, most courts have agreed that there arises either a permissible inference or a rebuttable presumption that had an adequate warning been given, plaintiff's physician would have altered the course of treatment appropriately. This rebuttable presumption, where adopted by state law, may permit a plaintiff to satisfy its *prima facie* showing of causation even where plaintiff has produced no direct evidence of, or testimony, concerning the adequacy of the warnings or the prospect of different treatment by plaintiff's physician.<sup>145</sup> The pharmaceutical manufacturer may seek to overcome this presumption by showing that even if a product's warning was inadequate, the ad-

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143. *See id.*; *see also* *Reyes v. Wyeth Labs., Inc.*, 498 F.2d 1264, 1281 (5th Cir. 1974) ("In the absence of evidence rebutting the presumption, a jury finding that the defendant's product was the producing cause of the plaintiff's injury would be sufficient to hold him liable.").

144. *See Chapman*, 388 N.E.2d at 547.

The rationale for this presumption is given by the court in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966):

If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided. This is particularly true if the injury takes place slowly, as is the case with the injury in question here.

*Id.* at 85.

145. *Id.* Availability of this presumption does not alter, from the plaintiff's prospective, the attraction of evidence that a fuller warning would have altered the prescribing physician's administration of the pharmaceutical or other prescription product. *See, e.g.*, *Batteast v. Wyeth Labs., Inc.*, 560 N.E.2d 315 (Ill. 1990) (evidence in action arising from drug overdose from administration of aminophylline suppositories raised jury issue as to warning inadequacy and causation; evidence indicated that the prescribing physician would have either declined to prescribe the drug or more closely monitored its administration had the manufacturer's package insert contained more detailed warnings and instructions).

ministering health professional was cognizant of the product's risks, and thus the alleged warning inadequacy was not the producing cause of the patient's injuries.<sup>146</sup>

Defendant's evidentiary burden in rebutting this presumption has been held unsatisfied by a prescribing physician's testimony that he had no duty to disclose to a patient the known risks of administration of the Sabin oral polio vaccine.<sup>147</sup> In contrast and illustrative of the operation of the presumption of comment *j* in the favor of the manufacturer, is the holding in *Seley v. G.D. Searle & Co.*<sup>148</sup> In that case, an action was brought by a woman alleging that she suffered a stroke and partial incapacitation due to her use of defendant's birth control pill.<sup>149</sup> Defendant adduced proof that the plaintiff had failed to inform the prescribing physician of her prior history of toxemia associated with pregnancy, and suggested that even had the defendant's warnings been in the form proposed by plaintiff, plaintiff's physician "could not have related those warnings to [plaintiff's] case."<sup>150</sup> The court determined that a jury could, therefore, conclude that an adequate warning by the defendant would have made no difference in the decision by plaintiff's physician as to either the prescription or the post-prescription monitoring appropriate for plaintiff, leaving plaintiff's cause of action fatally lacking in proof of proximate cause.<sup>151</sup>

A pharmaceutical manufacturer's arguably inadequate warning or instructions do not proximately cause plaintiff's injury where the prescribing physician knows of the relevant

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146. See *Stewart v. Janssen Pharm., Inc.*, 780 S.W.2d 910, 912 (Tex. App. 1989) (anesthesiologist who selected anesthetic drug Sufenta, aware of risks of renarcotization).

147. See *Snawder v. Cohen*, 749 F. Supp. 1473, 1475 (W.D. Ky. 1990).

148. 423 N.E.2d 831 (Ohio 1981).

149. See *id.* at 834.

150. *Id.* at 838.

151. See *id.* "Where, as here, an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter, the presumption established by comment *j* is rebutted, and the required element of proximate cause between the warning and ingestion of the drug is lacking." *Id.* at 838-39. See also *Douglas v. Bussabarger*, 438 P.2d 829, 831 (Wash. 1968) (en banc) (plaintiff's physician, relying, instead, on his own knowledge, specifically stated that he did not read allegedly inadequate warnings).

product risks and fails to inform the patient.<sup>152</sup> Consistently, a failure to warn claim may fail where there is proof that plaintiff's physician proceeded to administer a pharmaceutical, knowing that the patient had exhibited symptoms that the manufacturer advises commend discontinuation.<sup>153</sup> Also noteworthy is the case of *Tunnell v. Parke, Davis & Co.*<sup>154</sup> In that case, the court found that a drug manufacturer's failure to directly warn the prescribing physician was not a basis for liability because the prescribing physician's own testimony revealed that he had personal knowledge of the characteristics of Chloromycetin, and there was no evidence showing that the manufacturer failed to communicate the possible effects to the medical profession, generally.<sup>155</sup>

A New York appellate court affirmed the trial court's denial of summary judgment in a products liability case where the plaintiff, an infant, was born with permanent brain damage allegedly resulting from the mother's treatment with the drug Decumard during pregnancy. Even though the plaintiff and the court acknowledged that the package insert, which warned that the drug was contraindicated for pregnant women, was, itself, a proper package insert;<sup>156</sup> there is authority for the proposition that a question of fact still remained as to the adequacy of the manufacturer's efforts to bring the knowledge of the hazards of the drug to the attention of the medical profession. The court mentioned that the manufacturer had an obligation to keep

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152. See *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 105 (Fla. 1989) ("[I]t makes no difference that the mother testified that Dr. Greenwald did not warn her of the danger of taking Accutane while she was pregnant. While this would present a factual issue in a claim against the doctor, the drug manufacturer could not be penalized for the failure of the doctor to impart knowledge concerning the dangers of the drug of which the doctor had been warned and was aware.").

153. See, e.g., *White v. Slidell Mem. Hosp. & Med. Center*, No. Civ. 89-2691, 1990 U.S. Dist. LEXIS 9933 at \*3 (E.D. La. July 26, 1990) (manufacturer of Bactrim D.S. not liable in death of patient who allegedly suffered toxic epidermal necrolysis from taking drug for urinary tract problems; physician continued to prescribe medicine notwithstanding package insert recommending discontinuation should patient exhibit skin rash).

154. *Prod. Liab. Rep. (CCH) ¶ 8039* (Tenn. Ct. App. 1977). *But see* Schwartz, *supra* note 81, at 241.

155. *Tunnell v. Parke, Davis & Co.*, *Prod. Liab. Rep. (CCH) ¶ 8039* (Tenn. Ct. App. 1977).

156. *Baker v. Saint Agnes Hosp.*, 421 N.Y.S.2d 81, 85-86 (N.Y. App. Div. 1979).

abreast of knowledge of its product as gained through research, adverse reaction reports, scientific literature, and other available methods.<sup>157</sup> Additionally, the manufacturer must “take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession . . . [and] [t]he greater the potential hazard of the drug, the more extensive must be the manufacturer’s efforts to make that hazard known[.]”<sup>158</sup>

When a manufacturer of a potentially dangerous drug fails to change a warning that it knows is widely ignored, a jury may infer that the warning is inadequate. In *Salmon v. Parke, Davis & Co.*,<sup>159</sup> the court ruled that compliance with federal laws did not automatically excuse a manufacturer from liability. The manufacturer had given physicians a calendar advertising the drug chloramphenicol, along with a free sample that contained a warning about the drug. The court reasoned that the calendar might remain on the physician’s desk as a constant reminder to prescribe the drug, long after the sample and the memory of its warning were gone. Therefore, this over-promotion could diminish the effectiveness of a warning that would be adequate in all other respects.<sup>160</sup> The court also announced that a jury could infer unreasonableness on the part of a manufacturer who insisted on using the word “should” instead of the FDA suggested “must” when warning physicians to take certain precautions.<sup>161</sup>

The court in *Bristol-Myers Co. v. Gonzales*,<sup>162</sup> held that the misuse of a drug with an inadequate warning could be considered foreseeable, and therefore not a bar to recovery against the manufacturer.<sup>163</sup> In foreign markets, the choice of language for a warning may prove crucial, although the court in *Pierluisi v. E.R. Squibb & Sons, Inc.*,<sup>164</sup> found that because the Puerto Rican physician read and understood the English language, failure to

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157. *See id.*

158. *Id.*

159. 520 F.2d 1359 (4th Cir. 1975).

160. *See id.* at 1362.

161. *See id.* at 1363.

162. 548 S.W.2d 416 (Tex. Ct. Civ. App. 1976).

163. *See id.*

164. 440 F. Supp. 691 (D.P.R. 1977).

include a Spanish translation of the manufacturer's warning was not a proximate cause of the alleged injury.<sup>165</sup>

#### E. *Intergenerational Harm*

Chemical compounds and other toxic substances increasingly are claimed to have generated chromosomal alteration that may cause genetic defects in subsequent generations. If the child or grandchild of a person exposed to some toxin is born with a withered arm, or perhaps suffers a handicap much more severe, what ought be the potential of a tort action against the manufacturer that manufactured the product one or more generations before?

A leading expression of the view that recovery ought to be available only to the first generation or immediate offspring that was, in fact, exposed to the chemical in utero is *Grover v. Eli Lilly & Co.*<sup>166</sup> In *Grover*, a federal trial court certified this issue to the Ohio Supreme Court in the context of a grandchild's claim, through his representatives.<sup>167</sup> The claim, in *Grover*, was that the grandchild's severe birth defects were caused by defects in the mother's reproductive system, which were earlier caused by the grandmother's ingestion of the drug DES.<sup>168</sup> The Ohio Supreme Court noted that some courts in other jurisdictions, on similar but distinguishable facts, had not permitted actions to proceed for such "pre-conception" torts.<sup>169</sup> However, the Ohio high court quoted *Palsgraf v. Long Island R.R. Co.*<sup>170</sup> for the proposition that "[a]n actor does not have a duty to a particular plaintiff unless the risk to that plaintiff is within the actor's 'range of apprehension'."<sup>171</sup> In finding no cause of action inuring to the grandchild, the *Grover* court explained:

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165. *See id.* at 691.

166. 591 N.E.2d 696 (Ohio 1992).

167. *See id.* at 697.

168. *See id.*

169. *See id.* at 698 (citing *Albala v. City of New York*, 429 N.E.2d 786 (N.Y. 1981)). For an example of a court that did not permit "pre-conception" torts, see *Monusko v. Postle*, 437 N.W.2d 367 (Mich. Ct. App. 1989) (mother's physicians allegedly failed to inoculate mother with rubella vaccine prior to child's conception).

170. *See Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99, 100 (N.Y. 1928).

171. *Grover*, 591 N.E.2d at 700 (quoting *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99, 100 (N.Y. 1928)).

When a pharmaceutical company prescribes drugs to a woman, the company, under ordinary circumstances, does not have a duty to her daughter's infant who will be conceived twenty-eight years later. . . . Because of the remoteness in time and causation, we hold that [the grandchild] does not have an independent cause of action, and answer the district court's question in the negative. A pharmaceutical company's liability for the distribution or manufacturer of a defective prescription drug does not extend to persons who were never exposed to the drug, either directly or *in utero*.<sup>172</sup>

#### F. *Liability of Pharmacists and Pharmaceutical Distributors*

With respect to prescription pharmaceuticals, the pharmacist is considered a seller at retail. As such, he is generally vulnerable to all of the liabilities imposed by law on retail sellers. However, the traditional principles governing a non-manufacturing pharmaceutical seller's potential liability have, appropriately, been affected by two imposing policy imperatives: (1) the pharmacist is an essential and professional part of the delivery system of pharmaceuticals to countless persons;<sup>173</sup> and (2) this retailer sells products that if misused or inappropriate to a patient's therapy can have serious or even deadly effects.<sup>174</sup>

For claims brought by a patient alleging pharmacist negligence in the sale of a prescription product, the pharmacist's duty of care is properly a function of the magnitude of the risk to patient.<sup>175</sup> As is appropriate, the pharmacist is held to a standard of "the highest degree of prudence in filling a prescription."<sup>176</sup> By law and by custom, however, it is the physician, not

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172. *Grover*, 591 N.E.2d at 700-01.

173. See *Cackowski v. Wal-Mart Stores, Inc.*, 767 So.2d 319, 325 (Ala. 2000) (noting "inextricable" role of pharmacist in health care delivery system).

174. See generally Steven W. Huang, *Redefining Pharmacists' Legal Responsibilities*, 24 AM. J.L. & MED. 417 (1998); see also David J. Marchitelli, Annotation, *Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User*, 44 A.L.R. 5th 393 (1996).

175. *Morgan v. Walmart Stores, Inc.*, 30 S.W.3d 455, 469 (Tex. Ct. App. 2000) (holding pharmacist did not have a general duty to warn patient of potential adverse reactions to prescription drugs absent evidence of any special circumstances).

176. *Id.* at 464. See also Timothy E. Travers, Annotation, *Druggist's Civil Liability for Injuries Sustained as a Result of Negligence in Incorrectly Filling Drug Prescriptions*, 3 A.L.R. 4th 270 (1981), 32 AM. JUR. TRIALS 375, § 3 (1985). See also *Moss v. Meyer*, 454 N.E.2d 48, 51 (Ill. Ct. App. 1983) (holding that when a

the pharmacist, who is responsible for selecting and prescribing the drug. Therefore, the pharmacist generally has no liability when he dispenses the correct drug in the prescribed dosage. This is true whether the claim against him is based on negligence, implied warranty, or strict liability under *Restatement Second, Torts* § 402A.<sup>177</sup> The limiting phrase "in general" is necessary because some courts have identified exceptions to the rule in special circumstances. An example of such a circumstance is when the pharmacist fills a prescription that he should know will create health risks for a patient, based upon the pharmacist's knowledge of "a particular patient's unique medical problems or where a pharmacist fills two incompatible prescriptions."<sup>178</sup>

As to the specific issue of whether the pharmacist does not have a freestanding obligation to convey adequate warnings to the patient, the overwhelming authority illustrates that he does not.<sup>179</sup> A representative decision so holding is *Stebbins v. Concord Wrigley Drugs, Inc.*,<sup>180</sup> which involved a claim that the pharmacist who filled a prescription for the antidepressant Tofranil failed to advise the patient of the prescription's side effects, which include drowsiness.<sup>181</sup> The patient's automobile was subsequently involved in a collision with that of plaintiff.<sup>182</sup> Finding for the pharmacist, the state appellate court wrote, "[A] pharmacist has no duty to warn the patient of possible side effects of a prescribed medication where the prescription is proper on its face and neither the physician nor the manufacturer has

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pharmacy delivered capsules to a home, it was not foreseeable that minor would attempt suicide).

177. Compare *Martin v. Hacker*, 550 N.Y.S.2d 130 (N.Y. App. Div. 1989) (Reserpine distributor's dissemination of dispensing information along with pharmaceutical insufficient to raise question of fact as to representation of product as its own; held: no liability for suicide of user) with *McLeod v. W.S. Merrell Co.*, 174 So.2d 736 (Fla. 1965); *Bichler v. Willing*, 397 N.Y.S.2d 57 (1977); *Batiste v. American Home Products Corp.*, 231 S.E.2d 269 (N.C. Ct. App. 1977) (holding pharmacists not liable for plaintiffs' injuries allegedly suffered because of a prescription drug).

178. *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 388 (Mich. Ct. App. 1987).

179. See *id.* at 387-88.

180. 416 N.W.2d 381 (Mich. Ct. App. 1987).

181. See *id.* at 383-84.

182. See *id.*

required that any warning be given to the patient by the pharmacist.”<sup>183</sup>

One rationale for limiting patient redress against the pharmacist is that to create incentives for the pharmacist to second-guess the physician would carry with it a real danger of blurring the lines that define the latter’s responsibilities to his patient. As summarized by one court:

The imposition of a generalized duty to warn would unnecessarily interfere with the relationship between physician and patient by compelling pharmacists seeking to escape liability to question the propriety of every prescription they fill. Furthermore, a patient faced with an overwhelming number of warnings from his or her pharmacist may decide not to take a medication prescribed by a physician, who has greater access to and knowledge of the patient’s complete medical history and current condition than the pharmacist.<sup>184</sup>

When a pharmacist voluntarily chooses to advise a patient of some risks associated with a pharmaceutical, he should not categorically be considered to have waived the limited protection of the “learned intermediary” rule and assumed the duty to inform the patient of all such risks. An Illinois appeals court so held in *Kasin v. Osco Drug, Inc.*<sup>185</sup> In that case, a pharmacy customer (a kidney donee) and his brother (the kidney donor) claimed that the pharmacist should be liable for having advised the donee of some of the side effects of taking the drug Daypro, but failing to warn of others, such as the risk of kidney failure.<sup>186</sup> On the facts before it, the appellate court found that the druggist’s limited consultation with the customer did not trigger an omnibus obligation to warn of the entire spectrum of the drug’s potential side effects.<sup>187</sup> The court cautioned, however, that under the doctrine of “voluntary undertaking”<sup>188</sup> a different conclusion might be reached if the nature and breadth of the pharmacist’s words or actions were such as to reasonably invite

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183. *Id.* at 387-88. *Accord* *Frye v. Medicare-Glaser Corp.*, 605 N.E.2d 557, 561 (Ill. 1992).

184. *Morgan*, 30 S.W.3d at 467.

185. 728 N.E.2d 77 (Ill. App. Ct. 2000).

186. *See id.* at 77-78.

187. *See id.* at 80.

188. *See* RESTATEMENT (SECOND) OF TORTS § 323, 135 (1965).



the customer's reliance upon the correctness and the continuation of the pharmacist's counseling.<sup>189</sup>

The general rule that the pharmacist is not liable if he dispenses the correct drug in the prescribed dosage was followed in *Lemire v. Garrard Drugs*.<sup>190</sup> In that case, a products liability action was brought against a druggist because defendant's predecessor had sold the drug Diethylstilbestrol (DES) to the plaintiff's mother for use during the pregnancy.<sup>191</sup> Plaintiff claimed that the *in utero* exposure to the Diethylstilbestrol caused cervical cancer.<sup>192</sup> Complementary authority has precluded a claim against a pharmacy where there has been "no allegation that the pharmacy did any compounding or changed the drug in any way after receiving it from the manufacturer," or "substituted a different brand or generic version for the brand prescribed," or "exercised any independent discretion, skill, or knowledge in filling the prescription."<sup>193</sup>

Other authority, however, disfavors application of the ordinary remedies against product sellers to pharmacists and, instead, characterizes the pharmacist as a provider of services. An influential expression of this position was taken by the California Supreme Court in *Murphy v. E.R. Squibb & Sons, Incorporated*.<sup>194</sup> This was an action in which the plaintiff, the daughter of a woman who had been prescribed DES, sought to impose strict liability upon the pharmacist who had sold the drug and upon the manufacturer who had manufactured it.<sup>195</sup> The California court disagreed with plaintiff's argument that tort liability for pharmacists should not differ from that applied to retailers, to whom strict products liability had long been ap-

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189. *Kasin*, 728 N.E.2d at 80 (interpreting *Frye v. Medicare-Glaser Corp.*, 605 N.E.2d 557 (Ill. 1992)).

190. 291 N.W.2d 103 (Mich. Ct. App. 1980); *see also* *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987) ("[A] retail pharmacist is not required to provide to the patient-consumer such warnings as are required to be provided to physicians by the manufacturers of prescription drugs.").

191. *See Lemire*, 291 N.W.2d at 104.

192. *See id.*

193. *In re Raynor v. Richardson Merrell, Inc.*, 643 F. Supp. 238, 246 (D.D.C. 1986) (finding of no liability for pharmacy justified additionally on policy ground that contrary conclusion imposing duty would require the pharmacist to substitute its judgment for the prescribing physician).

194. 710 P.2d 247 (Cal. 1985).

195. *See id.*

plied.<sup>196</sup> The Court observed that under California law, pharmacists were recognized as professionals.<sup>197</sup> As such, the court concluded that the pharmacist's activity in the filling of a prescription executed by another, for a product manufactured by another, should be described as the provision of a service and not the sale of a product.<sup>198</sup>

The pharmacist should not be liable, pursuant to any implied warranty of merchantability claim, if he dispenses the drug as prescribed, in kind and dosage.<sup>199</sup> Express warranties by the pharmacist are rarely made, and, even if made, are not likely to be the factors relied on by the customer who is filling a prescription ordered by his doctor. It is not usually the drug-gist's skill and judgment in selection that is relied on, and thus the implied warranty of fitness for a particular purpose is not made. There may, however, be a foundation for liability in the breach of an implied warranty of merchantability where the drug is prescribed, but of improper quality, due to deterioration in storage or otherwise.

## V. Defenses—Generally

Where the physician's or the patient's negligence or assumption of the risk is of such an unforeseeable nature as to be considered a superseding cause, the culpable conduct of the pharmaceutical manufacturer may no longer be determined to

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196. *See id.*

197. *See id.* at 251-52.

198. *Murphy*, 710 P.2d at 252 discussed in Gary T. Walker, *The Expanding Applicability of Strict Liability Principles: How is a "Product" Defined?*, 22 Tort & Ins. L.J. 1, 8 (1986). For a discussion, see *Kohl v. American Home Products Corp.*, 78 F. Supp. 2d 885, 894 (W.D. Ark. 1999) (internal citations omitted). Some courts had held that pharmacies cannot be held strictly liable for dispensing a prescription drug. This conclusion is typically reached in one of two ways. First, some courts rely on the learned intermediary doctrine to reject the application of strict liability to pharmacists or pharmacies. Other courts follow the path suggested by the manufacturer defendants and draw a distinction between service providers and providers of products. *See Kohl*, 78 F. Supp. at 894. (citing *Raynor v. Richardson-Merrell, Inc.*, 643 F. Supp. 238, 246-47 (D.D.C. 1986) (application of learned intermediary doctrine to find no pharmacist liability); *see also Murphy v. E.R. Squibb & Sons, Inc.*, 710 P.2d 247, 251 (Cal. 1985) (strict products liability inapplicable as pharmacist "is engaged in a hybrid enterprise, combining the performance of services and the sale of prescription drugs"); *Zichichi*, 528 A.2d at 807 (finding service providers not strictly liable).

199. *See McLeod*, 174 So.2d at 736.

be the efficient contributing cause to the injury or harm.<sup>200</sup> Thus, for example, if a physician decides to administer a pharmaceutical and ignores the risks explained by the manufacturer, he may be considered the intervening, independent, and sole proximate cause of the patient's injuries.<sup>201</sup>

Where the conduct of the patient constitutes negligence or an assumption of the risk of such an unforeseeable nature as to be considered a superseding cause, the culpable conduct of the pharmaceutical manufacturer may no longer be considered the efficient contributing cause to the injury or harm.<sup>202</sup> For example, in *Lindsay v. Ortho Pharmaceutical Corp.*,<sup>203</sup> the court permitted the defendant manufacturer to go to the jury with its argument that the plaintiff was contributorily negligent in purchasing and using defendant's contraceptives without a prescription.<sup>204</sup> The legal standard for user conduct employed by that court was whether the plaintiff "knew or should have known about the dangers inherent in the drug with regard to injuries such as she has suffered, and in view of those dangers should have known about the importance of securing a prescription."<sup>205</sup>

In multi-defendant prescription drug cases, the different limitations periods which apply may be different than the ordinary statute of limitation issues in products liability claims.<sup>206</sup> For example, while a conventional warranty or tort limitation period may govern a claim against the pharmaceutical manufacturer, the law of a particular state may have a separate limitation period for actions against pharmacists where plaintiff's claim, if proven under state law, sounds in medical malpractice.<sup>207</sup>

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200. See *Taylor v. Wyeth Labs., Inc.*, 362 N.W.2d 293, 299-300 (Mich. 1984); see also *Richards*, 625 P.2d at 1196-97.

201. See *Formella v. Ciba-Geigy Corp.*, 300 N.W.2d 356, 358 (Iowa 1980).

202. See, e.g., *Lindsay v. Ortho Pharm. Corp.* 637 F.2d 87, 94 (2d Cir. 1980).

203. 637 F.2d 87 (2d Cir. 1980).

204. See *id.* at 94.

205. *Id.*

206. For a discussion on the limitation of actions, see OWEN ET AL., *supra* note 7, § 31.

207. See, e.g., *Robinson v. Williamson*, 537 S.E.2d 159 (Ga. Ct. App. 2000) (applying two-year "action for medical malpractice" limitation period to claim against pharmacist in suit against both pharmacy and pharmacist).

### A. *Physician or Pharmacist Negligence*

The failure of the prescribing physician or the pharmacist to discharge his professional duty of care to the patient may, where such failure constitutes the producing cause of the plaintiff's harm, generally operate to relieve the pharmaceutical manufacturer of liability. Where such substandard behavior on the part of the physician or the pharmacist is merely a joint cause of the injury (irrespective of whether the pharmacist, the physician, or both, are party defendants to the suit) their conduct may be properly considered relevant to the issues of comparative fault, apportionment, contribution, or indemnity.<sup>208</sup>

The manufacturer may escape liability if it can show (1) that it provided an adequate warning to the prescribing physician, (2) the physician was aware of the risks associated with the use of the drug, and (3) he or she nevertheless prescribed the drug without providing an adequate warning.<sup>209</sup> For example, in *Felix v. Hoffman-LaRoche*,<sup>210</sup> evidence adduced at trial demonstrated that plaintiff's physician prescribed the drug Accutane to plaintiff for severe acne.<sup>211</sup> Thereafter, plaintiff, unaware of the drug's teratogenic properties, became pregnant and gave birth to a severely deformed child.<sup>212</sup> The court found the manufacturer of the drug not liable for wrongful death based upon evidence that the manufacturer had, in fact, cautioned prescribing physicians of the drug's possible side effects by means of a package insert.<sup>213</sup> The court held that it was the physician, as a "learned intermediary," who had the duty to alert the patient of the contraindications of the drug.<sup>214</sup>

Regarding related effects, where the evidence indicates that the prescribing medical professional simply failed to read a demonstrably adequate warning in a package insert or elsewhere, the manufacturer should escape liability on the basis of

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208. See generally OWEN ET AL., *supra* note 7, § 15 (Comparative fault), § 24 (Multiple defendants—Joint liability), §25 (Multiple defendants—Contribution and indemnity).

209. *Thomas v. Hoffman-La Roche*, 731 F. Supp. 224, 228-30 (N.D. Miss. 1989).

210. 513 So.2d 1319 (Fla. Dist. Ct. App. 1987).

211. See *id.*

212. See *id.*

213. See *id.*

214. See *id.*

having fulfilled its informational obligation.<sup>215</sup> An example of such a failure to read an adequate warning is in *Schindler v. Lederle Laboratories*.<sup>216</sup> In *Schindler v. Lederle Laboratories*, the pediatrician did not read an explicit warning contained in a package insert that cautioned against the inoculation of polio vaccine in children with depressed immune response mechanisms.<sup>217</sup> On these facts, the pharmaceutical manufacturer should not be liable for the consequent injury to the child.<sup>218</sup> To be distinguished are decisions in which a triable issue of fact exists as to the foreseeability that the physician will fail to consult the PDR.<sup>219</sup> An example of a distinguishable decision is the New Mexico Court of Appeals in *Richards v. The Upjohn Co.*<sup>220</sup> In that case, the New Mexico Court of Appeals reversed the trial court's grant of summary judgment upon identification of a factual issue as to whether, in the context of prescribing the drug neomycin sulfate, the physician's omission and resulting misuse of the pharmaceutical was foreseeable, or whether it was a superceding cause of the plaintiff's deafness.<sup>221</sup>

By way of further example, in *Martin v. Hacker*,<sup>222</sup> suit was brought against the manufacturer and the distributor of the drugs hydrochlorothiazide (HCT) and Reserpine, following the suicide of a patient who had been prescribed both drugs.<sup>223</sup> The New York appellate court concluded that neither the manufacturer nor the distributor were liable, as the respective package inserts for the drugs had provided adequate warnings to the medical profession of potential contraindications and circum-

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215. See, e.g., *Schindler v. Lederle Labs.*, 725 F.2d 1036, 1039-40 (6th Cir. 1983) (finding pharmaceutical manufacturer should not be liable for consequent injury to child when the pediatrician did not read an explicit warning contained in the package insert).

216. See *id.*

217. See *id.*

218. See *id.* The warning read, in pertinent part: "Vaccinations should also be delayed in conditions having a suppressive effect on the immune response mechanism, such as therapy with immune serum globulin, steroids, radiation, cancer chemotherapeutic agents . . . lymphogenous disease, and disgamaglobinemia [.]" *Id.* at 1039.

219. See, e.g., *Richards*, 625 P.2d at 1195.

220. 625 P.2d 1192 (N.M. Ct. App. 1980).

221. See *id.* at 1198.

222. 586 N.Y.S.2d 407 (N.Y. App. Div. 1992).

223. See *id.* at 409.

stances advising discontinuation.<sup>224</sup> Specifically, the package insert for HCT stated that it might “add to or potentiate the action of other anti-hypertensive drugs,”<sup>225</sup> while the insert for Reserpine stated that the drug should be discontinued at any sign of despondence, early morning insomnia, appetite loss, impotence or self-deprecation.<sup>226</sup> The insert advised further that drug-related depression severe enough to result in suicide might persist some months following discontinuation.<sup>227</sup>

It has been held that a plaintiff need not produce expert testimony to prevail in a suit brought against a pharmacist for misfilling a customer’s prescription. The Maine Supreme Court so held in *Walter v. Wal-Mart Stores, Inc.*,<sup>228</sup> a suit arising from a claim that the pharmacist allegedly filled a customer’s prescription with the wrong chemotherapy drug.<sup>229</sup>

### 1. *Allergic or Idiosyncratic Reactions*

The pharmaceutical manufacturer’s duty to warn of unusual reactions to its product requires examination of the maker’s duty to be informed, its nature and its limits. It is no defense that the manufacturer marketed a drug in ignorance of its propensity for a particular harm. He has a duty to test his product adequately for dangers inherent in its use before putting it on the market, and if it is shown that such tests would have revealed the potential for harm, he will be liable if harm follows use.<sup>230</sup> The extent of the necessary testing is measured

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224. *See id.*

225. *Id.*

226. *See id.*

227. *See id.* also *Ashman v. S.K. & F Labs.*, 702 F. Supp. 1401 (N.D. Ill. 1988). In *Ashman*, the plaintiff was taken to the hospital in an unconscious state after ingesting a combination of Tagamet, an anti-ulcer pill, and Halcion, a sleeping pill. *See id.* at 1403. Plaintiff’s physician, knowing of the interactive effect of the two drugs both from a package insert of one of the two drugs and from the Physician’s Desk Reference, nevertheless prescribed them concurrently. *See id.* In addition, while plaintiff was unconscious, the physician proceeded to perform a lumbar puncture which left plaintiff paralyzed. *See id.* The court held that the manufacturer was not liable for plaintiff’s injuries upon the showing that not only did plaintiff’s physician function as a learned intermediary but also that plaintiff’s paralysis was not foreseeable. *See id.* at 1404-05.

228. 748 A.2d 961 (Me. 2000).

229. *See id.* at 965.

230. *See generally Hoffman-La Roche*, 731 F. Supp. 224 (N.D. Miss. 1989); *see also Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968) (infant

by the foreseeable risk of harm to users in the light of then current scientific and medical knowledge.<sup>231</sup> Therefore, the fact that an adverse effect which gives rise to a lawsuit is the first known occurrence with use of the drug will not necessarily prevent recovery.<sup>232</sup> In addition to the duty to make adequate tests, the manufacturer has a duty to keep itself informed of changed or newly available information concerning the effects of its products.<sup>233</sup>

While there is no liability for the failure to warn of the altogether unpredictable adverse patient reaction, prevailing authority is clear that the manufacturer will be required to warn of any known or knowable adverse result that can be predicted to follow the use of its drug—no matter how small the number of users to which it can be expected to occur. Liability will lie in the knowledge, not the number. Courts and commentators have variously described the range of frequency risk sufficient to trigger the duty to warn. Dean Prosser suggested that the manufacturer be “required to take into account allergies common to a substantial portion of the population.”<sup>234</sup> Decisional

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plaintiff suffered injuries such as mental retardation and seizures proximately caused by an injection of the drug Quadrigen administered to the infant); *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967) (plaintiff suffered injuries to cataracts from taking a drug for lowering blood cholesterol levels).

231. See *O'Hare v. Merck & Co.*, 381 F.2d 286 (8th Cir. 1967) (although evidence was found to be sufficient to support finding of a causal connection between the use of the drug Ka-50 and the small bowel lesion found in appellant, the Eighth Circuit held that the precautions given by the drug company to the medical profession at the time the drug was placed on the market were adequate and complied with the duty to warn).

232. See *Percival v. American Cyanamid Co.*, 689 F. Supp. 1060, 1060 (W.D. Okla. 1987) (recognizing that, under Oklahoma law, the manufacturer of the DPT vaccine “Tri-Immunol” has a duty to warn only the prescribing physician; held that the package insert distributed with the vaccine was adequate to warn physicians of the risks). See, e.g., *Cofnas v. Tomases*, 548 N.Y.S.2d 367, 367 (N.Y. Sup Ct. 1989) (finding manufacturer of prescription drug Etraform not liable to patient where the prescribing physician knew of the risks associated with administration of the drug and the manufacturer had given adequate warnings and instructions).

233. See *Hermes v. Pfizer, Inc.*, 848 F.2d 66, 68 (5th Cir. 1988) (stating a manufacturer has a duty to keep abreast of research, adverse reaction reports, and other scientific literature pertaining to its product); see also *McEwen*, 528 P.2d at 522 (plaintiff suffered blindness in her right eye and injuries to her left eye due to defendant's failure to adequately warn the medical profession of the potential dangers of an oral contraceptive).

234. William L. Prosser, *The Assault Upon the Citadel*, 69 YALE L.J. 1099, 1144-45 (1960):

law defined variously the threshold risk that will trigger a warning duty, identifying a duty to warn of “an allergic reaction to a product where the plaintiff is a member of an identifiable class of persons allergic thereto”,<sup>235</sup> an “appreciable number”,<sup>236</sup> a “substantial portion of possible users”,<sup>237</sup> or a number of foreseeable users sufficient to demonstrate reasonably foreseeable idiosyncrasies.<sup>238</sup>

### B. *Statutes of Limitation*

Due to the long latency period of many injuries or diseases that may be caused by pharmaceuticals, application of statutes of limitations to drug product cases may present special litigation issues. Ordinarily a statute of limitations begins to run when the cause of action accrues, and the cause of action accrues at the point at which the elements necessary to the plaintiff's successful claim have all come to exist.<sup>239</sup> Usually the last such element is the injury, and when it occurs, the cause of action is complete.<sup>240</sup> But what of the circumstance in which a person is given prescriptions for a particular drug which is then ingested over a long period of time, with the ultimate result of producing injury or death from untoward side effects?

An action against the drug's manufacturer will generally be one in tort to which the tort statute of limitations will be applied. Once a causal relation between the drug and the injury is conceded, it becomes clear that the “injury” may be said to have

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[T]he seller may expect, within some reasonable limits, that the product will be used by normal persons, and that he will not be held responsible when some idiosyncrasy peculiar to the plaintiff makes him abnormally sensitive to a product quite harmless to ordinary people. This must be qualified to the extent that he is required to take into account allergies common to a substantial portion of the population. This in turn must be qualified by his reasonable right to assume that those who have a common allergy—for example, to strawberries—will be aware of the fact, and will take measures to protect themselves, so that a warning on the label may be all that is required of him.

*Id.*

235. *Howard v. Avon Prods., Inc.*, 395 P.2d 1007, 1010 (Colo. 1964).

236. *Crotty v. Shartenberg's-New Haven, Inc.*, 162 A.2d 513, 516 (Conn. 1960).

237. *Magee v. Wyeth Labs., Inc.*, 29 Cal. Rptr. 322 at 352.

238. *Merrill v. Beaute Vues Corp.*, 235 F.2d 893, 898 (10th Cir. 1956).

239. See generally OWEN ET AL., *supra* note 7, § 31:1.

240. See *id.*



been sustained in at least some measure on the first ingestion of the drug, and the cause of action to be complete at that point. Under traditional rules, the limitations period would begin to run immediately. Often, however, injury from such a cause may not reveal itself in diagnosable symptoms of disease or injury for many years, frequently after the patient's opportunity to file a lawsuit in a timely fashion has expired.

Under a discovery rule, the limitations period begins to run at the time when the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, the illness and the relationship between a third party's conduct and that illness.<sup>241</sup> Illustrative of the application of such a discovery rule, albeit in the context of a defendant's verdict, is the conclusion reached in *Keith-Popp v. Eli Lilly & Co.*<sup>242</sup> *Keith-Popp* was an action commenced by a mother who experienced difficulties during her pregnancy with her second child comparable to those she had experienced with her first child, and which she attributed to her *in utero* exposure to DES.<sup>243</sup> The court held that the forum's three-year statute of limitations, governing her action in the pregnancy for her second child, commenced to run when she learned that the pregnancy problems with the first child were attributable to DES.<sup>244</sup> Other authority would apply a standard that the period of limitations would commence at the time the injury or damage first became ascertainable to the plaintiff or, where plaintiff is a minor, to those representing plaintiff.<sup>245</sup>

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241. See *Anthony v. Abbott Labs.*, 490 A.2d 43, 46 (R.I. 1985) (stating discovery rule is applicable where manifestation of the injury, the cause of the injury, and the facts sufficient to permit recognition of relation between manufacturer's conduct and the injury occur at different points in time).

242. 639 F. Supp. 1479 (W.D. Wis. 1986).

243. See *id.* at 1480-81.

244. *Id.* at 1482-83. The court concluded that the damages sought in plaintiff's second cause of action are consequences of DES-caused premature labor and delivery, and the claim is time-barred because it occurred more than three years before the filing of this lawsuit. See *id.*

245. See, e.g., *Cowan by Cowan v. Lederle Labs.*, 604 F. Supp. 438, 443 (D. Kan. 1985). In that action for damages for discoloration of a minor's teeth from ingestion of tetracycline, the court held that the application of Kansas's two-year statute of limitations presented factual questions as to when plaintiff last took the pharmaceutical manufactured by the defendant, and when the discoloration of plaintiff's teeth was first reasonably ascertainable to the plaintiff or to her parents. See *id.* at 444.

## VI. Conclusion

It cannot be gainsaid that one objective of public law and private law, as reflected in the many *Restatements*, is the provision of rules of general applicability that actors may appreciate and employ to govern their conduct accordingly, that attorneys can interpret rationally (assuming the ordinary latitude of the advocacy process), and that courts can apply evenhandedly. An *au courant* metaphor is “transparency.” As regards the accident law subcategory of products liability, the objective of the American Law Institute and the diverse state legislatures is to present standards that can be seen to be sufficiently elastic to accommodate the multitude of injury scenarios, yet sufficiently rigid to cabin the decisional law pursuant thereto into a moderately coherent whole.

Pharmaceutical products liability law departs from all other dimensions of products liability. This liability doctrine involves not simply products, but products that if defective can create the highest degree of risk of death or serious bodily injury. The same, of course, could be said of a multitude of products that might be purchased at any well provisioned hardware store. However prescription pharmaceuticals, blood, and biological products differ from ordinary products, because if defective, they will routinely create the *highest* levels of risk. At the same time, these ethical drugs and their biological counterparts are not simply products, but also medicines. A substantial proportion of such medicines have the highest importance in matters of private and public health.

As a consequence, pharmaceutical products liability law has endeavored to adopt a balanced regimen of liability rules that vigorously preserves the right of injured parties to gain indemnification for harm caused by defective products, while providing simultaneously a suitable degree of protection for the manufacturers of such products, in recognition of (1) the unavoidable risks posed by many pharmaceuticals and therapies; and (2) the societal desire that the research, development, and marketing of potentially important new drugs not be impeded by the more rigorous liability rules applicable to ordinary products.

No other realm of accident law has required the reconciliation of accident law policy for products importing the *highest*

levels of risk, but produced by manufacturers needing the *highest* degree of liability solicitude. In some settings, activities of an irreducible level of risk, such as the manufacture and handling of radioactive materials, have not been immunized from tort liability, in part because the legislative authors were unwilling to displace broad areas of state liability prerogatives.<sup>246</sup> In other products liability precincts, such as motor vehicles, which involve avoidable product defects and thus reasonably reducible risks, the manufacturers are subject to ordinary liability rules.<sup>247</sup>

*Restatement Second of Torts* § 402A, with its concomitant comments *j* and *k*, has represented a worthy resolution of the policy tension between (1) compensating persons injured by defective pharmaceuticals; and (2) creating a negligence safe harbor for manufacturers who market products reflecting the highest cautionary considerations known or knowable to the medical and scientific community. *Products Liability Restatement* § 6 refines this policy compromise with its quite specific circumference for the manufacturer's design or formulation obligations, essentially immunizing from liability sellers who properly market pharmaceuticals that do in fact have a therapeutic value to a recognized class of patients. As to warnings, the *Third Restatement* authors follow the widely-approved decisional law compromise that countenances the provision of warnings and instructions to the medical community, save in the very limited circumstances in which the health care provider's role as to or relationship with the patient is so remote as to commend direct warnings to the patient.

In sum, the Institute's widely followed *Restatement Second of Torts* § 402A, read together with the *Restatement (Third) of Torts: Products Liability* § 6, reflect a recognition of the most

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246. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). Referencing the Price Anderson Act, Pub. L. 94-197, 89 Stat. 1111 (codified as amended at 42 U.S.C. § 2210 (1994)), the Supreme Court observed that "Congress assumed that persons injured by nuclear accidents were free to utilize existing state tort remedies." *Id.* at 252. "For example, the [Joint] committee rejected a suggestion that it adopt a federal tort to replace existing state remedies, noting that such displacement of state remedies would engender great opposition." *Id.* at 254.

247. See generally OWEN ET AL., *supra* note 7, at §§ 21:1, 21:2, 21:3, discussing automotive products liability, including automotive design defects and the manufacturer's obligation to design a car that is reasonably "crashworthy."

difficult but tolerable tension between the tort goal requiring blameworthy actors to indemnify victims of defective products, while at the same time providing pharmaceutical manufacturers the breathing space to perform their optimal tasks, the development and marketing of often unavoidably unsafe, but frequently highly beneficial, prescription pharmaceuticals.

