

## **Manufacturers' Liability for Drugs and Medical Devices Under the Restatement (Third) of Torts: Products Liability <sup>‡</sup>**

*The Hon. William A. Dreier* \*

The question of liability for prescription drugs has engendered a three-way debate among: (1) the proponents of a pure negligence or risk-utility standard; (2) those who agree with the new formulations of section 6 of the 1966 Restatement (Third) of Torts: Products Liability (the Restatement (Third)); and (3) the adherents of section 402A, comment k, of the Restatement (Second) of Torts. In a 1994 law review article, Professor Richard L. Cupp comprehensively explained the middle-of-the-road negligence approach.<sup>1</sup> The Restatement (Third) approach, however, amended slightly to address unusual cases, strikes the proper balance between a plaintiff's interests and the interests of drug or medical device manufacturers. I agree with Professor Cupp and the Restatement (Third) Reporters that either approach is preferable to the incomprehensible old comment k, which proclaimed both liability and exoneration under the rubric of an unavoidable lack of safety.<sup>2</sup>

The Restatement (Third) section 6, excluding subsection (e) (concerning retail sellers) 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 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:

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<sup>1</sup> See Richard L. Cupp, *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 81-94 (1994).

<sup>2</sup> See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1966).

- (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 of 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 warning; 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.<sup>3</sup>

Subsection (a), which assesses liability for a defective drug or medical device and defines the terms “prescription drug or medical device,” while leaving the definition of “defect” to succeeding subsections, raises no real issues. Subsection (b) classifies possible defects according to the same three-part categories of section 2 of the Restatement (Third), which governs products liability generally. Commenters have not challenged subsection 2(b)(1), seemingly because they appear to agree that a manufacturing defect in this context, as with manufacturing liability in any other context, warrants accountability.

The hue and cry of the plaintiffs’ bar, however, centers on subsection (c), while the defendants’ bar bemoans subsection (d). Plaintiffs chastise the Reporters for absolving drug manufacturers from design defect liability if a reasonable health-care provider, knowing the foreseeable risks and therapeutic benefits, would “prescribe the drug or medical device for any class of patients.”<sup>4</sup> Thus, plaintiffs argue, manufacturers have a license to loose upon the world highly dangerous drugs that have but one obscure palliative purpose.

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<sup>3</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1997).

<sup>4</sup> *Id.* § 6(c).

This argument fails for three reasons. First, subsection (c) does not give manufacturers *carte blanche*. Instead, liability is subject to a threshold, albeit weak, risk-utility balancing analysis.<sup>5</sup> Nonefficacious drugs violate this provision, as do drugs whose meager benefits are far outweighed by significant risks. Next, the standard of judgment is not that of an untutored user, but rather that of a learned intermediary, a “reasonable [prescribing] health-care provider.”<sup>6</sup> Third, and most importantly, subsection (c) must be read in conjunction with subsection (d) in order to understand the full scope of liability. The assertion of the limited design defect risk-utility test is merely a precursor to the basic liability of section 6(d) for failure to provide adequate instructions or warnings.

A prescription drug or medical device manufacturer does not distribute its products directly to the public. Although mass advertising may create public demand, the prescription process controls supply. In the limited situations in which a patient or a nonprescriber maintains some control over distribution, such as when extended renewals are permitted, or in the case of mass vaccinations, section 6(d)(2) of the Restatement (Third) provides a basis for liability for failure to warn the patient directly. As noted later, the Reporters abandoned broader liability for advertising to potential patients without adequate warnings.

Generally speaking, however, the distribution scheme depends on the existence of a health-care professional who will scan the field of drugs or devices and choose the appropriate product. Thus, the fact that Thalidomide might provide relief for leprosy, but may cause birth defects, does not necessarily mean that the drug manufacturer defectively designed the drug. Under the risk-utility test of section 6 of the Restatement (Third), this drug is not defectively designed because it has a recognized and substantial beneficial use, even though extensive warnings are required to alert pregnant users of its disastrous side effects. A manufacturer, however, cannot prevent negligent prescription through a drug’s design. Instead, the manufacturer must adequately warn the prescribing health-care provider, thereby relegating the injured user to a warning defect or malpractice claim.

A harder case might be one in which the manufacturer has produced an efficacious drug that could have been made less risky. For example, years ago I sat on a case involving diphtheria, pertussis, and tetanus (DPT)

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<sup>5</sup> *See id.* (“[T]he risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits” so that it would not be prescribed “for any class of patients.”).

<sup>6</sup> *Id.*

vaccines.<sup>7</sup> One allegation concerned the various processes available to create the vaccine. The plaintiffs claimed that technology existed, the use of which would both produce a vaccine containing fewer toxins and greatly reduce the risk to recipients of the vaccine.<sup>8</sup> This technology, however, cost more to employ than the technology actually used to produce the subject DPT vaccine. Although the New Jersey Supreme Court decided the case by excluding vaccines from the rules that generally apply to drugs and other products, the questions raised in the appellate division opinion remain. Should a manufacturer be absolved of liability for producing the more dangerous drug or vaccine if that manufacturer provides adequate warnings of the additional dangers associated with its chosen process?

The Restatement (Third) answers this question in the affirmative. Under the Restatement (Third), the manufacturer is required merely to disclose the risks of one vaccine as opposed to another, and the health-care professional is required to make the choice, perhaps on the basis of cost, subject only to a plaintiff's malpractice remedy.

But, what if (1) the cost difference to the manufacturer is slight; (2) the competing manufacturers can place only a small amount of the safer product on the market and demand exceeds supply; or (3) the manufacturer is the sole supplier of the vaccine, and chooses not to use the safer process? Would warnings provide an adequate protection? Would the user or the health-care professional have any meaningful choice? Such cases might be some of the few that require courts to look beyond the risk-utility language of section 6(c) of the Restatement (Third), which employs the "any class of patients" standard. Instead, courts could look to the "reasonable alternative design" standard borrowed from section 2(b) of the Restatement (Third) to balance the "foreseeable risks of harm" and "foreseeable therapeutic benefits" called for by section 6(c).

This problem does not exist in the usual case. It certainly does not aid the tort system to turn each tort trial into a mini-FDA application procedure. A jury determination based upon trial proofs should not be substituted for the FDA's extensive drug-approval process (or the equivalent) for new and untried drugs. If such proofs are necessary, the alternative proposed by the plaintiff should be rejected.

Some alternative drugs or processes, however, may not have received FDA approval, or may have received FDA approval but are no longer on the market. For example, there may be a drug approved in another country whose approval process is as strict as our own. Notwithstanding the Thalidomide debacle in which European nations approved the drug, but the

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<sup>7</sup> See *Shackil v. Lederle Lab.*, 219 N.J. Super. 601, 608, 530 A.2d 1287, 1291 (App. Div. 1987), *rev'd*, 116 N.J. 155, 561 A.2d 511 (1989).

<sup>8</sup> See *id.* at 609, 530 A.2d at 1291.

FDA did not, there may be drugs with extensive trials and approvals that legitimately could pose as alternatives in the single-manufacturer or single-process case. Likewise, FDA-approved drugs or processes that the manufacturer has not placed on the market, has withdrawn from the market, or has made available in insufficient quantities, might serve as a basis for liability against a manufacturer who has instead chosen to market a more dangerous drug with warnings. In this narrowly defined class of cases, the Restatement (Third) rule may need modification.

The Restatement (Third) comment g to section 6, which requires a manufacturer both to test and to employ “risk-avoidance measures that such testing would reveal,” may provide the seed of an answer.<sup>9</sup> Thus, in the unusual and difficult case, the comments to section 6 may provide arguments for the very protection that the Restatement (Third) is accused of avoiding.

In most cases, however, section 6 focuses on adequate instructions and warnings, so that the prescribing health-care professional has proper information to protect the patient. The Restatement (Third) does not absolve manufacturers from liability. Instead, the Restatement (Third) focuses liability on the duty to disclose risks and benefits to the prescribing professional.

In a different area, the defendants’ bar points to subsection (d)(2) of section 6 as imposing undue liability based on a failure to warn a patient directly in some instances.<sup>10</sup> As noted earlier, this duty even might have been extended in the Restatement (Third) to include liability for products that are extensively advertised to the public. The first draft of the section so provided, but the position was abandoned during the drafting process. The Reporters’ notes reveal that only Massachusetts has adopted such a rule.<sup>11</sup> The Massachusetts logic is interesting and has caused advertising to be considered a factor in determining whether the learned intermediary rule

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<sup>9</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. g (1997). This comment is cross-referenced with comment m to section 2, in which the Reporters state that “[a] seller is charged with knowledge of what reasonable testing would reveal. If testing is not undertaken, or is performed in an inadequate manner, and this failure results in a defect that causes harm, the seller is subject to liability for harm caused by such defect.” *Id.* § 2 cmt. m.

<sup>10</sup> *See id.* § 6(d)(2). If “the manufacturer knows or has reason to know the health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings” then the manufacturer may be held liable. *Id.*

<sup>11</sup> *See, e.g.,* McDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68 (Mass. 1985). In *Edwards v. Basel Pharmaceuticals*, the Tenth Circuit made a similar inroad under Texas law. *See Edwards*, 116 F.3d 1341, 1342 (10th Cir. 1997). However, the Fifth Circuit made a contrary finding in *In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374, 379-80 (5th Cir. 1999). *See also* Perez v. Wyeth Labs., Inc., 161 N.J. 1, 734 A.2d 1245 (1999) (discussed *infra*).

should be applied. The American Law Institute, however, "has left to developing case law whether other exceptions to the learned intermediary law should be recognized."<sup>12</sup> The present rules, requiring that the manufacturer generally need warn only the health-care professional, are founded on the premise that such a prescriber is in a position to protect the user. If for some reason this is not so, then the manufacturer is placed in no better position than any other supplier of a product insofar as warnings through a learned intermediary are concerned.

Recently, in *Perez v. Wyeth Laboratories, Inc.*,<sup>13</sup> the New Jersey Supreme Court reversed an appellate court decision that found 2A:58C-4 of the New Jersey Statutes prohibited drug manufacturer liability for failure to provide an adequate warning in direct consumer advertisements.<sup>14</sup> The *Perez* decision avoided the express language of 2A:58C-4, which limits liability for warning defect in drug and medical device to situations in which there was a failure to warn prescribing physicians. This departure from the express language was directed at preventing pharmaceutical manufacturers from misleading the public through mass-media advertising.<sup>15</sup> A more appropriate approach to this issue, however, might have been to follow the lead of the United States Supreme Court in *Cipollone v. Liggett Group, Inc.*<sup>16</sup> Such an approach would have resulted in a finding that Wyeth Laboratories was not liable to the consumer under the New Jersey Products Liability Act for failing to warn in its advertisements. Wyeth might, however, upon the requisite proof, have been held liable for fraud, misrepresentation, or conspiracy in connection with its mass-media advertising campaign. Such a result would have honored the intent of 2A:58C-4, while providing a remedy for harm suffered by a consumer due to fraudulent or misleading advertisements.

Section 6 takes a reasoned approach to the question of liability for a defective drug or medical device. In a highly regulated industry in which the FDA acts as gatekeeper, the section breaks with the traditional tests for liability to focus on the real issue raised by most cases: adequate warnings. Although there may be some need of an amendment in the highly unusual

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<sup>12</sup> See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. e Reporters' notes (1997).

<sup>13</sup> 161 N.J. 1, 734 A.2d 1245 (1999).

<sup>14</sup> See *id.* at 8-9, 33, 745 A.2d at 1249-50, 1264. The court reversed the appellate decision despite the fact that the committee statements, to which the legislature specifically directed any questions of interpretation or construction (See N.J. STAT. ANN. § 2A:58C-1a (West 1987), explicitly stated that a warning accompanying prescription drugs is owed to the physician. See *Learned Intermediaries*, 157 N.J.L.J. 842, 842 (Aug. 30, 1999).

<sup>15</sup> See *id.* at 32, 734 A.2d at 1264.

<sup>16</sup> 505 U.S. 504 (1992). The Supreme Court held that federal law preempted claims based on failure to warn in advertisements and promotions, but did not preempt claims premised on fraud, misrepresentation, or conspiracy. See *id.* at 530-31.

cases noted earlier, we generally can follow where the Restatement (Third) leads.