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# Mass Immunizations, Learned Intermediaries and the Manufacturers' Duty to Warn

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PRODUCTS LIABILITY LAW—IMMUNIZATIONS, LEARNED  
INTERMEDIARIES, AND THE MANUFACTURER'S DUTY TO WARN

*Mazur v. Merck & Co., Inc.* (1992)

I. INTRODUCTION

In traditional products liability actions, section 402A of the Restatement (Second) of Torts governs a manufacturer's duty to warn. Section 402A dictates that a manufacturer is strictly liable for a product sold in a "defective condition unreasonably dangerous to the user or consumer."<sup>1</sup> Products sold absent adequate warnings of risks or dangers are deemed defective.<sup>2</sup> Under Pennsylvania law, however, courts consider certain prescription drugs, including vaccines, "unavoidably unsafe products."<sup>3</sup> As such, they fall outside the realm of section 402A strict liability.<sup>4</sup> Because section 402A does not apply to vaccines, the

1. RESTATEMENT (SECOND) OF TORTS § 402A (1965). Section 402A provides:

§ 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

*Id.* Pennsylvania adopted § 402A as law in *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966).

2. RESTATEMENT (SECOND) OF TORTS § 402A cmt. h (1965). Comment h provides in pertinent part:

A product is not in a defective condition when it is safe for normal handling and consumption. . . . Where, however, [the seller] has reason to anticipate that danger may result from a particular use, . . . [the seller] may be required to give adequate warning of the danger . . . and a product sold without such warning is in a defective condition.

*Id.*

3. *Id.* at cmt. k.

4. *Id.* Comment k provides in pertinent part:

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. Since the disease itself invariably leads to a

Supreme Court of Pennsylvania, in *Incollingo v. Ewing*, determined that vaccine manufacturers owe a "duty to exercise reasonable care" to inform users of the product's dangers.<sup>5</sup>

In *Mazur v. Merck & Co., Inc.*, the United States Court of Appeals for the Third Circuit evaluated whether, under Pennsylvania law, a vaccine manufacturer had met its duty to exercise reasonable care by informing vaccinees of the dangers of the MMR II vaccine.<sup>6</sup> First, the court examined whether the learned intermediary rule extended to a registered nurse who supervised student vaccinations.<sup>7</sup> Next, the court addressed whether a vaccine manufacturer satisfied its duty to adequately warn vaccinees by contractually obligating the Centers for Disease Control (CDC) to provide such warnings.<sup>8</sup>

Writing for the Third Circuit, Judge Scirica concluded that Merck &

dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. *Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.* . . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

*Id.* (emphasis added).

5. *Incollingo v. Ewing*, 282 A.2d 206, 220 & n.8 (Pa. 1971). The "reasonable care" standard is set forth in § 388 of the Restatement (Second) of Torts. Section 388 applies to chattels known to be dangerous for their intended uses, and provides in full:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

(a) knows or has reason to know that the chattel is likely to be dangerous for the use for which it is supplied, and

(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

RESTATEMENT (SECOND) OF TORTS § 388 (1965) (emphasis added).

In the prescription drug context, the Pennsylvania Supreme Court has held that § 388 applies to both negligence and strict liability actions. *Incollingo*, 282 A.2d at 219-20 & n.8.

6. *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1352 (3d Cir.), *cert. denied*, 113 S. Ct. 463 (1992). The Mazurs initially filed suit in the Philadelphia Court of Common Pleas, alleging claims against Merck under Pennsylvania law. *Id.* Merck subsequently removed the action to federal district court. *Id.* In evaluating whether Merck had met its duty of care, the Third Circuit applied Pennsylvania law, attempting to "predict how the Pennsylvania Supreme Court would decide th[e] case." *Id.* at 1353.

7. *Id.* at 1355-61.

8. *Id.* at 1364-66. "The CDC is an arm of the Public Health Service of the United States Department of Health and Human Services." *Id.* at 1350 n.1. By providing project grants to state and local agencies, the CDC assists in emer-

Co., Inc. (Merck) did not fulfill its duty to warn by providing warnings to a learned intermediary, because Pennsylvania courts would not extend the definition of a learned intermediary to include a registered nurse.<sup>9</sup> In addition, the *Mazur* court determined that Merck retained its duty to warn vaccinees directly because the Philadelphia Schools dispensed the MMR II vaccine in a mass immunization program.<sup>10</sup> Nevertheless, Judge Scirica ultimately opined that Merck fulfilled its duty to warn vaccinees by contractually obligating the CDC to provide adequate warnings directly to the consumer.<sup>11</sup>

This Casebrief first supplies a concise historical background on the learned intermediary doctrine, the mass immunization exception to that doctrine and the emerging notion of contractually obligating a third party to provide the required warnings.<sup>12</sup> Next, this Casebrief provides the factual and procedural circumstances surrounding the *Mazur* decision.<sup>13</sup> This Casebrief then investigates the Third Circuit's rationale for determining that Pennsylvania courts would deny registered nurses learned intermediary status.<sup>14</sup> Moreover, this Casebrief examines the implications of the Third Circuit's holding that Merck fulfilled its duty to warn vaccinees by adequately warning the CDC of the vaccine's risks.<sup>15</sup> Finally, this Casebrief concludes that the Third Circuit reasonably determined that Merck fulfilled its obligation to warn, but hastily relied on inappropriate Pennsylvania cases in determining that Pennsylvania courts would not grant learned intermediary status to a registered nurse under appropriate circumstances.<sup>16</sup>

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gency situations and aims to eliminate diseases such as measles. *Id.* For additional information regarding the scope of the CDC's powers, see *infra* note 94.

9. *Mazur*, 964 F.2d at 1358, 1369. In addition, the Third Circuit found that even if the Pennsylvania Supreme Court would extend the learned intermediary doctrine to include registered nurses, Nurse Frederick, who oversaw the administration of the vaccine to the plaintiff, did not qualify as a learned intermediary as a matter of law. *Id.* at 1358-60. For a full discussion regarding the qualifications of a learned intermediary and why Nurse Frederick did not qualify, see *infra* notes 48-60 and accompanying text.

10. *Mazur*, 964 F.2d at 1364.

11. *Id.* at 1350, 1367-69.

12. For a detailed history of the learned intermediary doctrine and the mass immunization exception, see *infra* notes 17-27 and accompanying text. For a brief discussion of contractually obligating a third party to provide the required warnings, see *infra* notes 28-31 and accompanying text.

13. For a detailed discussion see *infra* notes 32-44 and accompanying text.

14. For a detailed examination of the Third Circuit's analysis of the learned intermediary doctrine, see *infra* notes 48-60 and accompanying text. For a discussion of the Third Circuit's analysis of the applicability of the mass immunization exception to the learned intermediary doctrine, see *infra* notes 61-75.

15. For complete discussion, see *infra* notes 76-96 and accompanying text.

16. For a discussion of the implications of the Third Circuit's decision in *Mazur*, see *infra* text accompanying notes 97-101.

## II. BACKGROUND

A. *The Learned Intermediary Doctrine*

In 1966, the United States Court of Appeals for the Eighth Circuit first used the term "learned intermediary" to describe the role a physician plays in warning patients of prescription drug risks.<sup>17</sup> The learned intermediary doctrine requires a pharmaceutical manufacturer to provide adequate warnings to the prescribing physician, who then assumes the responsibility of passing on these warnings to the patient-consumer.<sup>18</sup> Almost all jurisdictions, including Pennsylvania, have adopted

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17. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966). In *Sterling*, the plaintiff developed a degenerative eye disease following use of the arthritis drug Aralen. *Id.* at 83. The Eighth Circuit reasoned that because patients rely on their physicians' judgements regarding medicinal use, "[when] dealing with a prescription drug . . . the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer." *Id.* at 85.

The Pennsylvania Superior Court described the learned intermediary's duty:

it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as 'it is for the prescribing physician to use his independent judgment, taking into account the data supplied to him by the manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.'

*Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987) (quoting *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 457 (Pa. Super. Ct. 1973)). See also Virginia H. Castleberry, Note, *Hill v. Searle Laboratories: The Decline of the Learned Intermediary Doctrine in Favor of Direct Patient Warnings of Drug Product Risks*, 43 ARK. L. REV. 821, 837-46 (1990) (discussing inception of the learned intermediary doctrine and its subsequent decline); Kathy Laughter Laizure, Note, *The Pharmacist's Duty to Warn When Dispensing Prescription Drugs: Recent Tennessee Developments*, 22 MEM. ST. U. L. REV. 517, 524-30 (1992) (discussing learned intermediary doctrine and pharmacist's duty to warn); Alan R. Styles, Note, *Prescription Drugs and the Duty to Warn: An Argument for Patient Package Inserts*, 39 CLEV. ST. L. REV. 111, 122-23 (1991) (discussing learned intermediary doctrine in relation to prescription drug package inserts).

18. *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971). According to the doctrine, "[s]ince the drug [is] available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor." *Id.* (emphasis added).

In *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir.), cert. denied, 419 U.S. 1096 (1974), the court expounded upon the policy underlying the learned intermediary doctrine:

[W]here *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn

the learned intermediary doctrine.<sup>19</sup>

Traditionally, courts reserved learned intermediary status solely for physicians.<sup>20</sup> Under certain circumstances, however, some courts have held that nurses may qualify as learned intermediaries.<sup>21</sup> To date, Penn-

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foreseeable ultimate users of dangers inherent in his products . . . As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

*Id.* (footnote omitted).

Although the learned intermediary doctrine applies to most pharmaceuticals, the manufacturer retains a duty to warn the consumer *directly* of the risks of certain drugs, including, *inter alia*, oral contraceptives, intrauterine devices, injectable contraceptives and the "morning after" pill. Donald E. Thompson II, *The Drug Manufacturer's Duty to Warn—To Whom Does it Extend*, 13 FLA. ST. U. L. REV. 135, 141 & n.38 (1985). The Food and Drug Administration requires that patient labeling or patient package inserts accompany the distribution of these drugs. *Id.*

19. Various circuit court opinions illustrate that many jurisdictions apply the learned intermediary doctrine. *See, e.g.*, *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1178 (5th Cir. 1988) (holding learned intermediary doctrine applies where patient receives prescription drug or vaccination from doctor who weighs risks and benefits); *Swayze v. McNeil Lab., Inc.*, 807 F.2d 464, 470 (5th Cir.) (same), *reh'g denied*, 812 F.2d 1405 (1987); *Walker v. Merck & Co., Inc.*, 648 F. Supp. 931, 934 (M.D. Ga. 1986) (same), *aff'd without op.*, 831 F.2d 1069 (11th Cir. 1987); *Plummer v. Lederle Lab.*, 819 F.2d 349, 356 (2d Cir.) (same), *cert. denied*, 484 U.S. 898 (1987); *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir.) (same), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (same).

As a general rule, Pennsylvania courts agree that the learned intermediary rule applies to physicians. *See, e.g.*, *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1386 (Pa. 1991) (holding physician owes duty to inform patient of dangers or side effects of drugs prescribed); *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971) (same); *White v. Weiner*, 562 A.2d 378, 384-85 (Pa. Super. Ct. 1989) (same); *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987) (same); *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 457 (Pa. Super. Ct. 1973) (same); *Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 252 (E.D. Pa. 1990) (same) [hereinafter *Mazur I*].

20. *Mazur I*, 742 F. Supp. at 253-55. Physicians qualify as learned intermediaries because they possess superior knowledge of the risks and benefits associated with the drugs they prescribe. This superior knowledge is based on medical literature, information provided by the manufacturer, and the physician's personal knowledge of the patient's medical history. *Mazur*, 964 F.2d at 1356.

21. *Mazur*, 964 F.2d at 1356. A leading case extending the learned intermediary doctrine to a nurse is *Walker v. Merck & Co.*, 648 F. Supp. 931 (M.D. Ga. 1986), *aff'd*, 831 F.2d 1069 (11th Cir. 1987). In *Walker*, the United States District Court for the Middle District of Georgia held that a licensed practical nurse, who administered the MMR II vaccine in a program aimed at inoculating select high school students, was a learned intermediary. *Id.* at 934. The *Walker* court reasoned that because so few students were to be immunized, it would be "highly impractical, if not impossible, for Merck to determine which students would need to receive the vaccine, and then to warn each recipient individually." *Id.* at 935.

sylvania courts have conferred learned intermediary status only upon physicians.<sup>22</sup>

### B. *The Mass Immunization Exception*

Although the learned intermediary doctrine routinely permits a pharmaceutical manufacturer to provide adequate warnings exclusively to the prescribing physician, the vaccine manufacturer retains the duty to warn patient-consumers *directly* in situations where vaccines are dispensed in an "assembly line fashion" and "without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception."<sup>23</sup> Such "mass immunization" settings first arose when federal, state and local governments dispensed a live-virus polio vaccine as part of a massive nation-wide immunization program aimed at curtailing a national polio epidemic.<sup>24</sup>

Pennsylvania courts have not yet addressed whether the mass immunization exception applies to smaller scale vaccination programs.<sup>25</sup> In fact, the Pennsylvania Supreme Court has yet to adopt expressly the mass immunization exception.<sup>26</sup> The Fourth Circuit has noted, however, that the mass immunization exception, established specifically for the

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In *Walker*, a licensed practical nurse, as opposed to a registered nurse, administered the MMR II vaccines. *Id.* at 932. In *Mazur*, the Third Circuit noted that Pennsylvania law recognizes that several types of healthcare professionals are generically referred to as nurses. *Mazur*, 964 F.2d at 1357 n.12. The *Mazur* court used the term "nurse" to refer to registered nurses only. *Id.*

22. *Mazur*, 964 F.2d at 1356. In *Mazur I*, the district court recognized that Pennsylvania had not addressed the question of whether a *nurse* could act as a learned intermediary. *Mazur I*, 742 F. Supp. at 254. The Third Circuit noted, however, that both the Supreme Court of Pennsylvania and the Pennsylvania Superior Court have declined to extend the learned intermediary rule to pharmacists. *Mazur*, 964 F.2d at 1356; see *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1386 (Pa. 1991)(holding pharmacists have no independent duty to warn consumers of risks attendant to dispensation of prescription drugs); *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987)(same).

23. *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1277 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974) (citing *Davis v. Wyeth Lab.*, 399 F.2d 121, 131 (9th Cir. 1968)).

The circuit courts in *Reyes* and *Davis* effectively reinstated the manufacturer's duty to warn consumers directly in mass immunization settings. For a discussion of the reasoning of the *Reyes* and *Davis* courts, see *supra* note 18 and *infra* notes 24 & 68-70 and accompanying text.

24. *Reyes*, 498 F.2d at 1269-70. *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968), is the seminal case invoking the mass immunization exception. In *Davis*, the Ninth Circuit opined that where a drug or vaccine is dispensed to "all comers at mass clinics without an individualized balancing by a physician of the risks involved" a warning must be given directly to the ultimate recipient. *Davis*, 399 F.2d at 131.

25. *Mazur*, 964 F.2d at 1361.

26. *Id.* The *Mazur* court assumed that the Pennsylvania Supreme Court would follow other jurisdictions and adopt the mass immunization exception "under the appropriate circumstances." *Id.*

polio vaccine, was "quite narrow and highly fact specific."<sup>27</sup>

C. *Contractually Obliging a Third Party to Provide Adequate Warnings*

Because section 402A of the Restatement (Second) of Torts does not apply to unavoidably unsafe products, section 388 governs the vaccine manufacturer's duty to warn.<sup>28</sup> Section 388 requires that the manufacturer exercise reasonable care to ensure that product users are adequately informed of the product's risks.<sup>29</sup> According to comment n to section 388, the manufacturer may satisfy this duty by providing adequate warnings to a third party, so long as the manufacturer reasonably relies on that party to pass on the warnings to the ultimate user or consumer.<sup>30</sup> Many jurisdictions that apply section 388 in cases involving unavoidably unsafe products also apply comment n.<sup>31</sup>

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27. *Rohrbough v. Wyeth Lab., Inc.*, 719 F. Supp. 470, 478 (N.D.W. Va. 1989)(quoting *Stanback v. Parke-Davis & Co.*, 657 F.2d 642, 647 (4th Cir. 1981)). In *Rohrbough*, the parents of a child who developed a seizure disorder after receiving a DPT vaccine sued the manufacturer for, *inter alia*, failure to warn. *Id.* at 472. The *Rohrbough* court followed the Fourth Circuit's holding in *Stanback*, which limited the mass immunization exception to cases involving the polio vaccine. *Id.* at 478. Accordingly, the *Rohrbough* court refused to apply the exception to a DTP case, even though the plaintiff received the DPT vaccine at a public health clinic. *Id.*

28. For a textual comparison of § 402A and § 388, see *supra* notes 1-5 and accompanying text.

29. For a comparison of the standards of care each section requires, see *supra* notes 1-5 and accompanying text.

30. RESTATEMENT (SECOND) OF TORTS § 388 cmt. n. Comment n provides in pertinent part:

Giving to the third person through whom the chattel is supplied all the information necessary to its safe use is not in all cases sufficient to relieve the supplier from liability. . . . [I]t is obviously impossible to state in advance any set of rules which will automatically determine in all cases whether one . . . has satisfied his duty . . . . There are, however, certain factors which are important in determining this question. There is necessarily some chance that information given to the third person will not be communicated by him to those who are to use the chattel. This chance varies with the circumstances existing at the time the chattel is turned over to the third person, . . . [t]hese circumstances include the known and knowable character of the third person and may also include the purpose for which the chattel is given. . . . [T]he care which must be taken always increases with the dangers involved.

*Id.*

31. See, e.g., *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968)("[I]t is the responsibility of the manufacturer to see that warnings reach the consumer *either by giving warning itself or by obligating the purchaser to give warning.*")(emphasis added). In *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984), however, the United States Court of Appeals for the Eighth Circuit found that delegating the duty to warn to a third party did not insulate the manufacturer from liability in a strict liability action. The Eighth Circuit decided *Petty* under Iowa law, which distinguishes between strict liability and negligence when formulating the duty to warn for unavoidably unsafe products. *Id.* at 1439. In strict liability actions, Iowa courts apply § 402A. *Id.* Conversely, Pennsylvania courts make no distinction between strict liability and negligence actions when

## III. FACTS AND PROCEDURE

A. *Substantive Facts*

In response to a late 1970s measles epidemic, the Philadelphia school system required all children between kindergarten and twelfth grade to be immunized against several diseases as a prerequisite to school attendance.<sup>32</sup> Registered school nurses supervised the vaccinations.<sup>33</sup> For simultaneous immunization against measles, mumps and rubella, the school district opted to use Merck's MMR II vaccine in its inoculation program.<sup>34</sup> The school district purchased the vaccine from the CDC.<sup>35</sup> Prior to this purchase, the CDC had entered a purchasing contract with Merck in which the CDC agreed to take "appropriate steps" to provide warnings to the vaccinees, either directly or through a learned intermediary.<sup>36</sup> In order to fulfill its contractual obligation to warn vaccinees, the CDC drafted an "Important Information Statement," which school nurses were to distribute to the vaccinees, their

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formulating the duty to warn for unavoidably unsafe products. *Mazur*, 964 F.2d at 1366 n.26. In Pennsylvania, a manufacturer's duty to warn is governed by § 388. *Id.*

32. *Mazur I*, 742 F. Supp. at 243. The school district required each child to be immunized against measles, mumps, rubella, polio, diphtheria and tetanus, unless a child had acquired natural immunity through past exposure to the disease. *Id.* To determine which vaccines each child needed, the school nurse reviewed school medical records. *Id.* The nurse required parents to document previous immunizations and illnesses, and to give written permission to have their child vaccinated. *Id.* If no adequate proof of prior immunization or acquired immunity existed, the school considered the child to be unimmunized. *Id.*

33. *Id.* The school nurse's responsibilities included: (1) sending out parental permission forms; (2) reviewing health records to check for medical conditions that might increase the risk of inoculation; and (3) assessing whether the children were in good health on the day of the vaccinations. *Id.* at 254. A technician then administered the MMR II vaccinations. *Id.* at 254 n.20.

34. *Id.* at 254. MMR II is a live-virus vaccine, containing an attenuated line of measles virus that causes the vaccinees body to generate antibodies to the disease. *Id.* at 243. Merck has manufactured the MMR II vaccine since 1978, pursuant to a license from the Food and Drug Administration (FDA). *Mazur*, 964 F.2d at 1350.

35. *Mazur*, 964 F.2d at 1350.

36. *Id.* at 1350-51. Merck was initially reluctant to sell MMR II to the CDC. *Id.* at 1351. Merck, however, acquiesced when the CDC agreed to provide warnings to the vaccinees. *Id.* The contract between Merck and the CDC provided as follows:

The [CDC] represents and agrees that it will (1) take all appropriate steps to assure that all vaccine supplied to various locations within the 50 states, . . . pursuant to the terms of this contract, shall be administered to each patient on the basis of an individualized medical judgment by a physician, or (2) take all appropriate steps to provide to such a patient (or to the patient's parent or guardian) meaningful warnings relating to the risks and benefits of vaccination, in form and language understandable to such patient, parent or guardian.

*Id.* at 1351.

parents or their guardians.<sup>37</sup>

An FDA-approved package insert describing the risks of MMR II accompanied each MMR II vaccine.<sup>38</sup> The insert contained warnings regarding the risk of contracting subacute sclerosing panencephalitis (SSPE), a serious and often fatal neurological disease, subsequent to receiving the MMR II vaccine.<sup>39</sup> In addition, the package insert included information regarding revaccination.<sup>40</sup> In conjunction with the school program, and over the objections of the mother, Mrs. Mazur, Lisa Mazur was vaccinated with MMR II.<sup>41</sup> Thereafter, doctors diagnosed Lisa with

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37. *Id.* at 1351.

38. *Mazur I*, 742 F. Supp. at 244. The FDA-approved package insert differs from the Important Information Statement issued by the CDC. Merck drafted the package insert to inform potential vaccine administrators of the risks of the MMR II vaccine. Thus, "the package circular's intended audience is not the ultimate user, but rather the learned intermediary." *Mazur*, 964 F.2d at 1348. In contrast, the CDC drafted the Important Information Statement to inform parents and guardians of the potential risks of vaccination and revaccination. *Id.*

39. *Mazur*, 964 F.2d at 1348. Pertaining to SSPE, the package insert contained the following information:

There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of natural measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccination distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 5-10 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the Center for Disease Control suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent risk of SSPE.

*Id.* (quoting Merck package insert).

SSPE is a fatal, slowly progressing inflammatory disease affecting the central nervous system. *Id.* at 245 n.4. SSPE most often strikes children between the ages of four and twenty, with onset marked by "insidious mental deterioration and psychological disturbances." *Id.* Symptoms include convulsions, seizures, visual difficulties and myoclonic jerks. *Id.* Death usually results within one to three years after the onset of SSPE. *Id.*

40. *Mazur I*, 742 F. Supp. at 244. The package insert included the following information pertaining to revaccination:

Based on available evidence, there is no reason to routinely revaccinate children originally vaccinated when 12 months of age or older; however, children vaccinated when younger than 12 months of age should be revaccinated. The decision to revaccinate should be based on evaluation of each individual case.

*Id.* (quoting Merck package insert).

41. *Id.* at 245. Mrs. Mazur claimed that she did not receive the Important Information Statement, although she admitted being aware of the immunization program at Lisa's school. *Id.* at 244. Because Lisa had received a measles vaccine at age four, Mrs. Mazur neither signed nor returned Lisa's permission slip. *Id.* at 245. Furthermore, Mrs. Mazur informed both the school principal and a Board of Education official that because Lisa had previously been immunized against measles, Mrs. Mazur would not consent to Lisa's revaccination. *Id.* "As a precaution, Mrs. Mazur kept Lisa out of school for approximately a week

SSPE.<sup>42</sup>

### B. Procedural History

Lisa Mazur and her parents sued Merck under both negligence and strict liability theories, for failure to warn that MMR II could cause a serious neurological illness.<sup>43</sup> Ultimately, the district court granted Merck's motion for summary judgment, concluding that Merck fulfilled its duty to warn by providing an adequate warning to a learned intermediary, and, in the alternative, by exercising reasonable care to warn vaccinees by contractually obligating the CDC to warn vaccine recipients.<sup>44</sup>

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before sending her back just prior to the day of the immunization program at Lisa's school." *Id.* Nevertheless, in the presence of the school nurse, a technician vaccinated Lisa with MMR II. *Id.* As a result of her prior vaccination, Lisa received a second dose of measles and rubella virus. *Id.* at 245 n.3.

42. *Id.* at 245.

43. *Mazur I*, 742 F. Supp. at 243. The Mazurs originally filed suit in the Philadelphia Court of Common Pleas. *Mazur*, 964 F.2d at 1352. Merck subsequently removed the action to federal district court based on diversity jurisdiction. *Id.* In addition to the failure to warn claim, the Mazurs sought recovery for: (1) design and manufacturing defects; (2) breach and reckless breach of the implied warranties of merchantability and fitness for a particular purpose; (3) intentional and negligent misrepresentation; and (4) negligent infliction of emotional distress. *Mazur I*, 742 F. Supp. at 242-43.

44. *Mazur*, 964 F.2d at 1350. Merck initially moved for partial summary judgment on several issues; the district court denied the motion in part and granted it in part. *Mazur I*, 742 F. Supp. at 243. The district court denied Merck's motion on the issues of federal preemption and statute of limitations. *Id.* The district court permitted additional discovery on the issues of whether or not:

- a. Merck acted in accordance with due care when it contracted with [CDC] to ensure the presence of a physician at inoculation or an adequate warning of the risks associated with vaccination was conveyed to recipients or to their parents or guardians,
- b. the school nurse who supervised the MMR II inoculation was a learned intermediary,
- c. the package circular contained an adequate warning of the revaccination risks,
- d. the proximate cause element of a duty to warn claim had been satisfied, and
- e. the cause-in-fact element of a duty to warn claim had been satisfied.

*Id.* at 250-66.

Although Pennsylvania courts had not faced the issue of whether a nurse could act as a learned intermediary, the district court in *Mazur I* opined that the Pennsylvania courts would allow such an extension of the learned intermediary doctrine in appropriate circumstances. *Id.* at 254. In reaching this conclusion, the *Mazur I* court looked to *Walker v. Merck & Co., Inc.*, 648 F. Supp. 931 (M.D. Ga. 1986), *aff'd*, 831 F.2d 1069 (11th Cir. 1987), an MMR II case applying the learned intermediary doctrine to "nurses in general, and, in particular, to the nurse who administered the vaccine." *Mazur I*, 742 F. Supp. at 254.

Although the *Mazur I* court acknowledged that two recent Pennsylvania decisions declined to extend the learned intermediary doctrine to include pharmacists, the court distinguished the roles nurses and pharmacists play in dispensing prescription drugs. *Id.* at 254-55. Specifically, the *Mazur I* court noted that while pharmacists are frequently mere retailers who are often unfamiliar with

## IV. ANALYSIS

The Third Circuit began its analysis in *Mazur* by determining that a vaccine qualifies as an unavoidably unsafe product under the Restatement (Second) of Torts § 402A.<sup>45</sup> As such, a vaccine manufacturer must exercise reasonable care to inform recipients of the risks attendant to the vaccine's use.<sup>46</sup> The court then addressed the issue of whether Merck had, in fact, met its duty of reasonable care.<sup>47</sup>

A. *The Learned Intermediary Issue*

At the outset, the Third Circuit recognized that, under Pennsylvania law, a prescription drug manufacturer may meet its duty to warn vaccinees by providing an adequate warning to a learned intermediary, as opposed to the general public or individual users.<sup>48</sup> In light of this rule, the court evaluated whether Pennsylvania courts would allow a nurse to qualify as a learned intermediary.<sup>49</sup>

Although the Third Circuit acknowledged that other jurisdictions have held that nurses may act as learned intermediaries in certain circumstances, the court rejected these holdings based on two Penn-

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their customers' medical histories, nurses customarily perform tasks similar to those of physicians and possess individualized information about each patient's records. *Id.* at 255. In addition, the *Mazur I* court relied on legislation to emphasize the connection between nurses and physicians. *Id.* The court opined that 42 Pa. Cons. Stat. Ann. § 8334(a), which provides liability immunity for physicians and nurses who dispense vaccines in mass immunization projects, demonstrates a legislative awareness of the similarities of doctors and nurses. *Id.*

After concluding that a nurse could qualify as a learned intermediary, the district court on remand examined whether Nurse Frederick, who administered the vaccinations was, in fact, a learned intermediary. *Mazur v. Merck & Co.*, 767 F. Supp. 697, 708 (E.D. Pa. 1991)[hereinafter *Mazur II*], *aff'd*, 964 F.2d 1348 (3d Cir.), *cert. denied*, 113 S. Ct. 463 (1992). The court closely examined Nurse Frederick's academic and employment history, experience with immunization programs, knowledge of the complications associated with certain vaccinations and preparation for the inoculation program at Lisa Mazur's school. *Id.* at 708-10. The *Mazur II* court acknowledged that Nurse Frederick was unaware that SSPE was a possible complication of measles or its vaccine. *Id.* at 709. Nevertheless, "[l]ooking at the totality of [Nurse Frederick's] qualifications and what she did," the *Mazur II* court determined that "it [was] clear that Nurse Frederick was acting as a learned intermediary at the time of Lisa's inoculation." *Id.* at 711.

45. *Mazur*, 964 F.2d at 1354. The Third Circuit based this conclusion on the Pennsylvania Supreme Court's decision in *Incollingo v. Ewing*, 282 A.2d 206, 220 & n.8 (Pa. 1971), which declared § 402A inapplicable to unavoidably unsafe pharmaceuticals. *Mazur*, 964 F.2d at 1354. For the pertinent provisions of § 402A, see *supra* notes 1-4 and accompanying text.

46. *Mazur*, 964 F.2d at 1354. The *Mazur* court determined that the correct standard of care was contained in § 388 of the Restatement (Second) of Torts. *Id.* at 1355. For a recitation of the text of § 388, see *supra* note 5.

47. *Mazur*, 964 F.2d at 1361-64.

48. See *Incollingo*, 282 A.2d at 220 ("Since the drug [is] available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor.").

49. *Mazur*, 964 F.2d at 1356-60.

sylvania cases that denied learned intermediary status to pharmacists.<sup>50</sup> First, the Third Circuit looked to the Pennsylvania Superior Court's decision in *Makripodis v. Merrell-Dow Pharmaceutical, Inc.*, where the court held that retail pharmacists owed patient-consumers no independent duty to warn.<sup>51</sup> The superior court reasoned that pharmacists were unable to provide adequate warnings because, unlike doctors, pharmacists were often unfamiliar with their customers' medical history and conditions, and therefore were unable to aid customers in evaluating the risks and benefits of the drugs that their physicians had prescribed.<sup>52</sup>

Next, the Third Circuit turned to *Coyle v. Richardson-Merrell, Inc.*,<sup>53</sup> a Pennsylvania Supreme Court case, which adopted the findings of the *Makripodis* court, and likewise refused to extend the learned intermediary doctrine to pharmacists.<sup>54</sup> The *Coyle* court opined that physicians, not pharmacists, are in the best position to evaluate the risks of the medication they prescribe.<sup>55</sup> Therefore, the *Coyle* court concluded that pharmacists could not be classified as learned intermediaries.<sup>56</sup>

50. *Id.* at 1356. The Third Circuit relied on cases *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383 (Pa. 1991), and *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987). *Mazur*, 964 F.2d at 1356. Both cases involved pharmacists, as opposed to nurses. The Third Circuit relied on these cases because the Pennsylvania courts had never examined whether a nurse could qualify as a learned intermediary. *Id.*

51. 523 A.2d 374 (Pa. Super. Ct. 1987). *Makripodis* was a products liability action centered on Benedectin, an anti-nausea drug prescribed to pregnant women in the early stages of pregnancy. *Id.* at 375. The plaintiff's infant was born with "certain congenital abnormalities," allegedly as a result of plaintiff's Benedectin ingestion. *Id.*

The *Makripodis* court asserted that to impose upon a retail pharmacist an independent duty to warn, "would be unwise and would ill serve the interests of the consuming public." *Id.* at 378.

52. *Mazur*, 964 F.2d at 1356-57 (citing *Makripodis*, 523 A.2d at 378). The *Makripodis* court distinguished pharmacists from physicians, noting that physicians, "trained in the diagnosis and treatment of diseases" and familiar with their patients' medical histories, are able to exercise "independent medical judgment" when prescribing drugs. *Makripodis*, 523 A.2d at 378.

53. 584 A.2d 1383 (Pa. 1991). As in *Makripodis*, the plaintiffs in *Coyle* were parents of an infant allegedly injured by the mother's ingestion of Benedectin during pregnancy. *Id.* at 1384. The plaintiffs sued the manufacturer and the pharmacy from whom the plaintiff purchased the drug. *Id.* The Pennsylvania Supreme Court affirmed the trial court's grant of summary judgment for the pharmacy. *Id.* at 1387-88.

54. *Mazur*, 964 F.2d at 1357.

55. *Id.* The *Coyle* court stated:

Under [the learned intermediary] rule, information about the risks of medicines is provided to the person who most needs and can best evaluate it—the physician—to be shared with and explained to the patient in the context of his or her individual medical circumstances. . . . [I]t is not the pharmacist on whom the public 'is forced to rely' to obtain the products they need.

*Coyle*, 584 A.2d at 1386-87.

56. *Id.* at 1387. Jurisdictions are split as to whether a pharmacist must warn patients of risks attendant to prescription drug use. Louis P. Milot, Note, 13 S.

Relying on the reasoning of *Coyle* and *Makripodis*, the Third Circuit likened nurses to pharmacists, noting that both groups are unable to prescribe drugs, are incapable of rendering independent medical judgments and that neither group is required to undergo the rigorous medical training of physicians.<sup>57</sup> Further, the *Mazur* court rejected the district court's assertion that nurses, unlike pharmacists, perform tasks similar to those performed by physicians.<sup>58</sup> The Third Circuit noted that nurses' "tasks are typically performed under the supervision of, or in collaboration with, physicians."<sup>59</sup> Ultimately, the Third Circuit concluded that the Pennsylvania Supreme Court would not grant learned intermediary status to a nurse who lacks the ability to make individualized medical assessments in prescribing drugs.<sup>60</sup>

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ILL. U. L.J. 1003, 1008 (1989). For a list of cases imposing a duty to warn on pharmacists *see id.* at 1008 n.25. For cases refusing to impose a duty to warn on pharmacists *see id.* at 1008 n.24.

57. *Mazur*, 964 F.2d at 1357.

58. *Mazur I*, 742 F. Supp. at 254-55.

59. *Mazur*, 964 F.2d at 1357-58. The *Mazur* court went on to note that although registered nurses administer drugs and vaccines, a physician must first order them. *Id.* at 1358. In addition, the prescribing agency or institution has established policies and procedures that nurses must follow when administering such agents. *Id.*

60. *Id.* at 1358. The Third Circuit went on to find that even if Pennsylvania law would recognize a nurse as a learned intermediary, Nurse Frederick, who supervised the immunization program at Lisa Mazur's school, was not a learned intermediary. *Id.* at 1360 ("We cannot agree [with the district court], as a matter of law, that Nurse Frederick acted as a learned intermediary on the facts here.").

The Third Circuit's analysis focused on Nurse Frederick's actions on the day of Lisa Mazur's inoculation. *Id.* at 1358-60. Nurse Frederick checked students' medical records, checked permission slips and examined students' physical appearance to determine if they appeared "ill that day or if there was some reason they should not get the vaccine." *Id.* at 1359-60. She did not ask students whether they were presently taking medication. *Id.* at 1360. Nurse Frederick then instructed the technician as to which vaccine to administer. *Id.* at 1359.

The Third Circuit also examined Nurse Frederick's educational background and experience with MMR II. *Id.* Specifically, the court noted that while she was aware of the potential side effects and complications that could result from a measles vaccination, Nurse Frederick was unaware of the possibility of contracting SSPE. *Id.* Moreover, Nurse Frederick did not remember reading the package circular that Merck included in each MMR II vaccine. *Id.* Rather, she recalled receiving information regarding the risks of MMR II from the Important Information Statement issued by the CDC. *Id.* As a result, the *Mazur* court concluded that Nurse Frederick did not possess "the cumulative medical knowledge and experience necessary to make an individualized judgment as to which students should have been vaccinated," and therefore, Nurse Frederick did not act as a learned intermediary on the day of Lisa's inoculation. *Id.*

In *Mazur I*, the district court noted that the technician who actually administered the vaccine did not qualify as a learned intermediary because a technician is not a medical professional. *Mazur I*, 742 F. Supp. at 254 n.20.

B. *Application of the Mass Immunization Exception*

The mass immunization rule dictates that where warnings are not given to patients through a learned intermediary, the duty to warn consumers directly remains with the manufacturer if the prescription drug or vaccine is dispensed in a mass immunization setting.<sup>61</sup> The rationale behind this exception rests on the notion that "the learned intermediary rule buckles where prescription drugs are dispensed without an individualized medical balancing of the risks and benefits to the user"<sup>62</sup> and where the manufacturer should reasonably foresee that there will be no such risk-benefit balancing.<sup>63</sup> The mass immunization exception is inapplicable, however, where a learned intermediary is present.<sup>64</sup>

Because the Third Circuit concluded that no learned intermediary was present on the day of Lisa Mazur's inoculation, the court next evaluated whether Pennsylvania courts would apply the mass immunization exception.<sup>65</sup> First, the court noted that other jurisdictions have applied the exception where vaccines were dispensed to "all comers at mass clinics" absent independent or individualized medical assessments.<sup>66</sup> In *Davis v. Wyeth Laboratories, Inc.*,<sup>67</sup> for example, the Ninth Circuit determined that the manufacturer of a polio vaccine, dispensed as part of a nation-wide program, was obligated to warn not only the immediate purchaser, but the ultimate vaccine recipients as well.<sup>68</sup> The court

61. *Mazur*, 964 F.2d at 1361. The Fifth and Ninth Circuits decided the seminal cases involving the mass immunization exception. *Reyes v. Wyeth Lab.*, 498 F.2d 1264 (5th Cir.) (applying mass immunization exception where vaccine is administered absent individualized assessment as to risks and benefits), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121 (9th Cir. 1968) (same).

62. *Mazur*, 964 F.2d at 1361.

63. *Mazur I*, 742 F. Supp. at 255-56.

64. *Mazur*, 964 F.2d at 1363 n.22 ("The duty to warn is imposed on the manufacturer and in a mass immunization context, where there is no learned intermediary, the duty extends to the ultimate recipient of the vaccine.") (alteration in original) (quoting *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984)).

65. *Mazur*, 964 F.2d at 1361-64. The Pennsylvania Supreme Court had not, and still has not, addressed the applicability of the mass immunization exception under Pennsylvania law. *Id.* at 1361. However, the *Mazur I* court held that the mass immunization exception did not apply because:

[T]here [was] no evidence to suggest that Merck foresaw that no learned intermediary would be present at inoculation, the Health Department program was not large enough to be considered a mass immunization program, and the vaccine was not dispensed to 'all comers.'

*Mazur I*, 742 F. Supp. at 257.

66. *Mazur*, 964 F.2d at 1361.

67. 399 F.2d 121 (9th Cir. 1968).

68. *Id.* at 131. At issue in *Davis* was the use of the Sabin oral polio vaccine, a live-virus inoculation. *Id.* at 122. The plaintiff, in good health at the time of vaccination, contracted polio within thirty days of receiving the inoculation. *Id.* The *Davis* court analogized dispensing vaccines *en masse* to dispensing over-the-counter drugs and concluded that lack of risk-benefit balancing by a physician rendered warnings to immediate purchasers insufficient. *Id.* at 130-31. Instead,

opined that because the vaccine was issued to all comers without the presence of a physician to assess the risks, the manufacturer retained the duty to warn each recipient individually or, alternatively, to ensure that the purchaser provide such individual warnings.<sup>69</sup>

The Third Circuit similarly relied on *Reyes v. Wyeth Laboratories, Inc.*,<sup>70</sup> which, like *Davis*, applied the mass immunization exception where inoculations were administered without risk-benefit balancing and where the defendant manufacturer *knew or had reason to know of the manner in which the vaccine was to be dispensed*.<sup>71</sup> The Third Circuit emphasized this latter criterion in rejecting Merck's argument that the school program, by virtue of its relatively small size, did not qualify as a mass immunization situation.<sup>72</sup> According to the court, "[p]rescription drug manufacturers are charged with knowledge of the distribution system in which their products are sold."<sup>73</sup> Having previously decided that the school nurse did not qualify as a learned intermediary on the day of Lisa's inoculation, and by charging Merck with the knowledge that its MMR II vaccine would be dispensed under clinic-like conditions, the Third Circuit concluded that the mass immunization exception applied to the school's program.<sup>74</sup> Consequently, the court held that Merck retained its duty to warn vaccinees of the risks associated with MMR II either directly or by obligating the purchaser to do so.<sup>75</sup>

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the *Davis* court held that the manufacturer retains a duty to warn the ultimate user or consumer. *Id.* at 131.

69. *Id.* ("[I]t is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning.")

70. 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974). In *Reyes*, as in *Davis*, the plaintiff contracted polio as a result of a polio vaccination that was administered as part of a nation-wide inoculation program in an attempt to combat a polio epidemic. *Reyes*, 498 F.2d at 1269. The Fifth Circuit held that where a pharmaceutical manufacturer knows or has reason to know that its vaccine will be dispensed without individualized risk-benefit balancing, the manufacturer must ensure that the ultimate consumer will be adequately warned of the risks attendant to receipt of the vaccine. *Id.* at 1276-77.

71. *Mazur*, 964 F.2d at 1363.

72. *Id.* Although the Third Circuit recognized that program size was relevant in determining the foreseeability that a vaccine would be dispensed in "clinic-like" conditions, the court found that size alone was insufficient to preclude the application of the mass immunization exception. *Id.*

73. *Id.* The *Mazur* court went on to quote *Reyes*:

A drug manufacturer is held to the skill of an expert in his field, and is presumed to possess an expert's knowledge of the arts, materials, and processes of the pharmaceutical business. Included in such expertise must be a familiarity with practices and knowledge common in the drug industry as to distribution and administration of pharmaceutical products.

*Id.* (footnotes omitted)(quoting *Reyes*, 498 F.2d at 1277).

74. *Mazur*, 964 F.2d at 1364.

75. *Id.* As the Third Circuit stated:

Because we believe the MMR II vaccine was dispensed under "clinic-like" conditions on the day that Lisa Mazur was inoculated and it was

C. *Contractually Delegating the Duty to Warn*

After concluding that Merck owed a duty to each individual vaccinee, the Third Circuit addressed whether Merck effectively complied with its duty to warn.<sup>76</sup> Initially, the *Mazur* court noted the Mazurs' assertion that the Pennsylvania Supreme Court, in *Berkebile v. Brantly Helicopter Corp.*,<sup>77</sup> a section 402A case, described the duty to warn as "non-delegable."<sup>78</sup> In *Berkebile*, a widow sued a helicopter manufacturer for failure to warn under section 402A, after her husband was killed in a helicopter crash.<sup>79</sup> The *Berkebile* court differentiated the duty to warn in negligence from the duty to warn in strict liability, and determined that under section 402A the duty to warn remained non-delegable.<sup>80</sup> The Third Circuit opined, however, that unlike in *Berkebile*, the action in *Mazur* centered on an unavoidably unsafe product.<sup>81</sup> Consequently, section the 388 "reasonable care" standard applied.<sup>82</sup> Further, the Third Circuit recognized that comment n to section 388 expressly allows

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foreseeable that the vaccine would be dispensed in this manner, we conclude that the mass immunization exception is applicable here, thus obligating Merck to warn users of the risks of its vaccine directly.

*Id.* *Accord Davis*, 399 F.2d at 131 ("[I]t is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning."); *Reyes*, 498 F.2d at 1276 ("[T]he manufacturer is required to warn the ultimate consumer, or to see that he is warned.").

76. *Mazur*, 964 F.2d at 1364-68.

77. 337 A.2d 893 (Pa. 1975).

78. *Berkebile*, 337 A.2d at 903. The *Berkebile* court stated:

Where warnings or instructions are required to make a product nondefective, it is the duty of the manufacturer to provide such warnings in a form that will reach the ultimate consumer and inform of the risks and inherent limits of the product. *The duty to provide a non-defective product is non-delegable.*

*Id.* (emphasis added).

79. *Id.* at 897.

80. *Id.* at 902-03. For a recitation of the *Berkebile* court's reasoning, see *supra* note 78.

81. *Mazur*, 964 F.2d at 1365. In *Berkebile*, the allegedly defective product was a helicopter. *Berkebile*, 337 A.2d at 897. Helicopters do not qualify as unavoidably unsafe products under comment k to § 402A; vaccines, by contrast, do. See RESTATEMENT (SECOND) OF TORTS, § 402A (1965)(including vaccines among unavoidably unsafe products). The *Mazur* court relied on the Pennsylvania Supreme Court's decision in *Incollingo v. Ewing*, 282 A.2d 206, 220 n.8 (Pa. 1971) when it concluded that § 388 (duty to use reasonable care to warn the ultimate user) governed Merck's duty to warn. *Mazur*, 964 F.2d at 1365.

For the pertinent text of § 388, see *supra* note 5. For a discussion of § 402A strict liability, see *supra* notes 1-4 and accompanying text.

82. *Mazur*, 964 F.2d at 1365. The reasonable care standard of § 388 may absolve the manufacturer of liability even if the warnings never reach the consumer. Comment l of the RESTATEMENT (SECOND) OF TORTS § 388 provides in pertinent part:

The supplier's duty is to exercise reasonable care to inform those for whose use the article is supplied of dangers which are peculiarly within his knowledge. If he has done so, he is not subject to liability, even

a manufacturer to fulfill its obligation by ensuring that the manufacturer provides adequate warnings to a third party who, in turn, relays the warnings to the ultimate consumer.<sup>83</sup>

Relying on section 388, the *Mazur* court concluded that "a vaccine manufacturer may satisfy its duty to warn in the mass immunization context by obligating the CDC to warn users directly."<sup>84</sup> The Third Circuit further noted, however, that warnings given to the CDC would suffice only if the manufacturer provided the agency with the pertinent information regarding the vaccine's dangers and "reasonably relie[d] on [the agency] to communicate such information to users in lay terms."<sup>85</sup> Based on this conclusion, the Third Circuit examined two issues. First, the *Mazur* court addressed whether, as a matter of law, Merck had adequately warned the CDC of the dangers of MMR II. Second, the Third Circuit examined whether, as a matter of law, Merck had reasonably relied on the CDC to warn vaccinees of MMR II's dangers, including the risk of contracting SSPE.<sup>86</sup>

The *Mazur* court began its analysis by evaluating the sufficiency of information Merck gave to the CDC.<sup>87</sup> Specifically, the court assessed the FDA-approved package insert that Merck included with each vial of the MMR II vaccine.<sup>88</sup> The package insert included: recommended uses, contraindications, a paragraph warning of the dangers of revaccination and a paragraph dedicated to the risk of contracting SSPE.<sup>89</sup> The Third Circuit ultimately agreed with the district court's finding in *Mazur II* that, based on the state of medical knowledge at the time of

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though the information never reaches those for whose use the chattel is supplied.

*Id.*

83. *Mazur*, 964 F.2d at 1365. For a recitation of the pertinent parts of comment n to § 388, see *supra* note 30.

84. *Mazur*, 964 F.2d at 1365.

85. *Id.* To avoid liability, the manufacturer has "some duty to insure that the purchaser is capable of passing the warning on to others in the distribution chain." *Bryant v. Technical Research Co.*, 654 F.2d 1337, 1347 (9th Cir. 1981). The Third Circuit further noted that the duty to provide the agency with pertinent information was continuous: Merck, therefore, retained an ongoing duty to apprise the CDC of any risks it later discovered or should have discovered through the exercise of reasonable care. *Mazur*, 964 F.2d at 1366.

86. *Id.* at 1366-69. The *Mazur* court limited its analysis to whether Merck reasonably relied on the CDC to warn MMR II vaccinees. *Id.* at 1366 n.27. The *Mazur* court, therefore, did not address whether it would be reasonable to rely on an organization other than the CDC. *Id.*

87. *Id.* at 1366-69.

88. *Id.* at 1366. Under Pennsylvania law, the "[a]dequacy of warnings is determined on the basis of the information that was known or knowable at the time the cause of action accrued." *Id.* (citing *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 458 (Pa. Super. Ct. 1973)). Further, warnings conforming to federal drug labeling requirements "are afforded some deference." *Id.* (citing *White v. Weiner*, 562 A.2d 378, 383 (Pa. Super. Ct. 1989)).

89. *Id.* at 1366-67. For a recitation of the package insert warnings pertaining to SSPE, see *supra* note 39.

Lisa Mazur's vaccination, the package circular provided adequate warnings as a matter of law.<sup>90</sup>

Next, the Third Circuit considered whether Merck's reliance on the CDC was reasonable.<sup>91</sup> The *Mazur* court determined that reasonableness depended upon the foreseeability that the CDC would fail to honor its contractual obligation to forward the warnings provided by Merck.<sup>92</sup> The Third Circuit noted that Merck relied on the CDC after receiving recommendations from physicians and consumer groups, and through past first-hand experience with the CDC.<sup>93</sup> Based on these factors, as well as the CDC's "expertise in immunology and public vaccination" and affiliation with various medical associations, the Third Circuit concluded that Merck's reliance on the CDC was reasonable.<sup>94</sup>

Ultimately, the Third Circuit concluded that Merck had satisfied its duty to warn vaccinees of the dangers of MMR II. Merck fulfilled this duty not by providing information to a learned intermediary, but by contractually obligating a third party, the CDC, to provide adequate warnings directly to the vaccinees.<sup>95</sup> Consequently, the Third Circuit granted summary judgment in favor of Merck on the issue of failure to warn.<sup>96</sup>

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90. *Mazur*, 964 F.2d at 1366-67. In *Mazur I*, the district court determined that the package insert provided sufficient warnings with respect to all risks associated with MMR II, except for the risks of revaccination. *Id.* at 1366. The *Mazur II* court, however, found that at the time of Lisa Mazur's inoculation, the revaccination paragraph in the package circular was adequate in light of the state of medical knowledge at the time. *Id.* at 1366-67. The Third Circuit agreed with the *Mazur II* court. *Id.* at 1367.

For a recitation of the portion of the package circular relevant to revaccination, see *supra* note 40.

91. *Mazur*, 964 F.2d at 1367.

92. *Id.* The Third Circuit stated that "[f]or purposes of this inquiry, we assume, as we must at this stage, that Mrs. Mazur never received the Important Information Statement." *Id.* Further, the court pointed out that whether the Important Information Statement was itself adequate was immaterial. *Id.* at n.30. Rather, the issue was whether Merck reasonably relied on the CDC, "not whether the CDC in fact developed an adequate warning and successfully disseminated it to vaccinees." *Id.* (emphasis added).

93. *Id.* at 1368.

94. *Id.* The court elaborated:

The CDC is an agency of the Public Health Service of the United States Department of Health and Human Services. It is empowered to conduct studies, evaluations, tests, and emergency programs in order to prevent the spread of disease and to improve the public welfare. With respect to vaccines, it plays a vital role in research, development, testing, and distribution. It publishes the *Morbidity and Mortality Weekly Report*, among other reports, studies, and journals, to educate public health and medical professionals about the risks and benefits of immunization.

*Id.* (citations omitted) (quoting *Mazur II*, 767 F. Supp. at 706).

95. *Mazur*, 964 F.2d at 1369.

96. *Id.*

## V. CONCLUSION

Based on the criteria set forth in section 388 of the Restatement, the Third Circuit logically determined that Merck, by contractually obligating the CDC to pass on adequate warnings, had met its duty to inform vaccinees, including Lisa Mazur, of the risks associated with the MMR II vaccine.<sup>97</sup> Therefore, the Third Circuit appropriately upheld the district court's decision to grant Merck's motion for summary judgment.

Although the Third Circuit determined that a registered nurse did not qualify as a learned intermediary, Pennsylvania courts, not bound by the Third Circuit's decision, may decide differently. The Third Circuit's reliance on previous Pennsylvania caselaw in reaching its conclusion is tenuous at best. Specifically, the Pennsylvania state court cases cited by the Third Circuit held that *pharmacists* could not qualify as learned intermediaries.<sup>98</sup>

Although nurses, like pharmacists, are unable to prescribe drugs or diagnose most illnesses, in an immunization setting nurses play similar roles to physicians. Nurses and physicians have access to the same medical records, perform similar tasks and, arguably, interact with vaccinees to the same extent.<sup>99</sup> While the Third Circuit may have correctly concluded that Nurse Frederick's behavior on the day of Lisa Mazur's inoculation did not render *her* a learned intermediary, Pennsylvania courts are not bound by the decision of the *Mazur* court. Accordingly, Pennsylvania courts may opt to follow the rationale adopted in other jurisdictions, and find that in certain instances a registered nurse may act as a learned intermediary.<sup>100</sup>

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97. *Id.* at 1364-68. For a complete discussion of the Third Circuit's examination of contractually delegating a third party to provide warnings, see *supra* notes 76-96 and accompanying text.

98. See *Mazur*, 964 F.2d at 1356-60 & 1369 (determining that Pennsylvania courts would not give registered nurses learned intermediary status because previous Pennsylvania decisions refused to grant learned intermediary status to pharmacists); See also *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383 (Pa. 1991)(granting summary judgment in favor of pharmacy on ground that pharmacist owes no independent duty to warn); *Makripodis v. Merrell-Dow Pharmaceutical, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987) (same).

For a list of various jurisdictional views regarding a pharmacist's duty to warn, see Milot, Note, *supra* note 56 at 1008 nn.24-25.

99. *Mazur I*, 742 F. Supp. at 255. In addition to the functional similarities between doctors and nurses, the *Mazur I* court noted that the Pennsylvania legislature, in 42 Pa. Cons. Stat. Ann. § 8334(a), has granted liability immunity to both doctors and nurses for adverse reactions to vaccines dispensed as part of a mass immunization project. *Id.* Thus, the *Mazur I* court predicted that Pennsylvania courts would extend the learned intermediary doctrine to nurses. *Id.*

100. See, e.g., *Rohrbough v. Wyeth Lab., Inc.*, 719 F. Supp. 470, 478 (N.D.W. Va. 1989)(qualifying registered nurse administering DPT vaccine as learned intermediary), *aff'd*, 916 F.2d 970 (4th Cir. 1990); *Walker v. Merck & Co.*, 648 F. Supp. 931 (M.D. Ga. 1986)(qualifying licensed practical nurse administering MMR II vaccine as learned intermediary), *aff'd*, 831 F.2d 1069 (11th Cir. 1987).

If Pennsylvania courts adopt the Third Circuit's approach, then the *Mazur* decision could have a profound effect on Pennsylvania product liability law. Denying learned intermediary status to registered nurses in mass immunization settings will force vaccine manufacturers to take added precautions to ensure that vaccinees are warned of risks. In addition, to avoid future liability for failure to warn, manufacturers may require the presence of *physicians*, recognized learned intermediaries, at all mass immunization sites. This would place an enormous burden on both the immunization programs and the physicians required to oversee them.

Denying learned intermediary status to nurses will undoubtedly increase the burden placed on vaccine manufacturers and distributors by requiring these entities to provide warnings *directly* to all vaccinees. The Third Circuit, however, has created a reasonable method for manufacturers to comply with this burden.<sup>101</sup> By allowing vaccine manufacturers to convey adequate warnings to consumers through contractual obligations with reliable third parties, pharmaceutical companies may concentrate on what they do best—researching and marketing new and much-needed vaccines. Ultimately, therefore, the *Mazur* decision could act to improve both available vaccines and public awareness of the risks and benefits of immunization.

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101. *Mazur*, 964 F.2d at 1365 (“[W]e believe a vaccine manufacturer may satisfy its duty to warn in the mass immunization context by obligating the CDC to warn users directly if it informs that agency of the facts which make its vaccine dangerous and reasonably relies on it to communicate such information to users in lay terms.”).