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# A Weighty Issue: Will Pharmacists Survive the Fen-Phen Feeding Frenzy? *Kohl v. American Home Products Corporation* and a Pharmacist's Duty to Warn of the Dangers of Prescription Drugs

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## A Weighty Issue: Will Pharmacists Survive the Fen-Phen Feeding Frenzy? *Kohl v. American Home Products Corporation* and a Pharmacist's Duty to Warn of the Dangers of Prescription Drugs

### I. INTRODUCTION

In 1996, pharmacists dispensed over 18 million prescriptions for fenfluramine in the United States.<sup>1</sup> As the more dangerous half of the diet drug combination popularly known as “Fen-Phen,” fenfluramine promised overweight Americans something that seemed too good to be true: the body of their dreams as excess flab melted away without hunger.<sup>2</sup>

The honeymoon, however, was short-lived. Americans' love affair with Fen-Phen came to a bitter end when, in July of 1997, the U.S. Food and Drug Administration (“FDA”) published a report linking valvular heart disease to the use of Fen-Phen.<sup>3</sup> On September 15,

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1. See Centers for Disease Control and Prevention, *Cardiac Valvulopathy Associated with Exposure to Fenfluramine or Dexfenfluramine: U.S. Department of Health and Human Services Interim Public Health Recommendations*, 46 MORBIDITY & MORTALITY WKLY. REP., Nov. 1997.

Fenfluramine was marketed under the trade name “Pondium.” See U.S. Dep't of Health & Human Servs., *FDA Announces Withdrawal of Fenfluramine and DexFenfluramine*, HHS NEWS, Sept. 15, 1997. Dexfenfluramine, which will be treated the same as fenfluramine for the purposes of this Note, was marketed under the trade name “Redux.” See *id.*

The U.S. District Court for the Eastern District of Pennsylvania estimates that from January 1995 to September 1997 approximately 6,000,000 people ingested some form of fenfluramine. *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, No. 99-20593, 2000 U.S. Dist. LEXIS 12275, at \*5-6 (E.D. Pa. Aug. 28, 2000).

2. Fen-Phen affects serotonin levels in the brain to trick the body into feeling full. See Centers for Disease Control and Prevention, *supra* note 1. Fen-Phen was such an effective appetite suppressant that one patient reported having to “force” herself to eat. See Cable News Network Interactive, *Dieters rah-rah over Fen-Phen*, at <http://www.cnn.com/HEALTH/9612/17/fen.phen/> (Dec. 17, 1996).

3. See U.S. Food and Drug Admin., *Reports of Valvular Heart Disease in Patients Receiving Concomitant Fenfluramine and Phentermine*, 27 FDA MED. BULL., July 8, 1997. The report featured thirty-three cases in which patients who were taking Fen-Phen were found to have valvular irregularities. See *id.* Nearly all of the patients were diagnosed with valvular heart disease. See *id.* About half of the patients also were diagnosed with pulmonary hypertension. See *id.* All of the patients were women between the ages of thirty-five and seventy-two who had been taking Fen-Phen for between one and sixteen months. See *id.*

1997, the FDA announced the withdrawal of fenfluramine from the market.<sup>4</sup> Sales ground to a halt,<sup>5</sup> stock plummeted,<sup>6</sup> and thousands of Fen-Phen consumers lined up at their doctor's offices for echocardiograms.<sup>7</sup>

No one was surprised<sup>8</sup> when these same consumers found their way *en masse* into lawyers' offices around the country as a wave of litigation ensued. As of May 2000, "approximately 18,000 individuals" had filed lawsuits against American Home Products, the maker of fenfluramine.<sup>9</sup> Although a federal judge recently approved a \$3.75 billion class action settlement against American Home Products,<sup>10</sup> 44,423 plaintiffs exercised their right to opt out,<sup>11</sup> thousands more are challenging the settlement as unfair,<sup>12</sup> and many more cases remain pending in state court.<sup>13</sup>

As the unwitting middlemen caught in a litigation feeding frenzy, pharmacists and the future of their profession are on shaky ground.<sup>14</sup> While courts traditionally have held pharmacists to a duty

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4. See U.S. Dep't of Health & Human Servs., *supra* note 1.

5. American Home Products, the manufacturer of fenfluramine, grossed \$191 million in fenfluramine sales in 1996 alone. See Cable News Network Interactive, *Too good to be true? Critics warn of Fen-Phen side effects*, at <http://www.cnn.com/HEALTH/9612/20/fen.phen4/> (Dec. 20, 1996).

6. The same day that the FDA announced the withdrawal of fenfluramine, American Home Products

issued a press release estimating total lost profits of 14 cents per share for 1997 and 1998 . . . as well as a one-time product withdrawal loss of \$200 million to \$300 million. On September 15, the day of the withdrawal announcement, the closing price of AHP common stock fell 3 11/16 points, to 73 1/4.

See *Oran v. Stafford*, 226 F.3d 275, 280 (3d Cir. 2000).

7. When the FDA announced the withdrawal of fenfluramine, it advised patients who had used the drug to "contact their doctors to discuss their treatment." U.S. Dep't of Health & Human Servs., *supra* note 1. An echocardiogram is a "special procedure that can test the functioning of heart valves." *Id.*

8. Least of all American Home Products, who grimly announced the day after the FDA announcement that it would "likely . . . face legal action." *Oran*, 226 F.3d at 280.

9. *In re Diet Drugs*, No. 99-20593, 2000 U.S. Dist. LEXIS 12275, at \*9 (E.D. Pa. Aug. 28, 2000).

10. See *id.*

11. Shannon P. Duffy, *\$3.75 Billion Fen-Phen Settlement Approved*, THE LEGAL INTELLIGENCER, Aug. 29, 2000.

12. See *In re Diet Drugs*, No. 99-20593, 2000 U.S. Dist. LEXIS 12275 (E.D. Pa. Aug. 28, 2000).

13. See Duffy, *supra* note 11.

14. See, e.g., *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 889 (W.D. Ark. 1999) (recognizing that "[t]he issue of whether a cause of action may be maintained against a retail pharmacy for filling a physician's prescription has been the subject of debate in both the

of clerical accuracy only, some courts recently have shown a willingness to extend this duty to include the duty to warn of the dangers of prescription drugs.<sup>15</sup>

*Kohl v. American Home Products Corporation*, the principal case in this Note, purported to apply the traditional rule but nevertheless suggested that a pharmacist could be held liable for failing to second-guess labeling information supplied by the manufacturer of fenfluramine.<sup>16</sup> While the holding itself is unimportant (the court eventually dismissed the plaintiff's claims on procedural grounds), the court's rationale is significant because it further muddied the waters of pharmacists' liability. More importantly, as the *Kohl* court was the only judicial body in the country to address squarely the issue of a pharmacist's duty to warn of the dangers of Fen-Phen, other courts will likely look to the *Kohl* rationale as the Fen-Phen litigation filters down into the state courts.

Part II of this Note gives a brief synopsis of the Fen-Phen controversy and traces the recent judicial history of pharmacists' liability. Part III gives the facts of *Kohl* and explains the court's reasoning in suggesting that a pharmacist could be held liable for failure to warn of the dangers of fenfluramine. Part IV analyzes the court's opinion, compares that opinion with other recent decisions involving a pharmacist's duty to warn, and argues that the court improperly expanded and confused the scope of pharmacists' liability. Furthermore, this Note concludes that the modern trend toward expanding pharmacists' liability could displace the physician's role and thereby compromise patient care.

## II. BACKGROUND

Fenfluramine leapt from relative obscurity in 1992 to become one of the hottest selling diet drugs of the century.<sup>17</sup> Sales were brisk

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case law and in the academic field.”).

15. See, e.g., *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994).

16. See *Kohl*, 78 F. Supp. 2d at 893. Although the court couched such a duty as a duty to “properly label . . . prescriptions,” the *Kohl* court nevertheless suggested that pharmacists should have “labeled” fenfluramine with warnings that had yet to be disclosed by the FDA. See *id.* While it is useful to distinguish between “warnings” and “labeling” in some contexts, this Note suggests that the duty to warn and the duty to label are indistinguishable when the pharmacist did not know and had no reason to know of the dangers at issue.

17. See *In re Diet Drugs*, 2000 U.S. Dist. LEXIS 12275, at \*5. This sales phenomenon is generally attributed to Michael Weintraub, M.D., who “advocated the use of Fenfluramine

until reports surfaced in 1997 linking fenfluramine to heart disease.<sup>18</sup> Although the Mayo Clinic suspected an association between the use of fenfluramine and valvular heart disease in March 1997, the FDA did not make those findings public until July 8, 1997.<sup>19</sup> When the FDA did issue a public warning about the use of fenfluramine, it pointed out that the evidence linking fenfluramine to heart disease was not yet conclusive.<sup>20</sup> The FDA did not officially withdraw fenfluramine from the market until September 15, 1997, over two months after the initial reports were made public.<sup>21</sup>

Most of the 18,000 plaintiffs that filed lawsuits against American Home Products claimed the manufacturer either knew or should have known of the adverse effects of fenfluramine well before the FDA's official withdrawal of the drug.<sup>22</sup> Likewise, the *Kohl* plaintiff alleged that the defendant pharmacy either knew or should have known of the dangerous defects of fenfluramine even before the FDA's announcement.<sup>23</sup> While courts have been receptive to such claims against drug manufacturers,<sup>24</sup> courts have traditionally declined to impose such a duty to warn on individual pharmacists.<sup>25</sup>

The sections below outline the doctrines and rationales supporting the traditional rule that pharmacists have no duty to warn and contrasts those rules with the modern view that a pharmacist's duty extends beyond clerical accuracy.<sup>26</sup>

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combined with phentermine." *Id.* Weintraub believed the combination lessened the adverse side effects "associated with using Fenfluramine alone," and thus "Fen-Phen" was born. *Id.*

18. *See id.* at \*7.

19. *See id.* The Mayo Clinic did not officially publish its results until August 28, 1997. *See id.*

20. *See* U.S. Food and Drug Admin., *supra* note 3.

21. *See* U.S. Dep't of Health & Human Servs., *supra* note 1.

22. *See In re Diet Drugs*, 2000 U.S. Dist. LEXIS 12275, at \*185-86.

23. *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 891-92 (W.D. Ark. 1999).

24. Last year a federal judge approved a \$3.75 billion settlement against American Home Products. *In re Diet Drugs*, 2000 U.S. Dist. LEXIS 12275, at \*214. That settlement was affirmed by the Third Circuit in an unpublished opinion on August 15, 2001. *See* The Fen-Phen e-Resource, *3rd Circuit Clears Up Final Obstacle to National Settlement*, at <http://www.fen-phen-eresource.com/third.cfm> (August 17, 2001).

25. *See, e.g.*, *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1386 (Pa. 1991).

26. The duty of clerical accuracy requires the pharmacist to dispense "the intended medication free of contamination from improper storage, and [to supply] correct and complete directions." Lauren Fleischer, Note, *From Pill-Counting to Patient Care: Pharmacists' Standard of Care in Negligence Law*, 68 FORDHAM L. REV. 165, 174 (1999) (citing David B. Brushwood, *The Pharmacist's Duty Under OBRA-90 Standards*, 18 J. LEGAL MED. 475 (1997)).

*A. Unavoidably Unsafe Drugs and Strict Liability*

This is not the first time that the dangerous effects of a prescription drug were discovered only after the drug was ingested by millions of consumers, and it will not be the last.<sup>27</sup> The competing interests of promoting useful medical innovations and protecting the public against dangerous products have led the American Law Institute to propose that prescription drugs should be excepted from the strict liability provision of the Restatement of Torts.<sup>28</sup> Many states have adopted the § 402A comment k exception to strict liability for prescription drugs under the view that all prescription medications are unavoidably unsafe.<sup>29</sup> In a further effort to protect prescription drugs, the Utah legislature declared that FDA-approved drugs are presumed to be free from defects as a matter of law.<sup>30</sup>

However, the Utah Supreme Court pointed out that the protections of comment k apply only when the plaintiff alleges a design defect.<sup>31</sup> Thus, only prescription drugs that are “properly prepared and accompanied by warnings of [their] dangerous propensities” will be sheltered under comment k.<sup>32</sup> Because of the above protections, most plaintiffs recognize that they face an uphill battle in proving a drug was sold in an unreasonably dangerous condition due to a defective design. Some plaintiffs, therefore, allege the product was rendered unreasonably dangerous by the

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27. For similar problems with the prescription drugs Bendectin and DES, see, respectively, *Johnson v. Richardson-Merrell, Inc.*, C.A. No. 83-3814, 1984 U.S. Dist. LEXIS 24662 (E.D. Pa. Aug. 1, 1984), and *Murphy v. E.R. Squibb & Sons*, 710 P.2d 247 (Cal. 1985). This Note analyzes pharmacists’ liability in light of Fen-Phen because it is the most recent and relevant example of mass tort liability in the field of prescription drugs.

28. Comment k of RESTATEMENT (SECOND) OF TORTS § 402A (1977) provides:

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.

*Id.*

29. See, e.g., *Grundberg v. Upjohn Co.*, 813 P.2d 89, 93-94 (Utah 1991) (citing *Brown v. Superior Court*, 751 P.2d 470, 482 (Cal.1988)).

30. UTAH CODE ANN. § 78-15-6 (2000). Plaintiffs may overcome this rebuttable presumption. See *id.*

31. See, e.g., *Grundberg*, 813 P.2d at 91.

32. *Id.* at 92. The court recognized that “[t]his limitation on the scope of comment k immunity is universally recognized.” *Id.*

pharmacist's failure to warn.<sup>33</sup>

Although Utah courts have yet to address the issue, such strict liability claims have been largely unsuccessful in other jurisdictions.<sup>34</sup> In support of these holdings, courts have recognized that subjecting pharmacists to strict liability would hardly serve the purposes of such a standard; namely, to provide an incentive for issuing safer products, "for the pharmacist presented with a prescription ordered by a duly licensed physician is not at liberty to substitute his judgment of the product's safety for the patient for that of the physician."<sup>35</sup>

In addition, courts have found that subjecting pharmacists to strict liability would produce untenable practical ramifications; namely, that such liability would impose on pharmacists the obligation to independently test new prescription drugs, thereby making them the "absolute insurer" of the products.<sup>36</sup> Courts also have speculated that, to avoid liability, pharmacists might even "refuse to fill prescriptions, notwithstanding decisions by licensed physicians that a particular drug was necessary and appropriate for their patients' medical treatment."<sup>37</sup> Such a cost to society, courts have concluded, would be "unduly high."<sup>38</sup>

More importantly, courts have pointed out that even a manufacturer's duty to warn does not extend to individual consumers, but only to prescribing physicians.<sup>39</sup> Thus, if drug manufacturers complied with their duty to warn physicians of dangerous side effects, the drug product as shipped to the pharmacy could not be considered unreasonably dangerous due to a defective

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33. See *Murphy v. E.R. Squibb & Sons*, 710 P.2d 247, 249 (Cal. 1985) (involving claim that pharmacist should be held strictly liable for failure to warn of the dangerous defects of DES); *Leesley v. West*, 518 N.E.2d 758, 762 (Ill. App. Ct. 1988) (same claim involving feldene); *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 87 (E.D. Pa. 1986) (same claim involving Bendectin).

34. See, e.g., *Ramirez*, 628 F. Supp. at 87 (listing courts that have "consistently rejected the application of strict liability to pharmacists.").

35. *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 895 (W.D. Ark. 1999) (quoting *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1387 (Pa. 1991)).

36. *Id.*; see also *Bichler v. Willing*, 397 N.Y.2d 57 (Sup. Ct. 1977) (refusing to hold pharmacist strictly liable for failure to warn of the hazardous effects of DES). For a similar rationale applied to drug manufacturers, see also *Brown v. Superior Court*, 751 P.2d 470, (Cal. 1988) (declining to impose strict liability on drug manufacturers because such a rule would not comport with the traditional goals of tort law, namely, deterrence and cost distribution).

37. *Kohl*, 78 F. Supp. 2d at 895 (quoting *Coyle*, 584 A.2d at 1387).

38. *Ramirez*, 628 F. Supp. at 87.

39. See *Leesley v. West*, 518 N.E.2d 758, 761 (Ill. App. Ct. 1988); *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 87 (E.D. Pa. 1986).

warning.<sup>40</sup> In order for the plaintiff to prevail in such a case, a court “would have to conclude that the product somehow became unreasonably dangerous in [the pharmacy’s] hands.”<sup>41</sup> Such a conclusion, one court noted, would be “unreasonable.”<sup>42</sup> Therefore, the majority of courts have declined to impose a more stringent duty to warn on pharmacists than that imposed on manufacturers.<sup>43</sup>

The common thread in the above arguments is that the duty to warn individual patients of the potential hazards of prescription drugs properly lies with the physician—not the pharmacist, or even the manufacturer. This traditional view finds its rationale in the “learned intermediary doctrine,” discussed next.

### B. *The Learned Intermediary Doctrine*

The learned intermediary rule, as described in *Coyle v. Richardson-Merrell, Inc.*, posits that the physician is the person who can best evaluate and explain the dangers of prescription drugs “to the patient in the context of his or her individual medical circumstances.”<sup>44</sup> The *Coyle* court noted that “[p]hysicians exercising sound medical judgment act as intermediaries in the chain of distribution, preempting, as it were, the exercise of discretion by the supplier-pharmacist, and, within limits, by the patient-consumer.”<sup>45</sup>

In keeping with the justification for strict liability, courts point out that it is not the pharmacist on whom the public is “forced to rely” for prescription drugs, but rather the physician.<sup>46</sup> Thus, courts are reluctant to impose any rule that would shift this reliance from the physician to the pharmacist because of the destructive effect it would have on the physician-patient relationship.<sup>47</sup> In the prescription drugs context, courts realize that pharmacists’

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40. *See Leesley*, 518 N.E.2d at 761.

41. *Id.* at 761–62.

42. *Id.* at 762; *see also Ramirez*, 628 F. Supp. at 87 (finding that “[i]t would be illogical and unreasonable . . . to impose a greater duty on the pharmacist . . . than is imposed on the manufacturer”); *Coyle*, 584 A.2d at 1386 (reasoning that “[i]f the manufacturer has no duty to directly warn patients of the risks of drugs, it would indeed be incongruous to hold pharmacists to such a duty in the dispensing of drugs”).

43. *See, e.g., id.*

44. *Coyle*, 584 A.2d at 1386.

45. *Id.*

46. *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 895 (W.D. Ark. 1999) (quoting *Coyle*, 584 A.2d at 1387).

47. *See, e.g., Coyle*, 584 A.2d at 1387.

interaction with patients comes only after the patient has obtained a signed prescription from the physician, during which time the dangers of the drug would presumably have already been discussed. Therefore, requiring the pharmacist to supplement the physician's warnings with his own would "have the effect of undermining the physician-patient relationship by engendering fear, doubt, and second-guessing."<sup>48</sup> In such a scenario,

the patient-consumer would be receiving information about the risks of medication, information he or she would likely be unable to properly assess and weigh, from someone unfamiliar with the patient's medical condition, *after* those risks had already been weighed by a physician having specific knowledge of the patient's medical needs.<sup>49</sup>

In short, these courts believe such a rule would significantly jeopardize the standard of health care in this country.<sup>50</sup>

### *C. Negligence*

Under the rationale of the learned intermediary doctrine, most, if not all, courts have declined to impose a strict liability duty to warn on pharmacists.<sup>51</sup> And while most courts apply the learned intermediary rule with equal force to negligence,<sup>52</sup> the modern view—that pharmacists should be required to do more than merely follow physicians' orders—appears to be gaining acceptance. Thus, the real controversy lies in how courts apply (or decline to apply) the learned intermediary rule to negligence cases.<sup>53</sup>

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48. *Id.*

49. *Id.*

50. The rationale of the learned intermediary doctrine is widely accepted. *See, e.g., Griffith v. Blatt*, 973 P.2d 385, 389–90 (Or. Ct. App. 1999). The *Griffith* court noted that many jurisdictions that have considered "whether pharmacists should be strictly liable for failure to warn of a prescription drug's dangerous propensities" have invoked the "learned intermediary" doctrine and, "apparently without exception, have refused to impose such liability." *Id.*

51. *See id.*

52. *See Leesley v. West*, 518 N.E.2d 758, 760–61 (Ill. App. Ct. 1988) (noting that "[i]n cases adopting the [learned intermediary] doctrine, the courts have applied it as frequently to negligence claims as to strict liability actions").

53. To date, no Utah court has ever ruled on this issue.

*1. The traditional view*

Under the traditional view, courts rely heavily on the learned intermediary rule. This view encourages the manufacturer, physician, and pharmacist to remain in their respective traditional roles. Accordingly, the manufacturer will provide adequate warnings to the physician, the physician will relay the warnings to the patient in the context of individual medical circumstances, and the pharmacist will fill the prescription according to the physician's instructions.<sup>54</sup> Under the traditional view, any deviation from these roles will jeopardize the standard of patient care.<sup>55</sup>

Thus, the traditionalists would limit a pharmacist's duty to "clerical accuracy."<sup>56</sup> While the modern view takes issue with denigrating the pharmacist's role to that of a mere "pill-counter," the traditionalists are quick to point out that the "clerical accuracy" rule is subject to some limitations. For example, pharmacists are responsible for spotting clear or patent errors, such as "obvious lethal dosages, inadequacies in the instructions, *known* contraindications, or incompatible prescriptions."<sup>57</sup>

Advocates of the traditional view also point to the practical implications of imposing a duty to warn on pharmacists. Because some drugs are shipped in bulk from the manufacturer to the pharmacist, each shipment contains only one package insert or warning. Thus, requiring pharmacists to reproduce the warning and give it to patients with every prescription filled would be unduly burdensome and unreasonable.<sup>58</sup> Moreover, federal statutory law specifically exempts prescription drugs from the package labeling requirements reserved for over-the-counter drugs.<sup>59</sup> Turning again to

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54. See, e.g., *Adkins v. Mong*, 425 N.W.2d 151, 154 (Mich. Ct. App. 1988) (holding that "there exists no legal duty on the part of a pharmacist to monitor and intervene with a customer's reliance on drugs prescribed by a licensed treating physician").

55. See *supra* Part II.B.

56. *Adkins*, 425 N.W.2d at 152. For a definition of clerical accuracy, see *supra* note 26. See also Dora A. Gonzalez, Note and Comment, *A Prescription for Litigation: In Pursuit of the Pharmacists' "Duty to Warn" of the Adverse Effects of Prescription Drugs*, 1 J. LEGAL ADVOC. & PRAC. 53, 54 (1999) (finding that "the traditional, and still majority position . . . holds that a pharmacist has no duty to warn").

57. *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1053 (Wash. 1989); See also *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131, 1133 (Kan. Ct. App. 1991); *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1253 (Pa. Super. Ct. 1986).

58. See *Leesley v. West*, 518 N.E.2d 758, 762 (Ill. App. Ct. 1988).

59. See *McKee*, 782 P.2d at 1054 (citing 21 U.S.C. § 353(b)(2)).

the learned intermediary rule, courts assert that it makes much more sense for the physician to provide such warnings in the context of the patient's individual medical circumstances.<sup>60</sup>

## 2. *The modern view*

In contrast to the traditional view, the modern view asserts that "pharmacists are trained professionals" and argues that, in some cases, pharmacists should be required to do more than "unquestionably obey the written orders [of] . . . physicians."<sup>61</sup> Specifically, the modern view takes offense at the learned intermediary rule's hesitation to vest pharmacists with any independent judgment and posits that, at least in some circumstances, pharmacists have a duty to warn consumers of the potential hazards of prescription drugs.<sup>62</sup>

*a. State statutory provisions.* Some courts have found justification for requiring pharmacists to exercise independent judgment in state statutory provisions.<sup>63</sup> The Utah Pharmacy Practice Act includes the following provisions under "Practice of Pharmacy": "(a) interpreting prescription orders; . . . [and] (f) providing information on drugs or devices, which may include advice relating to therapeutic values, potential hazards, and uses; . . . (i) providing patient counseling, including adverse and therapeutic effects of drugs."<sup>64</sup>

In perhaps the most liberal interpretation of a pharmacy statute, one court relied on the state pharmacy act to find not only that the pharmacist should have exercised his independent judgment over the physician's, but that, as between a physician and a pharmacist, "[e]ach has an affirmative duty to be, to a limited extent, his brother's keeper."<sup>65</sup>

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60. *See id.*

61. Kohl v. Am. Home Prods. Corp., 78 F. Supp. 2d 885, 891 (W.D. Ark. 1999) (quoting Riff v. Morgan Pharmacy, 508 A.2d 1247, 1247 (Pa. Super. Ct. 1986)).

62. *See* Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994).

63. *See, e.g., Riff*, 508 A.2d at 1251.

64. UTAH CODE ANN. § 58-17a-102(43) (1999). *See also* D.C. CODE ANN. § 2-2002 (1986); WASH. REV. CODE. § 18.64.011(11) (1989).

65. *Riff*, 508 A.2d at 1253. However, in this case the court found the pharmacist had a duty to exercise his independent judgment over the physician's in part because the instructions were patently inadequate. *See id.* Although this outcome could lend itself to the traditional view of the "limited duty" to detect patent errors, *see supra* Part II.C.1, the case is included here to show that some courts look to state statutory provisions to define a pharmacist's duty of care.

Although another court refused to use the state pharmacy act to define a pharmacist's duty, it did so in part because the act was not in effect at the time the pharmacist filled the prescription in question. Therefore, the court in *Raynor v. Richardson-Merrell, Inc.*<sup>66</sup> left open the possibility of applying the statute to define a pharmacist's duty at a later date.<sup>67</sup>

The traditionalists respond to these arguments by asserting that state statutory pharmaceutical provisions are definitional only, and do "not purport to set forth duties."<sup>68</sup> In specifically addressing whether, as the plaintiff alleged, the pharmacist *must* advise of the "therapeutic values, hazards, and the uses of drugs and devices,"<sup>69</sup> the *McKee* court concluded that the statutory language did not impose "a mandatory duty on all pharmacists to warn customers of all dangers associated with a drug."<sup>70</sup> Rather, the court construed the language to apply only where pharmacists possessed "prescriptive authority."<sup>71</sup>

*b. Standard of care vs. duty.* At least one court rejected the traditional rule by laboring to distinguish "duty" from "standard of care."<sup>72</sup> Although its line of reasoning was somewhat unclear, the Arizona Court of Appeals concluded without discussion that the

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66. 643 F. Supp. 238 (D.D.C 1986).

67. *Raynor*, 643 F. Supp. at 246 (holding that "[t]he [c]ourt makes no determination whether § 2-2002 imposes an actionable duty on pharmacies").

68. *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1052 (Wash. 1989); For purposes of comparison with the Utah Pharmacy Practice Act, the relevant provisions of the Washington Act are set out below:

"Practice of Pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

WASH. REV. CODE § 18.64.011(11).

69. *McKee*, 782 P.2d at 1051-52 (quoting WASH. REV. CODE § 18.64.011(11)).

70. *Id.* at 1052.

71. *Id.*

72. *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1131 (Ariz. Ct. App. 1994). Moreover, the court announced that the fatal mistake of courts following the traditional rule was that "they use details of the standard of conduct to determine whether a duty exists." *Id.*

pharmacist could have breached its duty to the patient.<sup>73</sup> The court noted that determining whether the pharmacist breached that duty required the trier of fact<sup>74</sup> to examine the standard of care for pharmacists. To determine the standard of care, the court relied on an expert affidavit that imposed a duty on pharmacists to “advise a customer of the addictive nature of a drug, to warn of the hazards of ingesting two or more drugs that adversely interact with one another, and to discuss with the physician the addictive nature of a prescribed drug and the dangers of long-term prescription of the drug.”<sup>75</sup> Thus, the court reversed the trial court’s grant of summary judgment in favor of the pharmacist.<sup>76</sup>

At most, the *Lasley* case suggests that pharmacists will always have a duty to warn their patients. Furthermore, the case stands for the proposition that whether or not a pharmacist breached the standard of care can be determined by any number of criteria, including expert witnesses<sup>77</sup> and standards enunciated by the American Pharmaceutical Association.<sup>78</sup>

Unlike the *Lasley* court, the *Kohl* court declined to distinguish “duty” from “standard of care.” Nevertheless, the *Kohl* court reached a similar result by suggesting that the defendant pharmacists could be held liable in negligence.<sup>79</sup> Although the two courts took different paths to reach the same result, both can be seen as expanding the scope of pharmacists’ liability.

### III. *KOHL V. AMERICAN HOME PRODUCTS, INC.*

#### A. *Facts*

Patricia Ann Kohl began taking fenfluramine as prescribed by her physician in May of 1996. Although the record is unclear as to how long she took the drug, Kohl filed suit against the manufacturers of fenfluramine<sup>80</sup> as well as Sims Drug and Clinic Pharmacy on October

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73. *See id.* at 1134.

74. *See id.* (concluding that, in considering “whether a failure to warn violates the applicable standard of conduct,” summary judgment is generally inappropriate).

75. *Id.* at 1134.

76. *See id.*

77. *See id.*

78. *See id.*

79. *See Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 893 (W.D. Ark. 1999).

80. Kohl filed suit against manufacturers American Home Products Corp., Wyeth-

8, 1999. Kohl “allege[d] she contracted valvular heart disease . . . as a result of taking [the] diet drugs.”<sup>81</sup>

The manufacturers sought to have the case transferred to the consolidated pretrial proceedings for the multi-district class action against American Home Products.<sup>82</sup> In response, the plaintiff moved to remand to state court on the grounds that the pharmacies, both Arkansas citizens, destroyed diversity of citizenship.<sup>83</sup> The defendants maintained that the pharmacies were fraudulently joined and asked the district court to stay the proceedings pending transfer to the class action.<sup>84</sup>

In order to rule on whether the defendant pharmacies were fraudulently joined, the court had to examine the merits of Kohl’s claims, specifically whether strict liability and negligence were valid causes of action against the pharmacies.<sup>85</sup> After examining the reasoning behind both the traditional and modern views of pharmacist liability, the court ruled that the strict liability claim against the defendant pharmacists was not cognizable, but that the negligence claim was valid.<sup>86</sup> The court’s reasoning for these conclusions is set out below.

### *B. The Court’s Reasoning*

#### *1. Strict liability*

In finding that the defendant pharmacists could not be held strictly liable for failure to warn the plaintiff of the potential hazards of fenfluramine, the court addressed two theories: (1) both public policy and the learned intermediary rule prohibit application of strict liability to pharmacists, and (2) plaintiff’s strict product liability claims fail because pharmacists provide a service, not a product.<sup>87</sup> The court dealt with each of these arguments in turn.

##### *a. The learned intermediary rule and the policy of strict liability.*

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Ayerst Laboratories, and A.H. Robbins. *See id.* at 885.

81. *Id.* at 887.

82. *See id.*; *see also In re Diet Drugs*, No. 99-20593, 2000 U.S. Dist LEXIS 12275 (E.D. Pa. Aug. 28, 2000).

83. *See Kohl*, 78 F. Supp. 2d at 887.

84. *See id.*

85. *See id.* at 888.

86. *See id.* at 893–94.

87. *Id.*

Siding with the majority of jurisdictions that have considered the question,<sup>88</sup> the court applied the learned intermediary rule to find that the duty to warn patients of the dangers of prescription drugs properly lies with the physician, not the pharmacist.<sup>89</sup> In so finding, the court relied on the reasoning set forth by the Pennsylvania Supreme Court in *Coyle v. Richardson-Merrell, Inc.*<sup>90</sup>

In *Coyle*, the court first noted the special policy protections afforded prescription drugs in comment k of § 402A of the Restatement (Second) of Torts.<sup>91</sup> The court then isolated four pertinent factors in comment c of the Restatement “which support the rule of strict product liability”:

(1) supplier liability makes a member of the marketing chain available to the injured plaintiff for redress; (2) strict liability provides an incentive to safety; (3) a supplier is in a better position to prevent the circulation of the defective products; and (4) the supplier can distribute the cost of compensating for injuries resulting from defects by charging for it in his business.<sup>92</sup>

When it applied these factors to pharmacists, the *Coyle* court found the policy reasons supporting application of strict liability to pharmacists to be lacking.<sup>93</sup> First of all, the court pointed out that “it is not the pharmacist on whom the public ‘is forced to rely’ to obtain the products they need.”<sup>94</sup> Rather, the court said, it is the “[p]hysicians [who] act as exclusive intermediaries.”<sup>95</sup>

Furthermore, the *Coyle* court found that “holding pharmacists to strict liability [would not] serve as an incentive to safety, for the pharmacist presented with a prescription ordered by a duly licensed physician is not at liberty to substitute his judgment of the product’s

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88. *See supra* Part II.A.

89. *See Kohl*, 78 F. Supp. 2d at 894.

90. *See id.* at 894–95; *see also* *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1387 (Pa. 1991) (holding that pharmacist had no strict liability duty to warn of the dangerous effects of Bendectin).

91. *See Kohl*, 78 F. Supp. 2d at 894; *supra* Part II.A. *See also Coyle*, 584 A.2d at 1385. The *Coyle* court first reprimanded the plaintiffs for basing their argument on § 402A, explaining that the language of the Restatement is “not to be considered controlling.” *Id.* at 1384. Ironically, however, the court then reconciled its reliance on comment k of the same section by pointing out that comment k had been incorporated by Pennsylvania case law. *See id.*

92. *Kohl*, 78 F. Supp. 2d at 895 (quoting *Coyle*, 584 A.2d at 1387).

93. *See Coyle*, 584 A.2d at 1387.

94. *Id.*

95. *Id.*

safety for the patient for that of the physician.”<sup>96</sup> The court sought to balance the minimal effect such a duty could have on preventing the circulation of defective products with patients’ need to acquire drugs that are “necessary and appropriate for . . . their treatment,” concluding that the needs of the public would be “ill-serve[d]” by imposing a duty that would encourage pharmacists to refuse to fill a physician-authorized prescription in an effort to avoid liability.<sup>97</sup>

In adopting the reasoning of the *Coyle* court, the *Kohl* court was unconvinced by the plaintiff’s argument that pharmacists are better able to distribute the cost of liability through insurance or indemnification.<sup>98</sup> Instead, the court found that “[r]eliance on cost-shifting . . . would result in absolute liability rather than strict liability.”<sup>99</sup> Based on the learned intermediary doctrine and the underlying policies of strict liability, the *Kohl* court “decline[d] to extend the rule of strict supplier liability to pharmacists.”<sup>100</sup>

*b. Service vs. product.* While the *Kohl* court based its strict liability holding on the above rationale, the defendants advanced an additional and entirely different argument; namely, that strict liability is inapplicable to pharmacists because they provide a service rather than a product.<sup>101</sup> In support of this argument, the pharmacists invoked an Arkansas statute providing that in order to prevail on a strict liability claim, the plaintiff must prove: “(1) the defendant pharmacies are engaged in the business of selling a product; (2) the product was supplied in a defective condition which rendered it unreasonably dangerous; and (3) the defective condition was a proximate cause of the harm.”<sup>102</sup> The pharmacists therefore maintained that because they were not “engaged in the business of selling a product,” but rather providing a service, the first prong of the three-part test was not satisfied and the plaintiff’s claim must fail.<sup>103</sup>

Despite the pharmacists’ attempt to distinguish services from

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96. *Id.*

97. *Id.*

98. *See Kohl*, 78 F. Supp. 2d at 895.

99. *Id.* (quoting *Coyle*, 584 A.2d at 1387).

100. *Id.* (quoting *Coyle*, 584 A.2d at 1387).

101. *See id.* at 894.

102. *Id.* (citing ARK. CODE ANN. § 4-86-102(a) (1996)). Utah law has similar requirements for strict products liability. *See, e.g.*, *Burns v. Cannondale Bicycle Co.*, 876 P.2d 415, 417 (Utah Ct. App. 1994).

103. *Kohl*, 78 F. Supp. 2d at 894.

products, the *Kohl* court remained unconvinced. While the court acknowledged that pharmacists do indeed provide a service, it also found that it is indisputable that pharmacists' "main function" is to provide a product.<sup>104</sup> Furthermore, the court was influenced by the fact that "the [pharmacists'] service is not separately billed from the product."<sup>105</sup> The court concluded that the defendants' argument was "rather shaky in the pharmacy context," but that nevertheless the learned intermediary rule precluded application of strict liability to the pharmacists.<sup>106</sup>

### C. Negligence

While the *Kohl* court precluded application of strict liability to pharmacists, it nevertheless found that a negligence claim against the defendant pharmacies was cognizable based on the pharmacist's failure to "supply Kohl and/or her doctor" with the manufacturer's labeling information and because "the pharmacies knew, or should have known, that the labeling information that was supplied was inaccurate."<sup>107</sup>

The court began by noting the current tension between the traditional and modern views of pharmacist liability.<sup>108</sup> Recognizing that the question before it was one of first impression in Arkansas, the court set out both sides of the argument in detail.<sup>109</sup> In the end, the court purported to side with the traditionalists in ruling that "pharmacies generally have no common-law or statutory duty to warn customers of the risks associated with the prescription drugs they purchase."<sup>110</sup> The court was persuaded to adopt the traditional view by the policies supporting the learned intermediary rule.<sup>111</sup> For example, the court pointed out that it would be "incongruous" to hold a pharmacist to a duty to warn individual consumers when such a duty is not even imposed on the manufacturer.<sup>112</sup> Rather, such warnings are provided "to the person who most needs and can best

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104. *Id.* at 895.

105. *Id.*

106. *Id.* at 895–96.

107. *Id.* at 893.

108. *See id.* at 890.

109. *See id.* at 889–93.

110. *Id.* at 893.

111. *See id.* at 892.

112. *See id.* at 893.

evaluate it—the physician—to be shared with and explained to the patient in the context of his or her individual medical circumstances.”<sup>113</sup>

Despite the above language, the court maintained that the defendant pharmacies could nevertheless be held liable in negligence under Arkansas law.<sup>114</sup> While the court declined to impose a “generalized” duty to warn, it noted that pharmacists “must be held to a duty to fill prescriptions as prescribed and properly label the prescriptions.”<sup>115</sup> Even though the court agreed that it would be “incongruous” to hold pharmacists to higher duty than manufacturers, the court still found that the defendant pharmacies could have breached their duty by failing to supply warnings in labeling information directly to the patient or her physician.<sup>116</sup> Moreover, the court found that the defendant pharmacies could have breached that duty by failing to question the adequacy of the warnings<sup>117</sup> supplied by the manufacturer.<sup>118</sup>

In short, the outcome in *Kohl* was surprising given the court’s endorsement of the traditional view of pharmacist liability.

#### IV. ANALYSIS

##### A. *Strict Liability and Unavoidably Unsafe Drugs*

###### 1. *The Kohl court correctly ruled that pharmacists should not be held strictly liable for failure to warn*

The *Kohl* court’s unwillingness to extend strict liability for failure to warn to pharmacists is unsurprising, for with the exception of patent prescription errors, virtually every court that has passed on the question has also refused to impose such liability.<sup>119</sup> While such decisions suggest that the imposition of strict liability is not an immediate threat to the pharmacist profession, it is worthwhile to

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113. *Id.* (quoting *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1386 (Pa. 1991)).

114. *See id.*

115. *Id.* Such language mirrors the language used to describe the traditional view of clerical accuracy only. *See, e.g., Coyle*, 584 A.2d at 1386.

116. *Kohl*, 78 F. Supp. 2d at 893.

117. “Warning” and “labeling” are used interchangeably here. *See supra* note 16.

118. *See Kohl*, 78 F. Supp. 2d at 893.

119. *See, e.g., Griffith v. Blatt*, 973 P.2d 385, 389–90 (Or. Ct. App. 1999).

emphasize the policies supporting these decisions, because the same policies support the traditional view of pharmacists' liability in negligence.<sup>120</sup> Specifically, the overwhelming authority agrees that holding pharmacists to a strict liability duty to warn would (1) undermine the patient-physician relationship, (2) jeopardize the standard of patient care, and (3) ill serve the policies of strict liability—to encourage safer products.<sup>121</sup>

*2. Strict liability should not be applied to hold pharmacists liable in other fenfluramine cases*

Relatively few jurisdictions have addressed the issue of whether pharmacists should be held strictly liable for failure to warn of the dangerous defects of prescription drugs,<sup>122</sup> and the *Kohl* case is the only case in the country to address these issues specifically in light of fenfluramine. Therefore, it is helpful to examine the likely scenario should one of the pending fenfluramine cases come before a court.

In Utah, for example, any strict products liability claim must meet a three-prong test. The plaintiff must show: “(1) that the product was unreasonably dangerous due to a defect or defective condition, (2) that the defect existed at the time the product was sold, and (3) that the defective condition was a cause of the plaintiff's injuries.”<sup>123</sup>

In 1991, the Utah Supreme Court raised the bar for strict liability actions pertaining to prescription drugs by holding that “all FDA-approved prescription medications . . . [are] ‘unavoidably unsafe.’”<sup>124</sup> This meant that “a drug approved by the United States Food and Drug Administration . . . , properly prepared, compounded, packaged, and distributed, cannot as a matter of law be ‘defective’ in the absence of proof of inaccurate, incomplete,

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120. For example, that pharmacists should only be held liable in negligence under exceptional circumstances.

121. *See, e.g., Griffith*, 973 P.2d at 389–90.

122. Even fewer of these decisions have come from western states. To date, the only western states to consider the strict liability issue are California, Oregon, Washington, and Arizona. *See* *Murphy v. E.R. Squibb & Sons*, 710 P.2d 247 (Cal. 1985); *Griffith v. Blatt*, 973 P.2d 385 (Or. Ct. App. 1999); *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045 (Wash. 1989); *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129 (Ariz. Ct. App. 1994).

123. *See* *Lamb v. B & B Amusements Corp.*, 869 P.2d 926, 929 (Utah 1993). *See also* UTAH CODE ANN. § 78-15-6 (1999).

124. *Grundberg v. Upjohn*, 813 P.2d 89, 90 (Utah 1991).

misleading, or fraudulent information.”<sup>125</sup> The 1991 holding was a logical extension of the statutory language of the Utah Product Liability Act, which provides that plaintiffs must overcome a rebuttable presumption that the product is free from defects if manufactured according to industry standards.<sup>126</sup>

When the above standards are applied to fenfluramine, it is apparent that plaintiffs are fighting an uphill battle because fenfluramine was FDA-approved until its official withdrawal on September 15, 1997. Consequently, most plaintiffs point out that while fenfluramine was FDA-approved, the combination of fenfluramine with phentermine was not.<sup>127</sup> This logic fails, however, in light of the fact that, in the official news release of the withdrawal of fenfluramine, the FDA specifically pointed out that phentermine was *not* being withdrawn.<sup>128</sup> It is therefore apparent that, according to the FDA, it was not the “Fen-Phen” combination that was dangerous, but the use of fenfluramine alone.<sup>129</sup>

The protection afforded prescription drugs by comment k<sup>130</sup> and legislative provisions like the Utah Product Liability Act lead most plaintiffs to make the alternative argument that fenfluramine was rendered unreasonably dangerous because of “inaccurate, incomplete, misleading or fraudulent information.”<sup>131</sup> These allegations seem particularly inapplicable to fenfluramine, because it is undisputed that even the FDA was unconvinced of the dangerous propensities of the drug until its official withdrawal in September 1997. To hold pharmacists responsible for knowing something that even the FDA did not know or acknowledge is highly suspect under a negligence standard, and to hold pharmacists strictly liable for

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125. *Id.*

126. UTAH CODE ANN. § 78-15-6(3) (1999).

127. *See, e.g., Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 892 (W.D. Ark. 1999).

128. *See* U.S. Dep’t of Health & Human Servs., *supra* note 1.

129. In its research supporting the withdrawal of fenfluramine, the FDA found the existence of cardiac irregularities was no greater in patients taking the Fen-Phen combination as in patients taking fenfluramine alone. *See* Centers for Disease Control and Prevention, *supra* note 1. Moreover, while the FDA admonished those taking fenfluramine—either alone or in the Fen-Phen combination—to “undergo a medical history and cardiovascular examination by their physician,” it declined to comment on the use of phentermine alone, other than acknowledging that phentermine had been FDA-approved since 1959 for the treatment of obesity. *Id.*

130. For the text of comment k, see *supra* note 28.

131. *Grundberg*, 813 P.2d at 90; *see also Kohl*, 78 F. Supp. 2d at 890, 893.

failing to provide such information directly to consumers borders on the absurd.

Notwithstanding the absurdity of requiring pharmacists' knowledge to exceed that of the FDA, holding pharmacists to strict liability would also significantly undermine the physician-patient relationship. In the typical fenfluramine scenario, a patient would seek the medical advice of her physician for help losing weight. After a consultation, the physician would prescribe the weight-loss drug to be filled at the patient's pharmacy. After this point, it would be counterproductive for a pharmacist to second-guess the physician's orders or substitute her judgment for that of the physician. The learned intermediary rule was implemented to prevent such a situation. Under that well-accepted 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."<sup>132</sup> Requiring pharmacists to evaluate independently individual medical circumstances, such as a patient's weight or eating and exercise habits, would wreak havoc on the assignment of responsibilities in the health care system.

Aside from the practical ramifications outlined above, requiring pharmacists to exercise independent judgment would ill serve the policy of strict liability—to encourage safer products. While holding manufacturers strictly liable for failure to warn of the dangerous propensities of their drugs that they knew or should have known may prevent the circulation of defective products, such a standard would be ineffective if applied to pharmacists. Pharmacists do not have the means to conduct independent tests and research on drugs to determine their dangerous effects. Instead, pharmacists might be left with only one option to protect themselves: to refuse to fill prescriptions "notwithstanding decisions by licensed physicians that a particular drug was necessary and appropriate for their patients' medical treatment."<sup>133</sup>

In *Kohl*, the plaintiff urged the court to adopt the strict liability standard in Arkansas because pharmacists are better able to distribute the cost of liability through insurance or indemnification.<sup>134</sup> While such an argument may be applicable to a large pharmaceutical chain,

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132. *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1386 (Pa. 1991).

133. *Id.* at 1387.

134. *See Kohl*, 78 F. Supp. 2d at 894.

it lacks teeth when applied to the small neighborhood pharmacy. Many of these pharmacies are family-owned and operated and lack the resources to distribute the cost of the landslide of litigation resulting from fenfluramine.

*3. It is unhelpful to distinguish between “services” and “products” in the strict liability context*

While the pharmacists in *Kohl* were unsuccessful in convincing the court that strict liability was inapplicable to them because they provided a service and not a product, other defendant pharmacists have had better luck with the theory. For example, in *Murphy v. E.R. Squibb & Sons*,<sup>135</sup> the California Supreme Court declined to apply strict liability to pharmacists in part because it found that pharmacists are “engaged in a hybrid enterprise.”<sup>136</sup> The court pointed out that “those who sell their services for the guidance of others . . . are not liable in the absence of negligence or intentional misconduct,”<sup>137</sup> but also acknowledged that “it cannot be disputed that a sale in fact occurs.”<sup>138</sup>

However, the *Murphy* court also discussed the policy reasons that prohibit application of strict liability to pharmacists. In addition to those discussed above, the court was persuaded by a policy consideration discussed in the amicus curiae brief filed by the California State Board of Pharmacy: “in order to assure that a pharmacy receives the maximum protection in the event of suit for defects in a drug, the pharmacist may select the more expensive product made by an established manufacturer” rather than a generic brand.<sup>139</sup>

Because the *Murphy* court intermingled its policy discussion with its distinction between products and services, it is difficult to determine whether the “hybrid enterprise” argument standing on its own would have been enough to save the defendant pharmacist from strict liability. In any case, it is difficult to see the utility of such an argument, because regardless of the pharmacists’ other duties, it is undisputed that pharmacists are indeed in the business of selling

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135. 710 P.2d 247 (Cal. 1985).

136. *Id.* at 251.

137. *Id.* at 250 (quoting *Gagne v. Bertran*, 275 P.2d 15 (Cal. 1954)).

138. *Id.* at 251.

139. *Id.* at 253.

products as required by state products liability statutory law.<sup>140</sup> In the end, the product vs. service argument is unnecessary because the policies supporting the learned intermediary rule, combined with the policies of the strict liability doctrine, are sufficient to preclude application of strict liability to pharmacists.

B. *Negligence*

1. *The Kohl court adopted the traditional view in theory but the modern view in practice*

While the *Kohl* court adopted the traditional view in theory, the court's result reflected the modern view. Without doubt, the court granted itself some leeway because it was merely required to decide whether joinder of the two pharmacies was fraudulent.<sup>141</sup> However, because *Kohl* is the only case in the country so far to address the issue of a pharmacist's duty to warn of the dangerous effects of fenfluramine, the court's reasoning could have ramifications that extend beyond the actual result.

a. *The duty to warn vs. the duty to label.* While the *Kohl* court stated that it rejected a "general duty to warn customers of potential drug side effects or to give advice on the efficacy of the drug absent the presence of some contraindication," it nevertheless agreed with the plaintiff that a pharmacist could be held to a duty to supply the manufacturer's labeling information to the patient or her doctor and to second-guess the manufacturer's labeling information that it "knew, or should have known" was inaccurate.<sup>142</sup> Although such language reveals the court's attempt to distinguish between the duty to warn and the duty to label, such a distinction is illogical in light of the facts of *Kohl*.

The facts clearly demonstrate that Kohl contracted valvular heart disease as a result of taking fenfluramine.<sup>143</sup> Thus, Kohl sued the pharmacy under the belief that her injury could have been prevented had the pharmacy provided her with information about the risks of fenfluramine.<sup>144</sup> Regardless of whether the court requires pharmacists

140. *See, e.g.*, ARK. CODE ANN. § 4-86-102(a) (1996).

141. *See Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 892 (W.D. Ark. 1999).

142. *Id.* at 892-93.

143. *Id.* at 887.

144. *See id.*

to provide such information in warnings or labels, the court is still asking the pharmacist to provide the patient or her doctor with information the pharmacist did not know and had no reason to know.<sup>145</sup>

While a valid distinction could be drawn between the duty to warn and the duty to label in a theoretical sense,<sup>146</sup> the circumstances of Fen-Phen litigation suggest that, as long as the plaintiff alleges heart-related injuries, the duty to warn and the duty to label will remain synonymous because pharmacists had no reason to know of such dangers until the FDA's withdrawal of the drug.

Thus, semantic distinctions fail to change the heart of the matter: despite the court's pointed rejection of the modern view of pharmacist liability, the suggestion that pharmacists are responsible for the accuracy of manufacturers' labeling information cannot be reconciled with the traditional view the court purported to employ.

*b. The learned intermediary rule and a pharmacist's duty.* Perhaps the court's most egregious inconsistency was its unqualified endorsement of the learned intermediary rule while at the same time validating the plaintiff's allegations that (1) pharmacies have a duty to supply individual consumers or their physicians with the manufacturers' labeling information, and (2) that pharmacies have a duty to *second-guess* manufacturers' labels that they "knew, or should have known" were inaccurate.<sup>147</sup> Such suggestions corrode the very core of the learned intermediary doctrine. The court's first suggestion—that pharmacists may have a duty to supply individual consumers with the manufacturer's warnings—can be attacked on many levels, not the least of which is practicality. In *Leesley v. West*, the Illinois Court of Appeals pointed out that many drugs are shipped to pharmacies in bulk from the drug manufacturer and contain only a single package insert with labeling and/or warning information.<sup>148</sup> The court concluded that it would be "unreasonable" to require a pharmacist to provide "every customer whose prescription was filled from that bulk container with a copy of the information contained in that single package insert."<sup>149</sup>

145. See U.S. Dep't of Health & Human Servs., *supra* note 1.

146. For example, if Kohl sued the pharmacy because it failed to indicate dosage instructions, the court could impose a duty to label without necessarily invoking a duty to warn.

147. *Kohl*, 78 F. Supp. 2d at 893.

148. 518 N.E.2d 758, 761–62 (Ill. App. Ct. 1988).

149. *Id.* at 762.

Even putting aside the practical arguments, requiring pharmacists to pass on warning information to individual consumers is in excess of what is required of manufacturers, who by law are required only to warn physicians of the dangerous propensities of their drugs.<sup>150</sup> The *Leesley* court called such a scheme “illogical,” “inequitable,” and unduly burdensome.<sup>151</sup> However, the burden on pharmacists is not as disturbing as the disastrous effect such a scheme could have on patient care—the very thing the learned intermediary rule was designed to protect. The *Leesley* court pointed out that the reason manufacturers are relieved of the duty to inform individual consumers about the hazards of their products is *not* to protect the manufacturers, but to protect the patients.<sup>152</sup> Similarly, pharmacists should not be required to warn individual consumers—not *only* because such a duty is unduly burdensome, but also because it is the physician, not the pharmacist or the manufacturer, who can best evaluate and explain the dangers of prescription drugs “to the patient in the context of his or her individual medical circumstances.”<sup>153</sup> Moreover, the Washington Supreme Court reasoned that it would be counterproductive for pharmacists to replicate the manufacturers’ package inserts for patients because such inserts are “written for the physician, are detailed and technical, and may confuse and frighten the patient.”<sup>154</sup> It is thus perplexing that, while the *Kohl* court clearly indicated that it felt bound to preserve the physician-patient relationship,<sup>155</sup> it fashioned a duty that would erode the very relationship it sought to protect.

Along with suggesting pharmacists have a duty to pass along manufacturers’ warnings to individual consumers, the court also suggested that the defendant pharmacists have a duty to second-guess manufacturers’ warnings that they “knew, or should have

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150. *See id.*

151. *Id.* It should be noted that in this section of the opinion the court was referring to strict liability. However, in the next paragraph the court added, “Our conclusion with respect to the negligence claim must ultimately be the same.” *Id.*

152. *See id.* at 761.

153. *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 893 (W.D. Ark. 1999) (quoting *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1386 (Pa. 1991)).

154. *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1055 (Wash. 1989). The court also stated that “a requirement that consumers receive the manufacturer’s insert effectively abrogates the learned intermediary doctrine and could impact not only pharmacists’ liability, but that of manufacturers and physicians as well.” *Id.*

155. *See Kohl*, 78 F. Supp. 2d at 893.

known” were inaccurate.<sup>156</sup> In the context of fenfluramine, it is easy to see the injustice of such a position from a pharmacist’s perspective: the court is suggesting that the pharmacists should have known something that not only the FDA did not yet know, but that the manufacturers did not know either.<sup>157</sup>

Furthermore, although the facts in *Kohl* are unclear as to what information the pharmacy’s labels actually contained, it is evident from the plaintiff’s complaint that she thought the pharmacy’s label should have warned her of fenfluramine’s propensity for causing heart disease.<sup>158</sup> Of course, whether or not fenfluramine actually causes heart disease is immaterial. The pertinent question is how much, if anything, pharmacists are required to know about the dangerous side effects of prescription drugs. Requiring them to know anything outside of patent prescription errors creates a slippery slope to limitless liability on the pharmacists’ side and substandard patient care on the consumers’ side.

Unfortunately, the question of what a pharmacist’s duty exactly entails is left open by the *Kohl* opinion. After the court stated that “a generalized duty to warn is inappropriate given the role of the physician in determining the appropriate drug to be prescribed,” it went on to characterize the pharmacists’ duty as “a duty to fill prescriptions as prescribed and properly label the prescriptions.”<sup>159</sup> Not even the staunchest advocates of the traditional rule could find fault with such a characterization of a pharmacist’s duty. However, if the court believes its own language, it is difficult to see how the above duty translates into passing on the manufacturer’s labeling information to doctors or individual consumers and second-guessing the manufacturer’s warnings.<sup>160</sup>

*c. Exceptions to the clerical accuracy rule.* One possible explanation for this anomaly is that while the court perhaps aligned itself with the traditional view in characterizing a pharmacist’s duty as clerical accuracy only, the court also suggested the pharmacies in *Kohl* breached that duty. However, this explanation fails under closer

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156. *Id.*

157. Whether or not the manufacturers were actually unaware of fenfluramine’s potential to cause heart disease is highly suspect. *See In re Diet Drugs*, No. 99-20593, 2000 U.S. Dist. LEXIS 12275 (E.D. Pa. Aug. 28, 2000). However, the manufacturers’ actual knowledge of this point is immaterial to the discussion at hand.

158. *Kohl*, 78 F. Supp. 2d at 892.

159. *Id.* at 893.

160. *See id.*

scrutiny. The authority is clear that the duty of clerical accuracy is limited to correctly filling the prescription as written by the physician and to be alert for patent prescription errors<sup>161</sup> such as overdoses or contraindications. Thus, not only does the *Kohl* court base its holding upon the speculation that the pharmacies could have breached their duty of clerical accuracy, it also seems to suggest that the clerical accuracy duty itself should be expanded.

Another possible explanation is that the court thought the pharmacy's actions fit into one of the established exceptions to the learned intermediary rule. The court peppered its opinion with exceptions to the general rule that pharmacies have no duty to warn, including "where there is evidence the pharmacy compounded . . . or changed the drug in some manner after receiving it from the manufacturer,"<sup>162</sup> or in the presence of some "contraindication."<sup>163</sup> However, neither of the above permutations seem to fit within the exception the court suggested: that pharmacists may have a duty to supply consumers with the manufacturer's label or second-guess the content of such labels.<sup>164</sup> Indeed, while there is ample authority to support the view that the clerical accuracy rule has exceptions, none of this authority extends the exceptions as far as the *Kohl* court suggested.

For example, in *McKee*, the Washington Supreme Court limited the patent prescriptions errors exception to "obvious lethal dosages, inadequacies in the instructions, *known* contraindications, or incompatible prescriptions."<sup>165</sup> In that case, the defendant pharmacy dispensed weight-loss medications to the plaintiff as prescribed by her physician.<sup>166</sup> After taking the medication for over ten years, the plaintiff subsequently became addicted to the drug and sued the pharmacy in negligence and strict liability.<sup>167</sup> The court found that despite the plaintiff's allegations, the pharmacy had fulfilled its duty

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161. *See, e.g.*, *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1052–53 (Wash. 1989).

162. *Kohl*, 78 F. Supp. 2d at 893.

163. *Id.* at 892.

164. *See id.* at 893.

165. *McKee*, 782 P.2d at 1053. It is worth noting that "inadequate instructions" should not be confused with Kohl's claim of "inaccurate labeling." The former merely suggests the patient was not informed of the correct dosage, while the latter suggests the pharmacists should have warned the patient about side effects of the drug.

166. *See id.* at 1046–47.

167. *See id.* at 1047.

“to be alert for clear errors or mistakes in the prescription,” holding that such a duty did not extend to “warn[ing] customers of the hazardous side effects associated with a drug, either orally or by way of the manufacturer’s package insert.”<sup>168</sup>

Likewise, in *Adkins v. Mong*, the Michigan Court of Appeals declined to find a patent prescription error when a pharmacy dispensed over 116 narcotic prescriptions over a period of six years to a patient who subsequently became addicted and sued the pharmacy in negligence.<sup>169</sup> The court held that the pharmacy’s duties did not extend to warning the patient of the addictive propensities of the narcotic.<sup>170</sup>

Thus, it seems clear that the *Adkins* and *McKee* courts would disagree with the possible suggestion of the *Kohl* court—that the duty to pass along manufacturers’ labeling information to consumers and the duty to exercise independent judgment regarding such labels should be incorporated as exceptions to the clerical accuracy rule.

*d. State statutory provisions.* Another possible way to reconcile the *Kohl* court’s dicta with its holding is that it relied on the Arkansas state statutory provisions to define the pharmacist’s duty. However, the extent to which the court relied upon such provisions is unclear. Initially, the court quoted the following provisions from the Arkansas Code:

The “practice of pharmacy” means the learned profession of:

[i]nterpreting prescriptions for drugs, medicines, poisons, or chemicals issued by practitioners authorized by law to prescribe drugs, medicines, poisons, or chemicals which may be sold or dispensed only on prescription . . .

[a]dvising and providing information concerning utilization of drugs and devices and participation in drug utilization reviews . . .

[p]roviding pharmacy care . . . .<sup>171</sup>

Then, without further elaboration on the above provisions, the court stated, “[g]iven the statutory provisions discussed<sup>172</sup> above, we

168. *Id.* at 1055–56.

169. 425 N.W.2d, 151, 152 (Mich. Ct. App. 1988).

170. *See id.*

171. *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 891 (W.D. Ark. 1999) (quoting ARK. CODE ANN. § 17-92-101(14)(A)(v), (viii), (x) (Supp. 1999)).

172. Despite the use of this word, the court in fact did not “discuss” the provisions of the

disagree with the defendant manufacturers' assessment of Arkansas law and believe a cause of action against the pharmacies is cognizable."<sup>173</sup> The court further held that "[w]hen faced with the issue [of whether the pharmacies were fraudulently joined], we believe Arkansas courts would hold that a pharmacy has a legal duty to exercise due care and diligence in the performance of its professional duties."<sup>174</sup> Therefore, the *Kohl* court suggested that the above Arkansas statutory provisions could impose a duty on pharmacies to pass a manufacturer's warnings on to individual consumers or provide such warnings to a patient's physician, as well as a duty to second-guess the accuracy of a manufacturer's warnings.<sup>175</sup>

Despite the *Kohl* court's willingness to interpret the Arkansas code as imposing a legal duty on pharmacists, some courts have taken the opposite view. In *McKee v. American Home Products*, the Washington Supreme Court declined to impose a duty to warn on pharmacists based on the state's "practice of pharmacy" statute.<sup>176</sup> Despite the plaintiff's contention that under the state statutory provisions the pharmacy had a duty to warn her of the addictive propensities of the weight-loss drug Plegine, the court determined that the statute "is definitional and does not purport to set forth duties."<sup>177</sup> The court then offered a conservative interpretation of several of the statutory provisions. First, although the state statute requires pharmacists "to orally explain the directions for use and give any additional information necessary to assure proper use of the drug," the court interpreted this requirement to include "nonjudgmental information, not affecting a decision to take or continue using a drug, such as: whether to take the drugs on an empty or full stomach, substances to avoid while using the drug, or not to drive or use heavy machinery while taking the drug."<sup>178</sup>

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Arkansas Code at all. Instead, the court merely quoted the statutory provisions, then listed the various allegations in the plaintiff's complaint before concluding that the Arkansas Code provided for consideration of plaintiff's allegations. *Id.* at 891-92.

173. *Id.* at 892.

174. *Id.*

175. *See id.* at 892-93.

176. 782 P.2d 1045, 1051-52 (Wash. 1989). The Washington Act in *McKee* mirrored the provisions of the Arkansas Act in *Kohl*. For the relevant provisions of the Washington Act, see *supra* note 68.

177. *McKee*, 782 P.2d at 1052.

178. *Id.* at 1052 n.7.

Secondly, although the state pharmacy act requires pharmacists to maintain a record on each patient, the court recognized that “a pharmacist typically does not have the patient’s complete medical history and there may be occasions where the pharmacist is unaware a drug is contraindicated.”<sup>179</sup>

If one takes the view that the *Kobl* court was attempting to enforce the traditional view of pharmacist liability, both of the *McKee* court’s observations should have been applied in *Kobl*. Although the *Kobl* court neglected to specify which Arkansas provisions in particular it relied on in its holding, the logical conclusion is that it thought “[a]dvising and providing information concerning utilization of drugs and devices”<sup>180</sup> imposed a duty to supply the consumer with the manufacturer’s warnings or inform the consumer of inadequate information. Under the *McKee* analysis, such a duty would require a pharmacist to exercise his independent judgment and would therefore be inappropriate.

Moreover, although the *Kobl* court stated that a “general duty to warn” is inappropriate “absent the presence of some contraindication,”<sup>181</sup> it neglected to temper such a statement with the *McKee* court’s recognition that pharmacists have limited access to patient information and cannot be responsible for every contraindication.<sup>182</sup>

In light of these observations, it should be noted that the *Kobl* court did not admit that it was aligning itself with either the traditional or the modern view. The fairest reading of the *Kobl* opinion suggests that the court was attempting to make up its own rule; while it agreed with the traditional view in theory, it was uncomfortable with the unqualified suggestion that pharmacists have no duty to warn. Therefore, the court tried to temper that rule with its own exceptions.<sup>183</sup> However, the court’s exceptions cut too far into the substance of the traditional view, thereby enlarging the potential scope of pharmacist liability and threatening patient care. The section below outlines exceptions to the general rule that pharmacists have no duty to warn, which exceptions can be

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179. *Id.* at 1053 n.9.

180. *Kobl*, 78 F. Supp. 2d at 891 (quoting ARK. CODE ANN. § 17-92-101(14)(A)(v), (viii), (x) (Supp. 1999)).

181. *Id.* at 892.

182. *See McKee*, 782 P.2d at 1052–53.

183. *Kobl*, 78 F. Supp. 2d at 890.

employed *without* threatening patient care.

2. *Negligence should be applied to pharmacists only in certain circumstances*

The principal argument of this Note is that pharmacist liability should be limited in order to protect not only pharmacists, but also patients and the health care system as a whole. However, even the most conservative traditionalists agree that the general rule prohibiting a duty to warn necessarily includes some exceptions.

a. *Limited duty rule.* The “limited duty” rule could also be characterized as clerical accuracy tempered with exceptions. Surprisingly,<sup>184</sup> even the *Kohl* court accurately summarized the generally recognized exceptions inherent in the limited duty rule. Under this rule, liability could attach if

the pharmacist altered the product, . . . dispensed the wrong drug, . . . knowingly dispensed a drug that was inferior or defective, or had additional information about the plaintiff’s condition from which a trier of fact could conclude a duty to warn existed and/or a duty to inquire of the prescribing physician whether such drugs were appropriate.<sup>185</sup>

Several cases have applied the limited duty rule while remaining within the scope of the traditional view. However, the few cases that have recognized such a duty are easily distinguished from the case at hand. In *Hand v. Krakowski*, the Supreme Court of New York held that the trial court had improperly granted summary judgment in the defendant pharmacy’s favor.<sup>186</sup> In that case, the pharmacy dispensed 728 units of psychotropic drugs to the plaintiff’s decedent, who was an alcoholic.<sup>187</sup> Because the pharmacy’s own records identified the decedent as an alcoholic, and because the psychotropic drugs were “commonly recognized to be contraindicated with alcoholism,” the court held the pharmacy “*may* have had a duty to warn decedent of the grave danger involved,” which precluded summary judgment.<sup>188</sup>

Similarly, in *Riff v. Morgan Pharmacy*, the court affirmed

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184. This is surprising because even though the court recognized these general exceptions, it proceeded to add exceptions of its own to the general rule that a pharmacist has no duty to warn.

185. *Kohl*, 78 F. Supp. 2d at 890.

186. 453 N.Y.S.2d 121, 123 (N.Y. App. Div. 1982).

187. *See id.*

188. *Id.* (emphasis added).

judgment against the defendant pharmacy.<sup>189</sup> In that case, plaintiff's physician prescribed rectal suppositories for the plaintiff's migraine headaches.<sup>190</sup> The pharmacy dispensed the medication to the plaintiff despite the fact that the physician's prescription contained a clear overdose and "patent inadequacies in the instructions."<sup>191</sup> The pharmacy also refilled the prescription twice, even though the physician had not authorized any refills.<sup>192</sup> Both *Hand* and *Riff* are readily distinguished from *Kohl* because they both involve the type of patent prescription errors described in the "limited duty" rule.<sup>193</sup>

It is important to note that courts have conservatively construed the exceptions in the limited duty rule. For example, the majority of jurisdictions have held that even if the pharmacists had actual or constructive knowledge of a drug's dangerous side effects, the pharmacists still had no duty to warn. For example, in *Raynor v. Richardson-Merrell, Inc.*, the court noted that "even assuming for the purpose of this [summary judgment] motion that [the pharmacy] knew Bendectin was teratogenic,<sup>194</sup> it had no duty to warn [the plaintiff]."<sup>195</sup>

Likewise in *Leesley v. West*, the court held the defendant pharmacy was under no duty to warn the plaintiff of peptic ulceration and gastrointestinal bleeding, even though such incidents were "known . . . side effects of Feldene."<sup>196</sup> The *Leesley* and *Raynor* decisions emphasize the futility of trying to determine what the pharmacists "knew, or should have known" as applied to the duty to warn. While the modern view advocates a case-by-case analysis to determine whether a pharmacist "knew, or should have known" of the dangerous effects of a drug it prescribed, the traditional view recognizes that even in those situations where a pharmacist actually knew of the dangerous side effects of a given drug, those side effects should be properly discussed with the patient by her physician and not the pharmacist. Furthermore, as the *McKee* court recognized, a patient's full medical record is often unavailable to the pharmacist,

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189. 508 A.2d 1247, 1253 (Pa. Super. Ct. 1986).

190. *See id.* at 1249.

191. *Id.* at 1253.

192. *Id.* at 1250.

193. *See McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1053 (Wash. 1989).

194. Causing infants to be born with malformed limbs.

195. 643 F. Supp. 238, 246-47 (D.D.C. 1986).

196. 518 N.E.2d 758, 760 (Ill. App. Ct. 1988).

therefore creating a risk of inaccurate or incomplete advice.<sup>197</sup> The very purpose of the learned intermediary rule is to bypass the difficulties, inequities, and dangers of imputing knowledge to a pharmacist.

*b. The limited duty rule and fenfluramine.* Under the reasoning of *Raynor* and *Leesley*, the *Kohl* decision clearly expands the scope of the limited duty rule to an unacceptable extent. When the *Kohl* court suggested that a pharmacist may have a duty to question a manufacturer's warnings that it "knew, or should have known" were inaccurate,<sup>198</sup> what it really suggested was that pharmacists have a duty to independently warn consumers if the pharmacists "knew, or should have known" that fenfluramine caused heart disease.

Even under a liberal reading of the limited duty rule, it is difficult to see how a pharmacist should be held responsible for the dangerous side effects of fenfluramine that were not made known by the FDA. Such a suggestion would imply that even a neighborhood pharmacist has means of testing and research at his disposal that surpass one of the government's largest administrative agencies.

Moreover, a conservative reading of the limited duty rule would recognize that whether or not fenfluramine really does cause heart disease is immaterial, for even assuming a pharmacy knew of the dangerous side effects of the drug, a pharmacist should still be protected under the learned intermediary rule.

The pharmacy in *Kohl* did none of the things that would qualify as an exception under the limited duty rule as it is generally understood. Specifically, it did not "alter[] the product, or dispense[] the wrong drug,"<sup>199</sup> and it could not have known that fenfluramine was "inferior or defective"<sup>200</sup> until after the FDA's withdrawal. Furthermore, the pharmacist did not have "additional information"<sup>201</sup> about the plaintiff's particular condition within the meaning of *Hand v. Krakowski*<sup>202</sup> that would require it to "inquire of the prescribing physician whether such drugs were appropriate."<sup>203</sup>

While the fact that the *Kohl* court was merely trying to determine

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197. *See McKee*, 782 P.2d at 1052.

198. *Kohl*, 78 F. Supp. 2d at 893.

199. *Id.* at 890.

200. *Id.*

201. *Id.*

202. 453 N.Y.S.2d 121, 123 (N.Y. App. Div. 1982); *see also supra* Part. IV.B.2.a.

203. *Kohl*, 78 F. Supp. 2d at 890.

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whether joinder of the defendant pharmacies was fraudulent prohibits the case from being the smoking gun that it otherwise might have been, the opinion could still be dangerous when read for all it is worth. The court's analysis cannot be cabined in traditional, modern, or limited duty doctrines. As such, it is something of a loose cannon that could be interpreted to expand pharmacist liability to an unacceptable extent and thereby endanger patient care.

#### V. CONCLUSION

The traditional view, tempered with the exceptions of the limited duty rule, is the best mechanism to protect the values fostered under the learned intermediary rule. In contrast, the modern view endangers patient care, undermines the learned intermediary rule, and threatens to supplant the physician's role in the health care system with that of the pharmacist, who is ill-equipped for such responsibility. The court's opinion in *Kohl*, while paying lip service to the traditional view, encourages an expansive view of pharmacist liability without taking responsibility for the implications. If the *Kohl* opinion is followed, pharmacists likely will not survive the Fen-Phen feeding frenzy.

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