

# THE PHARMACIST'S DUTY TO WARN: *LASLEY V. SHRAKE'S COUNTRY CLUB* PHARMACY

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## INTRODUCTION

In March 1994, the Arizona Court of Appeals handed down a decision in *Lasley v. Shrake's Country Club Pharmacy*<sup>1</sup> that should cause Arizona pharmacists to take a second look at their practice habits. In its opinion, the Court of Appeals applied the Arizona Supreme Court's interpretation of duty,<sup>2</sup> and declined to pass judgment on whether specific conduct on the part of the pharmacy met its duty, remanding the case back to the trial court for that determination.<sup>3</sup> Considering the relatively recent statutory changes that require pharmacists to do more than merely fill prescriptions,<sup>4</sup> this decision is likely to be persuasive and precedential in future cases, despite the fact that few decisions in the past have held pharmacists responsible for warning patients of side effects.<sup>5</sup>

Part I of this Note will look briefly at the facts underlying the decision in *Lasley v. Shrake's Country Club Pharmacy*.<sup>6</sup> Part II will address the national legal setting and background in which it was decided,<sup>7</sup> and Part III will follow with an analysis of the decision.<sup>8</sup> Finally, Parts IV and V will explore the impact the decision is likely to have in the future.<sup>9</sup>

## I. LASLEY V. SHRAKE'S COUNTRY CLUB PHARMACY

In *Lasley v. Shrake's Country Club Pharmacy*, plaintiffs George Lasley and his wife Velma Lasley sued Williams K. Helms, M.D., Shrake's Country Club Pharmacy, Inc. [Shrake's], and Mary I. Shrake for injuries resulting from

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1. 179 Ariz. 583, 880 P.2d 1129 (Ct. App. 1994), *review denied* (Oct. 4, 1994).

2. *See infra* notes 158-78 and accompanying text.

3. 179 Ariz. at 588, 880 P.2d at 1134.

4. Traditionally, regulations concentrated on the pharmacist's filling of the prescription in a manner that was safe for the public, and on record-keeping requirements. ARIZ. COMP. ADMIN. R. & REGS. R4-23-402(A) (1990). Title IV of the Omnibus Budget Reconciliation Act of 1990, and new Arizona regulations require the pharmacist to do more than merely fill the prescription correctly by mandating consultation with the patient regarding the use of the drug. *See infra* notes 138-51 and accompanying text.

5. *See infra* notes 83-89, 131-34 and accompanying text.

6. 179 Ariz. 583, 880 P.2d 1129 (Ct. App. 1994), *review denied* (Oct. 4, 1994). *See infra* notes 10-28 and accompanying text.

7. *See infra* notes 29-157 and accompanying text.

8. *See infra* notes 158-92 and accompanying text.

9. *See infra* notes 193-215 and accompanying text.

prescription drugs taken by George Lasley.<sup>10</sup> Dr. Helms had prescribed the drugs, Doriden and codeine, and Shrake's had filled the prescriptions.<sup>11</sup> Plaintiffs alleged the prescribed drugs were potent and addicting, and taking them necessitated in-patient hospitalization for detoxification and psychiatric treatment for addiction;<sup>12</sup> taking the prescribed drugs also allegedly caused Lasley to suffer from clinical depression and related disorders.<sup>13</sup> Plaintiffs claimed that the pharmacy had breached a duty to Lasley "to exercise that degree of care, skill and learning expected of reasonable and prudent pharmacies and pharmacists in the profession."<sup>14</sup>

The plaintiffs brought the case in Maricopa County Superior Court in March 1991.<sup>15</sup> Plaintiffs claimed Shrake's owed Lasley a duty of reasonable care, and that it was a question for the trier of fact whether Shrake's met or breached that duty.<sup>16</sup> Defendants argued that as a matter of law, a pharmacist has no duty to warn a patient of a drug's side effects, nor a duty to monitor and control a patient's drug use where a licensed physician prescribes the drugs.<sup>17</sup> In spite of an expert's affidavit and portions of the American Pharmaceutical Association Standards of Practice for the Profession of Pharmacy, both of which indicated that a pharmacist has an obligation to inform patients of side effects and contraindications, the trial court granted Shrake's motion to dismiss.<sup>18</sup> The court held that Shrake's owed no duty to Lasley to warn of the possibility of addiction, nor to refuse to fill the legitimate prescriptions written by Dr. Helms.<sup>19</sup> The trial court denied plaintiffs' motion for reconsideration, and entered judgment for Shrake's, dismissing the complaint against Shrake's with prejudice.<sup>20</sup> Plaintiffs appealed, contesting the issue of whether the defendants owed the plaintiffs a duty of reasonable care.<sup>21</sup> The Arizona Appellate court reversed<sup>22</sup> what they called the trial court's grant of summary judgment,<sup>23</sup> and remanded the case to the trial court for further proceedings.<sup>24</sup>

The Appellate court addressed two issues: first, whether Shrake's owed a duty in general to Lasley; and second, if there was a duty, whether Shrake's breached that duty in the care given to Lasley.<sup>25</sup> The Court held that Shrake's

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10. 179 Ariz. 583, 880 P.2d 1129 (Ct. App. 1994), *review denied* (Oct. 4, 1994).

11. *Id.* at 585, 880 P.2d at 1131.

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.* at 588, 880 P.2d at 1134.

23. *Id.* at 584-85, 880 P.2d at 1130-31. The trial court considered matters outside the pleadings, such as the expert's affidavit, drug information, answers to interrogatories, and the excerpts from the American Pharmacy Association's Standards of Practice for the Profession of Pharmacy. Therefore the appellate court treated the motion as a motion for summary judgment. For a discussion of the Standards, see *infra* notes 154-57 and accompanying text.

24. *Id.* at 588, 880 P.2d at 1134.

25. *Id.* at 585-86, 880 P.2d at 1131-32.

did owe Lasley a duty of care,<sup>26</sup> and that they could not say as a matter of law that Shrake's did not breach that duty.<sup>27</sup> This Note addresses both issues in Part III.<sup>28</sup>

## II. SUMMARY OF LEGAL SETTING AND BACKGROUND

### A. Case law establishing no duty to warn

There are numerous cases across the country in which courts have consistently held that there is no legal duty for a pharmacist to warn patients of potential or actual side effects of legitimately and correctly prescribed drugs.<sup>29</sup> All of these cases involved prescriptions that were legitimate and written correctly.<sup>30</sup> The issue the courts focus on is: given a valid, properly written prescription, whether the pharmacist is responsible for providing information on side effects and other potential hazards of taking the medication, beyond that which is requested by the physician or manufacturer.<sup>31</sup> It is important to note that the majority of this case law developed prior to the passage of statutes and regulations requiring pharmacists to counsel their patients.<sup>32</sup>

#### 1. *Jones v. Irvin*

In *Jones v. Irvin*,<sup>33</sup> the court granted the defendant-pharmacist's motion to dismiss, holding that the pharmacist has no duty to warn the patient or notify the prescribing physician that prescription drugs are being over-prescribed, or over-used, or of the potential for side effects in the prescribed quantities.<sup>34</sup> The patient alleged that the pharmacist should have recognized the excessive quantity of drugs being taken, and should have notified either the patient or the doctor of a potential problem, and of the potential side effects.<sup>35</sup> The court felt it was the *physician's* duty, not the pharmacist's, to know the characteristics of the drugs he is prescribing and to monitor the patient, as well as warn the patient of potential side effects and adverse reactions.<sup>36</sup> To impose a duty to

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26. *Id.* at 586, 880 P.2d at 1132. Shrake's admitted in its answer that it owed Lasley a duty to comply with the applicable standard of care. *Id.*

27. *Id.* at 588, 880 P.2d at 1134.

28. See *infra* notes 158-92 and accompanying text.

29. See *infra* notes 33-89 and accompanying text.

30. See *infra* notes 33-89 and accompanying text.

31. See *infra* notes 33-89 and accompanying text.

32. The federal regulations were effective December 1, 1990. Pub. L. No. 101-508 § 1301, 104 Stat. 1388 (1990). The Arizona state regulations were effective May 16, 1990. ARIZ. ADMIN. R. & REGS. R4-23-402 (May 16, 1990). The primary cases relied upon in this Note were decided between 1985 and 1989. See *infra* notes 33-89 and accompanying text. Walker v. Jack Eckerd Corp., 434 S.E.2d 63, 69 (Ga. Ct. App. 1993), also cited in this Note, involved facts that arose prior to the enactment of federal regulations, which was noted by the court in the opinion, stating that the case would not be controlling precedent for future cases arising after the passage of regulations. See *infra* notes 76-82 and accompanying text.

33. 602 F. Supp. 399 (S.D. Ill. 1985).

34. *Id.* at 402.

35. *Id.* at 400.

36. *Id.* at 401. See also *Pysz v. Henry's Drug Store*, 457 So.2d 561 (Fla. Dist. Ct. App. 1984) (where prescribing doctor knew of the patient's addiction, and the quantity of drugs being prescribed, pharmacist was under no duty to warn the patient or the physician); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987) (pharmacist has no duty to warn a patient of possible side effects of medication unless the physician or manufacturer required or requested such warnings).

warn upon the pharmacist would "compel the pharmacist to second-guess every prescription" merely to escape liability.<sup>37</sup>

### 2. *Ingram v. Hook's Drugs, Inc.*

The court in *Ingram v. Hook's Drugs, Inc.*<sup>38</sup> was also concerned with pharmacist interference in the physician-patient relationship. The court first held that the existence of a duty between the pharmacist and the patient was a question of law.<sup>39</sup> Finding no statutory duty to warn, nor any case law supporting a duty to warn,<sup>40</sup> the court then considered the practicality of imposing a duty upon the pharmacist to warn patients of possible side effects. The court felt the decision resulting from weighing the advantages and disadvantages of the use of particular drugs rests with the physician, who has the benefit of the patient's medical history and examinations.<sup>41</sup> The pharmacist does not enjoy the same benefits in the retail setting.<sup>42</sup> Thus, the court felt "the better rule to be one which places the duty to warn of the hazards of the drug on the prescribing physician and requires of the pharmacist only that he include those warnings found in the prescription."<sup>43</sup> Accordingly, the court held the pharmacist had no duty to warn the patient of the side effects of a prescribed drug.<sup>44</sup>

### 3. *Eldridge v. Eli Lilly & Co.*

In *Eldridge v. Eli Lilly & Co.*,<sup>45</sup> the plaintiff sued for the wrongful death of his wife, alleging the pharmacist was negligent in filling prescriptions for Darvon and other drugs for quantities that were larger than usual, and for failing to notify the doctor of the unusual quantities. The plaintiff did not allege that the pharmacist did anything but fill the prescriptions as written.<sup>46</sup> The court found no common law or statutory duty that the pharmacist warn the physician that a prescription is written for excessive quantities.<sup>47</sup> The court noted that "[a] prescription which is excessive for one patient may be entirely reasonable for the treatment of another."<sup>48</sup> Relying on *Jones v. Irvin*,<sup>49</sup> the court refused to impose a duty upon the pharmacist to warn patients of side

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37. 602 F. Supp. at 402.

38. 476 N.E.2d 881 (Ind. Ct. App. 1985).

39. *Id.* at 883.

40. *Id.* at 884-85.

41. *Id.* at 886-87. *See also* *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991) (the decision about whether to use a drug or not rests with the physician and his unique knowledge).

42. 476 N.E.2d at 887.

43. *Id.*

44. *Id.*

45. 485 N.E.2d 551 (Ill. App. Ct. 1985).

46. *Id.* at 552.

47. *Id.* at 554-55.

48. *Id.* at 553. *See also* *Fakhouri v. Taylor*, 618 N.E.2d 518 (Ill. App. Ct. 1993) (learned intermediary doctrine applies to physicians, not pharmacists); *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991) (to impose a duty upon the pharmacist to warn the patient of potential harm would intrude on the doctor-patient relationship).

49. *See supra* notes 33-37 and accompanying text.

effects since such a duty might endanger the doctor-patient relationship, and in effect, cause the pharmacist to practice medicine without a license.<sup>50</sup>

4. *Ramirez v. Richardson-Merrell, Inc.*

In *Ramirez v. Richardson-Merrell, Inc.*,<sup>51</sup> the plaintiffs alleged that defendant Queen Pharmacy was negligent in failing to warn plaintiff Rosa Ramirez of the potential hazards of birth defects associated with taking Bendectin. However, the court felt it would be unreasonable to impose a higher duty to warn the patient on the pharmacist than is imposed on the manufacturer of the drug, and declined to do so.<sup>52</sup> Additionally, the court felt the imposition upon the pharmacist of a duty to warn the patient of side effects from a prescribed drug would have the effect of placing the pharmacist between the physician and the patient, leading to more harm than good.<sup>53</sup> In the court's opinion, only the doctor is thoroughly familiar with the patient's condition and medical history, and the court felt it would not be in the patient's best interest to impose a duty to warn upon the pharmacist who is not as informed as to the patient's medical condition.<sup>54</sup>

5. *Adkins v. Mong*

The facts of *Adkins v. Mong*<sup>55</sup> are somewhat similar to *Lasley v. Shrake's Country Club Pharmacy*,<sup>56</sup> the subject of this Note. The plaintiff obtained numerous valid prescriptions for narcotics and had them filled at various pharmacies, resulting in addiction.<sup>57</sup> The plaintiff alleged the pharmacist was negligent in failing to maintain profiles and records, failing to identify over-prescribing physicians, failing to determine the plaintiff was a drug abuser, failing to notify other pharmacies of his condition, and filling his prescriptions.<sup>58</sup> Relying on *Stebbins v. Concord Wrigley Drugs, Inc.*,<sup>59</sup> the court reiterated that the defendant pharmacy had no duty to warn the plaintiff of the potential side effects of the dispensed drugs.<sup>60</sup> Additionally, the court refused to consider the Standards of Practice adopted by the American

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50. 485 N.E.2d at 553. See also *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987) (pharmacist has no duty to warn a patient of possible side effects of medication unless the physician or manufacturer required or requested such warnings).

51. 628 F. Supp. 85 (E.D. Penn. 1986).

52. *Id.* at 87.

53. *Id.* at 88. See also *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991) (to impose a duty upon the pharmacist to warn the patient of potential harm would intrude on the doctor-patient relationship).

54. 628 F. Supp. at 88.

55. 425 N.W.2d 151 (Mich. Ct. App. 1988).

56. 179 Ariz. 583, 880 P.2d 1129 (Ct. App. 1994), review denied (Oct. 4, 1994).

57. 425 N.W.2d at 152.

58. *Id.*

59. 416 N.W.2d 381 (Mich. Ct. App. 1987) (pharmacist has no duty to warn a patient of possible side effects of medication unless the physician or manufacturer required or requested such warnings).

60. 425 N.W.2d at 152.

Pharmaceutical Association,<sup>61</sup> noting that the association is not a legal authority, and would not be treated as such.<sup>62</sup>

#### 6. *Leesley v. West*

In *Leesley v. West*,<sup>63</sup> a patient who suffered from side effects due to a prescription medication sued her pharmacy for failing to warn her of the potential problem. The court relied on three factors in determining whether a legal duty exists, stating that the determination of a legal duty is a question of law for the court.<sup>64</sup> The factors include the foreseeability of the injury; the burden to the defendant of guarding against the injury and the consequences of imposing the burden; and public policy.<sup>65</sup> In its analysis, the court felt the foreseeability of injury depended upon the particular patient and the relevant medical history—information to which the pharmacist does not have access.<sup>66</sup> Second, the court concluded the burden of passing on the information provided by manufacturers would be very cumbersome, expensive, and impractical.<sup>67</sup> Third, the court felt it was against public policy to impose liability upon a pharmacist to give a warning that the physician did not request.<sup>68</sup> Overall, the court believed its position was consistent with the State's legislative policy against expanding the liability risks of health professionals.<sup>69</sup>

#### 7. *McKee v. American Home Prods. Corp.*

In *McKee v. American Home Prods. Corp.*,<sup>70</sup> the Washington Supreme Court held the pharmacist was under no duty to warn patients of the hazardous side effects associated with a drug, nor to judge the propriety of a prescription.<sup>71</sup> The plaintiff received a drug, an appetite suppressant, which had a recommended use of only a few weeks, yet the patient took the medication for ten years. Citing *Terhune v. A.H. Robins, Co.*,<sup>72</sup> the court reaffirmed its

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61. See *infra* notes 154–57 and accompanying text.

62. 425 N.W.2d at 153. See also *Kampe v. Howard Stark Professional Pharmacy, Inc.*, 841 S.W.2d 223 (Mo. Ct. App. 1992) (rejecting the idea that non-legal authorities can impose legal duties for pharmacists).

63. 518 N.E.2d 758 (Ill. App. Ct. 1988). See also Louis P. Milot, Casenote, *Tort Law—The Manufacturer's and Pharmacist's Duty to Warn Consumers of Risks and Side Effects of Prescription Drugs*, *Leesley v. West*, 13 S. ILL. U. L.J. 1003 (1989).

64. 518 N.E.2d at 762.

65. *Id.*

66. *Id.* See also *Fakhouri v. Taylor*, 618 N.E.2d 518 (Ill. App. Ct. 1993) (learned intermediary doctrine applies to physicians, not pharmacists).

67. 518 N.E.2d at 762–63.

68. *Id.* at 763. The court cited *Jones v. Irvin*, 602 F. Supp. 399 (S.D. Ill. 1985), which held that requiring pharmacists to warn either patients or physicians would compel a pharmacist to second guess every prescription to avoid liability. The court also felt it was inconsistent with the learned intermediary doctrine that exempts drug manufacturers from warning physicians or patients. 518 N.E.2d at 762–63.

69. 518 N.E.2d at 763.

70. 782 P.2d 1045 (Wash. 1989). See also Terence C. Green, Casenote, *Licking, Sticking, Counting and Pouring—Is That All Pharmacists Do?* *McKee v. American Home Products Corp.*, 24 CREIGHTON L. REV. 1449 (1991); Elizabeth D. Smith, Note, *Are Pharmacists Responsible for Physicians' Prescription Errors?* *McKee v. American Home Products*, 65 WASH. L. REV. 959 (1990).

71. 782 P.2d at 1055–56.

72. 577 P.2d 975 (Wash. 1978) (finding that the manufacturer's duty to warn extended only to the physician, not the patient).

position that it is incumbent upon the physician, not the pharmacist, to warn the ultimate consumer.<sup>73</sup> The court relied on the theory that the doctor was the learned intermediary between the patient and the manufacturer.<sup>74</sup> The court narrowly defined the pharmacist's duties as accurately filling prescriptions, being alert for clear errors or mistakes in the prescription, and taking corrective measures as to those errors or mistakes.<sup>75</sup>

#### 8. *Walker v. Jack Eckerd Corp.*

In *Walker v. Jack Eckerd Corp.*,<sup>76</sup> a patient sued his pharmacy for dispensing a drug without warning the patient that prolonged use could result in glaucoma.<sup>77</sup> The patient alleged the pharmacist had a duty to warn him of the danger, or to refuse to fill his prescriptions.<sup>78</sup> The court found no statutory duty to warn or to refuse to fill the prescription.<sup>79</sup> The court relied on *Jones v. Irvin*<sup>80</sup> to determine that the pharmacist had no duty to warn the patient or physician of excessive quantity or dose.<sup>81</sup> The court recognized however, that Georgia had passed regulations that took effect January 1, 1993 requiring patient counseling, and thus the decision was not intended to control cases involving pharmacists' duties arising after the implementation of those regulations.<sup>82</sup>

#### 9. Summary

Thus, the courts have found a wide variety of reasons not to hold pharmacists to a legal duty to warn patients of side effects. In some cases, if the pharmacist could demonstrate that the doctor knew what prescriptions the patient was getting and how often, the court found that the pharmacist had no obligation to intervene.<sup>83</sup> Other courts emphasized that it is exclusively the

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73. 782 P.2d at 1049.

74. *Id.* Under the learned intermediary doctrine, drug manufacturers are under no obligation to warn patients of the side effects of their products. The manufacturers are to provide the warnings to physicians, who function as the learned intermediary between the manufacturer and the patient. For a thorough explanation of this doctrine and its application, see William G. Adamson and Adam S. Levy, *Duty to Warn for Products Used in the Industrial Workplace—"Sophisticated User" and "Learned Intermediary" Defenses*, 65 PA. B. ASS'N Q. 26 (1994). See also *Fakhouri v. Taylor*, 618 N.E.2d 518 (Ill. App. Ct. 1993) (learned intermediary doctrine applies to physicians, not pharmacists); *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991) (pharmacist is under no duty to warn the patient since the doctor is the learned intermediary).

75. 782 P.2d at 1053. See also *Nichols*, 817 P.2d at 1133 (duties of the pharmacist are to accurately fill prescriptions and to be alert for clear errors).

76. 434 S.E.2d 63 (Ga. Ct. App. 1993).

77. *Id.* at 63.

78. *Id.* at 67.

79. *Id.*

80. See *supra* notes 33-37 and accompanying text.

81. 434 S.E.2d at 67-68.

82. *Id.* at 69.

83. See *Pysz v. Henry's Drug Store*, 457 So.2d 561 (Fla. Dist. Ct. App. 1984) (where the physician knew of the patient's frequent and extended medication, pharmacist is under no duty to warn either the patient or the physician). Cf. *Ferguson v. Williams*, 399 S.E.2d 389 (N.C. Ct. App. 1991) (pharmacist voluntarily providing information to patient must do so correctly).

doctor's duty to warn,<sup>84</sup> or that it would be burdensome and against public policy to place a duty to warn upon the pharmacist.<sup>85</sup> The most common arguments are that the doctor is in the superior position to assess the use of drugs,<sup>86</sup> and to require a pharmacist to review and assess the prescription beyond that assessment needed to fill the prescription accurately would potentially interfere with the doctor-patient relationship.<sup>87</sup> Other reasons offered included that the courts would not consider non-legal professional guidelines to set legal standards,<sup>88</sup> nor allow state regulations to define legal standards.<sup>89</sup>

### *B. Cases establishing a duty to warn*

In contrast to the numerous cases in which courts held pharmacists had no legal duty to warn the patient of potential side effects of the prescribed medications, three decisions hold that there may be a duty of some sort between the pharmacist and the patient, beyond merely filling a valid prescription accurately. However, the facts in each of these cases can be distinguished from *Lasley v. Shrake's Country Club Pharmacy*.

#### *1. Hand v. Krakowski*

In *Hand v. Krakowski*,<sup>90</sup> the basis of the action involved the dispensing of certain drugs that were contraindicated<sup>91</sup> by the patient's condition, this condition being known to the dispensing pharmacist.<sup>92</sup> Defendant Condo's Pharmacy [Condo's] had dispensed per legitimate, signed prescriptions, certain

84. See *Jones v. Irvin*, 602 F. Supp 399 (S.D. Ill. 1985); *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63 (Ga. Ct. App. 1993); *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991); *Kinney v. Hutchinson*, 449 So.2d 696 (La. Ct. App. 1984); *Makripodis v. Merrell-Dow Pharmaceuticals*, 523 A.2d 374 (Pa. Super. Ct. 1987); *McKee v. American Home Prods. Corp.*, 782 P.2d 1045 (Wash. 1989).

85. See *Leesley v. West*, 518 N.E.2d 758 (Ill. App. Ct. 1988); *Hook's SuperX, Inc. v. McLaughlin*, 632 N.E.2d 365 (Ind. Ct. App. 1994).

86. See *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp 85 (E.D. Pa. 1986); *Fakhouri v. Taylor*, 618 N.E.2d 518 (Ill. App. Ct. 1993); *Leesley*, 518 N.E.2d 758; *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. App. Ct. 1985); *Ingram v. Hook's Drugs*, 476 N.E.2d 881 (Ind. Ct. App. 1985); *Nichols*, 817 P.2d 1131.

87. See *Ramirez*, 628 F. Supp 85; *Jones*, 602 F. Supp 399; *Walker*, 434 S.E.2d 63; *Eldridge*, 485 N.E.2d 551 (Ill. App. Ct. 1985); *Hook's SuperX*, 632 N.E.2d 365; *Nichols*, 817 P.2d 1131.

88. See *Adkins v. Mong*, 425 N.W.2d 151 (Mich. Ct. App. 1988); *Kampe v. Howard Stark Professional Pharmacy, Inc.*, 841 S.W.2d 223 (Mo. Ct. App. 1992).

89. See *Kampe*, 841 S.W.2d 223.

90. 453 N.Y.S.2d 121 (N.Y. App. Div. 1982).

91. A contraindication is "any condition which renders a particular line of treatment improper or undesirable." DORLAND'S POCKET MEDICAL DICTIONARY 166 (23d ed. 1982). The *Hand* court used a more strict definition: "[A] 'contraindication' refers to a circumstance under which the drug must never be given. It is absolute and admits of no exceptions." 453 N.Y.S.2d at 123 (quoting *Baker v. St. Agnes Hosp.*, 421 N.Y.S.2d 81, 83 (N.Y. App. Div. 1979)).

92. 453 N.Y.S.2d at 122.



psychotropic<sup>93</sup> drugs to plaintiff's decedent<sup>94</sup> who was an alcoholic.<sup>95</sup> The defendants knew of the decedent's alcoholism.<sup>96</sup> In the ten-month period preceding the decedent's death, Condo's dispensed 728 units of the psychotropic drugs that are contraindicated with the use of alcohol.<sup>97</sup> The court ruled that the defendant's conduct could breach the pharmacist's duty of ordinary care owed to the patient, and therefore a material issue of fact existed, precluding summary judgment.<sup>98</sup>

Note, however, that this case is distinguishable from most because here the pharmacist knew personally of the patient's alcoholic condition, and dispensed drugs that are contraindicated for such a condition. In the cases finding no duty to warn, no similar allegations are made, nor are any made in *Lasley v. Shrake's*.

## 2. *Riff v. Morgan Pharmacy*

In *Riff v. Morgan Pharmacy*,<sup>99</sup> the patient sued the pharmacy and the prescribing physician for injuries sustained from a prescription dispensed without adequate warning as to side effects and toxic doses.<sup>100</sup> The pharmacy appealed from a jury verdict finding the pharmacy and physician jointly liable for the injuries caused by their negligence.<sup>101</sup> Declaring the evidence sufficient to sustain the verdict,<sup>102</sup> the judgment was affirmed.<sup>103</sup>

Dr. Stack, the defendant physician (not party to the appeal) issued a prescription to the plaintiff for twelve Cafergot suppositories, with directions to insert one suppository rectally every four hours.<sup>104</sup> The doctor did not authorize any additional refills on the face of the prescription.<sup>105</sup> The pharmacist filled the prescription as written, including the directions, without informing either the patient or the physician that the maximum dosage is one or two suppositories per migraine headache attack, not to exceed five suppositories per week.<sup>106</sup> After filling the initial prescription, Mrs. Riff used three or four suppositories before obtaining relief from her migraine.<sup>107</sup> About three months later, Mrs. Riff developed another migraine and used the remainder of the first prescription. She obtained a refill and continued to use the suppositories, one every four hours for three and a half to four days, for a total of 15-17

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93. A psychotropic drug "exert[s] an effect on the mind." DORLAND'S POCKET MEDICAL DICTIONARY 575 (23d ed. 1982).

94. Suzanne Welch Hand sued on behalf of Marion Mazula, deceased, in her position of Preliminary Executrix of the Estate of Marion Mazula. 453 N.Y.S.2d 121 (N.Y. App. Div. 1982).

95. *Id.* at 122.

96. *Id.*

97. *Id.* at 123.

98. *Id.* The court stated that the duty of ordinary care as applied to a pharmacist was "the highest practicable degree of prudence, thoughtfulness, and vigilance commensurate with the dangers involved and the consequences which may attend inattention." *Id.* at 122.

99. 508 A.2d 1247 (Pa. Super. Ct. 1986)

100. *Id.* at 1249.

101. *Id.* at 1248.

102. *Id.*

103. *Id.* at 1254.

104. *Id.* at 1249.

105. *Id.*

106. *Id.* at 1249-50.

107. *Id.* at 1249.

suppositories for the attack.<sup>108</sup> Four months later, Mrs. Riff again suffered a migraine headache. Once more the pharmacy refilled her prescription, and Mrs. Riff used five or six suppositories for this attack.<sup>109</sup> Within a few days, Mrs. Riff was admitted to a hospital for complications determined to be the result of a Cafergot overdose.<sup>110</sup> Mrs. Riff suffered permanent damage due to the Cafergot overdose.<sup>111</sup>

Although the pharmacy raised fifteen arguments in support of its appeal, the court addressed only two, those relating to legal causation and joint tortfeasor status.<sup>112</sup> The pharmacy claimed its only function and duty was to fill the prescription as written, therefore it was the doctor's omission of a warning or correct instructions that caused the harm, not the pharmacist's actions.<sup>113</sup> The court disagreed, stating that it is not the duty of a pharmacist to merely supply drugs unquestioningly, but that the pharmacist is held to a much higher duty.<sup>114</sup> The court stated that state law did not require any extraordinary skill, but at least that level of skill that is characteristic of the profession.<sup>115</sup> The court determined that the pharmacy had a legal duty to "exercise due care and diligence in the performance of its professional duties,"<sup>116</sup> and that sufficient evidence was presented for the jury to find that the pharmacy had breached that duty by failing to alert the patient or the physician to the inadequacies of the written prescription.<sup>117</sup> But for the pharmacist's negligence, the patient would have been instructed as to the proper use, and the injuries would not have occurred, therefore causation was established.<sup>118</sup>

These facts too, are distinguishable from the cases finding no duty to warn, and from *Lasley v. Shrake's*. Here, the prescription was not a properly written prescription. The prescribed quantity was clearly an overdose as written, and even the cases finding no duty to warn have recognized that a pharmacist is responsible for detecting and correcting clear errors.<sup>119</sup> This case

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108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.* at 1250.

113. *Id.* at 1251.

114. *Id.* The court described the duty as follows:

In the performance of his professional duties [the pharmacist] will be held to the standard of care, skill, intelligence [sic] which ordinarily characterizes the profession. Public policy requires that pharmacists who prepare and dispense drugs and medicines for use in the human body must be held responsible for the failure to exercise the degree of care and vigilance commensurate with the harm which would be likely to result from relaxing it.

*Id.*

115. *Id.* (citing *Titchell v. United States*, 681 F.2d 165 (3rd Cir. 1982)).

116. *Id.* at 1251-52.

117. *Id.* at 1252.

118. *Id.*

119. See *Hook's SuperX, Inc. v. McLaughlin*, 632 N.E.2d 365, 369 (Ind. Ct. App. 1994) (a pharmacist's duty is limited to identifying errors, contraindications, and incompatibilities); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 387-88 (Mich. Ct. App. 1987) (no duty to warn where the prescription is proper on its face); *Kampe v. Howard Stark Professional Pharmacy, Inc.*, 841 S.W.2d 223, 226 (Mo. Ct. App. 1992) (the pharmacist has a duty to inquire if there are irregularities on the face of the prescription); *McKee v. American Home Prods. Corp.*, 782 P.2d 1045, 1053 (Wash. 1989) (pharmacists should have a duty to be alert for clear errors and take corrective measures).

also included a question of the pharmacist refilling the prescription without authorization, another factor that is not seen in *Lasley v. Shrake's* or the cases finding no duty to warn.

### 3. *Dooley v. Everett*

In *Dooley v. Everett*,<sup>120</sup> the Dooleys sued their son's doctor and pharmacy over the prescribing and dispensing of two different prescription drugs that interacted with one another to cause seizures after their son took both as prescribed.<sup>121</sup> The two medicines, theophylline and erythromycin, were prescribed by the same doctor at different times, and filled by the same pharmacy at different times.<sup>122</sup> When taken together, the erythromycin causes the blood levels of the theophylline to rise to dangerous levels; therefore, the manufacturer of the erythromycin product warned against concomitant use that could result in theophylline toxicity unless the dose of the theophylline was reduced appropriately.<sup>123</sup> The pharmacist admittedly did not know of the interaction, and thus failed to warn either the patient or the physician.<sup>124</sup>

The defendant pharmacy, Revco, moved for summary judgment on the basis that as a matter of law, the pharmacist has no duty to warn patients of potential drug interactions.<sup>125</sup> In response, the plaintiffs filed an affidavit from an expert witness who asserted that under accepted standards of care, a pharmacist should be checking for drug interactions to prevent side effects.<sup>126</sup> The witness additionally testified that computer technology existed that would have alerted the pharmacist to drug interactions, and specifically to the erythromycin-theophylline interaction.<sup>127</sup> As to the pharmacy's assertion that the pharmacist has no duty to warn patients, the court stated that the existence of a duty is a question of law to be determined by the court, but the scope of the duty is a question of fact to be decided by the trier of fact.<sup>128</sup> Since there was a disputed issue as to whether the pharmacist's duty encompassed a responsibility to warn of potential drug interactions, the Court of Appeals reversed the lower court's granting of summary judgment for the defendant pharmacy, finding the issue of whether the pharmacy had a duty to warn a customer of a potential drug interaction was a question of fact that precluded summary judgment.<sup>129</sup>

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120. 805 S.W.2d 380 (Tenn. Ct. App. 1990). See also John A. Day and Catherine Marks, *Duty to Warn of Potential Drug Interactions: The Pharmacist's Role*, 14 TRIAL DIPL. J. 107 (1991); Kathy L. Laizure, Note, *The Pharmacist's Duty to Warn When Dispensing Prescription Drugs: Recent Tennessee Developments*, 22 MEM. ST. U. L. REV. 517 (1992).

121. 805 S.W.2d at 382.

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.* at 383.

126. *Id.*

127. *Id.*

128. *Id.* at 384. The court described the pharmacist's duty as follows: "The pharmacist is a professional who has a duty to his customer to exercise the standard of care required by the pharmacy profession in the same or similar communities as the community in which he practices his profession." *Id.* at 385.

129. *Id.* at 385-86. Under the applicable state rules of civil procedure, for summary judgment there must be no genuine issue of material fact. *Id.* at 383.

Note that this decision is in the minority in holding that the issue of duty is a question for the trier of fact, not a question of law for the court.<sup>130</sup>

Again, these facts are distinguishable from cases finding no duty to warn and from *Lasley v. Shrake's*. Here, two drugs were dispensed that should not be used in conjunction with each other without strict monitoring of blood levels. The interaction was known to the pharmacy industry, and was readily detectable with available computer technology. This was not a case merely alleging the pharmacist's failure to warn of a side effect, for this involved an actual contraindication.

#### 4. Summary

The few courts that have found that the pharmacist was under some kind of duty to warn the patient or the doctor have done so not under a general duty, but usually because of an additional factor that should have alerted the pharmacist to a clear problem with the patient taking the prescription as written.<sup>131</sup> Those additional factors include knowledge possessed by the pharmacist that certain drugs were dangerous to a particular patient,<sup>132</sup> directions for use of the prescription that were clearly an overdose,<sup>133</sup> and dispensing two different drugs to the same patient that were dangerous to take together without appropriate dosage adjustments.<sup>134</sup>

#### C. Statutes and Regulations

The relatively recent passage of statutes and regulations regarding a pharmacist's responsibility to provide certain information to her patients is likely to change the scope of duty the courts have been finding. Peculiarly, the existence of the regulations is mentioned in only one of the recent cases.<sup>135</sup> In *Lasley's* case, his treatment ended prior to the enactment of the current state or federal law.<sup>136</sup> Nevertheless, the regulations are relevant to this Note because even had the *Lasley* court found there was no duty to warn as a matter of law,

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130. Only four out of twenty decisions cited in this Note for this proposition have found that the issue of duty was not a question of law for the court: *Lasley v. Shrake's Country Club Pharmacy*, 179 Ariz. 583, 880 P.2d 1129 (Ct. App. 1994), *review denied* (Oct. 4, 1994); *Dooley*, 805 S.W.2d 380; *Hand v. Krakowski*, 453 N.Y.S.2d 121 (N.Y. App. Div. 1982); and *Riff v. Morgan Pharmacy*, 508 A.2d 1247 (Pa. Super. Ct. 1986).

131. One court held that although there was no general duty to warn, if the pharmacist voluntarily undertakes to advise the patient of side effects, the pharmacist is under a duty to give an accurate warning. *Ferguson v. Williams* 399 S.E.2d 389, 393 (N.C. Ct. App. 1991) (citing *Batiste v. American Home Prods. Corp.*, 231 S.E.2d 269 (N.C. Ct. App. 1977)). *See also Heredia v. Johnson*, 827 F. Supp. 1522 (D. Nev. 1993) (a pharmacist must be held to a duty to fill prescriptions as prescribed and properly label them, which includes the proper warnings).

132. *See Hand v. Krakowski*, 453 N.Y.S.2d 121 (N.Y. App. Div. 1982), and *supra* text accompanying notes 90-98.

133. *See Riff v. Morgan Pharmacy*, 508 A.2d 1247 (Pa. Super. Ct. 1986) and *supra* text accompanying notes 99-119.

134. *See Dooley v. Everett*, 805 S.W.2d 380 (Tenn. Ct. App. 1990) and *supra* text accompanying notes 120-30.

135. *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63 (Ga. Ct. App. 1993) (holding pharmacy had no duty to warn, but the decision is not intended as controlling precedent for cases involving pharmacists duties arising after new counseling regulations take effect).

136. *Lasley v. Shrake's Country Club Pharmacy*, 179 Ariz. 583, 585, 880 P.2d 1129, 1131 (Ct. App. 1994), *review denied* (Oct. 4, 1994); ARIZ. COMP. ADMIN. R. & REGS. R4-23-402 (May 16, 1990); 42 U.S.C. § 1396r-8 (Supp. V 1993).

subsequent decisions have to address statutes that require warning patients of side effects for many, if not most, prescriptions.<sup>137</sup>

### 1. Federal Law (OBRA '90)

Title IV of the Omnibus Budget Reconciliation Act of 1990 ["OBRA"] contains measures related to prescription dispensing and use.<sup>138</sup> All the measures apply to prescriptions for Medicare and Medicaid patients.<sup>139</sup> The Act requires states to establish programs that assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results.<sup>140</sup> The Act mandates that states shall provide for prospective drug use reviews, including screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of treatment, drug-allergy interactions, and clinical abuse or misuse.<sup>141</sup> Besides requiring physicians and pharmacists to be alert to potential problems, the Act provides that states enact legislation requiring pharmacists to discuss with the patients common, severe side or adverse effects that may occur.<sup>142</sup> Pharmacists must also discuss with their patients potential interactions due to the prescribed medication, and therapeutic contraindications, including how to avoid them.<sup>143</sup>

Under current law, had Lasley been a Medicare or Medicaid patient filling a prescription after 1990, the pharmacist at Shrake's would have been

137. See *infra* notes 138-51 and accompanying text.

138. 42 U.S.C. § 1396r-8 (Supp. V 1993).

139. *Id.*

140. *Id.* at § (g)(1)(A).

141. *Id.* at § (g)(2)(A). The regulations are designed to ultimately reduce costs. If the physician or pharmacist discovers potential medical problems due to drug therapy, and prevents those problems, she will be conserving medical costs. For example, a pharmacist or physician can prevent drug misadventures in several ways: (1) notice that the patient is taking two different types of the same medication, which could simply result in useless excess therapy or could result in an overdose; (2) learn that a patient is allergic to the drug prescribed (and thus prevent harmful allergic reactions); or (3) detect that a patient has another disease of which the prescribing doctor is unaware such that the second disease will affect the prescribed medication and render it useless, or worse, result in complications.

142. The Act specifically requires the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

42 U.S.C. § 1396r-8 (g)(2)(A)(ii) (Supp. V 1993).

143. *Id.*

under a federal obligation to inform him of common side effects and adverse effects, including the potential for addiction.

## 2. State Law

The vast majority of states have taken the measures mandated by the Act and applied them not only to Medicare and Medicaid patients, but to all patients.<sup>144</sup> In most cases, the pharmacist must counsel the patient personally, face-to-face.<sup>145</sup> Similarly, most states also require that pharmacists maintain patient profiles.<sup>146</sup>

Arizona has incorporated the required measures through regulations established by the Arizona Board of Pharmacy, effective May, 1990.<sup>147</sup> The standards are not limited to Medicaid and Medicare patients, but apply to *all* persons in outpatient settings.<sup>148</sup> Arizona requires the pharmacist (or a pharmacy intern<sup>149</sup> under the supervision of a pharmacist) to counsel patients orally, and the counseling must include the drug's name, directions for use, and any special instructions, precautions, or storage requirements.<sup>150</sup> The

144. National Assoc. of Boards of Pharmacy, 1994-95 NABP Survey of Pharmacy Law [hereinafter NABP Survey]. The few states not requiring counseling for all patients are Colorado, Connecticut, Hawaii, Minnesota, Puerto Rico, South Carolina, and Wyoming. Regulations are pending in the District of Columbia and Michigan. *Id.* at 50. In Arizona, the new regulations took effect following the events that gave rise to Lasley's claim. See ARIZ. COMP. ADMIN. R. & REGS. R4-23-402 (May 16, 1990).

145. NABP Survey at 50. The two states not requiring face-to-face personal counseling are Maryland and Nebraska. Regulations are pending in the District of Columbia and Michigan.

146. *Id.* The states not requiring pharmacists to maintain patient profiles are Alaska, Arizona, Colorado, Maryland, Massachusetts, Missouri, and Puerto Rico. Although the specifics may vary state to state, patient profiles generally contain the patient's name, address, date of birth, disease states, allergies, and prescriptions the patient is taking or has taken in the past few years.

147. The Board of Pharmacy is authorized to pass such regulations through ARIZ. REV. STAT. ANN. § 32-1904(A)(1) (1992).

148. ARIZ. COMP. ADMIN. R. & REGS. R4-23-402(B) (1990). "'Outpatient' or 'Outpatient setting' means a person that receives medical treatment as a result of not being a residential patient in a health care institution, or a location where medical treatment is provided to patients not required to be overnight residents of the facility." ARIZ. COMP. ADMIN. R. & REGS. R4-23-110(T.) (1993). Thus, the regulations apply to *all* prescriptions filled by the community or retail pharmacy.

149. A pharmacy intern is a student of pharmacy registered with the board of pharmacy as an intern and licensed to work in a pharmacy. ARIZ. COMP. ADMIN. R. & REGS. R4-23-301 (1993).

150. ARIZ. COMP. ADMIN. R. & REGS. R4-23-402 (1990).

R4-23-402 Pharmacist and pharmacy intern

...

B. The pharmacist or pharmacy intern shall personally provide oral communication, which shall include directions for use, name of prescribed medication, and any special instructions, precautions or storage requirements, to the patient or patient's agent in all outpatient settings including the provision of hospital discharge medications whenever any of the following occurs:

1. The prescribed medication has not been previously dispensed to the patient or a new prescription number is assigned to a previously dispensed medication;

2. The prescription drug has not previously been dispensed to the patient in the same strength, dosage form, or directions;

3. In the professional judgment of the pharmacist, it is deemed warranted.

4. Upon request of the patient or the patient's agent.

regulations prohibit counseling solely through printed material (except where the prescription is obtained through delivery services), and require that the pharmacist or pharmacy intern, not a technician or other personnel, must provide the information.<sup>151</sup> Under the new counseling requirements, Lasley surely should have been advised of the potential of addiction to the prescribed drugs.<sup>152</sup> However, Lasley's treatment ended in 1990, the year the new regulations took effect.<sup>153</sup>

#### *D. Professional Standards of Practice*

The profession of pharmacy as a whole has recognized, and in fact expounded, the duties of a pharmacist. In 1979, the American Pharmaceutical Association and the American Association of Colleges of Pharmacy introduced "Standards of Practice for the Profession of Pharmacy."<sup>154</sup> The Standards attempt to cover in extraordinary detail every aspect of pharmacy. The Standards explore tasks and responsibilities related to general management and administration, processing the prescription, patient care, and education of other health care professionals and patients.<sup>155</sup> Significantly, the Standards also assert a responsibility to advise patients of the possible effects of drug use upon the

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C. When prescriptions are delivered to the patient or patient's agent outside of the immediate area of the pharmacy and a pharmacist is not present, the prescription shall be accompanied by written or printed patient medication information sufficient to satisfy the requirements in R4-23-402(B). This information shall include a telephone number for consultation with a pharmacist.

*Id.*

151. *Id.*

152. In a recent opinion, the Georgia Court of Appeals held that the defendant-pharmacist had no duty to warn the plaintiff-customer under the previous law, but specifically stated that the case could not be controlling precedent for other cases arising after the implementation of the new counseling laws. *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63, 69 (Ga. Ct. App. 1993).

153. *Lasley v. Shrake's Country Club Pharmacy*, 179 Ariz. 583, 585, 880 P.2d 1129, 1131 (Ct. App. 1994), *review denied* (Oct. 4, 1994).

154. Samuel H. Kalman and John F. Schlegel, *Standards of Practice for the Profession of Pharmacy*, AM. PHARMACY, Mar. 1979, at 21 [hereinafter *Standards*]. Despite being fifteen years old, the standards are still considered current, and have not been revised. *See also infra* note 214.

155. *Id.*

patient.<sup>156</sup> However, more than one court has refused to consider these professional duties when determining whether a legal duty exists.<sup>157</sup>

### III. ANALYSIS OF *LASLEY V. SHRAKE'S*

#### A. *Duty v. Standard of Care*

The crux of the appellate court's decision in *Lasley v. Shrake's* was that court's finding that the trial court had confused the concept of duty with that of the standard of care.<sup>158</sup> With that finding, the appellate court dismissed the impact of twelve cases from other jurisdictions that held the pharmacist is under no duty to warn.<sup>159</sup> The difference in results seems to be how the appellate court defines duty.

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156. The Standards provide the following:

*Responsibility No. 6:* Advises patient of potential drug-related or health-related conditions which may develop from the use of the medication for which patient should seek other medical care.

...

*Tasks:*

...

4. Explains possible side effects of drug use to patient.

(a) Explains to patient how to recognize the signs and/or symptoms that indicate:

(i) Therapeutic response.

(ii) Therapeutic failure.

(iii) Pertinent side effects.

(b) Advises patient what to do if signs and/or symptoms occur.

(c) Advises patient how to minimize side effect.

(d) Assesses whether patient understands explanation.

Standards, *supra* note 154, at 31.

157. See *Adkins v. Mong*, 425 N.W.2d 151 (Mich. Ct. App. 1988); *Kampe v. Howard Stark Professional Pharmacy, Inc.*, 841 S.W.2d 223 (Mo. Ct. App. 1992).

158. *Lasley v. Shrake's Country Club Pharmacy*, 179 Ariz. 583, 586, 880 P.2d 1129, 1132 (Ct. App. 1994), *review denied* (Oct. 4, 1994).

159. *Id.* at 587, 880 P.2d at 1133, nn. 2-5. The court divided the cases into two groups as follows: One group generally found no duty to warn of side effects of prescribed medications because the imposition of a duty would lead to "harmful interference in the patient-physician relationship." *Id.* at 587, 880 P.2d at 1133. See *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85 (E.D. Pa. 1986) (alleging that pharmacy negligently failed to warn pregnant plaintiff that Bendectin could cause birth defects); *Leesley v. West*, 518 N.E.2d 758 (Ill. App. Ct. 1988), *appeal denied*, 522 N.E.2d 1246 (1988) (alleging that pharmacy negligently failed to warn of known but infrequent adverse side effects of Feldene); *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881 (Ind. Ct. App. 1985) (alleging that pharmacy's failure to warn of possible side effects of Valium proximately caused injuries customer suffered in fall from ladder); *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991) (alleging that pharmacy negligently dispensed to pregnant plaintiff prescription that caused bone abnormalities in subsequently born child); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987) (alleging that pharmacy negligently failed to warn customer of side effects of Tofranil and that he should not drive after taking the drug).

The second group generally found no duty to warn either the patient or the physician of excessive doses of a drug because the imposition of a duty would place the pharmacist in a position of second-guessing every prescription in order to preempt liability. See *Jones v. Irvin*, 602 F. Supp. 399 (S.D. Ill. 1985) (considering whether pharmacist is negligent for failing to warn customer or notify physician that drug is being prescribed in dangerous amounts, that customer is being over-medicated, or that various prescribed drugs in combination with others could cause adverse reactions); *Pysz v. Henry's Drug Store*, 457 So.2d 561 (Fla. Dist. Ct. App. 1984) (alleging that pharmacy negligently failed to warn customer of addictive propensities of Quaaludes while filling Quaalude prescription for more than nine years and negligently failed to



The decisions finding no duty to warn were specific, and acknowledged that the pharmacist is under other duties towards the patient.<sup>160</sup> The *Lasley* appellate court took a different view, stating there was a duty in general, and the jury was to determine the standard of care needed to meet that duty.<sup>161</sup> The *Lasley* appellate court stated that every other jurisdiction was confusing duty with standard of care by "us[ing] details of the standard of conduct to determine whether a duty exists."<sup>162</sup> This concept was introduced by Arizona Supreme Court Justice Feldman in *Coburn v. City of Tucson*,<sup>163</sup> then reiterated in *Markowitz v. Arizona Parks Board*,<sup>164</sup> which is the case the *Lasley* court cites for this concept.<sup>165</sup>

### 1. *Coburn v. City of Tucson*

In *Coburn*, the plaintiffs argued that the City was under a duty to remove a bush at a particular intersection, and the City argued that they were under no such duty to remove the bush.<sup>166</sup> The trial court held that the City had no duty to remove the bush, and the court of appeals affirmed.<sup>167</sup> The Arizona Supreme Court granted review to clarify the distinction between standard of conduct and duty.<sup>168</sup> The court emphasized that the City is under a *general duty* to keep its streets reasonably safe for use by the public.<sup>169</sup> Once the general duty is confirmed, details of conduct are considered for determination of whether they meet the standard of care.<sup>170</sup> If there is a genuine issue as to whether they meet

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inform physician of customer's known addiction); *Fakhouri v. Taylor*, 618 N.E.2d 518 (Ill. App. Ct. 1993), appeal denied, 622 N.E.2d 1204 (1993) (alleging that pharmacy negligently filled prescriptions for quantities of Imipramine beyond those normally prescribed and negligently failed to warn physician or customer of excessive and unsafe quantities); *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. App. Ct. 1985) (alleging that pharmacy negligently filled prescriptions for quantities of Darvon and other drugs beyond those normally prescribed and negligently failed to warn physician that prescriptions were for an excessive quantity); *Adkins v. Mong*, 425 N.W.2d 151 (Mich. Ct. App. 1988) (alleging that pharmacy negligently supplied plaintiff with excessive amounts of prescribed controlled substances for six years); *Kampe v. Howard Stark Professional Pharmacy, Inc.*, 841 S.W.2d 223 (Mo. Ct. App. 1992) (alleging that pharmacy failed to monitor or evaluate plaintiff's use of prescribed drugs during the two and a half years it filled the prescriptions); *McKee v. American Home Prods. Corp.*, 782 P.2d 1045 (Wash. 1989) (alleging that pharmacists who filled plaintiff's drug prescriptions for ten years had duty to warn her of adverse side effects of long-term administration of drug).

160. See *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 387-88 (Mich. Ct. App. 1987) (no duty to warn where the prescription is proper on its face); *Kampe v. Howard Stark Professional Pharmacy, Inc.*, 841 S.W.2d 223, 226 (Mo. Ct. App. 1992) (the pharmacist has a duty to inquire if there are irregularities on the face of the prescription); *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1053 (Wash. 1989) (pharmacists should have a duty to be alert for clear errors and take corrective measures).

161. *Shrake's* admitted in its answer that it owed a duty to *Lasley* to comply with the applicable standard of care. 179 Ariz. at 586, 880 P.2d at 1132. The court then imposed a higher standard of care than that of a reasonably prudent person because pharmacists are health care professionals. *Id.*

162. *Id.* at 588, 880 P.2d at 1134.

163. 143 Ariz. 50, 691 P.2d 1078 (1984), *reconsideration denied* (Jan. 8, 1985).

164. 146 Ariz. 352, 706 P.2d 364 (1985).

165. *Lasley v. Shrake's Country Club Pharmacy*, 179 Ariz. 583, 586, 880 P.2d 1129, 1132 (Ct. App. 1994), *review denied* (Oct. 4, 1994).

166. 143 Ariz. at 51, 691 P.2d at 1079.

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.* at 52, 691 P.2d at 1081.

the standard of care, it becomes a question for the trier of fact; if there is no issue, then the court is correct in granting summary judgment on the matter.<sup>171</sup> The Supreme Court pointed out what it saw as faulty in the lower court's decision: rather than finding a duty and allowing the trier of fact to determine the scope, the lower court condensed the two steps and found the City had no duty to remove the bush.<sup>172</sup> The Supreme Court said this was confusing the concept of duty with the standard of care.<sup>173</sup>

## 2. *Markowitz v. Arizona Parks Board*

A year later, the Supreme Court once again granted review in *Markowitz v. Arizona Parks Board*<sup>174</sup> to examine the theory of duty.<sup>175</sup> David Markowitz and his mother, Ruth, sued after David was injured when he dove into water that was too shallow for diving. The Markowitzes claimed that there should have been warnings against diving posted in that area. The lower courts found there was no duty, for various reasons, and the Arizona Supreme Court once again counseled against confusing duty with details of conduct.<sup>176</sup> The Court states that in Arizona, possessors of land are under an affirmative duty to make the land safe for use by invitees,<sup>177</sup> so the Arizona Parks Board plainly had a duty. Whether that duty meant warning signs should have been posted must be evaluated under the standard of care required to meet the duty.<sup>178</sup>

## 3. Summary

In a negligence action, the question of duty rests on the relationship between two people, and whether the relationship requires one to use care to avoid or prevent injury to the other.<sup>179</sup> If the relationship requires such care, then there is a duty arising out of the relationship.<sup>180</sup> Generally, the court decides the question of duty as a matter of law.<sup>181</sup> The scope of the duty is defined by how much care is required,<sup>182</sup> and how much care is required is determined by the applicable standard of care.<sup>183</sup> Ordinarily, the standard of care is that of the conduct of a reasonably prudent person under the circumstances.<sup>184</sup> If it can be said as a matter of law that the standard of care was not breached, then a court may do so.<sup>185</sup> If there is a genuine issue as to

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171. *Id.*

172. *Id.* at 51, 691 P.2d at 1079.

173. *Id.*

174. 146 Ariz. 352, 706 P.2d 364 (1985).

175. *Id.* at 354, 706 P.2d at 366.

176. *Id.*

177. *Id.* at 355, 706 P.2d at 367.

178. *Id.*

179. *Lasley v. Shrake's Country Club Pharmacy*, 179 Ariz. 583, 585, 880 P.2d 1129, 1131 (Ct. App. 1994), *review denied* (Oct. 4, 1994).

180. *Id.*

181. *Id.*, citing *Alhambra School District v. Maricopa County Superior Court*, 165 Ariz. 38, 41, 796 P.2d 470, 473 (1990).

182. 179 Ariz. at 586, 880 P.2d at 1132.

183. *Id.*

184. *Id.*, citing *Bell v. Maricopa Medical Ctr.*, 157 Ariz. 192, 194, 755 P.2d 1180, 1182 (Ct. App. 1988).

185. 179 Ariz. at 586, 880 P.2d at 1132.

whether the standard of care was met, then the issue must go to the trier of fact.<sup>186</sup>

### B. Duty in *Lasley v. Shrake's Country Club Pharmacy*

The *Lasley* court, in citing *Markowitz* and *Coburn*, was therefore echoing the Arizona Supreme Court's concern that it is not for a trial court to find a duty or no duty to perform a specific act, but rather the act should be evaluated by the trier of fact in relation to the standard of care required. The trial courts for *Lasley* and every other decision that specifically found the pharmacist was under no duty to warn the patient of side effects were overlooking the fact that the pharmacist clearly had a duty of general care to the patient, and the scope of that duty fell under the separate issue of the standard of reasonable care.

Unlike the two courts that would not consider the pharmacy profession's Standards of Practice regarding the issue of duty,<sup>187</sup> the Court of Appeals in *Lasley v. Shrake's Country Club Pharmacy*<sup>188</sup> found the standards to be relevant to the scope of duty. Non-legal sources may not automatically create a legal duty, but they may shape the scope of a legal duty.<sup>189</sup> In dismissing the Standards entirely, the courts were confusing the standard of conduct needed to fulfill a duty (for which the Standards are relevant) with the duty itself.

The Arizona Supreme Court in *Coburn v. City of Tucson*<sup>190</sup> and *Markowitz v. Arizona Parks Board*<sup>191</sup> and the *Lasley* court were understandably reluctant to prescribe a code of conduct. A determination of a duty by looking at specific conduct will lead the court into making a risk-utility analysis before deciding whether it is prudent to find a particular duty.<sup>192</sup> A duty needs to be kept broad and general, so as to give room for flexibility and changing circumstances. The scope of the duty depends on the conduct of a reasonably prudent person under the circumstances. Thus a rule that imposes a duty to behave in a certain manner may be appropriate under one set of circumstances, yet the same behavior could be entirely inappropriate under a changed set of circumstances. In the case of pharmacists and warning patients, there are many times that a patient should have certain information regarding a medication, whether or not the physician or manufacturer requested it. Simple examples include drugs that cause drowsiness or stomach upset, or drugs that make the patient more sensitive to the sun. Therefore, a blanket rule imposing a specific duty, or excepting a specific duty, that is in actuality mandatory or

186. *Id.* at 588, 880 P.2d at 1134.

187. See *Adkins v. Mong*, 425 N.W.2d 151 (Mich. Ct. App. 1988); *Kampe v. Howard Stark Professional Pharmacy, Inc.*, 841 S.W.2d 223 (Mo. Ct. App. 1992).

188. 179 Ariz. 583, 880 P.2d 1129.

189. For example, a plaintiff claiming that a pharmacist did not meet the standard of care would have to establish what the standard is. The Standards of Practice that list the responsibilities of pharmacists may persuade the trier of fact that the defendant pharmacist did not in fact conform with the usual standard for pharmacists.

190. 143 Ariz. 50, 691 P.2d 1078 (1984), *reconsideration denied* (Jan. 8, 1985).

191. 146 Ariz. 352, 706 P.2d 364 (1985).

192. This is exactly what some courts did when they determined that the pharmacist had no duty to warn of side effects. See *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85 (E.D. Pa. 1986) (placing a duty to warn on the pharmacist would lead to more harm than good); *Leesley v. West*, 518 N.E.2d 758 (Ill. App. Ct. 1988) (factors in the determination of a legal duty include the burden to the defendant of guarding against the injury, and the consequences of imposing the burden).

proscribing conduct, does not serve the interest of all patients. Nor will it serve justice to have the courts stepping into the function of the jury in determining whether the defendant met the duty of reasonable care.

#### IV. SCOPE OF THE CASE

##### A. *Effect on future decisions*

This decision is likely to encourage courts to reconsider the concept of duty, and how the court applies it to the facts. The concept of duty as defined in *Lasley* is not limited to pharmacists. One month after the *Lasley* decision, the opinion was cited in another case involving the concept of duty in an unrelated area. In *Maurer v. Cerkvenik-Anderson Travel, Inc.*,<sup>193</sup> the trial court made the same mistake Justice Feldman warns against by holding that a travel agency had no duty to a customer regarding a tour package the customer purchased, and subsequently granting summary judgment on the issue.<sup>194</sup> The Court of Appeals reversed, stating that the travel agency has a duty to act with the care and skill of like agencies,<sup>195</sup> and whether the travel agency fulfilled that duty is an issue that precludes summary judgment.<sup>196</sup> Thus the Arizona Supreme Court's position on confusing duty with the standard of care is likely to be applied not only to the facts which gave rise to it, but to every case in which there is a question of duty in Arizona.<sup>197</sup>

##### B. *New issues raised but not addressed by court*

The *Lasley* court did not address concerns set out by the other jurisdictions that hesitated to hold the pharmacist to a duty to warn. The *Lasley* court did so because the cases themselves were so readily dismissed on the basis that the courts confused duty with standard of conduct.<sup>198</sup> But the issues raised are of valid concern, especially in those jurisdictions where the issues controlled the outcome.<sup>199</sup>

In response to the policy arguments raised by the courts *against* finding a duty to warn, there are arguments *in favor* of the pharmacists providing warnings to the patients. Courts resisted finding a duty so as not to interject the pharmacist between the patient and the physician.<sup>200</sup> However, the medical field has changed drastically, and this argument becomes weak in light of the changes. For starters, few patients have a single doctor who takes care of all

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193. 165 Ariz. Adv. Rep. 51 (Ariz. App. Div. 2 May 17, 1994).

194. *Id.* at 52.

195. *Id.* at 53.

196. *Id.* at 55.

197. This is one important implication of the *Lasley* opinion that is not at all affected by the state and federal law regulating pharmacy.

198. *Lasley v. Shrake's Country Club Pharmacy*, 179 Ariz. 583, 588, 880 P.2d 1134 (Ct. App. 1994), *review denied* (Oct. 4, 1994).

199. See discussion *supra* part II.A.

200. See *Jones v. Irvin*, 602 F. Supp. 399 (S.D. Ill. 1985); *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63 (Ga. Ct. App. 1993); *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991); *Kinney v. Hutchinson*, 449 So.2d 696 (La. Ct. App. 1984); *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987); *McKee v. American Home Prods. Corp.*, 782 P.2d 1045 (Wash. 1989).

their medical needs.<sup>201</sup> There is rarely, then, a single doctor-patient relationship upon which the pharmacist will allegedly encroach. Many patients see several different doctors for their different needs, and nurses, dietitians, therapists, and, of course, pharmacists may also be involved. The different providers may not be aware of concurrent therapies,<sup>202</sup> making the community pharmacist the one professional most likely to be able to know about and assess the drug interactions and contraindications.<sup>203</sup> The relationships between the medical professionals are much more complex than they used to be, and care is generally provided by medical teams, members of which must work together—pharmacists included.<sup>204</sup> Additionally, with the rapid expansion of managed care, a patient may not even see the same doctor for routine care. In the managed-care setting, a patient generally sees whichever doctor is available first.

In response to the argument that the doctor is in the more knowledgeable position, this point is conceded only as to the decision of *which* or *what* drug to use. But as far as *side effects* and *adverse reactions* of particular drugs, and *how the drugs interact* with one another, the pharmacist is likely to be more knowledgeable, and able to convey that information to the patient. The pharmacist has five to six years of training regarding drugs, where the typical doctor has four months.<sup>205</sup> Plus, pharmacists frequently have the computer technology readily available to fortify that information.<sup>206</sup> Physicians may be

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201. Kim J. Sveska, *Pharmacist Liability*, AM. J. HOSP. PHARMACY, July 1993, at 1432.

202. *Id.*

203. Granted, if a patient fills prescriptions at multiple pharmacies, the pharmacist will not be in any better position than the physicians.

204. A 1986 report of the Nuffield Foundation in England said that pharmacists collaborating with physicians in patient care can increase the effectiveness of that care, and reduce costs. David. L. Cowen, *Changing Relationship Between Pharmacists and Physicians*, AM. J. HOSP. PHARMACY, Nov. 1992, at 2719.

205. For pharmacists, a five-year baccalaureate program became a national requirement in 1960, and many schools now offer or require a six-year degree leading to a doctor of pharmacy degree. *Id.* at 2718. In contrast, as recently as 1974, one in six medical schools did not require any course in pharmacology (the study of drugs). *Id.* at 2717. In 1988 the American College of Physicians acknowledged that the pharmacology training for physicians was lacking. *Id.* at 2717–18. Today, it is still possible that doctors have no formal classroom training in pharmacology because accreditation merely requires that the curriculum include the *content* of the discipline traditionally titled pharmacology and therapeutics; the standards for accreditation do not specify how that content should be taught. Liaison Committee on Medical Education, *Standards for Accreditation of Medical Education Programs Leading to the M.D. Degree*, in FUNCTIONS AND STRUCTURE OF A MEDICAL SCHOOL, at 13 (1993).

206. The available pharmacy systems may contain any or all of the following:

*Patient profile*

- Name, address telephone number, date of birth (or age), and gender
- Individual history information, including disease state or states, known allergies and drug reactions, and comprehensive list of medications and relevant devices
- Location for pharmacist comments relevant to the individual's drug therapy
- Prescription and OTC medication profiles
- Medical device profile

*Drug information: complete on-line compendia from approved sources such as:*

- American Hospital Formulary Service
- United States Pharmacopeia

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- American Medical Association Drug Evaluations
  - Peer-reviewed journals

*Therapeutic duplication (taking more than one of the same type of drugs)*

- Screen for therapeutic duplication
- Ability to override warning

*Drug-disease contraindication*

- Disease database to check against prescription and OTC medications listed on the patient profile
- Warns of inconsistent medications based on available diseases
- Ability to override warning

*Drug-drug interactions*

- Screens for drug-drug interactions
- Drug interaction information from a reputable publisher
- Interaction displays significance level
- Interaction trigger level can be set by pharmacy manager
- Ability to override warning

*Drug-OTC interactions*

- OTC data from the patient profile should be compared to the active prescriptions and should display appropriate messages
- Interaction information from a reputable publisher
- Interaction displays significance level
- Interaction trigger level can be set by pharmacy manager
- Ability to override warning

*Incorrect drug dosage*

- Drug dosage monitored and then compared with theoretical usage
- Dosage information from a reputable publisher
- Theoretical dosage can be set by pharmacy manager

*Duration of treatment*

- Use of a “days supplied” field to monitor for early refill and duration of treatment

*Drug-Allergy interactions*

- Allergies entered in the patient profile should warn against any prescription or OTC problem
- Allergy information from a reputable publisher
- Ability to override warning

*Clinical abuse or misuse screening*

- Through the use of warnings regarding duration of treatment, overdose, early refills, etc., clinical abuse or misuse problems should be identified as the prescription is processed

*Underutilization screening*

- Automatic notification of patients with underutilization problems
- The ability to print refill reminder reports

*Pharmacist intervention monitoring*

unable to keep up with the large number and complexity of drugs in addition to their other job responsibilities,<sup>207</sup> where the pharmacist's job is to do exactly that—a job which is made easier with the availability of expansive computer technology.

It is in the patient's best interest to have the pharmacist provide information that helps the patient manage the drugs. One proposal is that the physician performs the risk assessment for the use of a drug, and provides warnings to obtain informed consent. Once the physician has prescribed the drug, the pharmacist follows with information that results in risk management.<sup>208</sup> The doctor, who has the complete medical history and condition of the patient makes the decision on which drug to use.<sup>209</sup> The pharmacist does not need this history and condition to provide information as to side effects on drugs.<sup>210</sup> By providing that information, the pharmacist helps the patient manage potential side effects and adverse reactions to the drugs, which may reduce the risks of drug taking.<sup>211</sup>

The enactment of statutes mandating that pharmacists counsel patients as to side effects and other information, not to mention the advantages of having the pharmacist provide this information, leaves little room for any further successful policy arguments against the provision of this information.

## VI. CONCLUSION

Today, the issue of whether a pharmacist has a duty to warn patients of side effects may be moot. With the passage of regulations requiring pharmacists to provide information on side effects, the new issue is likely to be: how much information is required? This will fall under the issue of standard of care, which for health professionals is "the usual conduct of other members...of the...profession in similar circumstances."<sup>212</sup> To this issue, professional standards of practice will be relevant.

Other jurisdictions are likely to move in the direction of the *Lasley* court, whether or not they rely on the reasoning in *Lasley*. Because of OBRA, and the vast majority of states that have implemented patient counseling

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- Date/time of intervention
  - How much time was spent on the consult or problem
  - Link to the prescription
  - Quantifiable rationale or problem report
  - Include pharmacist recommendations

Renato Cataldo, Jr., *Maximizing Computer Applications*, in OBRA '90: A PRACTICAL GUIDE TO EFFECTING PHARMACEUTICAL CARE, 41, 46 (Bruce R. Canaday, ed., 1994).

207. Sveska, *supra* note 201, at 1432.

208. See David B. Brushwood & Larry M. Simonsmeier, *Drug Information for Patients: Duties of the Manufacturer, Pharmacist, Physician and Hospital*, 7 J. LEGAL MED. 279, at 307 (1986); Sveska, *supra* note 201, at 1432.

209. See Brushwood & Simonsmeier, *supra* note 208, at 307.

210. *Id.*

211. *Id.*

212. *Lasley v. Shrake's Country Club Pharmacy*, 179 Ariz. 583, 586, 880 P.2d 1129, 1132 (Ct. App. 1994), *review denied* (Oct. 4, 1990) (citing *Bell v. Maricopa Medical Ctr.*, 157 Ariz. 192, 194, 755 P.2d 1180, 1182 (Ct. App. 1988)).

requirements, the courts will find it easy to determine the pharmacist has a duty to warn the patient of side effects and adverse reactions.<sup>213</sup>

For more than fifteen years, the pharmacy profession has been advocating the advantages of informing patients about their drugs.<sup>214</sup> Colleges of pharmacy have been emphasizing the need for patient education to get better patient outcomes. Federal regulations have been in place for more than four years, and in Arizona, providing information on side effects has been required for nearly five years. Yet, change has been slow.<sup>215</sup> Pharmacists will need to adapt their habits to ensure that their practices are consistent with the accepted standards of practice, or face legal liability. Perhaps holding pharmacists legally liable for the provision of this information is the catalyst needed.

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213. See *supra* notes 138–51 and accompanying text.

214. See *Standards*, *supra* note 154 at 31. The American Pharmaceutical Association's Code of Ethics also reflects the changes in the profession. The Association has deleted from the Code provisions that deny pharmacists the right to discuss drug action with the patient, and in its place are provisions that encourage the pharmacist to use their knowledge and provide information to patients. Cowen, *supra* note 204, at 2718.

215. According to some pharmacy representatives, even a ten percent compliance rate with OBRA '90 patient counseling requirements may be overstating the actual rate in some parts of the country. Ken Rankin, *FTP Survey Uncovers Counseling Non-Compliance*, DRUG STORE NEWS FOR THE PHARMACIST, Apr. 11, 1994, at 25.