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## NEGLIGENCE LIABILITY'S ROLE IN CHANGING PHARMACOTHERAPY RESPONSIBILITIES

Andrew F. Spillane\*

*Negligence liability has failed to keep up with the changing divisions of labor between physicians and pharmacists. Based on factual assumptions regarding the relative competencies and responsibilities of these health professionals, the courts have shouldered physicians with the greatest treatment responsibility and have accordingly relegated pharmacists to the role of pill counters except in especially serious circumstances. These rules now exist alongside an emerging health care industry standard in which pharmacists command greater expertise of drugs than doctors do and in which doctors have taken on too many duties in light of their own competencies. Many commentators have advocated for greater collaboration between physicians and pharmacists in light of these issues, and such change is coming. To account for these changes and keep malpractice liability current, the courts should do away with many of the doctrinal limits on these professionals' tort duties and instead adopt an overall reasonableness test.*

### INTRODUCTION

Place yourself in the shoes of a parent, a parent with a teenage daughter crippled by depression. Her emotional challenges interfere with her schoolwork and rob her of the ability to enjoy

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her daily life.<sup>1</sup> Worried about your child, you take her to see a psychiatrist. After diagnosing your daughter as suffering a Major Depressive Episode, the psychiatrist prescribes Prozac, a member of the selective serotonin reuptake inhibitor (SSRI) class of antidepressants<sup>2</sup> commonly used as the first medication for adolescent depression patients.<sup>3</sup> After beginning this drug regimen, your daughter's depression continues, unrelentingly. In response, the psychiatrist additionally prescribes Parnate, a monoamine oxidase inhibitor (MAOI) "suited for patients who have failed to respond to the drugs more commonly administered for depression."<sup>4</sup> The psychiatrist writes down a dosage amount for the Parnate but does not tell you when your daughter should begin taking it.

Now envision yourself as a licensed pharmacist. When the parent above tries to obtain the Parnate prescription and a Prozac refill, you realize that the two drugs should never be taken together.<sup>5</sup> According to the *Physician's Desk Reference* (*PDR*) kept at the pharmacy,<sup>6</sup> SSRIs and MAOIs can interact to produce "serious, sometimes fatal, reactions (including hyperthermia,<sup>7</sup> rigidity, myoclonus,<sup>8</sup> autonomic instability<sup>9</sup> with

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1. This narrative is based in part on the DSM-IV's definition of a Major Depressive Episode's essential features. DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 317, 320 (4th ed. 1994) [hereinafter DSM-IV]. The "DSM-IV is a classification of mental disorders that was developed for use in clinical, educational, and research settings." *Id.* at xxiii.

2. PHYSICIAN'S DESK REFERENCE 1941 (64th ed. 2010) [hereinafter PDR]. All references in this Article to the *PDR* point to the most recent edition, published in 2010, unless otherwise specified.

3. Glen R. Elliott & Susan Smiga, *Depression in the Child and Adolescent*, 50 PEDIATRIC CLINICS N. AM. 1093, 1101 (2006) ("At present, an SSRI generally is the first-line pharmaceutical agent for treating depression in youth.").

4. PDR, *supra* note 2, at 1584; Michael Van Ameringen et al., *Pharmacotherapy for Social Anxiety Disorder: An Update*, 46 ISR. J. PSYCHIATRY & RELATED SCI. 53, 55 (2009) ("[D]ue to dietary restrictions[] and risk of serious adverse events associated with the use of these agents . . . [MAOIs] are now reserved for those non-responsive to other drug treatments.").

5. PDR, *supra* note 2, at 1584.

6. At least one anecdotal account of prescription errors involves pharmacists consulting this reference. Dennis Miller, *Pharmacists' Errors*, in DRUG INJURY: LIABILITY, ANALYSIS AND PREVENTION 223, 238 (James T. O'Donnell ed., 2d ed. 2005).

7. Hyperthermia denotes an "extremely high fever," sometimes accompanied by muscle rigidity in its malignant form. STEDMAN'S MEDICAL DICTIONARY 926, 928

possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma)."<sup>10</sup>

As a pharmacist faced with this severe danger, what do you do? Like many in your profession, you are overwhelmed with the number of prescriptions that need to be filled, leaving little time to call doctors and research drug interactions.<sup>11</sup> Furthermore, the psychiatrist has ostensibly already exercised professional judgment in writing the prescription,<sup>12</sup> and you lack the voluminous patient information that the treating physician had available.<sup>13</sup> Yet, tapping into your pharmacological<sup>14</sup>

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(28th ed. 2006).

8. Myoclonus is defined as "[o]ne or a series of shocklike contractions of a group of muscles, of variable regularity, synchrony, and symmetry." *Id.* at 1272.

9. Autonomic instability occurs when there are irregularities in the functioning of the autonomic nervous system, which controls the involuntary and often vital functions of the body. *Id.* at 186 (defining autonomic as "[r]elating to the autonomic nervous system"); *accord id.* at 1924 (listing a number of functions controlled by the autonomic nervous system).

10. PDR, *supra* note 2, at 1584. That these drugs can concurrently cause death is also recognized in medical journals. Elliott & Smiga, *supra* note 3, at 1102 ("[A]n MAOI potentially can interact with any other class of antidepressant to cause severe adverse effects that include marked hypertension and death."); Charles M. Beasley, Jr. et al., *Possible Monoamine Oxidase Inhibitor-Serotonin Uptake Inhibitor Interaction: Fluoxetine Clinical Data and Preclinical Findings*, 13 J. CLINICAL PSYCHOPHARMACOLOGY 312, 316 (1993) ("The seven deaths [reported in the journal article] occurred when the MAOI was added to or started after an established regimen of fluoxetine [the generic name for Prozac.]); John P. Feighner et al., *Adverse Consequences of Fluoxetine-MAOI Combination Therapy*, 51 J. CLINICAL PSYCHIATRY 222, 224 (1990) ("Death has been reported after starting tranylcypromine [the generic name for Parnate] treatment shortly after fluoxetine treatment was discontinued.").

11. Miller, *supra* note 6, at 244; Jennifer L. Smith, Comment, *Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists' Expanding Liability and Duty to Warn*, 2 HOUS. J. HEALTH L. & POL'Y 187, 231-32 (2002).

12. A fear of pharmacists "second-guessing" a treating physician's judgment has already justified court decisions restricting pharmacists' duties to warn. Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1386 (Pa. 1991); Brian L. Porto, Annotation, *Civil Liability of Pharmacists or Druggists for Failure to Warn of Potential Drug Interactions in Use of Prescription Drug*, 79 A.L.R. 5th 409 (2000). Courts have also phrased this problem as pharmacists interfering with the physician-patient relationship. E.g. Eldridge v. Eli Lilly & Co., 485 N.E.2d 551, 553 (Ill. App. Ct. 1985). That said, one pharmacist stated that physicians tend to be cooperative when he calls them about possible errors on a prescription. Interviews with Chuck Becker, licensed pharmacist, Walgreens, in Milwaukee, Wis. (2010).

13. McKee v. Am. Home Prods. Corp., 782 P.2d 1045, 1050-51 (Wash. 1989).

education and experience,<sup>15</sup> you were able to pick out a potentially fatal error. The psychiatrist may even be aware that Prozac and Parnate should be staggered at least five weeks apart;<sup>16</sup> she just may have absentmindedly forgotten to note as much on the prescription. Last but not least, you have the chance to prevent serious injury to this teenager. Before she takes these medications, your chance may be the last.<sup>17</sup>

Perhaps this situation presents easy answers. The serious risks presented in this scenario clearly outweigh the minor and transitory impediments to correcting the error. But the courts analyzing pharmacist negligence<sup>18</sup> have not uniformly articulated how pharmacists and physicians should react to, and prevent, these errors. According to some courts, pharmacists may not have a duty to warn physicians of errors on prescriptions,<sup>19</sup> their only clear responsibility being to dispense prescribed medications as ordered by the treating physicians without questioning the physician's judgment.<sup>20</sup> Other courts<sup>21</sup>

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14. Pharmacology is defined as "[t]he science concerned with drugs, their sources, appearance, chemistry, actions, and uses." *STEDMAN'S MEDICAL DICTIONARY*, *supra* note 7, at 1473.

15. See discussion *infra* p. 459–88.

16. PDR, *supra* note 2, at 1584; DAVID S. TATRO, DRUG INTERACTION FACTS 1508 (2010); ARNOLD W. KARIG & EDWARD A. HARTSHORN, COUNSELING PATIENTS ON THEIR MEDICATIONS: ONE OF THE PRINCIPLE RESPONSIBILITIES OF THE HEALTH CARE PRACTITIONER 157 (1991).

17. David B. Brushwood, *The Challenges of Pharmacogenomics for Pharmacy Education, Practice, and Regulation*, in PHARMACOGENOMICS: SOCIAL, ETHICAL, AND CLINICAL DIMENSIONS 207, 212 (Mark A. Rothstein ed., 2003) ("[P]harmacists are the final professional risk evaluators in a long chain of careful decisions about risk that precede dispensing of a medication to a patient.").

18. Though the pharmacist liability also can be considered under the rubric of strict liability, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (1998), and breach of warranty, U.C.C. §§ 2-313, 2-314, 2-315 (2005), these theories are beyond the scope of this Article.

19. *E.g.* Johnson v. Walgreen Co., 675 So. 2d 1036, 1037 (Fla. Dist. Ct. App. 1996); *Kampe v. Howard Stark Prof'l Pharmacy, Inc.*, 841 S.W.2d 223, 226 (Mo. Ct. App. 1992), *overruled by* *Horner v. Spalitto*, 1 S.W.3d 519, 522 (Mo. Ct. App. 1999); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 387–88 (Mich. Ct. App. 1987).

20. 2 FRANK C. WOODSIDE, DRUG PRODUCT LIABILITY § 13.03[g][i] (2010); 28 C.J.S. *Drugs and Narcotics* § 108 (2010); 25 AM. JUR. 2D *Drugs and Controlled Substances* § 247 (2010); DAN B. DOBBS, THE LAW OF TORTS 679–80 (2000) (citing David J. Marchitelli, Annotation, *Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User*, 44 A.L.R.5th 393 (1996)).

21. *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1130 (Ariz.

and commentators<sup>22</sup> have advocated for duties beyond the minimal clerical functions of pharmacy practice. But most prevailing legal duties, including the broader ones, outline specific affirmative acts a pharmacist can perform to avoid liability, such as accurately filling and dispensing prescriptions<sup>23</sup> and guarding against only known or obvious errors.<sup>24</sup> Physicians' pharmacotherapy decisions, on the other hand, are measured by the general professional and reasonableness standards, normally without the safe harbors protecting pharmacist decision-making.<sup>25</sup> As a part of an entire system of liability, these doctrines have shouldered doctors with the primary responsibility for medication decisions,<sup>26</sup> with pharmacists merely following orders.<sup>27</sup>

Tort law should more holistically examine the responsibilities of physicians and pharmacists, including when they collaborate, to prevent erroneous prescriptions from ever reaching patients. To accomplish this goal, the physician-pharmacist relationship should be measured by a basic, overall reasonableness test. This test would avoid the moral hazards created by this smattering of duties and allow legal doctrines to keep up with changing patient-care management norms.

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Ct. App. 1994); *Dooley v. Everett*, 805 S.W.2d 380, 386 (Tenn. Ct. App. 1990).

22. *Smith, supra* note 11, at 189; Michele L. Hornish, *Just What the Doctor Ordered—Or Was It?: Missouri Pharmacists' Duty of Care in the 21st Century*, 65 MO. L. REV. 1075, 1076 (2000); Edward Casmere, *Comment, Rx for Liability: Advocating the Elimination of the Pharmacist's No Duty to Warn Rule*, 33 J. MARSHALL L. REV. 425, 459-62 (2000); Lauren Fleischer, *Note, From Pill-Counting to Patient Care: Pharmacists' Standard of Care in Negligence Law*, 68 FORDHAM L. REV. 165, 166-67 (1999). The cited articles and comments focus primarily on the pharmacy side of the liability equation. This Article seeks to examine physician and pharmacist liability together, demonstrating why substantive, and substantial, liability reform is necessary to recalibrate physicians' and pharmacists' duties of care.

23. *E.g. Adkins v. Mong*, 425 N.W.2d 151, 152 (Mich. Ct. App. 1988).

24. *E.g. Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1129 (Ill. 2002); *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1063 (Wash. 1989).

25. Some states have adopted practice standards that allow physicians to state compliance with the standards as a defense to a malpractice suit. *DOBBS, supra* note 20, at 642-47. However, most states have not adopted these practice standards. *Id.* at 646.

26. *See McKee*, 782 P.2d at 1050-51.

27. *See, e.g., Horner v. Spalitto*, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999).

Among today's developments in patient-care management are pharmacists' high level of clinical expertise,<sup>28</sup> their role as pharmacological experts supplementing physicians' medical knowledge,<sup>29</sup> and the pharmacist-physician relationship's continuing evolution.<sup>30</sup> Like other reasonableness tests, its contextual focus ensures that the courts can keep up with the health care field's shifting divisions of labor among various professionals.<sup>31</sup> With effective advocacy from the parties and the assistance of competent expert testimony, injured patients and the courts can scrutinize changing pharmacist-physician relationship paradigms to ensure the ultimate end for which physicians and pharmacists alike should strive—the public health.

Part I will begin with a brief history of how the courts have treated physician and pharmacist liability for medication errors. Part II will critique these duties in light of emerging trends in

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28. Michael R. Cohen & Judy L. Smetzer, *One Organization's Advocacy Effort for Error Prevention: The Institute for Safe Medication Practices*, in THE PATIENT SAFETY HANDBOOK 645, 657 (Barbara J. Youngberg & Martin J. Hatlie eds., 2004); Gregory J. Higby, *Evolution of Pharmacy*, in REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 7, 14–15 (Daniel Limmer et al., eds., 20th ed. 2000) (highlighting changes from the American Pharmacists' Association's Code of Ethics from 1952, where deference to physicians was the preferred course, to 1969, where that rule was revised to suggest that a pharmacist "should render to each patient the full measure of his ability as an essential health practitioner"); Smith, *supra* note 11, at 188 (citing David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 DRAKE L. REV. 439, 457–58 (1996)).

29. GEORGE D. POZGAR, LEGAL ASPECTS OF HEALTH CARE ADMINISTRATION 274 (9th ed. 2004) ("Because of the immense variety and complexity of medications now available, it is impossible for nurses or doctors to keep up with all of the information required for safe medication use. The pharmacist has become an essential resource in modern hospital practice."); Brushwood, *supra* note 17, at 207.

30. See Randal P. McDonough & William R. Doucette, *Dynamics of Pharmaceutical Care: Developing Collaborative Working Relationships Between Pharmacists and Physicians*, 41 J. AM. PHARMACISTS ASS'N (2001), available at <http://www.medscape.com/viewarticle/406728>.

31. Valerie DeBenedette, *Pharmacy Education: Change is the Only Constant*, DRUG TOPICS (Mar. 19, 2007), <http://drugtopics.modernmedicine.com/drugtopics/Pharmacy+News/Pharmacy-education-Change-is-the-only-constant/ArticleStandard/Article/detail/411524>

The move to a Pharm.D. "is recognition that the dispensing role is not going to be the only role that we contribute to health care in the long term," said Marilyn K. Speedie, Ph.D., dean and professor at University of Minnesota College of Pharmacy and president of AACP. "It is a major paradigm shift."

how physicians and pharmacists divide their roles in providing drug therapy. Part III will propose a duty to exercise reasonable care to ensure that the doctor determines that a chosen drug therapy option will not severely harm a patient, providing justifications based on new paradigms in the pharmacist-physician relationship and assuring injured patients, judges, and juries a meaningful role to examine these changes for their reasonableness.

### LIABILITY RULES GOVERNING PHARMACEUTICAL TREATMENT AND COUNSELING

Many courts begin their health care provider liability analyses with a concept familiar to students of common law negligence: the general duty of care.<sup>32</sup> The courts' first-level statements of this duty are many and varied: some refer to pharmacists and physicians exercising ordinary care;<sup>33</sup> others speak of reasonable care;<sup>34</sup> some cases impose a duty to act with the highest degree of care;<sup>35</sup> and other courts hold doctors and pharmacists to a general professional standard.<sup>36</sup>

However the courts choose to word these duties, most jurisdictions hold that whether a health care provider owes

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32. 3 J.D. LEE & BARRY A. LINDAHL, *MODERN TORT LAW: LIABILITY AND LITIGATION* § 25:117 (2d ed. 2002).

33. *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1125, 1129–30 (Ill. 2002); *Taughner v. Ling*, 187 N.E. 19, 21 (Ohio 1933); *Tremblay v. Kimball*, 77 A. 405, 407 (Me. 1910).

34. *Downing v. Hyland Pharmacy*, 194 P.3d 944, 948 (Utah 2008); *Nowatske v. Osterloh*, 543 N.W.2d 265, 269 (Wis. 1996).

35. *Peters v. Johnson*, 41 S.E. 190, 191 (W. Va. 1902) (quoting *Howes v. Rose*, 42 N.E. 303 (Ind. Ct. App. 1895) (“Apothecaries, druggists and all persons engaged in manufacturing, compounding or vending drugs, poisons, or medicines, are required to be extraordinarily skillful, and to use the highest degree of care known to practical men to prevent injury from the use of such articles and compounds.”)). See also *Krueger v. Knutson*, 111 N.W.2d 526, 532 (Minn. 1961) (“[R]egistered pharmacists selling drugs must exercise the highest degree of caution . . . .”); *Fuhs v. Barber*, 36 P.2d 962, 963 (Kan. 1934) (“[T]he general rule is that [pharmacists] are required to use great care in the sales made.”).

36. *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1132 (Ariz. Ct. App. 1994); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 434 (Tenn. 1994) (“Pharmacists have a duty to exercise the standard of care required of the pharmacy profession in the same or similar communities.”).



patients a specific duty in the first place presents a question of law.<sup>37</sup> When giving shape to medical malpractice liability, the courts tend to hold doctors to a general standard of care, whether measured against the physician-defendants' professional community standards or an independent objective reasonableness analysis.<sup>38</sup> By contrast, a solid majority of courts have imposed doctrinal limits on pharmacists' duties of care.<sup>39</sup> Their boundaries become apparent particularly when patients sue pharmacists for their failure to warn those patients or their prescribing physicians about drug effects or to correct errors on prescriptions. The following sections will examine this multitude of liability regimes.

#### *PHYSICIANS' DUTIES: LEARNED PROFESSIONALS WITH PRESCRIPTION PADS*

Tort law shoulders physicians with myriad responsibilities. Though the prevailing standard of care in most jurisdictions was once consistent with the defendant-physician's medical community,<sup>40</sup> some courts have either explicitly adopted a different reasonableness standard<sup>41</sup> or have allowed objective reasonableness calculations to creep into the professional standard.<sup>42</sup> Beyond general errors in judgment, physicians can also face medical malpractice liability if they fail to secure patients' informed consent.<sup>43</sup>

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37. E.g. *Wiegert v. Goldberg*, 676 N.W.2d 522, 524 (Wis. Ct. App. 2004); *Happel*, 766 N.E.2d at 1123.

38. See discussion *supra* p. 457, n.25.

39. *Id.*

40. Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 204 (2000) ("[F]ewer than half of the states clearly endorse a custom-based standard of care. Even in these states, the custom-based standard of care often is not enforced unless the plaintiff directly challenges an undisputed custom.").

41. *Id.* at 174–75 (counting the jurisdictions adopting the reasonableness test).

42. *DOBBS*, *supra* note 20, at 633 n.22 (citing *Starcher v. Byrne*, 687 So. 2d 737, 740 (Miss. 1997)); *Peters*, *supra* note 40, at 187–88.

43. Leonard J. Nelson III, *Informed Consent – Duty to Warn or Inform*, in 4 LOUSELL & WILLIAMS, *MEDICAL MALPRACTICE* § 22.04[3][a] (2010) ("A physician may be held liable under the doctrine of informed consent 'regardless of whether the injuries were the consequence of negligence or otherwise.'" (quoting *Housh v.*

*Professional Standards*

In many jurisdictions, doctors must conform their conduct to the standards prevailing in their medical professional community.<sup>44</sup> As such, as long as other doctors within the relevant geographic area would have acted as the defendant-physician did, notwithstanding the suboptimal outcomes that physician's choice of treatment produced,<sup>45</sup> that physician would not have committed malpractice.<sup>46</sup>

These general duties apply to doctors' pharmacotherapeutic decisions.<sup>47</sup> The details of duty-breach in each case are generally left to the fact-finder. That said, a few trends have emerged in determining what standard of care applies in a given case. A doctor must weigh different medications' costs and benefits, such as the potential for adverse effects and the extent of the patient's illness or condition requiring drug therapy.<sup>48</sup>

Sometimes, the errors can be facially obvious. For example, in *Rotan v. Greenbaum*, a patient's estate sued a physician that prescribed an antibiotic to treat mumps, a viral infection.<sup>49</sup> Fifteen minutes after the patient took the penicillin, the patient suffered anaphylactic shock and died.<sup>50</sup> At trial, the defendant-physician admitted that prescribing penicillin for mumps only would not qualify as "good practice" in the District of

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Morris, 818 S.W.2d 39, 42 (Tenn. Ct. App. 1991)).

44. DOBBS, *supra* note 20, at 631–32; see WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS 162 (4th ed. 1971) (defining the professional standard to require that the defendant "have the skill and learning commonly possessed by members of the profession in good standing").

45. DOBBS, *supra* note 20, at 633–34.

46. *Id.* at 633 ("[T]he professional standard asks the trier only to determine whether the defendant's conduct conformed to the medical standard or medical custom in the relevant community.").

47. In fact, most medical malpractice actions claim negligence arising from medication errors. JACK SCHRODER, IDENTIFYING MEDICAL MALPRACTICE 83 (1990). A study conducted in 1992 demonstrated that medication errors accounted for fifty percent of medical malpractice lawsuits. RICHARD M. PATTERSON, HARNEY'S MEDICAL MALPRACTICE 451 (4th ed. 1999).

48. 2 WOODSIDE, *supra* note 20, § 11.04[2].

49. *Rotan v. Greenbaum*, 273 F.2d 830, 830–32 (D.C. Cir. 1959).

50. *Id.* at 831.

Columbia.<sup>51</sup> A fact issue remained whether the physician prescribed the penicillin solely for the patient's mumps or also for a throat infection,<sup>52</sup> and so the U.S. Court of Appeals for the D.C. Circuit remanded the case for a new trial.<sup>53</sup>

Sometimes, determining which drug is more appropriate for a particular patient can be subject to disagreement in the medical community. Despite such differences of opinion, doctors are entitled to choose one school of thought over another, and the standard practice within those schools measures member-physicians' care.<sup>54</sup> In *Lowry v. Henry Mayo Newhall Memorial Hospital*, a physician responded to a Code Blue alert that a patient was suffering from cardiac arrest after an automobile accident.<sup>55</sup> The physician claimed that he responded immediately to the alert, but his medication of choice, Atropine, differed from that recommended by the American Heart Association, Epinephrine.<sup>56</sup> The California Court of Appeal upheld the trial court's summary judgment in favor of the physician because the physician acted in good faith when he deviated from the American Heart Association's guidelines.<sup>57</sup>

### *Reasonableness Standards*

A minority of states require physicians to exercise their medical skill and judgment in an objectively reasonable manner, notwithstanding whether the practices and procedures they choose are accepted in their professional communities.<sup>58</sup>

Wisconsin is one member of this minority. In *Nowatske v. Osterloh*, the Wisconsin Supreme Court held,

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51. *Id.*  
52. *Id.*  
53. *Id.* at 832.  
54. PROSSER & KEETON ON THE LAW OF TORTS 187 (W. Page Keeton et al. eds., 5th ed. 1984).  
55. *Lowry v. Henry Mayo Newhall Memorial Hosp.*, 185 Cal. App. 3d 188, 191 (1986).  
56. *Id.*  
57. *Id.* at 196.  
58. Peters, *supra* note 40, at 174-75 (noting that twelve states have rejected the professional standard).

The standard of care applicable to physicians in this state can not be conclusively established either by a reflection of what the majority of practitioners do or by a sum of the customs which those practitioners follow. It must instead be established by a determination of what it is reasonable to expect of a professional given the state of medical knowledge at the time of the treatment in issue.<sup>59</sup>

In that case, a patient sued his physician for causing him permanent blindness.<sup>60</sup> The patient sought a physician to treat his blurred vision.<sup>61</sup> After diagnosing him with a detached retina, the physician performed a common procedure to reattach it.<sup>62</sup> Before, during, and after the procedure, the physician only checked the patient's intraocular pressure with his finger and without a tonometer.<sup>63</sup> This failure made up part of the patient's theory of his negligence suit against this physician.<sup>64</sup> Nonetheless, the trial court ruled in the physician's favor.<sup>65</sup>

The Wisconsin Supreme Court remanded the case to the court of appeals with instructions to apply a reasonableness test in lieu of a professional standard.<sup>66</sup> The test has two basic conceptual components, though it assesses physicians' care under the same general rubric of reasonable prudence. First, the court flatly rejected that professional custom could itself be determinative.<sup>67</sup> Though the court admitted that in many cases, what is reasonable may be equivalent to what is professionally accepted, there still is a risk that the medical profession may, "through its 'laxness or carelessness,' . . . 'establish a local standard of care that was below that which the law requires.'"<sup>68</sup>

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59. *Nowatske v. Osterloh*, 543 N.W.2d 265, 272 (Wis. 1996), *overruled on other grounds* by *Nommensen v. Am. Continental Ins. Co.*, 629 N.W.2d 301 (Wis. 2001).

60. *Nowatske*, 543 N.W.2d at 268.

61. *Id.* at 267.

62. *Id.*

63. *Id.*

64. *Id.* at 267-68.

65. *Id.* at 268.

66. *Id.* at 276-77.

67. *Id.* at 271-72.

68. *Id.* at 271 (quoting *Shier v. Freedman*, 206 N.W.2d 166, 171 (Wis. 1973); *Pederson v. Dumouchel*, 431 P.2d 973, 977 (Wash. 1967)).

Instead of allowing doctors to become complacent in their community's practices, physicians must keep abreast of developments in medical knowledge and technology. In the Wisconsin Supreme Court's words,

[a]n emphasis on reasonable rather than customary practices... [e]nsures that custom will not shelter physicians who fail to adopt advances in their respective fields and who consequently fail to conform to the standard of care which both the profession and its patients have a right to expect.<sup>69</sup>

Wisconsin has applied this rule to cases involving adverse drug reactions arising from negligently ordered prescriptions. In *Weigert v. Goldberg*, a patient sought medical treatment for an inflammatory/autoimmune disorder whose symptoms returned.<sup>70</sup> The physician prescribed Temazepam to relieve her symptoms,<sup>71</sup> but the drug caused the patient's mental health to deteriorate.<sup>72</sup> It eventually subjected her to a manic episode, which drove her to chase her husband's car, remove her clothing, and cut portions of her body with shards of glass.<sup>73</sup> After the patient was admitted to another hospital, a psychiatrist stated that the Temazepam caused her manic episode,<sup>74</sup> and the patient subsequently sued her prescribing physician for medical malpractice.<sup>75</sup> The Wisconsin Court of Appeals dismissed the case as time-barred,<sup>76</sup> but the court did recognize that the physician had a duty to monitor his patient while she was on the Temazepam regimen.<sup>77</sup> This duty, the court notes, is part of the negligence analysis applied in all cases,<sup>78</sup> with no differences taking hold solely because the case involved potential medical

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69. *Nowatske*, 543 N.W.2d at 272.

70. *Wiegert v. Goldberg*, 676 N.W.2d 522, 523 (Wis. Ct. App. 2004).

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.* at 524.

76. *Id.* at 527.

77. *Id.*

78. *Id.* at 524 (citing *Paul v. Skemp*, 625 N.W.2d 860, 865 (Wis. 2001)).

malpractice.<sup>79</sup>

*Prudent-Patient Standard in Informed Consent Cases*

A physician may also be liable for malpractice should the physician fail to adequately warn a patient about the dangers attendant to the universe of possible pharmacotherapeutic plans.<sup>80</sup>

Most jurisdictions analyze this duty to disclose with a professional standard, incorporating the general professional standard used in other malpractice cases.<sup>81</sup> This approach seeks to protect the physician's judgment as a professional, such that only deviations from the community practice will create liability.<sup>82</sup> As a further justification, one court expressed the fear that moving away from the professional standard would encourage physicians to disclose every possible risk attending a treatment or procedure, which would waste valuable time and even scare a patient away from an objectively reasonable course of action.<sup>83</sup>

By contrast, a minority of courts apply a prudent-patient standard, which "sets out a general standard of reasonableness under which the physician's duty to disclose is determined by the informational needs of a prudent patient in like circumstances."<sup>84</sup> One *raison d'être* for this rule parallels the

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79. *Wiegert*, 676 N.W.2d at 524 ("A claim for medical malpractice, like any claim for negligence, requires four elements . . .").

80. 1 STEVEN E. PEGALIS, *AMERICAN LAW OF MEDICAL MALPRACTICE* 3D § 4:1 (2010).

81. Leonard J. Nelson III, *Scope of Disclosure*, in 4 LOUISELL & WILLIAMS, *MEDICAL MALPRACTICE* § 22.05[2] (2010).

The professional standard rule has been adopted . . . in a majority of states, including Alabama, Arizona, Arkansas, Colorado, Connecticut, Idaho, Illinois, Indiana, Maine, Michigan, Missouri, Nevada, New York, North Carolina, Texas, Virginia, and Wyoming. The professional standard has been adopted by statute in other states, including Florida, Idaho, Kentucky, Maine, and Nebraska.

*Id.*

82. *Id.* (quoting *Natanson v Kline*, 350 P.2d 1093, 1106 (Kan. 1960)).

83. *Id.*

84. *Id.* § 22.05[3].

Wisconsin Supreme Court's justification for a reasonableness standard in *Nowatske*: "Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."<sup>85</sup> Moreover, the California Supreme Court in *Cobbs v. Grant* applied the prudent-patient standard to tether physicians' standard of care to patients' needs.<sup>86</sup>

In a case before the U.S. Court of Appeals for the Ninth Circuit applying California's prudent-patient standard, *Hutchinson v. United States*, an asthmatic patient filed a medical malpractice suit against the United States under the Federal Tort Claims Act (FTCA).<sup>87</sup> When the patient visited the United States Public Health Service Hospital to seek treatment for flu-like symptoms, a physician diagnosed the patient as suffering an asthma attack.<sup>88</sup> Though the patient's drug regimen started more conservatively, the physician began prescribing higher amounts of Prednisone.<sup>89</sup> This drug had the capability to produce severe side effects, "including aseptic necrosis of the femoral heads (collapse of the ball and socket hip joint)."<sup>90</sup> The physician did not mention this possibility, and this severe risk

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85. *Canterbury v. Spence*, 464 F.2d 772, 784 (D.C. Cir. 1972).

86. *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972). See also Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 219 (1985) ("Judges and legal scholars have long asserted the importance of patient autonomy in medical decisionmaking.").

87. *Hutchinson v. United States*, 915 F.2d 560, 561 (9th Cir. 1990). The FTCA currently provides:

[T]he district courts . . . shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages[] . . . for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

28 U.S.C. § 1346(b)(1) (2006). Given the alleged malpractice in *Hutchinson* took place in San Francisco, the district court and the Ninth Circuit properly applied California law in this case.

88. *Hutchinson*, 915 F.2d at 561.

89. *Id.*

90. *Id.*

became a reality.<sup>91</sup> The patient's aseptic necrosis required numerous surgical operations on his hip, and his condition threatened him with lifetime confinement to a wheelchair.<sup>92</sup> The patient countered with an FTCA lawsuit against the United States.<sup>93</sup> The United States initially received summary judgment in its favor, with the district court noting that evidence suggested that physicians typically prescribe Prednisone for asthma. In effect, the district court premised its decision on the professional standard, and the Ninth Circuit thought as much when the patient appealed the court's summary judgment.<sup>94</sup> Noting *Cobbs v. Grant*,<sup>95</sup> the Ninth Circuit sent the case back to the district court to apply California's prudent-patient standard.<sup>96</sup>

On remand, the district court ruled against the patient again, this time stating that the patient produced insufficient evidence to show that a reasonably prudent asthmatic patient would have changed his or her decision to take the drug.<sup>97</sup> The Ninth Circuit reversed and remanded this judgment as well for being a clearly erroneous factual finding.<sup>98</sup> This error rested on two grounds. First, the Ninth Circuit believed that the district court mistakenly assumed that Prednisone's risks had different probabilities of materializing in asthmatic patients from those not suffering from asthma.<sup>99</sup> Second, the Ninth Circuit compared Prednisone's risk of adverse events and therapeutic value with the costs and benefits of the patient's prior conservative treatment plan, deciding that a patient in the plaintiff's position would not have consented to taking Prednisone when the conservative treatment plan could produce

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91. *Id.*

92. *Id.*

93. *Id.*

94. *Hutchinson v. United States*, 841 F.2d 966, 967-68 (9th Cir. 1988).

95. *Id.* at 967 (citing *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972)).

96. *Hutchinson*, 841 F.2d at 967-68.

97. *Hutchinson*, 915 F.2d at 561.

98. *Id.* at 563.

99. *Id.* at 562.



mostly the same therapeutic effects without the severe risks.<sup>100</sup>

*Manufacturers' Instructions and Warnings*

Whether the courts scrutinize physicians' drug therapy choices and orders under the professional community, reasonableness, or prudent-patient rubrics, many also look to manufacturers' labeling and package inserts as part of their negligence inquiry. The courts split, however, on the extent of these instructions' evidentiary impact.<sup>101</sup>

Some courts have held that deviations from manufacturer warnings and recommendations are *prima facie* negligent.<sup>102</sup> For example, in *Mulder v. Parke Davis & Co.*, the trustee for the heirs of a deceased patient sued the physician that prescribed chloromycetin, the antibiotic that caused the patient's death.<sup>103</sup> This patient sought the doctor to treat an ear infection.<sup>104</sup> The physician diagnosed the patient's problem as "acute purulent otitis media" and as such prescribed chloromycetin.<sup>105</sup> Though the patient's condition worsened, the physician continued to prescribe this medication, ignoring the manufacturer's warning that anemia could result.<sup>106</sup> The accumulation of these medications ultimately caused the patient to become severely anemic and develop bone marrow depression.<sup>107</sup> These conditions ultimately caused her death.<sup>108</sup>

The Minnesota Supreme Court reversed the trial and appellate courts' findings that the physician did not act negligently.<sup>109</sup> This disposition resulted from the rule the court

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100. *Id.* at 562–63.

101. David Carl Minneman, Annotation, *Medical Malpractice: Drug Manufacturer's Package Insert Recommendations as Evidence of Standard of Care*, 82 A.L.R.4th 166, § 2a (2010).

102. *Id.*

103. *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 884 (Minn. 1970).

104. *Id.*

105. *Id.*

106. *Id.* at 884–85.

107. *Id.* at 884.

108. *Id.*

109. *Id.* at 887.

pronounced: “[w]here the dosage is prescribed by the manufacturer, testimony of the physician’s failure to adhere to its recommendation is sufficient evidence to require him to explain the reason for his deviation.”<sup>110</sup> Such reasons can be shown in some cases,<sup>111</sup> but the *Mulder* court suggested that ignoring manufacturers’ warnings can at least raise an inference of negligence.

Other courts accord manufacturers’ warnings some probative value but not controlling weight.<sup>112</sup> In a New Jersey case, *Canesi ex rel. Canesi v. Wilson*, a patient sued her physicians and an unnamed pharmaceutical manufacturer for wrongful birth of a child with a limb reduction birth defect.<sup>113</sup> The defect arose from the woman ingesting Provera, a drug that the *PDR* warned can cause congenital anomalies in fetuses.<sup>114</sup> The case does not disclose whether its facts established that the physicians knew about these warnings,<sup>115</sup> but both physicians the woman saw told her not to worry about whether the drugs would have adverse effects on the children she carried.<sup>116</sup> As the court described the results, the woman’s “[p]regnancy was not without incident.”<sup>117</sup> One child died,<sup>118</sup> and the other twin suffered from congenital impairment of bilateral limb reduction.<sup>119</sup>

When the New Jersey Supreme Court heard this case, the plaintiffs argued “that the *PDR*, which contained specific warnings that Provera could cause bilateral limb reduction, the retention of a defective ovum, and general genetic anomalies, constituted evidence of the standard of care governing the

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110. *Id.*

111. 3 LEE & LINDAHL, *supra* note 32, § 25:17.

112. Minneman, *supra* note 101, § 2a.

113. *Canesi ex rel. Canesi v. Wilson*, 730 A.2d 805, 810 (N.J. 1999).

114. *Id.* at 809.

115. *See id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.* at 810.

doctors' duty of disclosure."<sup>120</sup> That said, because "PDR warnings are written 'for many reasons including compliance with FDA requirements, advertisement, the provision of useful information to physicians, and an attempt to limit the manufacturer's liability[,]'"<sup>121</sup> the Supreme Court refused to recognize that the PDR by itself could establish the standard of care.<sup>122</sup>

### PHARMACISTS' DUTIES: PILL-COUNTERS AND CLINICAL ADVISORS

In assessing the general duty of care owed by pharmacists, courts often begin by stating that the dangers attending pharmacy practice should enlighten the applicable standard of care.<sup>123</sup> The most obvious of these dangers lies in pharmacists' stock in trade: the medications they dispense. Nearly any pharmaceutical can be dangerous.<sup>124</sup> Medical practice manuals are replete with warnings of drugs being potentially fatal in themselves<sup>125</sup> or taken simultaneously with other medications.<sup>126</sup> In fact, some drugs that effectively and safely treat typical patients may produce idiosyncratic but serious side effects in others.<sup>127</sup> Furthermore, many pharmacists operate on a hectic and demanding schedule, especially in the retail setting.<sup>128</sup> The

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120. *Id.* at 816.

121. *Id.* (quoting *Morlino v. Medical Ctr. of Ocean County*, 706 A.2d 721 (N.J. 1998)) (italics added).

122. *Id.*

123. 3 LEE & LINDAHL, *supra* note 32, § 25:117.

124. 3 PEGALIS, *supra* note 80, § 17:2 (citing Robert B. Diasio, *Principles of Drug Therapy*, in CECIL TEXTBOOK OF MEDICINE 124, 132 (Lee Goldman & Dennis Ausiello eds., 22d ed. 2004)); SCHRODER, *supra* note 47, at 405.

125. For example, a severe overdose of hydrocodone, one of the active ingredients in the analgesic Vicodin, can produce "apnea, circulatory collapse, cardiac arrest, and death . . ." PDR, *supra* note 2, at 561; see also Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients*, 279 JAMA 1200, 1203 (1998) ("Fatal ADRs [short for 'adverse drug reactions'] appear to be between the fourth and sixth leading cause of death.").

126. Lazarou, *supra* note 125, at 1203.

127. Brushwood, *supra* note 17, at 208 ("Pharmacists have, with frustration, long observed the idiosyncratic effects of usually safe and effective drugs that fail to help some patients and actually harm other patients."). Sometimes, these reactions result from unpredictable "toxic or immunologic adverse response[s]." 3 PEGALIS, *supra* note 80, § 17:2.

128. Miller, *supra* note 6, at 245-46.

fast pace inevitably means that pharmacists and technicians can and do make mistakes when extra time devoted to each prescription could cut down on these mistakes.<sup>129</sup> So far as these baseline duties are concerned, to avoid negligence liability, pharmacists must act in accordance with the risks posed by the drugs that they dispense and the surrounding circumstances attending their day-to-day practice.<sup>130</sup>

These general rules' simplicity belies, however, the multitude of doctrinal limits on pharmacist liability. Many courts have ruled as a matter of law that pharmacists can escape liability should they perform certain enumerated acts,<sup>131</sup> regardless of whether those acts are objectively unreasonable.<sup>132</sup> The following subsections discuss representative court cases creating these seemingly categorical limitations.

#### *Liability for the Pharmacists' Own Mistakes*

Putting aside the ongoing debate surrounding how much pharmacists should counsel patients about their medications and consult with prescribing physicians about contraindications<sup>133</sup> and drug interactions,<sup>134</sup> pharmacists in the last 100 years have, at the very least, been responsible for accurately filling prescriptions.

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129. James T. O'Donnell, *Pharmacist Malpractice and the Infamous Courtney Case*, in *DRUG INJURY: LIABILITY, ANALYSIS AND PREVENTION* 657, 657 (James T. O'Donnell ed., 2d ed. 2005); Smith, *supra* note 11, at 231.

130. David J. Marchitelli, Annotation, *Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User*, 44 A.L.R.5th 393, 34a (1996).

131. DOBBS, *supra* note 20, at 679–80; e.g. *Adkins v. Mong*, 425 N.W.2d 151, 152 (Mich. Ct. App. 1988) (citing *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 383 (Mich. Ct. App. 1987); *Lemire v. Garrard Drugs*, 291 N.W.2d 103, 104–05 (Mich. Ct. App. 1980); *Troppi v. Scarf*, 187 N.W.2d 511, 513 (Mich. Ct. App. 1971)).

132. See DOBBS, *supra* note 20, at 679 (“Under this no duty rule, the question of reasonable care is not adjudicated at all.”).

133. A drug is “contraindicated” for someone when the drug will produce an adverse reaction. See 3 PEGALIS, *supra* note 80, § 17:9. By contrast, a drug is “indicated” for a patient when it will safely and effectively induce its intended therapeutic effects. See *id.*

134. See, e.g., Miller, *supra* note 6, at 245 (noting “[t]he battle of pharmacy as ‘fast food,’ versus ‘pharmacy as true profession’”).

In many pharmacist negligence cases,<sup>135</sup> a pharmacist dispenses a drug different from the one the prescription orders.<sup>136</sup> These errors sometimes arise from two drugs with completely different purposes bearing similar names.<sup>137</sup> A Mississippi case, *French Drug Co. v. Jones*, illustrates the consequences that could result from mistaking the drug prescribed and another drug kept at the pharmacy.<sup>138</sup> In *French Drug*, a patient with circulation problems resulting from frostbite suffered during the Battle of the Bulge in World War II sought medical treatment to ameliorate his pain.<sup>139</sup> After extensive testing, the patient was released from the hospital, with a prescription for Ethatab from his physician in hand to aid circulation.<sup>140</sup> When the patient took the prescription to a pharmacy, the pharmacist did not dispense the Ethatab listed on the prescription, instead giving the patient Estratab, a female hormone drug.<sup>141</sup>

In the roughly eleven months the patient took the

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135. O'Donnell, *supra* note 129, at 657 (providing a chart from the Pharmacists Mutual Insurance Claims Study 2000 stating that 49.7% of claims made from 1989 to 1999 resulted from dispensing the wrong drug). In that study and a newer Pharmacists Mutual study, dispensing the wrong drug occurred in the majority of claims made against pharmacists, the latter study showing that dispensing the wrong drug appeared in 50.4% of claims. *Id.* at 657-58.

136. Timothy E. Travers, Annotation, *Druggist's Civil Liability for Injuries Sustained as Result of Negligence in Incorrectly Filling Drug Prescriptions*, 3 A.L.R.4th 270, § 2a (1981) (collecting cases).

137. *E.g.* *Burke v. Bean*, 363 S.W.2d 366, 366 (Tex. Ct. App. 1962) (involving a physician prescribing Oxacholin tablets and a pharmacist filling this prescription with Oxsoralen). In fact, an anti-heartburn medication called Losec had its name changed to Prilosec, due the former name's confusing similarity to Lasix, which is "used to treat high blood pressure and swelling associated with congestive heart failure." *Losec Changes its Name - to Prilosec*, FDA CONSUMER (Dec. 1990), [http://findarticles.com/p/articles/mi\\_m1370/is\\_n10\\_v24/ai\\_9246250/](http://findarticles.com/p/articles/mi_m1370/is_n10_v24/ai_9246250/).

138. See *French Drug Co. v. Jones*, 367 So. 2d 431, 432-33 (Miss. 1978). In fact, substituting a drug called for in a prescription with another not listed could constitute negligence per se. 2 WOODSIDE, *supra* note 20, § 13.03[b][1][B][ii] (citing *Trach v. Thrift Drug Inc.*, 46 Pa. D. & C. 4th 231, 234-35 (2000); *Forbes v. Walgreen Co.*, 566 N.E.2d 90, 90 (Ind. Ct. App. 1991); *Harris v. Groth*, 645 P.2d 1104, 1106 (Wash. Ct. App. 1982), *aff'd*, 663 P.2d 113, 120 (Wash. 1983); *French Drug Co.*, 367 So. 2d at 433).

139. *French Drug Co.*, 367 So. 2d at 432.

140. *Id.*

141. *Id.* at 432-33.

Estratab,<sup>142</sup> the patient's circulation problems did not abate, and the Estratab produced a series of adverse reactions: enlarged breasts, memory loss, hair loss, psychological problems, physical and mental fatigue, and nausea.<sup>143</sup> All of the patient's effects waned after he stopped taking the Estratab, except for impotence, which he had only begun to experience after taking the drug.<sup>144</sup> The Mississippi Supreme Court accordingly held, citing numerous decisions supporting a higher standard of care,<sup>145</sup> that the pharmacist "did not use the required degree of care by substituting the female hormone drug for the blood circulation drug called for in appellee's prescription."<sup>146</sup>

The second most common pharmacist error<sup>147</sup> is dispensing the correct drug but in a strength or dosage out of sync with that set forth in the prescription.<sup>148</sup> In one case, *Cazes v. Raisinger*, a physician prescribed Lanoxin for a patient with heart problems, with instructions for her to take one tablet each morning.<sup>149</sup> Instead, after the patient made a return trip to the emergency room, the physician found a medicine bottle with instructions for the patient to take "[o]ne tablet four times a day."<sup>150</sup>

Further complications arose from then onward. The patient was hospitalized for congestive heart failure, began seeing a psychiatrist to treat her fear of taking medications, and was admitted to the hospital again because of another bout of congestive heart failure and acute anteroseptal myocardial

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142. *See id.*

143. *Id.* at 433.

144. *Id.*

145. *Id.* at 434 (citing *Tombari v. Connors*, 82 A. 640 (Conn. 1912); *Knoefel v. Atkins*, 81 N.E. 600 (Ind. Ct. App. 1907); *Fuhs v. Barber*, 36 P.2d 962 (Kan. 1934); *Troppi v. Scarf*, 187 N.W.2d 511 (Mich. Ct. App. 1971); *Edelstein v. Cook*, 140 N.E. 765 (Ohio 1923); *Hoar v. Rasmusen*, 282 N.W. 652 (Wis. 1938)).

146. *French Drug Co.*, 367 So. 2d at 434.

147. O'Donnell, *supra* note 129, at 657 (showing in the same study cited in footnote 135 that dispensing the correct drug in the wrong strength to be the second-most-common error, accounting for 25.1% of all claims).

148. Travers, *supra* note 136, § 3b.

149. *Cazes v. Raisinger*, 430 So. 2d 104, 104 (La. Ct. App. 1983).

150. *Id.* at 104-05.

infarction.<sup>151</sup> The lattermost illness ultimately caused her death.<sup>152</sup> The appellate court thus recognized that "Mrs. Cazes suffered an adverse reaction that was due to the negligence of the pharmacist."<sup>153</sup>

These two types of errors at one time accounted for around seventy-five percent of all claims against pharmacies,<sup>154</sup> but pharmacists can make mistakes dispensing pharmaceuticals in many other ways. Sometimes, pharmacist liability may arise from placing inadequate warnings on the drugs' labels,<sup>155</sup> improperly storing medications,<sup>156</sup> compounding drugs in a way different from that prescribed,<sup>157</sup> and substituting a generic for a brand name when the generic is less effective.<sup>158</sup>

*No Liability if Prescription Medication Is Accurately Dispensed*

Though the courts uniformly hold pharmacists responsible for failing to fulfill the basic clerical duties attending pharmacy practice, the courts split in nearly innumerable directions as to whether pharmacists can be held liable because they filled a prescription in perfect conformity to the physicians' orders, however erroneous. Put another way, pharmacist negligence cases can turn on whether a pharmacist owes a patient the duty to consult with physicians about prescription errors. To further complicate matters, the courts are wrestling with the extent to which OBRA '90 informs or establishes a duty for pharmacists to review prescriptions and offer pharmacotherapy counseling to patients.

Some court decisions appear at first to limit pharmacists' tort duties to the practice's clerical functions. Florida, Georgia, Michigan, and Texas seem to endorse this position at this time,

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151. *Id.* at 105.

152. *Id.*

153. *Id.* at 107.

154. O'Donnell, *supra* note 129, at 657.

155. Travers, *supra* note 136, § 7.

156. *Id.* § 8.

157. *Id.* § 4.

158. 2 WOODSIDE, *supra* note 20, § 13.03[2][b][v].

but they have not directly confronted whether pharmacists must correct subjectively known or objectively obvious physician error.<sup>159</sup> The Michigan appellate courts, for example, have explicitly left the question of pharmacist liability for filling obviously dangerous prescriptions unanswered. In *Lemire v. Garrard Drugs, Inc.*, the Michigan Court of Appeals stated that, "as a general rule, . . . druggists are not liable for correctly filling a prescription."<sup>160</sup> A later case, *Stebbins v. Concord Wrigley Drugs*, involved a plaintiff injured in an automobile accident caused by a defendant feeling the drowsy effects of Tofranil, an antidepressant.<sup>161</sup> The plaintiff alleged that neither the defendant's physician nor his pharmacist warned the defendant about the drug's side effects.<sup>162</sup> As such, the plaintiff sued the physician, the pharmacist, and the pharmacist's employer.<sup>163</sup> After the trial court granted summary judgment to all of these judgments, the plaintiff appealed.<sup>164</sup>

The Michigan Court of Appeals refused to recognize a duty to warn patients of a prescription drug's adverse effects.<sup>165</sup> That said, the court distinguished cases involving obvious errors on a prescription's face.<sup>166</sup> At the end of the opinion, the court noted

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159. *Johnson v. Walgreen Co.*, 675 So. 2d 1036, 1038 (Fla. Dist. Ct. App. 1996); *Pysz v. Henry's Drug Store*, 457 So. 2d 561, 562 (Fla. Dist. Ct. App. 1984); *Chamblin v. K-Mart Corp.*, 612 S.E.2d 25, 27-28 (Ga. Ct. App. 2005); *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63, 69 (Ga. Ct. App. 1993); *Adkins v. Mong*, 425 N.W.2d 151, 153 (Mich. Ct. App. 1988); *Lemire v. Garrard Drugs*, 291 N.W.2d 103, 105 (Mich. Ct. App. 1980); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 466 (Tex. Ct. App. 2000). The duty to take some kind of corrective action regarding known contraindications or obvious errors on prescriptions appears to be the prevailing rule in the courts directly treating such cases. See sources cited and discussed *infra* pp. 480-87.

160. *Lemire*, 291 N.W.2d at 105.

161. *Stebbins v. Concord Wrigley Drugs, Inc.* 416 N.W.2d 381, 383 (Mich. Ct. App. 1987).

162. *Id.*

163. *Id.*

164. *Id.*

165. *Stebbins* did not squarely address whether the pharmacist had a duty to warn the *physician* about the prescription's errors. The opinion thus did not explicitly foreclose liability under such a duty to warn theory from ever attaching.

166. *Id.* at 387 (citing *Hand v. Krakowski*, 453 N.Y.S.2d 121, 123 (N.Y. App. Div. 1982); *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1253-54 (Pa. Super. Ct. 1986)).



that it "need not consider a pharmacist's liability in situations such as where the pharmacist knows of a particular patient's unique problems or where a pharmacist fills two incompatible prescriptions."<sup>167</sup> In a later case, *Adkins v. Mong*, the same court of appeals that decided *Stebbins* held that pharmacists likewise have no duty to warn physicians of potential adverse drug reactions.<sup>168</sup> Again, however, the court did not address whether known or obvious physician error must be corrected if the dispensing pharmacist is to avoid liability.<sup>169</sup>

When the Florida, Georgia, Michigan, and Texas courts do confront fact patterns with known or clear prescription errors, they will probably expand pharmacist liability beyond inaccurate dispensation if they follow the current trend. So much occurred in the New York courts. An appellate division case from 105 years ago did not find a jury question about whether a pharmacist is liable for filling an obviously erroneous prescription. In *Laturen v. Bolton Drug Co.*, a physician prescribed "Elixir Pinous Comp. cum Heroin."<sup>170</sup> "Cum" is a Latin word for "with,"<sup>171</sup> so the pharmacist added "1/24 of a grain of Heroin to the dose, and thereby literally filled the prescription."<sup>172</sup> Because the elixir contained morphine on its own, the patient alleged that he was poisoned by the overdose. As such, the injured patient sued the pharmacy that filled the erroneous prescription claiming that the pharmacists committed negligence.<sup>173</sup> The appellate division recognized that the prescription was "obviously wrong,"<sup>174</sup> but the court refused to hold that a jury could find the pharmacy liable because there was little evidence that the excessive amount of morphine would have caused the patient's poisoning.<sup>175</sup> The New York Court of

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167. *Stebbins*, 416 N.W.2d at 388.

168. *Adkins v. Mong*, 425 N.W.2d 151, 152 (Mich. Ct. App. 1988).

169. *See generally id.*

170. *Laturen v. Bolton Drug Co.*, 93 N.Y.S. 1035, 1036 (N.Y. App. Div. 1905).

171. *Id.*

172. *Id.*

173. *Id.* at 1036-37.

174. *Id.* at 1038.

175. *Id.* at 1037.

Appeals affirmed *Laturen* in a summary disposition.<sup>176</sup>

A New York appellate division later recognized that pharmacists would act negligently if they dispensed a prescription drug that was contraindicated for someone with the patient's characteristics. In *Hand v. Krakowski*, a plaintiff filed a negligence claim against a pharmacy because the store's pharmacists dispensed psychotropic medications to an alcoholic patient.<sup>177</sup> The patient died as a result of "pancreatitis associated with a severe degree of cirrhosis" caused by the drugs.<sup>178</sup> The appellate division held that the pharmacists "could be found to [have] constitute[d] a breach of a druggist's duty of ordinary care in that [they] knowingly ignore[d] the danger and consequences of ingestion by an alcoholic of prescription drugs commonly recognized to be contraindicated."<sup>179</sup>

Though the appellate division defined contraindication as "a circumstance under which the drug must never be given" as an "absolute" rule that "admits of no exceptions,"<sup>180</sup> the court likewise suggested that expert testimony at trial might demonstrate that the drugs could have been appropriately prescribed and dispensed in spite of the decedent's alcoholism.<sup>181</sup> Therefore, questions of material fact remained to be resolved.<sup>182</sup> As such, the appellate division explicitly recognized the possibility that the drug store and its pharmacists are not protected from liability because they followed the prescription to the letter.

The Missouri courts went a step further than New York's appellate division did in *Hand*. The Missouri Supreme Court overruled outright a decision following Florida's and Michigan's current law. The precedentially defunct case, *Kampe v. Howard*

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176. *Laturen v. Bolton Drug Co.*, 80 N.E. 1112, 1112 (N.Y. 1907).

177. *Hand v. Krakowski*, 453 N.Y.S.2d 121, 122 (N.Y. App. Div. 1982).

178. *Id.*

179. *Id.* at 123.

180. *Id.* (quoting *Baker v. St. Agnes Hosp.*, 421 N.Y.S.2d 81, 83 (N.Y. App. Div. 1979)).

181. *Hand*, 453 N.Y.S.2d at 123.

182. *See id.*

*Stark Professional Pharmacy*, began when a patient sued a pharmacy under a negligence theory.<sup>183</sup> The pharmacy's employees accurately filled all of the patient's relevant prescriptions,<sup>184</sup> but the plaintiff claimed that the pharmacists there should have monitored his medication use and counseled him accordingly.<sup>185</sup> Tracking the Florida and Michigan courts decisional process, the *Kampe* court rejected cases expanding pharmacist liability.<sup>186</sup> Instead, latching onto Missouri's pharmacy practice statutes' language,<sup>187</sup> *Kampe* held that, "[b]y properly filling legal prescriptions that contained no apparent discrepancies on their face, the pharmacy fulfilled its duty to appellant."<sup>188</sup> *Kampe* remained good law for about seven years.

When 1999 came, a Missouri court of appeals overruled that case in *Horner v. Spalitto*.<sup>189</sup> In *Horner*, a physician prescribed fifty 750-milligram doses of Placidyl – one dose to be taken every eight hours – and fifty ten-milligram doses of Diazepam also to be taken one dose every eight hours.<sup>190</sup> After consulting a pharmacy manual, which suggested that the one should only take Placidyl in one 500- or 750-milligram dose before going to bed and that the sedative effects would be exacerbated by adding a central nervous system depressant like Diazepam, the pharmacist called the doctor's office.<sup>191</sup> Though the pharmacist was concerned, someone at the physician's office gave the okay to fill the prescription.<sup>192</sup> The pharmacist filled the prescriptions.<sup>193</sup> Less than a week later, the patient died, with the cause of death being "adverse effects of multiple medications

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183. *Kampe v. Howard Stark Prof'l Pharmacy, Inc.*, 841 S.W.2d 223, 223 (Mo. App. 1992).

184. *Id.*

185. *Id.* at 223–24.

186. *Id.* at 224–25.

187. *Id.* at 225–26 (citing MO. REV. STAT. §§ 388.010, 388.010.1, 388.015.2 (Supp. 1991)).

188. *Id.* at 227.

189. *Horner v. Spalitto*, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999).

190. *Id.* at 521.

191. *Id.*

192. *Id.*

193. *Id.*

(drugs), especially [P]lacidyl (ethchlorvynol), which was near the toxic range."<sup>194</sup> Though the trial court granted the pharmacist's motion for summary judgment, relying on *Kampe's* duty-to-dispense rule,<sup>195</sup> the court of appeals reversed.

In reaching its reversal, the *Horner* court subjected *Kampe* to withering criticism, suggesting,

[t]o hold as *Kampe* did would denigrate the expertise which a pharmacist's education provides concerning drugs and their therapeutic use. The *Kampe* holding also failed to comprehend the role a pharmacist must play in making the valuable, but highly dangerous, service of drug therapy as safe and reliable as it can be.<sup>196</sup>

In stark contrast to *Kampe's* view "[r]elegating a pharmacist to the role of order filler,"<sup>197</sup> a number of other Missouri and federal statutes and regulations to which *Horner* refers obligate pharmacists to take on greater patient-counseling responsibilities.<sup>198</sup> Not only are pharmacists trained to spot potentially errant prescription orders, they may in some cases have greater knowledge about pharmacotherapy than a prescribing physician.<sup>199</sup> As such, *Horner* held that pharmacists must conform their conduct to what "'a reasonably prudent and careful health care provider would have [done] under similar circumstances[.]'"<sup>200</sup>

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194. *Id.*

195. *Id.* at 521-22.

196. *Id.* at 522.

197. *Id.* at 524.

198. *Id.* at 522-23 (citing MO. REV. STAT. §§ 388.010.1, 538.205(5), 538.210.1, 538.225.1 (1994); Omnibus Budget Reconciliation Act of 1990 (OBRA '90), 42 U.S.C. § 1396r-8 (1994); 4 C.S.R. § 220-2.190).

199. *Horner*, 1 S.W.3d at 524. Such greater expertise on the pharmacists' part is not a theoretical possibility, as is discussed *infra* at p. 489-92. For a reported case involving such disparate knowledge, see *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1121 (Ill. 2002), where a pharmacist testified that another pharmacist would have known that a drug was contraindicated for a patient but the physician had no such knowledge at the time he prescribed that medication.

200. *Horner*, 1 S.W.3d at 523 (citing MO. REV. STAT. § 538.225.1 (1994)).

*Liability for Known Contraindications or Obvious Physician Error*

In the states following *Horner's* and *Hand's* lead in expanding liability beyond mistakes made in counting pills and accurately dispensing prescription medication, there are generally two fact patterns that give rise to a duty to warn prescribing physicians about the risks involved in an erroneous prescription.

First, some courts have ruled that pharmacists act negligently when they follow the prescriptions orders despite subjective knowledge that a drug presents serious contraindications for persons in the patient's situation. As noted above, *Hand* endorsed such liability in New York.<sup>201</sup> Illinois also recognized this rule in *Happel v. Wal-Mart Stores*.<sup>202</sup> In that case, the plaintiff-patient sued her physician and the pharmacy for prescribing and dispensing a drug contraindicated for her.<sup>203</sup> After the patient complained to the physician about her menstrual cramps, the patient's physician prescribed Toradol to treat the patient's intense pain.<sup>204</sup> Toradol is contraindicated for patients with allergies to aspirin, such as the patient in *Happel*, but the physician was not aware of that contraindication.<sup>205</sup> Though the facts were in dispute as to which pharmacist filled the prescription and when, the pharmacist allegedly on duty at the time the Toradol was dispensed testified that "she was aware that Toradol was contraindicated for persons who were sensitive to aspirin and ibuprofen."<sup>206</sup> In all events, the

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201. *Hand v. Krakowski*, 453 N.Y.S.2d 121, 122 (N. Y. App. Div. 1982). It appears that in New York, pharmacists do not become liable for filling objectively obvious but not subjectively known errors and contraindications appearing on a prescription. See, e.g., *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 212 (E.D.N.Y. 2004) (applying New York law).

202. *Happel*, 766 N.E.2d at 1129.

203. *Id.* at 1120.

204. *Id.* at 1121.

205. *Id.*

206. *Id.*

pharmacy's computer system would have flashed a "drug interaction" warning, and Wal-Mart's standard operating procedure was to halt the dispensation process until the physician instructed the pharmacist to fill the prescription.<sup>207</sup>

Nevertheless, the patient's prescription was dispensed anyway. When the patient began taking the medication, she began suffering from "more frequent asthma attacks, as well as seizures and a worsening of her multiple sclerosis."<sup>208</sup> Though the trial court granted Wal-Mart summary judgment, the Court of Appeals reversed, holding that pharmacists have a duty to warn in these circumstances.<sup>209</sup>

The Illinois Supreme Court affirmed the Court of Appeals' judgment,<sup>210</sup> recognizing the danger posed by known contraindications that pharmacists are in a position to correct if needed. In analyzing whether to impose a duty to warn patients and physicians of known contraindications, the court stated multiple reasons for imposing a duty to warn in these circumstances. First, it would be reasonably foreseeable that substantial injury would befall patients taking contraindicated medications, and the pharmacists had "superior knowledge" of these potential dangers.<sup>211</sup> Second, using this knowledge to convey to the physician or the patient the possible adverse drug reactions posed by taking contraindicated medication imposes a very minimal burden on pharmacists.<sup>212</sup> Third, Wal-Mart and its pharmacists "need only pass along to the customer or the physician the information it already possess about the contraindication for this specific customer."<sup>213</sup> Conversely, a narrow duty to warn of known contraindications would not require pharmacists "to learn the customer's condition, . . .

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207. *Id.*

208. *Id.* at 1122.

209. *Id.* (citing *Happel v. Wal-Mart Stores, Inc.*, 737 N.E.2d 650, 657 (Ill. Ct. App. 2000)).

210. *Happel*, 766 N.E.2d at 1130.

211. *Id.* at 1124.

212. *Id.*

213. *Id.*

render . . . medical judgment[s,] or interject itself into the doctor-patient relationship."<sup>214</sup>

As such, the Illinois Supreme Court set forth the following rule to govern future pharmacist liability cases:

[A] narrow duty to warn exists where, as in the instant case, a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient. In such instances, a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger.<sup>215</sup>

As such, the Supreme Court remanded the case to the trial court for further proceedings.<sup>216</sup>

Beyond known contraindications, a pharmacist may be legally answerable to the patient if the pharmacist fills a prescription with patently obvious errors on its face, regardless of whether the pharmacist subjectively knows about the error.<sup>217</sup> Most courts have adopted this rule in some form,<sup>218</sup> though some disagreement arises as to whether a pharmacist has a duty to consult a physician about any obvious error, including apparently excessive dosages.<sup>219</sup>

Though allowing recovery from pharmacists for acting on obviously erroneous prescriptions appears to expand liability

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214. *Id.*

215. *Id.* at 1129.

216. *Id.* at 1130.

217. DOBBS, *supra* note 20, at 679. One commentator suggests that pharmacist liability beyond inaccurate dispensation may be based on a pharmacist's constructive knowledge regarding drugs' characteristics and attendant risks. Marchitelli, *supra* note 20, § 2[a].

218. 2 WOODSIDE, *supra* note 20, § 13.03[2][f][i]; 25 AM. JUR. 2D *Drugs and Controlled Substances* § 249 (2004) (citing *Murphy v. E. R. Squibb & Sons, Inc.*, 710 P.2d 247 (Cal. 1985); *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991); *Gassen v. East Jefferson General Hosp.*, 628 So. 2d 256 (La. Ct. App. 1993); *McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045, 1046 (Wash. 1989)).

219. *Compare People's Serv. Drug Stores, Inc. v. Somerville*, 158 A. 12, 14 (Md. Ct. App. 1932) ("Of course this does not mean that pharmacists can safely fill prescriptions calling for doses that are obviously fatal . . ."), with *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551, 553 (Ill. App. Ct. 1985) (refusing to impose a duty on a pharmacist to warn that a prescription calls for excessive dosages because "[t]he propriety of a prescription depends not only on the propensities of the drug but also on the patient's condition").

when compared to the rules adopted in Florida, Georgia, Texas, and Michigan, this rule still operates as a limit on pharmacists' tort duties. On this point, the Washington Supreme Court's decision in *McKee v. American Home Products* is instructive. In that case, a patient took Plegine, an appetite suppressant, on a regular basis for ten years.<sup>220</sup> This medication regimen directly conflicted with warnings and instructions listed in the 1984 edition of *PDR*.<sup>221</sup> That edition of the *PDR* stated that, because of the drug's tendency to cause addiction, the drug should be discontinued after a few weeks of usage.<sup>222</sup> The *PDR* further showed that the risks wrought by overusing Plegine include "extreme fatigue and mental depression after abrupt cessation, intense psychological dependence and severe social dysfunction, and at an extreme, psychosis."<sup>223</sup> Nevertheless, her physician continued to sign prescriptions and authorize refills, and the two defendant pharmacists continued to dispense these drugs.<sup>224</sup> In a lawsuit to recover for the physical and psychological harms brought on by her Plegine regimen, the patient sought recovery from Plegine's manufacturer, the prescribing physician, and the dispensing pharmacists.<sup>225</sup>

The Washington Supreme Court held that the patient could not state a negligence claim against the pharmacists, in part because pharmacists do not owe their patients a duty to warn

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220. *McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045, 1046 (Wash. 1989).

221. In *McKee*, the first physician began prescribing Plegine in 1974. *Id.* In the year before, the *PDR* included no warning regarding Plegine's dependency dangers. *PHYSICIAN'S DESK REFERENCE* 576 (27th ed. 1973). That said, the *PDR*'s 29th edition, published in 1975, warned that Plegine can subject patients addicted to it to a laundry list of serious consequences, including "severe social dysfunction" and, in some cases, "psychosis, often clinically indistinguishable from schizophrenia." *PHYSICIAN'S DESK REFERENCE* 592 (29th ed. 1975). Similarly to the 1984 edition cited in *McKee*, the 1975 *PDR* warns that "[t]olerance to the anorectic effect of PLEGINE develops within a few weeks." *Id.* at 592. As such, knowledge existed in the medical field regarding Plegine's dangerously addictive effects while the *McKee* plaintiff's first physician continued to prescribe that drug. *McKee*, 782 P.2d at 1046.

222. *McKee*, 782 P.2d at 1046.

223. *Id.*

224. *Id.*

225. *Id.* at 1047.



treating physicians that their prescribed medication has caused the patient dependency.<sup>226</sup> The court stated that physicians, not pharmacists, are in the best position to determine whether one particular form of pharmacotherapy is more appropriate than another.<sup>227</sup> This is so because "only the physician . . . can relate the propensities of the drug to the physical idiosyncrasies of the patient."<sup>228</sup> The court quoted the Prosser & Keeton hornbook, which states, "[i]t is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy."<sup>229</sup> Pharmacists, however, lack "the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship."<sup>230</sup>

Though the court recognized that obvious prescription error could obligate pharmacists to take some corrective action, such as notifying the physician, the court believed that this patient's Plegine regimen resulted from the physician's exercise of professional judgment.<sup>231</sup> Recognizing that physicians may have legitimate reasons for disregarding a manufacturer's recommendations, the court was reluctant to encourage pharmacists to doubt a multitude of prescriptions that come before them and potentially antagonize the physician.<sup>232</sup> Thus, the Washington Supreme Court limited the duty to warn to obvious errors.<sup>233</sup> Though the court did not elaborate as to how a physician's prescription error could rise to the level of obviousness, prescribing a drug for ten years when it can create dependency within a few weeks was not so obvious an error as to suggest that the *McKee* pharmacist acted negligently.<sup>234</sup>

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226. *Id.* at 1055–56.

227. *Id.* at 1051.

228. *Id.* at 1050.

229. *Id.* at 1050–51 (citing PROSSER & KEETON, *supra* note 54, at 688).

230. *McKee*, 782 P.2d at 1051.

231. *Id.* at 1053.

232. *Id.*

233. *Id.* at 1055–56.

234. *See id.* at 1055–56.

When a physician insists that a prescription is correct as written, the difficulties the courts have found in attempting to balance physician judgment against guarding patients from potentially serious physician error are exacerbated. Sometimes, pharmacist and physician disagreement as to the proper drug therapy scheme can not only produce acrimony between the physician and pharmacist,<sup>235</sup> but it might also confuse, agitate, and even scare<sup>236</sup> patients with time-sensitive medication needs. So much occurred in *Hendricks v. Charity Hospital of New Orleans*, where a physician prescribed Dilantin to treat a patient's epilepsy.<sup>237</sup> Though the doctor intended to prescribe only 500 milligrams daily, the prescription included instructions to take 500 milligrams every eight hours.<sup>238</sup>

When the pharmacist in the case was confronted with the prescription, she refused to fill the prescription and sent the patient back to the doctor to discuss the dosage.<sup>239</sup> The patient did not bring the prescription with him to his next meeting with his physician, so when the physician checked the hospital chart showing that he prescribed the intended 500-milligram daily dosage, the physician unwittingly insisted that the prescription was correct as written.<sup>240</sup> The pharmacist then attempted to reach the physician, but to no avail.<sup>241</sup> With the patient growing impatient and stating that the physician insisted that the prescription was accurate, the pharmacist filled the prescription but provided with it a warning to "consult Physician about dosage."<sup>242</sup> After the patient became "seriously ill" from Dilantin toxicity,<sup>243</sup> the patient filed negligence claims.<sup>244</sup>

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235. *Id.* at 1053.

236. *See, e.g., id.* at 1054 ("[U]nnecessary warnings to the patient could cause unfounded fear and mistrust of the physician's judgment.").

237. *Hendricks v. Charity Hosp. of New Orleans*, 519 So. 2d 163, 164 (La. Ct. App. 1987).

238. *Id.*

239. *Id.* at 164–65.

240. *Id.* at 165.

241. *Id.*

242. *Id.*

243. *Id.*

The Louisiana Court of Appeal recognized that a pharmacist has a duty to take steps to protect patients from excessive dosages,<sup>245</sup> but the court ultimately deferred to the trial court's factual determinations to decide the case.<sup>246</sup> Among these facts were that the patient needed the medication quickly to treat his epilepsy, and thus, simply refusing to fill the prescription would not have proven feasible in these circumstances.<sup>247</sup> Moreover, the only warning given was the one affixed to the label, and the court noted that the pharmacist may have "breached a duty to take some reasonable steps to locate plaintiff and warn him of the dangerous position he was in."<sup>248</sup> All in all, this case presented, according to the court, a "close fact call,"<sup>249</sup> and the Court of Appeal thus upheld the trial court's decision.<sup>250</sup>

*Liability for Any Failure to Conform to Professional Standards*

Two recent cases, however, do not impose doctrinal limitations on pharmacist liability's scope. These cases come from a Tennessee Court of Appeals in *Dooley v. Everett*<sup>251</sup> and an Arizona Court of Appeals in *Lasley v. Shrake's Country Club Pharmacy, Inc.*<sup>252</sup> Both of these decisions hold that pharmacists are held to a general duty to act in conformity with the pharmacy professional community, without any of the doctrinal limits on pharmacist liability.<sup>253</sup>

The Tennessee case, *Dooley v. Everett*, involved a patient's suit against a pharmacist alleging that the pharmacist committed

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244. *Id.* at 164.

245. *See id.* at 165.

246. *Id.* at 166.

247. *Id.*

248. *Id.* at 165.

249. *Id.* at 166.

250. *Id.*

251. *Dooley v. Everett*, 805 S.W.2d 380 (Tenn. Ct. App. 1991).

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

253. Gary G. Cacciatore, *Pharmacist's Duty to Warn*, 51 AM. J. HOSP. PHARMACY 2824, 2826 (1994) ("The court in *Lasley* . . . did not limit its holding to the particular situation present.").

negligence by not warning him or his prescribing physician about potentially dangerous drug interactions.<sup>254</sup> Here, the treating physician prescribed both Theophylline and Erythromycin.<sup>255</sup> The latter drug has a tendency to increase Theophylline serum levels and thus heighten the risk of Theophylline toxicity, a condition that inflicts nausea, vomiting, and seizures.<sup>256</sup> The patient's physician knew about these potential side effects and prescribed the drugs anyway.<sup>257</sup> On the other hand, the pharmacist that filled the patient's prescription had no knowledge of this list of potential adverse drug reactions.<sup>258</sup> For the patient, this potential became a reality, and he suffered cerebral seizures, prompting a negligence suit against the physician and the pharmacy where the prescription was filled.<sup>259</sup>

The trial court granted the pharmacy's motion for summary judgment, holding that the pharmacist owed the patient no "duty to warn a customer and/or the customer's physician of the potential interaction between two different prescription drugs written by the same physician on two different days and which are filled as written by the same pharmacist on different days."<sup>260</sup> The Tennessee Court of Appeals reversed, separating the question of duty – whether the law shoulders pharmacies with a duty of care in dispensing drugs – from the standard of care – whether the pharmacist acted consistently with that legal duty.<sup>261</sup> Using the fact-law dichotomy, the pharmacy owed a duty to the patient generally.<sup>262</sup> Whether this duty included warning the physician or patient of the possibility of adverse drug interactions raised a factual question inappropriate for

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254. *Dooley*, 805 S.W.2d at 382.

255. *Id.*

256. *Id.*

257. *Id.*

258. *Id.*

259. *Id.* at 381–82.

260. *Id.*

261. *Id.* at 384.

262. *Id.* at 385.

summary adjudication.<sup>263</sup> The Arizona Court of Appeals in *Lasley v. Shrake's Country Club Pharmacy, Inc.* took the same position as *Dooley*.<sup>264</sup>

### PREVAILING AND DISPUTED COMPETENCIES AND RESPONSIBILITIES

To the extent that these liability rules embody the legal system's conception of reality, they suggest that the doctor is the ultimate and final decision-maker regarding how a patient's pharmacotherapy should be monitored.<sup>265</sup> Conversely, the pharmacist, especially in jurisdictions limiting their legal duties to accurate dispensation, is simply an order-filler executing the professional judgments made by the prescribing physician.<sup>266</sup> Even when obvious or known contraindications and errors appear on the face of a prescription, the courts have generally shouldered pharmacists with a duty to consult the prescribing physician, refuse to fill the prescription, or simply warn the patient.<sup>267</sup> Otherwise, the pharmacist runs the risk of antagonizing the physician, questioning the physician's judgment, and potentially instilling fear in patients regarding the uncertainty of drug choices and therapy management.<sup>268</sup>

The reality painted by these cases, however, does not reflect the expertise and experience that pharmacists and physicians share. Nor does it parallel the calls by health care professionals and commentators for different pharmacological service paradigms. To bring the stark differences between current health care management practices and the state of health care provider liability law, the following sections cover physicians' and pharmacists' general capabilities and responsibilities.

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263. *Id.* at 386.

264. *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994) (citing *Dooley*, 805 S.W.2d 380, 386).

265. See *McKee v. American Home Products, Corp.*, 782 P.2d 1045, 1050-51 (Wash. 1989).

266. *Horner v. Spalitto*, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999).

267. See *Hendricks v. Charity Hosp. of New Orleans*, 519 So. 2d 163, 165 (La. Ct. App. 1987).

268. *McKee*, 782 P.2d at 1053-54.

*RELATIVE EDUCATION AND EXPERIENCE*

Physicians' pharmacological expertise relative to that of pharmacists' begins with each profession's educational background. To be sure, "pharmacists focus between five and seven years of study on medications, while medical students spend approximately three semesters on pharmaceuticals."<sup>269</sup>

Medical students have likewise voiced complaints about their pharmacology education. For example, one medical student reported that she believes that she has not received enough training on specific drugs, and these deficiencies could in part explain why students at that medical school have historically done poorly on that portion of the national board examinations.<sup>270</sup> Furthermore, another student complained that tutorials in pharmacology, which lasted only three and a half weeks, are "frustrating in allowing so little time. The lectures are good, organized, [and] competent, but it is all taught so fast with no time to come back to anything."<sup>271</sup> Both of these issues, the lack of detail and time in pharmacological education, were corroborated by another student, who expressed, "I did not always get enough time to know the details, particularly in biochemistry and pharmacology."<sup>272</sup>

The extent of medical school education in pharmacology has as such drawn substantial criticism. At least one commentator has suggested that radical improvements in medical education need to take place such that physicians have a better understanding of pharmacology and individual drugs.<sup>273</sup>

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269. Hornish, *supra* note 22, at 1099.

270. ROBERT H. ROSS & HARVEY V. FINEBERG, *INNOVATORS IN PHYSICIAN EDUCATION: THE PROCESS AND PATTERN OF REFORM IN NORTH AMERICAN MEDICAL SCHOOLS 208-09* (1996).

271. *Id.* at 220.

272. *Id.* at 194.

273. E.g. F. Sjöqvist, *The Past, Present and Future of Clinical Pharmacology*, 55 *EUR. J. CLINICAL PHARMACOLOGY* 553, 555 (1999) ("A major prerequisite for better prescribing of drugs is to radically change emphasis of the education in pharmacology in medical schools. . . . It is urgent to work out pedagogic strategies leading to a relevant drug education . . .").

Those within the medical education community recognize these deficiencies as well. Even the Harvard Medical School suffers in this regard, and that school has tried to integrate more pharmacology into its courses and even at one time offered an elective pharmacology course.<sup>274</sup> For its part, the John Hopkins University School of Medicine sought to integrate more pharmacology into the third-year curriculum through its "Rational Therapeutics" course, taught by "pharmacology and clinical faculty working in teams."<sup>275</sup>

Despite these inroads and calls to cover more pharmacology in medical schools, medical school education in pharmacology pales in comparison to the extent to which pharmacy students cover this subject. In the United States, prospective pharmacists can now only seek one professional degree in pharmacy: the Doctor of Pharmacy (PharmD).<sup>276</sup> These rigorous programs "concentrate[] on pharmacotherapy and the application of pharmaceutical care."<sup>277</sup> To that end, pharmacy students will take basic science courses in "pharmacology, medicinal chemistry, pharmaceuticals, [and] biopharmaceuticals . . ."<sup>278</sup> Moreover, in the last forty years, pharmacy practice has begun to assume more clinical functions,<sup>279</sup> and pharmacy school curricula have begun to reflect that shift by "including therapeutics courses and clinical clerkships that enable[] students to apply these principles to patient care."<sup>280</sup>

Pharmacy school curricula will likely continue to expand

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274. Marc T. Silver, *The Student Experience*, in *NEW PATHWAYS TO MEDICAL EDUCATION: LEARNING TO LEARN AT HARVARD MEDICAL SCHOOL* 123, 125 (Daniel C. Tosteson et al. eds., 1994).

275. Catherine D. De Angelis, *The Clinical Years*, in *THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE CURRICULUM FOR THE TWENTY-FIRST CENTURY* 80, 80-81 (Catherine D. De Angelis ed., 1999).

276. Joseph L. Fink III, *Scope of Pharmacy*, in *REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY* 3, 3 (David B. Troy ed., 21st ed., 2006).

277. Henry Cohen & Antonia Alafiris, *Antidepressants: Clinical Use and Litigation*, in *DRUG INJURY: LIABILITY, ANALYSIS AND PREVENTION* 379, 387 (James T. O'Donnell ed., 2d ed. 2005).

278. Fink, *supra* note 276, at 3.

279. *Id.* at 4.

280. Jere E. Goyan, *Foreword to CLINICAL PHARMACY AND THERAPEUTICS* v, v (Eric T. Herfindal & Joseph L. Hirschman eds., 3d ed. 1984).

educational opportunities on the clinical side of pharmacy practice with support from the Accreditation Council for Pharmacy Education (ACPE) and its recommendations that pharmacy schools provide more background in drug-information activities, such as, to name a few, “[i]dentifying and reporting medication errors and adverse drug reactions[;] . . . [p]articipating in therapeutic protocol development[;] . . . [and p]erforming prospective and retrospective financial and clinical outcomes analysis to support formulary recommendations and therapeutic guideline development.”<sup>281</sup>

In short, whereas physicians will obtain a general background in pharmacology amid their courses in anatomy, physiology, and bioethics and their hands-on clinical experience, pharmacy students focus their education primarily on medications and their properties and uses.

Once physicians and pharmacists enter their practices, the informational chasm created by their educational backgrounds become even more stark, especially when new drugs enter the market. Physicians may be familiar with a few medications being sold when they just began their medical training and career.<sup>282</sup> But with the constant bombardment of new drugs entering the market, it is nearly impossible for physicians to keep track of them all.<sup>283</sup> By contrast, current pharmacy education, according to one commentator, aims to graduate professional learners that can make it their lives’ work to understand the science and clinical therapeutics behind new medications. Pharmacists are thus expected to become “experts

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281. Allison C. Bernknopf et al., *Drug Information: From Education to Practice*, 29 PHARMACOTHERAPY 331, 333–34 (2009).

282. SCHRODER, *supra* note 47, at 407.

283. *Id.* Even if the advertising and promotional material physicians receive regarding new drugs on the market include warnings requiring Food & Drug Administration (FDA) approval, there is no guarantee that the drugs themselves are safe. See discussion *infra* p. 499. Coupled with all of the other aspects of medical practice for which physicians are responsible—especially reaching a proper diagnosis before even considering pharmacotherapy as an option—physicians cannot possibly devote the same amount of time pharmacists do to understanding the composition and utility of pharmaceuticals entering the market.



on the thousands of medications available today, how each works in the body, and the ways to use each safely."<sup>284</sup>

### *PRESCRIPTION PROCEDURE*

Despite the disparities in pharmacological education and expertise between physicians and pharmacists, physicians still assume the primary role in prescribing medication. Making matters more difficult for physicians, they are charged with making a dizzying multitude of professional judgments.

Though drug treatment schemes vary tremendously from patient to patient,<sup>285</sup> they all follow a general pattern.<sup>286</sup> First, in any case, a patient makes an appointment at a hospital or doctor's office because he or she perceives that something is wrong.<sup>287</sup> The hope, of course, is that the physician can pin down what that something is. At this point, the physician must gather as much information and data on the patient as is justifiable in the circumstances,<sup>288</sup> factoring in "the goal of the physician who collects the information[;] . . . the amount of time the physician has to collect the information[;] . . . the cost of data collection" and so on.<sup>289</sup>

Physicians' first questions seek the most important reasons a patient has for consulting the doctor for medical

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284. Cohen & Alafaris, *supra* note 277, at 388.

285. MICHAEL SWASH, *HUTCHISON'S CLINICAL METHODS* 3 (20th ed. 1995).

286. Robert Lowes, *Medical Education Has Become an Assembly Line*, *MODERN MEDICINE* (Jan. 10, 2000), <http://www.modernmedicine.com/modernmedicine/Young+Doctors%27+Resource+Center%3a+Medical+Career%2fPersonal+Development+for+Physicians/Medical-education-has-become-an-assembly-line/ArticleStandard/Article/detail/124089> ("Every new patient needs a history, examination, lab studies, and orders.").

287. James O. Woolliscroft, *The Clinical Approach to the Patient*, in *KELLEY'S TEXTBOOK OF INTERNAL MEDICINE* 255, 256 (H. David Humes et al. eds., 4th ed. 2000).

288. See Thomas H. Lee, *Using Data for Clinical Decisions*, in *CECIL MEDICINE* 40, 40 (Lee Goldman & Dennis Ausiello eds., 23d ed. 2007) ("An additional concern is the cost of information gathering, including the direct costs of the tests themselves and the indirect costs that flow from decisions made on the basis of the test results.").

289. J. Willis Hurst, *The Evolution of the Format*, in *MEDICINE FOR THE PRACTICING PHYSICIAN* 1, 1-2 (J. Willis Hurst ed., 4th ed. 1996).

intervention.<sup>290</sup> From there, a doctor will attempt to guide the patient so that he or she can disclose every piece of needed information about his or her medical history and background, including basic biographical and demographical information such as “age, gender, ethnic background, and occupation”; “[o]ther physicians involved in the patient’s care”; “[h]istory of the presenting reason for seeking medical care”; “[p]ast medical and surgical history”; “[a]llergies and adverse reactions”; “[s]ocial and occupational history”; “[r]isk factors” such as drug and alcohol use; and “[f]amily history.”<sup>291</sup> After a patient communicates this information, the physician may then question the patient about any changes that the patient has noticed, such as fluctuations in sensory capacities.<sup>292</sup> If time permits and the need arises, physicians may be able to consult practice manuals<sup>293</sup> in order to generate more questions and to pinpoint where on the patient the physician should perform a physical examination.<sup>294</sup>

The vital importance of collecting this information and doing so accurately and precisely lies in this interview and examination process’s purpose: to reach and articulate a diagnosis. Outcomes that eliminate or at least ameliorate the patient’s condition inextricably depend on a correct diagnosis of the underlying condition.<sup>295</sup> In fact, a 1973 survey conducted by the Department of Health, Education, and Welfare demonstrated that more doctors blamed “[p]oor communication between doctors and patients” for medical malpractice lawsuits than any

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290. David L. Simel, *Approach to the Patient: History and Physical Examination*, in CECIL TEXTBOOK OF MEDICINE 18, 18 (Lee Goldman & Dennis Ausiello eds., 22d ed. 2004).

291. *Id.* at 19.

292. *Id.* at 20.

293. Some practice manuals and consults are organized for busy physicians that have little time to conduct in-depth research on a medical issue. See Jeffrey Schaider et al., *Preface to ROSEN & BARKIN’S 5-MINUTE EMERGENCY MEDICINE CONSULT v, v* (Jeffrey Schaider et al. eds., 2d ed. 2003) (“The focus [of this consult] is to provide concise, formatted information that will allow the busy clinician to respond to challenges in a timely fashion.”); Hurst, *supra* note 289, at 1.

294. Simel, *supra* note 290, at 18.

295. 3 PEGALIS, *supra* note 80, § 17:1.

other individual factor.<sup>296</sup>

Information gathered in the initial interview will often prove sufficient to diagnose the patient's condition correctly.<sup>297</sup> Sometimes, however, the patient may state complaints that suggest that one of multiple medical conditions could be present. In those cases, physicians may engage in a process called differential diagnosis, which is "the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings."<sup>298</sup> Doctors may also interpret the presence of some characteristics in the examination or the patient's history to rule out possibilities.<sup>299</sup>

With the probabilities considered, the doctor then determines that the patient's problem rests in a specific medical condition. The next step is creating an optimal treatment plan. This will not necessarily involve pharmaceutical care.<sup>300</sup> In fact, as a general rule, physicians should prescribe the smallest dosage that can produce the needed therapeutic effects and then try to wean their patients off of their medication.<sup>301</sup> However, when patients can benefit from drug therapy without exposing themselves to unreasonable risks, pharmaceuticals can be attractive.

After a physician and patient agree that drug therapy is the best option, the physician must take into account a myriad of factors in order to choose the best medication for that patient. A patient's personal characteristics and the physician's diagnosis can whittle down the possible treatment plans to the classes of medications that the doctor may use.<sup>302</sup> Intense pain may

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296. SCHRODER, *supra* note 47, at 42.

297. Woolliscroft, *supra* note 287, at 255.

298. STEDMAN'S, *supra* note 7, at 531.

299. *Id.* (defining the process of diagnosis by exclusion).

300. J.K. Aronson, *Drug Therapy*, in DAVIDSON'S PRINCIPLES AND PRACTICE OF MEDICINE 147, 148 (Christopher Haslett et al. eds., 19th ed. 2002).

301. *Id.* at 153 ("Generally, start with a dosage at the lower end of the recommended dosage range.").

302. *Id.* at 151.

require analgesics such as Percocet and Vicodin,<sup>303</sup> and anxiety and panic disorders are often treated with benzodiazepines like Xanax or Ativan.

From there, a physician may choose subcategories of a class of drugs in light of more specific concerns. For example, within the antibiotic class are penicillins, cephalosporins, tetracyclines, aminoglycosides, macrolides, and quinolones, each of which treats specific kinds of microbial diseases.<sup>304</sup> Then, the choices are whittled down to individual drugs within those categories. Such choices of subclasses turn on more factors still, including their overall degree of effectiveness compared to the risk of adverse drug reactions and interactions, whether the patient's condition calls for expeditious or long-term therapy, and, of course the condition's details regarding its source and cause.<sup>305</sup>

After the physician chooses a drug, the physician must then determine the proper route of administration, formulation, and dosage.<sup>306</sup> Sometimes, minute details regarding administration can mean the difference between proper therapy and serious adverse reactions, as demonstrated by the patient's experience in *Wyeth v. Levine*.<sup>307</sup> That case involved Phenergan, an antihistamine used to treat nausea.<sup>308</sup> This drug could be administered intravenously (IV).<sup>309</sup> A physician deciding to inject drugs intravenously can opt to use either the "push" method, whereby the IV forces the drug directly into a vein, or by the "drip" method, in which the drug is dissolved into a solution that enters the patient's veins more slowly.<sup>310</sup> Phenergan generally should not be injected with the push method, because the drug had a tendency to produce gangrene

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303. *Id.* at 152.

304. *Id.* at 151.

305. *Id.* at 151–52.

306. *Id.* at 152–53.

307. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1190–91 (2009).

308. *Id.* at 1191.

309. *Id.*

310. *Id.*

when in contact with artery blood.<sup>311</sup> In *Wyeth*, after a physician chose just that route of administration, gangrene developed and the patient had to have her hand and forearm amputated.<sup>312</sup> As such, the proper administration method can be of crucial importance. More typical concerns revolve around how efficiently the drug will enter the person's body, with IV injection being the most efficient.<sup>313</sup>

In order to determine the proper dosage, physicians have to take into account numerous pharmacological factors. These factors include pharmacokinetics, "the quantitative analysis of the processes of drug absorption, distribution, and elimination that determine the time course of drug action,"<sup>314</sup> and pharmacodynamics, "the mechanism of drug action."<sup>315</sup> Also factoring in is drug metabolization and clearance. Such matters touch upon how to structure dosages in light of the "first-pass" effect,<sup>316</sup> in which "a significant portion of the dose may be metabolically inactivated in either the intestin[es] . . . or the liver before the drug reaches the systemic circulation,"<sup>317</sup> and whether someone suffers from kidney diseases that would stifle the patient's ability to metabolize the drug, meaning a dosage administered for someone with adequate kidney functioning could be toxic for a patient with renal insufficiencies.<sup>318</sup> These factors address whether and how the chemical molecules meant to induce therapeutic effects reach the places in a person's body

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311. *Id.*

312. *Id.*

313. Robert B. Diasio, *Principles of Drug Therapy*, in CECIL MEDICINE 139, 139 (Lee Goldman & Dennis Ausiello eds., 23d ed. 2007).

314. Arthur J. Atkinson, Jr., *Introduction to Clinical Pharmacology*, in PRINCIPLES OF CLINICAL PHARMACOLOGY 1, 4 (Arthur J. Atkinson, Jr. et al. eds., 2d ed. 2007).

315. *Id.* See also Iain L. O. Buxton, *Pharmacokinetics and Pharmacodynamics: The Dynamics of Drug Absorption, Distribution, Action, and Elimination*, in GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 1, 1 (Laurence L. Brunton et al. eds., 11th ed. 2006).

316. Buxton, *supra* note 315, at 4.

317. *Id.* at 11.

318. See Atkinson, *supra* note 314, at 5–6 ("Failure to appreciate that a patient has impaired renal function is a frequent cause of dose-related adverse drug reactions with digoxin and other drugs that normally rely primarily on the kidneys for elimination.").

where the drug can produce those desired effects.<sup>319</sup>

After the doctor settles on a treatment plan and writes a prescription, the patient will typically then take the prescription to a pharmacist to have it filled. Due to the demanding schedules in pharmacy practice, especially in the retail setting, pharmacists may not have the time to assume any more responsibility than accurate pill-counting.<sup>320</sup> Some computer programs like the one in *Happel* will flag potentially harmful drug interactions, but this software might not indicate the scope and nature of the danger posed by such an interaction.<sup>321</sup> Despite their onerous schedules, pharmacists generally will place calls to the prescribing doctor's office when they are confronted with a potentially problematic prescription.<sup>322</sup> Once the doctor clarifies or reiterates his or her orders, the pharmacist may simply fill the prescription and warn the patient about the possible dangers in the medications.<sup>323</sup>

#### *CALLS FOR INTERDEPENDENT RELIANCE*

Many commentators are pushing for more physician-pharmacist collaboration.<sup>324</sup> Among the justifications are relieving physicians of some of their pharmacotherapy decision-making burden<sup>325</sup> and carving out a more meaningful role for

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319. One theory on how medications produce these effects is the receptor theory, in which a drug molecule attaches to the receptor and triggers the receptor to produce more action (an "agonist") or inhibits its functioning (an "antagonist"). J. Mitchell & P. Seeman, *Drug Receptors*, in *PRINCIPLES OF MEDICAL PHARMACOLOGY* 91, 91, 95-96 (Harold Kalant & Walter H. E. Roschlau eds., 6th ed. 1998); D.J. Triggle, *Receptor Theory*, in *RECEPTORS IN PHARMACOLOGY* 2, 2 (John R. Smythies & Ronald J. Bradley eds., 1978).

320. Smith, *supra* note 11, at 230-31.

321. See Steven A. Scott, *The Prescription*, in *REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY* 1823, 1827 (David B. Troy et al. eds., 21st ed. 2006).

322. See Interviews with Chuck Becker, *supra* note 12.

323. *Id.*

324. E.g. Am. Soc'y of Health Sys. Pharmacists (ASHP), *ASHP Guidelines on Preventing Medication Errors in Hospitals*, 50 *AM. J. HEALTH-SYSTEMS PHARMACY* 305, 305-306 (1993), available at <http://www.ashp.org/DocLibrary/BestPractices/MedMisGdlHosp.aspx>.

325. Richard P. Penna, *Pharmaceutical Care: Pharmacy's Mission for the 1990s*, 47 *AM. J. HOSP. PHARMACY* 543, 546 (1990) ("Pharmaceutical care must be rendered in

pharmacists as clinical drug experts.<sup>326</sup>

As this Article's preceding sections demonstrate, doctors must exercise judgment with regard to a daunting battery of issues. At any point, the physician may slip up and act on mistaken beliefs of fact, whether in terms of the patient's characteristics or the science behind various drug therapy plans. They can and do make determinations based on mental shortcuts, such as the representativeness heuristic, where a physician probes a patient to find symptoms that confirm whether the patient falls within a representative sample of people to which the physician assigned the patient,<sup>327</sup> or the availability heuristic, where a physician makes determinations based on the most readily available knowledge on the physician's mind.<sup>328</sup>

The subconscious use of mental shortcuts pervades drug therapy choices as well. To contend with the time-sensitive demands endured by busy schedules, physicians without time to research drugs newly entering the market may resort to relying on pharmaceutical companies' advertisements.<sup>329</sup> Though warnings about drug effects and interactions must be approved by the Food & Drug Administration (FDA) before the drug can be marketed, subsequent clinical trials and studies can conflict with the recommendations the manufacturers and the FDA issue regarding a drug's usage. For example, one psychiatrist noted to this paper's author that prescriptions for medications calling for dosages above these recommended

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cooperation with physicians, nurses, dentists, optometrists, podiatrists—all those who treat illnesses and prescribe or administer drugs. We know from experience with clinical pharmacy services in hospitals that the pharmacist-physician team makes better drug therapy decisions than does either professional functioning alone.”).

326. See, e.g., Cohen & Smetzer, *supra* note 28, at 657 (“Although pharmacists have long focused on the distribution aspects of their profession, today's pharmacists must turn to a broader and more clinical role to prevent errors effectively.”).

327. Daniel B. Mark, *Decision-Making in Clinical Medicine*, in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 8, 9 (Eugene Braunwald et al. eds., 15th ed. 2001).

328. *Id.*

329. SCHRODER, *supra* note 47, at 406.

ranges may be appropriate once clinical studies show that therapeutic effects can be gained from the additional dosage without undue adverse reactions.<sup>330</sup> But sometimes, an excessive dosage might produce adverse reactions and even drug toxicity.

The FDA too will err in approving a drug and issuing recommendations. Though some review is in many respects preferable to no pre-marketing approval, the FDA's mandated studies and trials bring their own shortcomings. As one professor of preventive medicine suggests, "[t]he randomized trials generally lack the power to detect adverse effects that are infrequent, have a long latency, or affect only certain types of patients."<sup>331</sup> And so, FDA approval does not guarantee safe and effective treatment.

All things considered, the dangers and uncertainty in prescribing medication are manifold and severe. The number and complexity of the judgments physicians make against this background can be overwhelming if physicians must deal with them without outside assistance.<sup>332</sup> If a pharmacist does not step in to correct the error or at least consult the physician about a potential error, then his or her patients are put in danger.<sup>333</sup>

Also motivating calls for collaboration is often a fundamental question about the pharmacy profession's role: Should pharmacists simply execute doctors' orders or should they assume greater responsibilities in making professional judgments about patient care?<sup>334</sup> In the mid-twentieth century, pharmacy practice was largely restricted to order-filling. For its part, the American Pharmacists Association's (APhA) code of

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330. Interview with Jennifer Derenne, M.D., Consulting Psychiatrist, Marquette University Counseling Center, in Milwaukee, Wis. (Oct. 4, 2010).

331. Wayne A. Ray, *Population-Based Studies of Adverse Drug Reactions*, 349 *NEW ENG. J. MED.* 1592, 1592 (2003).

332. Charles D. Hepler & Linda M. Strand, *Opportunities and Responsibilities in Pharmaceutical Care*, 47 *AM. J. HOSP. PHARMACY* 533, 541 (1990) ("Drug therapy has become so complex that one professional should no longer be expected to control the entire process alone."); Penna, *supra* note 325, at 546.

333. See Michael R. Cohen, *Preventing Medication Errors Related to Prescribing*, in *MEDICATION ERRORS* 8.1, 8.20 (Michael R. Cohen ed., 1999).

334. Miller, *supra* note 6, at 245.



ethics in 1952 “prohibited the pharmacist from discussing ‘therapeutic effects or composition of a prescription with a patient.’”<sup>335</sup> Later into the twentieth century, a movement arose to carve out more meaningful roles for pharmacists beyond their pill-counting status.<sup>336</sup> Some segments of the pharmacy and other health care professions resist this change,<sup>337</sup> the former including chain-store pharmacists that feel they cannot take on any more responsibilities in their overburdened schedules<sup>338</sup> and the latter fearing “that pharmacists are attempting to encroach on their territories.”<sup>339</sup> However, amid broader clinical education at the pharmacy school level and OBRA ‘90’s mandate that pharmacists conduct drug reviews and offer counseling,<sup>340</sup> the pharmacy profession is currently trending toward more decision-making regarding appropriate drug therapy schemes.

Notwithstanding the good intentions to expand pharmacists’ knowledge bases and responsibilities, implementing these goals has not been without obstacles. Some commentators have voiced concern that “[p]harmacists and pharmacy managers have attempted to develop and implement

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335. Hepler & Strand, *supra* note 332, at 534.

336. *Id.*

337. In a 2007 study, 98% of pharmacists responded that they believe state regulations should allow multidisciplinary collaboration in long-term care facilities. By contrast, 71% of medical directors opposed allowing such collaboration in that same study. Mark Holthaus, *Long-Term Care: A Test Bed for Coming Health Care Reform*, GERIATRICS (July 1, 2009), <http://geriatrics.modernmedicine.com/reform>.

338. DeBenedette, *supra* note 31, at 40; Smith, *supra* note 11, at 230–31; Hepler & Strand, *supra* note 332, at 534.

339. Penna, *supra* note 325, at 546. In fact, the American Medical Association (AMA) recently published a paper that “contained references to limitations in pharmacists’ education and capabilities, and warnings about doctors’ participation in collaborative drug therapy management (CDTM) agreements with pharmacists.” Thomas E. Menighan, *Pharmacy Response to the “AMA Scope of Practice Data Series: Pharmacists,”* DRUG TOPICS (June 15, 2010), <http://drugtopics.modernmedicine.com/drugtopics/Associations/Pharmacy-response-to-the-AMA-Scope-of-Practice-Dat/ArticleStandard/Article/detail/673895>; see also Reid Paul, *R.Ph.s’ Prescribing Impact to Reach \$145 Billion by 2012*, DRUG TOPICS (Dec. 10, 2007), <http://www.modernmedicine.com/modernmedicine/Hospital%2fHealth-System+Pharmacy/RPhs-prescribing-impact-to-reach-145-billion-by-20/ArticleStandard/Article/detail/477615> (“Not surprisingly, the biggest factors inhibiting the move toward pharmacist prescribing are concerns from physicians. Some doctors worry that pharmacists are not sufficiently trained for diagnosis.”).

340. 42 U.S.C. § 1396r-8(g) (2006).

clinical pharmacy services by using models of pharmacy practice that lack a clear philosophy and a definition of clinical work."<sup>341</sup> As a symptom of this lack of direction, the idea of clinical pharmacy and collaborative pharmaceutical care has been implemented in a piece-meal fashion. In Canada, one survey showed that as few as "one in four (25%) pharmacists strongly agree that they regularly collaborate with physicians and other healthcare professionals."<sup>342</sup>

But amid the clinical pharmacy concept's slow adoption, physicians have started looking to pharmacists to supplement their knowledge of pharmacology.<sup>343</sup> For example, pharmacists and physicians have begun joint efforts to manage blood pressure in patients.<sup>344</sup> Granted, the floor of pharmacists' professional responsibilities is accurately dispensing prescriptions.<sup>345</sup> But, at the same time, "[p]armacists are rightly obligated to promote a good relationship with the physicians with whom they work . . . ." <sup>346</sup> Though some physicians argue that they resent being questioned by pharmacists regarding prescription errors,<sup>347</sup> one pharmacist related to the author of this paper that physicians are generally cooperative when he calls them about medication errors.<sup>348</sup> Likewise, many commentators express the hope that greater pharmacist-

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341. Linda M. Strand et al., *Integrated Patient-Specific Model of Pharmacy Practice*, 47 AM. J. HOSP. PHARMACY 550, 554 (1990).

342. Brett Ruffell, *Mapping Out This Year's Pharmacy Trends*, 26 PHARMACY PRAC., Sept. 2010, at 28, 29.

343. Pozgar, *supra* note 29, at 274; Miller, *supra* note 6, at 238 (relating a story where a physician that prescribed Compazine in five times the recommended dosage asked a pharmacist what the recommended dosage of Compazine should be for a child).

344. *M.D.-Pharmacist Collaboration Helps Hypertensive Patients, Pharmacist Role in Smoking Cessation Less Straightforward*, MODERN MEDICINE (Oct. 12, 2010), <http://www.modernmedicine.com/modernmedicine/Modern+Medicine+Now/MD-Pharmacist-Collaboration-Helps-Hypertensive-Pat/ArticleNewsFeed/Article/detail/690877>.

345. DAVID A. GETTMAN & DEAN ARNESON, PHARMACOETHICS: A PROBLEM-BASED APPROACH 58 (2003).

346. *Id.*

347. *E.g. Hendricks v. Charity Hosp. of New Orleans*, 519 So. 2d 163, 165 (La. Ct. App. 1987).

348. Interviews with Chuck Becker, *supra* note 12.

physician collaboration will prevail in the future.

### TOWARD CONTEXTUAL JUDICIAL REVIEW OF PHARMACIST- PHYSICIAN RELATIONSHIPS

The only parallel between the state of the health care professions' divisions of labor and the liability rules governing them is that they are in a state of flux.<sup>349</sup> On the legal side, the courts are slowly moving away from the traditional rules holding physicians to a pure professional standard and pharmacists to a strictly cabined set of negligence rules treating them as mere order-fillers.<sup>350</sup> Nevertheless, with these rightful strides come a majority of courts that still restrict pharmacists' legal duties without similar limitations for the benefit of physicians.<sup>351</sup> On the health care side, the aspirations of clinical pharmacy and pharmacist-physician collaboration are becoming a reality,<sup>352</sup> but a sizable group of health care practitioners are resisting these changes, whether as a matter of defending their professional territories<sup>353</sup> or refusing to take on more responsibilities on top of already onerous workloads.<sup>354</sup>

#### THE CURRENT LIABILITY RULES' SHORTCOMINGS

The law has been slow to catch up to the changes described in Part II. The courts still apply rules based on a health care context that has long since passed. The rules themselves draw unmalleable bright lines, meaning that ostensibly unreasonable or even unprofessional conduct will persist undeterred<sup>355</sup> and the injury resulting from that conduct uncompensated.<sup>356</sup> To

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349. See DeBenedette, *supra* note 31, at 38, 40.

350. E.g. Horner v. Spalitto, 1 S.W.3d 519, 522 (Mo. Ct. App. 1999).

351. See discussion *supra* Part I.

352. *Supra* note 344; McDonough & Doucette, *supra* note 30.

353. Penna, *supra* note 325, at 546.

354. Smith, *supra* note 11, at 230-31.

355. See Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 39 (1972) (suggesting that if compliance with industry custom operated as a defense to a negligence action, potential injurers would not be induced to change their behavior even if the benefits of safer conduct outweighed their costs).

356. See Valerie Witmer, *A Patient Perspective: Focusing on Compensating Harm*, 13

plug these holes in tort liability as well as relieve legal responsibility when those duties place greater burdens than can be reasonably met, the courts should do away with the antiquated limits on liability discussed above.

*The Physician Professional Standard's Unreasonable Expectations*

Under the professional standard, the scope of physician liability risks being both over- and under-inclusive. As noted above, the professional standard draws from the medical practices accepted within a physician's relevant community. Whatever amounts to due care in the circumstances ebbs and flows with each community's practices, including when a community's standards take on too little or too much responsibility.

That certain conduct may create liability, regardless of its own objective reasonableness,<sup>357</sup> becomes most apparent when facing the courts' treatment of pharmaceutical manufacturers' instructions and warnings. Recall that some jurisdictions use these companies' statements to mold physicians' standard of care.<sup>358</sup> Under this rule, if a physician's treatment plan deviates from a pharmaceutical company's recommendations, then the physician's actions are *prima facie* negligent.<sup>359</sup> Against these background liability rules, physicians prescribe drugs outside of the manufacturers' recommended dosage ranges or in spite of noted contraindications at their own peril.

But sometimes venturing outside of the warnings, warnings necessitating FDA approval and generated through a

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ANNALS HEALTH L. 589, 597 (2004) (charging that legislatively imposed non-economic damage caps would prevent plaintiffs from obtaining full compensation). No liability for unreasonable conduct would rebuke the compensation principle all the more.

357. Richard N. Pearson, *The Role of Custom in Medical Malpractice Cases*, 51 IND. L.J. 528, 528 (1976) ("[I]t is medical custom, rather than standards of reasonableness determined by judges and juries, against which the conduct of a physician is measured.").

358. Minneman, *supra* note 101, § 2a.

359. *Id.*

manufacturers' own series of clinical trials, can amount to good medical practice. Future clinical studies may find that prescribing higher dosages might induce greater therapeutic effects with minimal risks.<sup>360</sup> Dosages might have to be further adjusted to account for an individual patient's idiosyncratic metabolic systems, such as impaired kidney functioning.<sup>361</sup> As to contraindications, some of which arise out of possible adverse drug interactions, it may be reasonable to expose a patient to such a risk.<sup>362</sup>

Yet, the courts using manufacturers' instructions and warnings to raise an inference of negligence would penalize these practices with tort liability should a risk that a therapeutic benefit outweighed materialize. Allowing some leeway for physicians, these courts generally suggest that this inference can be overcome. But such leeway may not mean much to a physician trying to avoid liability. Instead, physicians acting in an otherwise objectively reasonable fashion would effectively have to gamble that a court and a jury would understand his or her reasoning behind such a deviation. That risk of liability may be enough to deter the physician from taking action for which the current state of medical science would advise.

Furthermore, a professional standard might mean that a doctor may exercise a judgment or prescribe a medication that is on balance unreasonable in the circumstances and still escape liability. Some commentators "express concern that the profession is in a position to retain sub-optimally low levels of care, essentially insulating itself from external scrutiny and accountability."<sup>363</sup> This fear motivated the Wisconsin Supreme Court in *Nowatske*, which rejected the professional standard as allowing established practices that entrench "laxness or

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360. Interview with Jennifer Derenne, *supra* note 330.

361. Atkinson, *supra* note 314, at 5–6.

362. 3 PEGALIS, *supra* note 80, § 17:9 ("If an 'indication' and relative 'contraindication' exist at the same time, then truly a judgmental risk-vs-benefit evaluation must be employed by the physician.").

363. James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Health Care Marketplace?*, 11 ANNALS HEALTH L. 125, 131 (2002).

carelessness."<sup>364</sup> In the famous *T.J. Hooper* case, Judge Learned Hand echoed these concerns, suggesting that "a whole calling may have unduly lagged in the adoption of new and available devices."<sup>365</sup> As *Nowatske* rightfully recognized, in many—perhaps most—cases treating malpractice claims, objective reasonableness standards and community practice will require the same level of care.<sup>366</sup> However, the general tendency for these standards to parallel each other does not detract from the continued presence of exceptions.

Beyond the prospect of a medical profession's conspiracy in setting lower standards and refusing to testify against its own members, further problems of proof arise from the use of custom to determine the standard of care. Where the standards are in flux, a court cannot define community practice and thus, cannot define the standard of care, with any degree of precision and consistency.<sup>367</sup> Granted, the danger of inconsistent and even irreconcilable standards presents itself in the general run-of-the-mill negligence case where custom does not itself determine the standard of care.<sup>368</sup> But, at least the reasonableness analysis examines objectively and normatively cost- and benefit-justified alternative courses of conduct. The professional standard, by contrast, requires that a court police a potentially non-existent custom.

Finally, the professional standard may impliedly endorse the traditional practice of shouldering physicians with all of the decisions necessary to determine what medications are most appropriate for a particular patient. As noted above, physicians cannot be expected to keep up with every new drug that enters

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364. *Nowatske v. Osterloh*, 543 N.W.2d 265, 271 (Wis. 1996) (citing *Shier v. Freedman*, 206 N.W.2d 166, 171 (Wis. 1973) (quoting *Pederson v. Dumouchel*, 431 P.2d 973, 977 (Wash. 1967))).

365. *T.J. Hooper*, 60 F.2d 737, 740 (2d Cir. 1932).

366. *Nowatske*, 543 N.W.2d at 272.

367. James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1391 (1994).

368. Joseph H. King, Jr., *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213, 1218 (1975).

the market year to year.<sup>369</sup> Thus, to the extent that accepted medical practice is to have physicians commandeer prescription decisions without outside input, sometimes based on physicians protecting their own professional territories from encroachment by other health care practitioners,<sup>370</sup> the courts applying a professional standard are left reinforcing what could amount to an unreasonable custom motivated by merely provincial concerns.

*The Pharmacist Duties' Moral Hazards*

The same issues plaguing the professional standard as applied to doctors present themselves when assessing pharmacist responsibility. That said, a wholesale professional standard has only taken hold in Arizona and Tennessee, whereas the majority of jurisdictions apply a rule limiting pharmacists' responsibilities to narrow affirmative duties.

These cabined duties effectively operate as safe harbors. Generally, safe harbors provide that if certain named actors conform their conduct to those rules' strictures, then they will avoid liability. For example, under the Digital Millennium Copyright Act, an Internet service provider (ISP) can shield itself from infringement liability if it promptly removes copyright-infringing material specified in a takedown notice.<sup>371</sup> Likewise, in the four jurisdictions that at this time appear to require only that a pharmacist dispense medications to the prescription's letter, a pharmacist cannot be held answerable to a patient injured by an adverse drug reaction, side effects, or drug interactions.<sup>372</sup>

Of all of the rules governing pharmacist negligence, this accurate dispensation rule is the worst offender. As *Horner* noted, the rule relegates pharmacists to the menial role of order

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369. POZGAR, *supra* note 29, at 274.

370. Penna, *supra* note 325, at 546.

371. 17 U.S.C. § 512(c)(1)(A)(iii) (2006).

372. See cases cited *supra* note 159.

filler.<sup>373</sup> Beyond labels on an entire highly educated profession, the rule also creates moral hazards. In the first instance, a pharmacist need not warn a physician at all about an error on a prescription, no matter how little the cost or inconvenience to the pharmacist to avert however serious the danger lurking in the medications may be. In effect, the limits on tort duties separate the pharmacist from the consequences of their own actions in filling potentially dangerous prescriptions. Given the dangers attending pharmacy practice, such moral hazards should not be tolerated.

Even the courts that have extended pharmacist negligence liability beyond mistakes in dispensation run into these same issues with regard to known or obvious errors. The jurisdictions requiring corrective action when confronted with a prescription implicating known contraindications do so with terminology out of sync with health care practice. To these courts, "contraindication" means that the drug should *never* be given to a patient with certain characteristics.<sup>374</sup> In practice, a physician may determine that a contraindicated drug's risks are outweighed by the therapeutic necessities of a patient's multiplicity of conditions.<sup>375</sup> More fundamentally, under the known contraindication rule, pharmacists can hide behind substandard expertise to show that they were not negligent in a given case because they simply lacked subjective knowledge of a contraindication. A pharmacist's ignorance then becomes a defense to liability for negligence, making pharmacist liability an island in tort law.<sup>376</sup> The obvious error rule injects some

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373. *Horner v. Spalitto*, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999).

374. *Hand v. Krakowski*, 453 N.Y.S.2d 121, 123 (1982); *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1120 n.1 (Ill. 2002).

375. 3 PEGALIS, *supra* note 80, § 17:9.

376. Such a position is particularly ill-advised given that pharmacists are professionals commanding specialized knowledge pertaining to drugs and their properties. Compare RESTATEMENT (SECOND) OF TORTS § 290, cmt. b (1965)

Where the issue is as to the requirement of minimum knowledge demanded by the standard of the reasonable man, as stated in this Section, the actor is held to the same conduct as if he were in fact convinced that the fact is true, even though he may in reality be entirely ignorant of it.



objectivity into the pharmacist negligence analysis, but only where the consequences are particularly serious and clear. As limited to obvious errors and not any and all errors, pharmacists can still avoid liability under this rule when they merely have doubts about a prescription, even when faced with a doubt that poses such foreseeable and substantial risks that failure to inquire and to investigate further would be unreasonable.

The courts also err in suggesting types of corrective action that a pharmacist can or should take when faced with an erroneous prescription.<sup>377</sup> Some guidance is appropriate to the extent that pharmacists are put on notice about what actions the law may regard as meeting their duties under tort law, an area notorious for its ambiguities emanating from the reasonableness standard.<sup>378</sup> However, each course of conduct brings its own weaknesses. Refusal to fill a prescription might delay the use of necessary medication when a condition calls for immediate relief.<sup>379</sup> In fact, a prisoner managed to survive a motion for summary judgment on an Eighth Amendment claim against a pharmacist that refused to fill an anticonvulsant prescription, resulting in the prisoner suffering epileptic seizures.<sup>380</sup> Moreover, warning the patient<sup>381</sup> amounts to passing responsibility to someone often without health care training to determine what is best for themselves.<sup>382</sup> Finally, consulting the physician may resolve many issues, but the courts have had difficulty contending with fact patterns in which physicians

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*Id.*, with *id.* § 290, cmt. f ("If the actor has special knowledge, he is required to utilize it, but he is not required to possess such knowledge, unless he holds himself out as possessing it or undertakes a course of conduct which a reasonable man would recognize as requiring it.").

377. See *Hendricks v. Charity Hosp. of New Orleans*, 519 So. 2d 163, 165 (La. Ct. App. 1987).

378. Cf. IRA E. WILLIAMS, FIRST, DO NO HARM: THE CURE FOR MEDICAL MALPRACTICE 52 (2004) ("A legal definition for an acceptable standard of care found in many state statutes is 'one used by a reasonably prudent practitioner.' This is so vague as to be meaningless.").

379. *Hendricks*, 519 So. 2d at 166 (La. Ct. App. 1987).

380. *Johnson v. Hay*, 931 F.2d 456, 456, 458 (8th Cir. 1991).

381. *Hendricks*, 519 So. 2d at 166.

382. Interviews with Chuck Becker, *supra* note 12.

insist that an erroneous prescription is correct as written.<sup>383</sup> Most pertinent to the evolution of pharmacist and physician responsibilities, some of these affirmative suggestions may themselves become outdated in a few years.

*A PROPOSAL FOR A REASONABLENESS TEST GOVERNING BOTH  
PHYSICIANS AND PHARMACISTS*

Adopting an overall reasonableness test for physicians' and pharmacists' tort law duties, and thus treating physician and pharmacist negligence like most other negligence cases, would ameliorate or altogether avoid the problems plaguing the current state of health care practitioner malpractice. Such a rule would provide primarily three benefits: allowing the courts to pass judgment on how one of these practitioners should have acted beyond policing the professions' standards, providing a malleable fact-based standard that can keep up with and even push developing technology going forward, and giving injured patients a voice in the ongoing discussion about how physicians and pharmacists should divide their pharmacological expertise for better treatment outcomes.

*To Examine Community Practices' Reasonableness*

A reasonableness test first gives the courts and juries, well-versed in the common sense ethics and experience independent of the health care fields, a chance to probe the normative implications of a given diagnosis or drug therapy plan.<sup>384</sup> Some may charge that lay jurists cannot comprehend the intricacies of pharmacology, pathology, and biochemistry,<sup>385</sup> arguing that tort

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383. 2 WOODSIDE, *supra* note 20, § 13.03[2][f][iii].

384. See generally FRANK FISCHER, *CITIZENS, EXPERTS, AND THE ENVIRONMENT: THE POLITICS OF LOCAL KNOWLEDGE* (2000) (arguing that citizens can play a meaningful role in democracy, despite the hyper-technical nature of modern-day social issues, by expressing normative judgments about these issues).

385. NEIL VIDMAR, *MEDICAL MALPRACTICE AND THE AMERICAN JURY: CONFRONTING THE MYTHS ABOUT JURY INCOMPETENCE, DEEP POCKETS, AND OUTRAGEOUS DAMAGE AWARDS* 7 (1995).

law should instead defer to the experts.<sup>386</sup> But historical experience has shown jurors' capabilities of handling complex issues.<sup>387</sup> With the aid of expert witnesses, judges and juries are fully capable of assessing a treatment plan's reasonableness.

This is not to say that medical practice should not enjoy any weight or deference. To the contrary, courts should give health care standards the same weight as other industry customs as a doctrinal matter, rather than letting it control in its entirety with no flexibility in every case but the most patently obvious instances of negligence. As such, the probative weight as to the overall question of reasonableness should be allowed to expand and contract depending on the ultimate question of how reasonable the practice is.

*To Keep up with Shifting Professional Divisions of Labor*

Grounding physician and pharmacist malpractice in the unreasonableness of their decisions and orders would generally turn on the facts of each case, allowing the scope of their standards of care to meet the needs and capabilities present at any given time. Generally, the current liability rules only partly depend on the facts of each case. Instead, the courts define practitioners', especially pharmacists', duties based on the judges' own determinations about the general state of medical and pharmacy practice.<sup>388</sup> Such factual policy bases suggest a certain reality that perhaps was true at the time those judicial opinions were drafted, circulated, and disseminated, but much can change in a few years. And change has come. One major change has come by way of a new legal duty. OBRA '90 is a federal mandate that pharmacists are charged with following, such that they must offer drug counseling and other services.<sup>389</sup> More change is on the way given the continuing debate surrounding whether pharmacists' roles should be expanded to

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386. King, *supra* note 368, at 1249.

387. *Id.*

388. See discussion *supra* pp. 488–89.

389. 42 U.S.C. § 1396r-8(g)(2)(A) (2006).

tap into their pharmacological training and expertise.<sup>390</sup>

With the state of health care management itself evolving over time, negligence liability rules surrounding and scrutinizing it should likewise be structured to adapt to changing circumstances. One way to allow for legal rules to track emerging treatment paradigms and scrutinize them along the way is through a circumstantial fact-based test, such as the standard of reasonable care. This way, the same policy arguments that justified limiting pharmacist liability can be introduced as factual arguments in a given case. Or they might not be introduced because they are no longer notable at the moment. At any specific point in time, no one knows whether and how certain corners of the health professions will mold themselves around each other. Rather than premise negligence liability rules on a state of facts that might not arise in later cases, those facts should play a role instead in determining whether the standard of care was met, not whether a duty existed in the first instance.<sup>391</sup>

### *To Give Injured Patients to Voice*

With physician-pharmacist responsibilities reorganizing as they have been in the last few decades, patients have a keen and unique interest in how these practitioners structure their relationships. To be sure, patients are the primary beneficiaries of physicians' and pharmacists' judgment calls, as well as the

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390. See discussion *supra* pp. 498–502.

391. This position invariably allows for fewer bright lines than does the current law, which could in turn impose higher litigation costs on health care providers and their insurers defending a tort suit. That said, another justification for getting pharmacists more involved is that their input would actually reduce the overall cost of health care. See, e.g., Reid Paul, *Employers and Pharmacists Team Up to Drive Down Healthcare Costs*, DRUG TOPICS (May 12, 2008), <http://drugtopics.modernmedicine.com/drugtopics/Pharmacy/Employers-and-pharmacists-team-up-to-drive-down-he/ArticleStandard/Article/detail/515481>. Even if medical malpractice litigation had a substantial effect on other costs related to health care like malpractice insurance premiums, and they arguably do not, see generally TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* (2007), the costs could be offset to some extent by further pharmacist intervention.

parties most acutely harmed when these professionals commit medication errors.

One paramount goal of medical malpractice actions is compensating injured patients within a particular case.<sup>392</sup> This is perhaps the most visible function of tort law, a function immediately relevant to the parties of an individual case.<sup>393</sup> But there is also a public interest concern driving tort liability and the private rights of action that vindicate them: "uncovering dangerous products and practices."<sup>394</sup>

Injured parties can promote safer drug therapy plans and express their needs both in indirect and direct manners. Indirectly, the mere threat of a malpractice or an informed consent lawsuit itself acts to deter careless treatment. Moreover, after a series of lawsuits covering a particular drug, health care professionals and pharmaceutical manufacturers may back off from using or making a drug entirely. Such was the fate of Accutane, an anti-acne medication that was responsible for various severe birth defects.<sup>395</sup> Crushed under the weight of tort suits, Accutane's manufacturer eventually pulled that drug from the market.<sup>396</sup> Directly, a particular malpractice claim could provide a factual background for patients and their advocates to uncover how various health care practitioners may have failed. Patients' attorneys and their experts can show the presence of safer alternative treatment plans.<sup>397</sup> They can show that a practitioners' chosen therapy scheme or other judgment calls were not cost-justified.<sup>398</sup> Given the eminent public concerns regarding the efficient and safe administration of patient care, the discussion on how this can best be accomplished should

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392. VASANTHAKUMAR N. BHAT, *MEDICAL MALPRACTICE: A COMPREHENSIVE ANALYSIS* 9–10 (2001).

393. THOMAS H. KOENIG & MICHAEL L. RUSTAD, *IN DEFENSE OF TORT LAW* 1, 1 (2001).

394. *Id.* at 2; PROSSER & KEETON, *supra* note 54, at 25–26.

395. PDR, *supra* note 2, at 2832.

396. John Jesitus, *Exit Accutane: Derms' Reactions Mixed As Roche Pulls Long-Standing Remedy*, *DERMATOLOGY TIMES*, Aug. 1, 2009, at 1.

397. The Ninth Circuit itself noted such alternatives in *Hutchinson v. United States*, 915 F.2d 560, 563 (9th Cir. 1990).

398. *See, e.g., id.*

include those affected most: patients.

## CONCLUSION

Against the background of calls for greater collaboration among health professionals and change in malpractice liability, in many cases, physicians and pharmacists may not communicate at all with each other. To some extent, this is ideal, as the physician may have arrived at a medication decision on his or her own without requiring the expertise of a pharmacist. Likewise, a pharmacist may not have to consult a physician to verify that a reasonable prescription is correct. When a patient takes the medications approved by these practitioners and sees improvement in the condition that ails him or her, there is little concern about whether mistakes were made in the process. The concern of tort law, after all, is not to scrutinize actions that cause no harm.

The need to determine which health professional is responsible for unreasonable missteps arises when adverse drug reactions or interactions occur. However, the current state of negligence liability rules governing pharmacy and medical malpractice stifles the ability of all interested parties—patients, health care providers, the courts, and the public at large—to confront. Falling back on traditional negligence principles, namely the standard of reasonable care, can ameliorate that problem.