THE OBRA 90 MANDATE AND ITS DEVELOPING IMPACT ON THE PHARMACIST'S STANDARD OF CARE

*Kenneth R. Baker**

In 1990, Congress passed the Omnibus Budget Reconciliation Act of 1990,[1] which contained provisions affecting the way pharmacists would be required to handle prescription requests of Medicaid recipients.[2] This new law also required states to enact legislation or regulations requiring pharmacist drug review of Medicaid prescriptions, counseling of Medicaid patients, and prescription record-keeping for these patients.[3] These requirements are referred to as "OBRA 90" requirements.

To receive matching federal Medicaid funds, OBRA 90 required the states to enact prospective and retrospective drug review programs by January 1, 1993.[4] The prospective drug review design ensured that Medicaid patients would receive the benefit of a pharmacist drug review prior to having their prescriptions filled, thus providing those patients with pharmacist counseling at that time.[5] While these federal requirements refer only to Medicaid prescriptions, by 1994 at least forty states had passed regulations or statutes extending the prospective drug review requirements of OBRA 90 to all prescriptions.[6]

The pharmacy profession played an important role in placing these new requirements upon itself. Although Congress passed the OBRA 90 changes, the ideas behind the new requirements came from within the pharmacy profession. Congress worked toward finding ways to decrease the growing cost of Medicaid.[7] Pharmacy leaders convinced the Senate committee that introduced the new requirement that through the use of drug reviews and counseling, hospitalizations could be reduced and many otherwise noncompliant patients could be successfully treated by drugs rather than more expensive alternatives such as surgery.[8] Many pharmacists recognized a

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* Vice President, General Counsel, Pharmacists Mutual Insurance Company. B.S., Pharmacy, Purdue University, 1967; J.D., Indiana University School of Law at Indianapolis, 1975.

1. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (codified in scattered sections of 42 U.S.C.).

2. *See* 42 U.S.C. § 1396r-8(g).

3. *Id.* § 1396r-8(g)(2).

4. *Id.* § 1396r-8(g)(2)(A).

5. *See id.* § 1396r-8(g)(2)(A)(i).

6. NATIONAL ASS'N OF BOARDS OF PHARMACY, SURVEY OF PHARMACY LAW 50 (1994).

7. David G. Schulke, Inappropriate Drug Therapy and Drug Use Review: An Annotated Bibliography for State Policymakers, Address Before the American Drug Utilization Review Symposium (Feb. 20, 1991).

8. John M. Coster, OBRA '90, Address Before the Rhode Island Department of Health (Oct. 22, 1992); *see also* MICHAEL T. RUPP, THE PHARMACEUTICAL ECONOMICS RESEARCH

decrease in profits from utilizing only the dispensing function of pharmacies and therefore determined they needed to find a better way of using their specialized knowledge of drugs to enhance their professional recognition and earning power.

During the 1970s, pharmacists began searching for a new role—one more compatible with their education and knowledge. Unwilling to be relegated to the simple functions of "count, pour, lick and stick," pharmacists increasingly counseled patients regarding their prescription medications. Additionally, pharmacists became less hesitant in questioning physicians concerning possible overdoses or use of contraindicated drugs. A coordinated effort developed among pharmacists to maintain patient profile histories of medication filled by the pharmacy. Pharmacy associations started to champion the role of the pharmacist as monitor of prescription drugs. The National Association of Boards of Pharmacy and several individual states adopted new and expanded definitions of the practice of pharmacy.[9]

Many factors combined during this period to change the role of the pharmacist from a compounder and dispenser to an expert in drugs and drug usage. One factor was the desire of pharmacists to establish for themselves a more professional role. The pharmacist lost the role of compounder and manufacturer of drugs to the pharmaceutical industry, which by the 1960s precompounded most prescription items. Individual pharmacists, schools of pharmacy, and pharmacy organizations recognized that unless pharmacy developed new roles, highly educated professional pharmacists risked the perception that pharmacists were an expensive luxury.

As pharmacists began advising patients about prescription medications, they increasingly found that they enjoyed the opportunity to use their education and knowledge, as well as the opportunity to fulfill a more challenging professional function. Pharmacists began searching for ways to expand the use of their specialized knowledge and increase the public perception of their value. The role of drug counselor and expert thus followed a natural progression for pharmacists.

Beginning in the late 1960s and early 1970s, the public started taking a more active role in its own health. Patients no longer accepted taking medications with unfamiliar and unexpected side effects. Patients instead demanded more information regarding prescription and over-the-counter drugs. Pharmacists were more accessible than physicians and were more willing to supply answers. In addition, pharmacists tended not to charge for the advice.

Pharmacy schools recognized the need for students to gain a more complete education of the effects and side effects of prescription medications. As a result, pharmacy students trained during the 1970s and 1980s were more technically prepared for the role of counselor. As new, more powerful drugs

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CENTER, FINAL REPORT: PRESCRIBING PROBLEMS AND PHARMACIST INTERVENTIONS IN COMMUNITY PRACTICE (1991).

9. *See, e.g.*, MODEL STATE PHARMACY ACT art. I, § 103 (Nat'l Ass'n of Boards of Pharmacy 1977).

reached the marketplace, an increasing need for better understanding among the public of how, when, and why medication should be taken occurred. The skyrocketing cost of health care reinforced the notion to patients, physicians, pharmacists, and legislators that drugs taken correctly can save the cost of more expensive treatments.[10]

Pharmacy competition also changed during the 1970s and 1980s. The established pharmacy industry, which competed increasingly on price, experienced a proliferation of new pharmacy outlets that could compete very effectively with lower prices. Deep discount pharmacies, grocery stores, and department stores recognized pharmacy departments were "traffic builders" and were willing to accept a lower profit margin. Mail order pharmacies found ways to sell at lower prices and were aided by the increasing development of the third-party-payer. The third-party payers recognized a way of increasing their value to their customers—the large employers who paid more and more of prescription costs through employee benefit programs. Because a large segment of the population was convinced that the products of one pharmacy were the same as all others, third-party-payers were able to convince employers that employees' needs could be satisfied with a limited selection of participating pharmacies in prescription drug plans. As competition among pharmacies for third-party contracts increased, margins became even smaller.

This intense competition eventually forced pharmacists to look for other methods of differentiating their products from the products sold in other pharmacies. Increasingly, pharmacies looked to value-added services, such as mail order and patient counseling, as a means of differentiating their products.

Factors leading to increased counseling and increased recognition of pharmacists as drug experts have not been lost on the legal profession. Attorneys started recognizing that pharmacists were in a position to help patients prevent harmful side effects and injuries from drugs through better warnings. More significantly, attorneys realized that if pharmacists had the ability to assist patients in avoiding injury, they may also have a duty to do so. Consequently, attorneys began naming pharmacists as additional defendants when representing clients injured by harmful side effects of prescription medication. Previously, attorneys considered only physicians and drug manufacturers as potential defendants. Courts, however, were not easily convinced of this newly discovered duty of pharmacists.

A series of cases against pharmacists, known as "duty to warn" cases, developed during the 1970s, 1980s, and 1990s. Patients who believed their injuries occurred, at least partly, because the pharmacist did not warn them of the side effects of their medication filed lawsuits against pharmacists. In *Ingram v. Hook's Drugs Inc.*,[11] for example, the plaintiff, Mr. Ingram, filled a prescription for Valium at the defendant drug store, Hook's Drugs Inc., in Indiana.[12] A few days later, Ingram injured himself in a fall.[13] Ingram's

10. *See* RUPP, *supra* note 8, at 32-34.

11. Ingram v. Hook's Drugs Inc., 476 N.E.2d 881 (Ind. Ct. App. 1985).

12. *Id.* at 883.

attorney filed suit against Hook's Drugs alleging that the store pharmacist did not warn Ingram that Valium could cause drowsiness and other side effects.[14] Ingram's attorney argued that the lack of warning constituted negligence and was a proximate cause of Ingram's injuries.[15] Hook's Drugs' attorney filed a summary judgment motion asking the court to find, as a matter of law, that pharmacists have no duty to warn patients of side effects of prescription medication.[16] Ingram's attorney argued that a jury should decide the question.[17] The trial court agreed with Hook's Drugs and granted summary judgment.[18]

Ingram appealed to the Indiana Court of Appeals.[19] The court reviewed case law from other jurisdictions[20] and examined the definition of the "practice of pharmacy" in the Indiana Code, which stated that "the practice of pharmacy . . . means . . . the responsibility for *advising, as necessary, as to the contents, therapeutic values, hazards, and appropriate manner of use of drugs or devices*."[21] The court found this definition did not create a "mandatory duty on the part of a pharmacist filling a prescription to warn a customer of all possible hazards associated with that drug."[22] The court said that the Board of Pharmacy has the authority to regulate the pharmacy profession and its regulations "require[d] a pharmacist only to include directions for use as contained in the prescription."[23] The Indiana Court of Appeals determined that the duty to warn was "part and parcel of the physician-patient relationship."[24] The court added:

> The injection of a third-party in the form of a pharmacist into the physician-patient relationship could undercut the effectiveness of the ongoing medical treatment. We perceive the better rule to be one which places the duty to warn of the hazards of the drug on the prescribing physician and requires of

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13. *Id.*
14. *Id.*
15. *Id.*
16. *Id.* at 884.
17. *Id.*
18. *Id.* at 887.
19. *Id.* at 883.
20. *Id.* at 885-87 (reviewing McLeod v. W.S. Merrell Co., 174 So. 2d 736, 738 (Fla. 1965) (stating that the patient-purchaser did not rely on the judgment of the retail pharmacist; confidence had been placed in the physician who prescribed the remedy); Bichler v. Willing, 397 N.Y.S.2d 57, 59 (App. Div. 1977) (holding that consumer does not rely on pharmacist's judgment but instead places confidence and reliance in the physician who prescribed the remedy); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 274 (N.C. Ct. App.) (holding that defendant-pharmacist was not qualified or licensed to advise the plaintiff because the pharmacist was not a physician), *review denied*, 233 S.E.2d 921 (N.C. 1977)).
21. *Id.* at 884 (citing IND. CODE § 25-26-13-1 (1982)).
22. *Id.* at 884-85.
23. *Id.*
24. *Id.* at 886.

> the pharmacist only that he include those warnings found in the prescription.[25]

The Indiana court was not alone in holding that pharmacists had no duty to warn. Before and after the Indiana decision in 1985, "no duty to warn" became the majority opinion in state appellate courts deciding the question.[26] Although exceptions to this rule existed, they were usually based on the facts of the particular case. In 1982, a New York appellate court sent a case back to the trial court for the jury to decide the issue of negligence when a pharmacist dispensed a drug contraindicated with the use of alcohol to a patient who the pharmacist knew was an alcoholic.[27] A Pennsylvania court let stand a jury verdict finding a pharmacist negligent for failing to warn a patient of the maximum safe dosage of Cafergot suppositories[28] when the physician's prescription contained "obviously inadequate" directions for use.[29] The Pennsylvania court rejected the pharmacy's argument that no duty to warn existed stating:

> The appellant [pharmacy] would seem to argue that a pharmacy is no more than a warehouse for drugs and that a pharmacist has no more responsibility than a shipping clerk who must dutifully and *unquestioningly* obey the written orders of omniscient physicians. Such is not the case.
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> The pharmacist is a professional. . . . Public policy requires that pharmacists who prepare and dispense drugs and medicines for use in the human body must be held responsible for the failure to exercise the degree of care and vigilance commensurate with the harm which would be likely to result from relaxing it.[30]

Additionally, the court noted that physicians occasionally err and that fatality can result from such an error, thus requiring each member of the health care team to assume a limited duty to be "his brother's keeper."[31] In holding that the pharmacist breached his duty to warn the patient or to notify the

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25. *Id.* at 887.

26. David B. Brushwood, *The Pharmacist's Duty to Warn: Toward a Knowledge-Based Model of Professional Responsibility*, 40 DRAKE L. REV. 1, 10 (1991); *see, e.g.*, Kinney v. Hutchinson, 449 So. 2d 696, 698 (La. Ct. App. 1984); McKee v. American Home Prods. Corp., 782 P.2d 1045, 1048-49 (Wash. 1989).

27. Hand v. Krakowski, 453 N.Y.S.2d 121, 122-23 (App. Div. 1982).

28. Cafergot suppositories are prescription drugs which have "beneficial effects in treating migraine headaches, due to [their] action in constricting blood vessels." Riff v. Morgan Pharmacy, 508 A.2d 1247, 1249 (Pa. Super. Ct. 1986), *appeal denied*, 524 A.2d 494 (Pa. 1987).

29. *Id.*

30. *Id.* at 1251.

31. *Id.* at 1253.

prescribing physician of the obvious inadequacies on the face of the prescription, the court noted:

> If the consensus of the medical community is that a safety net of overlapping responsibilities is necessary to serve the best interests of patients, it is not for the judiciary to dismantle the safety net and leave patients at the peril of one man's human frailty.[32]

In 1988, a North Carolina appellate court reviewed a case in which a patient died of an anaphylactic reaction after taking a dose of Indocin filled by the defendant pharmacist.[33] Testimony revealed evidence that the patient had asked the pharmacist if it was problematic to take the Indocin considering his allergy to aspirin.[34] Allegedly, the pharmacist indicated it was safe.[35] Reversing the trial court's dismissal of the case against the pharmacist, the appellate court remanded the case for a jury trial. The court held that "[w]hile a pharmacist has no duty to advise absent knowledge of the circumstances, . . . once a pharmacist is alerted to the specific facts and he or she undertakes to advise a customer, the pharmacist then has a duty to advise correctly."[36]

A Tennessee appellate court approached the question of pharmacists' duty to warn differently in its 1991 decision, *Dooley v. Everett*.[37] The case involved an asthmatic child who had been treated by his physician with prescriptions for Theophyllin, filled by the defendant, Revco Drug Stores.[38] When the child developed an infection, the physician prescribed Erythromycin and the same Revco store filled the prescription.[39] The Erythromycin caused the levels of Theophyllin in the blood to increase, which allegedly caused brain damage.[40] The plaintiffs filed suit against the physician and Revco, and Revco filed a motion for summary judgment asserting that the pharmacist had no duty to warn the plaintiffs of the potential interaction.[41] The plaintiffs opposed the motion and filed an affidavit of an expert witness, a retail pharmacist in Tennessee.[42] The expert testified that the minimum standard of practice for a pharmacist in that community required the pharmacist to maintain a patient profile.[43] The pharmacist would then know which other medications the patient was taking before filling a new

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32. *Id.* at 1254.
33. Ferguson v. Williams, 374 S.E.2d 438 (N.C. Ct. App. 1988).
34. *Id.* at 440.
35. *Id.*
36. *Id.*
37. Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990).
38. *Id.* at 382.
39. *Id.*
40. *Id.*
41. *Id.* at 383.
42. *Id.* at 382.
43. *Id.* at 383.

prescription.[44] Additionally, the expert testified the pharmacist should have recognized the potential problem created by filling the prescription for Erythromycin to a patient on Theophyllin.[45] Should the pharmacist fail to recognize the problem on his own, the expert explained, computer software existed which could have warned him.[46] Also, according to the expert, the minimum standard of practice required the pharmacist to warn either the physician or patient of the potential problem.[47] The plaintiffs argued that the Revco pharmacist did none of this and thus Revco failed to meet the minimum standard of care.[48] The trial court subsequently dismissed the suit against Revco, finding neither the pharmacist nor pharmacy had a duty to warn.[49]

The Tennessee appellate court reversed the trial court's decision that there was no duty to warn.[50] The court stated that the question of whether the duty to warn of a potential drug interaction is included within the pharmacist's duty to his customer is a question to be determined by the trier of fact.[51] The court remanded the case to the trial court for a jury to decide the scope of the duty to warn.[52] The court reasoned:

> "[D]uty" is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases, the duty is always the same—to conform to the legal standard of reasonable conduct in the light of the apparent risk. What the defendant must do, or must not do, is a question of the standard of conduct required to satisfy the duty.[53]
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> Professionals are judged according to the standard of care required by their profession. . . .[54]
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> . . . [O]ne who undertakes to render services in the practice of a profession or trade is required to exercise the skill and knowledge normally possessed by members of that profession or trade in good standing in similar communities.[55]

The significance of *Dooley* lies in its shift from focusing on a pharmacist's duties to focusing on the standard of practice of pharmacy—thus

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44. *Id.*
45. *Id.*
46. *Id.*
47. *Id.*
48. *Id.* at 384.
49. *Id.* at 382.
50. *Id.* at 386.
51. *Id.*
52. *Id.*
53. *Id.* at 384 (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 53, at 356 (5th ed. 1984)).
54. *Id.* at 384-85.
55. *Id.* at 385 (citing RESTATEMENT (SECOND) OF TORTS § 299A (1965)).

shifting from a legal to a factual analysis. *Dooley* also becomes important in determining the effect of OBRA 90 and various state laws and regulations required by OBRA 90 regarding the question of pharmacists' duties in the future. As part of its discussion, the *Dooley* court examined Tennessee law regulating and defining the practice of pharmacy.[56] The Indiana Court of Appeals in *Ingram v. Hook's Drug Stores*[57] also reviewed state law and pharmacy board regulations. After January 1993, courts looking to state law and regulations for guidance will find OBRA 90-type pronouncements. The real effect of OBRA 90 will be its effect on the determination of the minimum standard of practice of pharmacy.

The prospective drug review provision of OBRA 90 requires states to enact legislation or regulations requiring pharmacists to provide counseling and drug utilization review services on all Medicaid prescriptions filled after January 1, 1993, in order to be eligible for federal Medicaid matching funds.[58] As each state enacted the required regulations some differences appeared.[59] A majority of states mandated that the requirements of the prospective drug review provision of OBRA 90 apply to all prescriptions,[60] while a minority of states applied the requirements only to Medicaid prescriptions.[61]

The prospective drug review section of OBRA 90 also requires maintenance of patient profiles, performance of a drug review on each prescription, and an offer to discuss the benefits of drugs being prescribed with each patient.[62] Each of these "requirements" has conditions, provisos, and limitations.[63] In addition to potential increased civil liability, failure to fulfill each requirement may also subject the pharmacist to disciplinary action by the state's Board of Pharmacy.

The federal act requires that a "reasonable effort must be made by the pharmacist to obtain, record, and maintain" certain information for each patient, including:

> (aa) Name, address, telephone number, date of birth (or age) and gender.
> (bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

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56. *Id.*

57. Ingram v. Hook's Drugs Stores, Inc., 476 N.E.2d 881 (Ind. Ct. App. 1985).

58. 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

59. Richard H. Gastineau, *Drug Therapy Counseling: Whose Duty to Warn?*, 2 J. PHARMACY & L. 293, 321 (1994).

60. *Id.*

61. *See* NATIONAL ASS'N OF BOARDS OF PHARMACY, *supra* note 6, at 50. This article discusses the basic federal requirements. Attorneys should consult their own state regulations or statutes for specific language in their state.

62. 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

63. *Id.*

> (cc) Pharmacist comments relevant to the individual drugs [sic] therapy.[64]

Because the pharmacist is only required to make "a reasonable effort" to obtain this information, it is anticipated that the required information will come directly from the patient, a caregiver, or family member sent by the patient to the pharmacy. Only in extraordinary cases would the pharmacist be required to call the physician's office for this information. Because of the volume of prescriptions filled in most pharmacies, requiring such a call would be unduly burdensome and could jeopardize the program.

Armed with the patient profile information, the pharmacist must conduct "a review of drug therapy before each prescription is filled or delivered to an individual . . . typically at the point-of-sale or point of distribution."[65] OBRA 90 states that the drug review:

> shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.[66]

OBRA 90 also requires each state to establish standards for counseling by pharmacists.[67] The federal act requires state law regarding pharmacist counseling to include at least the following:

> (I) The pharmacist must offer to discuss with each individual . . . or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:
> (aa) The name and description of the medication.
> (bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.
> (cc) Special directions and precautions for preparation, administration and use by the patient.
> (dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
> (ee) Techniques for self-monitoring drug therapy.
> (ff) Proper storage.

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64. *Id.* § 1396r-8(g)(2)(A)(i)(II).
65. *Id.* § 1396r-8(g)(2)(A)(i).
66. *Id.* § 1396r-8(g)(2)(A)(ii)(I).
67. *Id.* § 1396r-8(g)(2)(A)(ii).

(gg) Prescription refill information.
(hh) Action to be taken in the event of a missed dose.[68]

The prospective drug review portion of OBRA 90 concludes by stating that "[n]othing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual . . . or caregiver of such individual refuses such consultation."[69]

Whether a pharmacist can be held liable for failing to warn a patient that a drug may cause drowsiness or for failing to alert a physician or patient of potential interaction between two prescribed drugs involves two threshold questions.[70] The first question is whether the pharmacist has a legal duty to the patient.[71] If a legal duty exists, the second question becomes whether the pharmacist has met the standard of care required.[72] Without a legal duty, addressing the question of the standard becomes unnecessary because no action for negligence can stand.[73]

Many courts considering the question of pharmacist liability in situations in which a physician's prescription was correctly filled by the pharmacist have addressed only the issue of legal duty. A Michigan appellate court, in *Stebbins v. Concord Wrigley Drugs, Inc.*,[74] held "that a pharmacist has no duty to warn the patient of possible side effects of a prescribed medication where the prescription is proper on its face and neither the physician nor the manufacturer has required that any warning be given to the patient by the pharmacist."[75] The *Stebbins* court did not go beyond this pronouncement in its discussion of lack of legal duty, but seemed to accept the premise as policy. Before imposing a legal duty, courts have considered the relationship of the parties, the reasonable foreseeability of harm, and public policy.[76]

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68. *Id.*
69. *Id.*
70. *See* Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1131-32 (Ariz. Ct. App. 1994).
71. *Id.*
72. *Id.* at 1132.
73. *Id.* at 1131-32; *see also* Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 386 (Mich. Ct. App. 1987) (holding that pharmacy had no duty to warn consumer of potential side effect of the drug Tofranil).
74. Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381 (Mich. Ct. App. 1987).
75. *Id.* at 388.
76. *E.g.*, Webb v. Jarvis, 575 N.E.2d 992, 995 (Ind. 1991). The Indiana Supreme Court determined that a duty existed when a pharmacist refilled a controlled substance at an unreasonably faster rate than the prescription indicated in the physician's directions. Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 517 (Ind. 1994). This case did not overrule *Ingram v. Hook's Drugs, Inc.*, in which the appeals court held that a pharmacist had no duty to warn, but rather it distinguished the case based on the facts. Hook's SuperX v. McLaughlin, 642 N.E.2d at 518 (stating that *Ingram* did not involve the rate at which the customer used the drugs).

Public policy concerns seem to form the basis of the cases holding that no duty to warn exists. In *Jones v. Irvin*[77] the court held, in part, that requiring a pharmacist to warn "would only serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability."[78] The Indiana Court of Appeals in *Ingram* discussed "duty" in granting summary judgment in favor of the defendant, Hook's Drugs.[79] The court looked at the Board of Pharmacy regulation on the information a pharmacist was required to give a patient.[80] The court then concluded that the regulation required only that the pharmacist include directions for use as contained in the prescription.[81] The question was thus a matter of law rather than a question of fact.[82]

Later courts also examined the question of legal duty. The Arizona Court of Appeals, in *Lasley v. Shrake's Country Club Pharmacy, Inc.*,[83] rejected the notion that pharmacists have no duty to warn patients of the addictive nature of prescription drugs and the dangers of long-term use.[84] The court reversed the summary judgment granted by the trial court, opining that the trial court confused the concept of duty with standard of care.[85] The *Lasley* court reasoned that:

> legal duty . . . [i]s a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases the duty [if it exists] is always the same—to conform to the legal standard of reasonable conduct in light of the apparent risk. What the defendant must do, or must not do, is a question of the standard of conduct required to satisfy the duty.[86]

For courts viewing the legal duty of pharmacists as a matter of public policy, OBRA 90 regulations may have taken the matter out of the court's control. Prior to the enactment of Indiana's version of OBRA 90, the Indiana Court of Appeals in *Ingram* looked to the then-existing Board of Pharmacy

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77. Jones v. Irvin, 602 F. Supp. 399 (S.D. Ill. 1985).

78. *Id.* at 402 (cited with approval in Fakhouri v. Taylor, 618 N.E.2d 518, 520 (Ill. App. Ct.), *appeal denied*, 622 N.E.2d 1204 (Ill. 1993); Eldridge v. Eli Lilly & Co., 485 N.E.2d 551, 552 (Ill. App. Ct. 1985); Walker v. Jack Eckerd Corp., 434 S.E.2d 63, 67-68 (Ga. Ct. App. 1993); Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d at 387; Docken v. Ciba-Geigy, 790 P.2d 45, 47 (Or. Ct. App.), *review denied*, 795 P.2d 554 (Or. 1990)).

79. Ingram v. Hook's Drugs Inc., 476 N.E.2d 881, 883-87 (Ind. Ct. App. 1985).

80. *Id.* at 884-85.

81. *Id.* at 885.

82. *Id.* at 887.

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

84. *Id.* at 1133-34.

85. *Id.* at 1133.

86. *Id.* at 1132 (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 53, at 356 (5th ed. 1984)).

regulations and declared that "a pharmacy had no duty to warn the customer of hazards associated with prescription drugs where no warnings were found in the prescription."[87] The law now places on the pharmacist a duty other than filling the prescription exactly as written.[88] In light of the OBRA 90 regulations passed by the Indiana Board of Pharmacy subsequent to the decision in *Ingram*, the *Ingram* court would now have difficulty arriving at the same decision.[89]

In *Walker v. Jack Eckerd Corp.*,[90] the Georgia Court of Appeals held, as a matter of law, that a pharmacist did not have a duty to warn a patient about the long-term effects of a prescription eye drop.[91] However, the court noted that the decision was not intended to serve as controlling precedent for cases involving pharmacists' duties arising after January 1, 1993, the date that Georgia's OBRA 90 regulations became effective.[92] For prescriptions filled after January 1, 1993, the Georgia court left open the question of whether it would apply a Georgia Board of Pharmacy regulation entitled Patient Counseling.[93] The regulation requires the pharmacist to "consult[] [with] patients regarding their medications and various conditions which could affect or be affected by the use of those medications."[94] The pharmacist must also maintain patient records[95] and perform a prospective drug review on each prescription.[96] If a pharmacist recognizes a problem of therapeutic appropriateness while completing the prospective drug review, "the [p]harmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the [p]ractitioner."[97]

Similarly, an Indiana statute now requires the Indiana Board of Pharmacy to establish "standards for a pharmacist to counsel individuals

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87. Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881, 887 (Ind. Ct. App. 1985).

88. *See* IND. CODE ANN. § 25-26-13-4(b)(2) (Burns 1995); IND. ADMIN. CODE tit. 856, r. 1-33-2(a)(4) (1995).

89. After the symposium and presentation of this paper at Drake University, the Indiana Supreme Court reversed an appellate court decision holding a pharmacist did not have a duty to warn as a matter of law. Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514 (Ind. 1994) The Indiana Supreme Court in *Hooks SuperX*, however, did not overrule *Ingram* and did not decide the case based on Indiana's OBRA 90 regulations. *Id.* at 518-19. The prescriptions in question in *Hooks SuperX* predated the OBRA 90 regulations. *Id.* at 516.

90. Walker v. Jack Eckerd, Corp., 434 S.E.2d 63 (Ga. Ct. App. 1993).

91. *Id.* at 69.

92. *Id.*

93. *See* GA. COMP. R. & REGS. r. 480-31-.01 (1995). The court in *Walker* indicated that if faced with the question of applying state OBRA 90-type regulations to the question of a pharmacist's duty, it may consider the purpose of the regulation. *See* Walker v. Jack Eckerd, Corp., 434 S.E.2d at 69. If the purpose is merely to comply with a federal mandate, however, the court may be less inclined to look at the regulations as setting standards. While, if the purpose is public safety, it may.

94. GA. COMP. R. & REGS. r. 480-31-.01.

95. *Id.* r. 480-31-.01(a)(1).

96. *Id.* r. 480-31-.01(b)(1).

97. *Id.* r. 480-31-.01(b)(2).

regarding the proper use of drugs." [98] The regulations promulgated pursuant to this statute direct the pharmacist to perform drug reviews, maintain patient profiles, and "be responsible for the initiation of an offer to discuss matters (counsel) which, in the pharmacist's professional judgment, are significant to optimizing drug therapy." [99] In 1985, the Indiana Court of Appeals declared in *Ingram* that the defendant pharmacist had no duty to warn that Valium may cause drowsiness and affect balance.[100] After 1993, pharmacists in Indiana were mandated by regulation to initiate an offer of counseling which may include "[c]ommon adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur." [101] Both *Ingram* and the Indiana Court of Appeals' decision in *Hooks SuperX* would likely be decided differently after the implementation of OBRA 90.[102]

The question of pharmacists' legal duty to warn has been statutorily or administratively[103] resolved in most states through OBRA 90-type statutes, rules, or regulations.[104] Questions, however, remain. For example, a few states, such as Connecticut, require counseling only for Medicaid patients[105] because OBRA 90 only mandated that requirement. There should not, however, be two different standards of conduct or two legal duties—one for welfare patients, and another lesser duty for paying patients. If a pharmacist can be required to perform a drug review and to counsel a patient—the two taken together form a "duty to warn"—the pharmacist will be held to act with the same standard of care for all patients to whom the same drug is prescribed.[106]

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98. IND. CODE § 25-26-13-4(b)(2) (1995).

99. IND. ADMIN. CODE tit. 856, r. 1-33-2(a) (1995) (requiring patient counseling); IND. ADMIN. CODE tit. 856, r. 1-33-3 (1995) (requiring patient profiles).

100. Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881, 883 (Ind. Ct. App. 1985).

101. IND. ADMIN. CODE tit. 856, r. 1-33-2(a)(4) (1995).

102. While the Indiana Supreme Court decision in *Hooks SuperX* reversed the court of appeals decision, the Indiana Supreme Court did not overrule *Ingram* and did not consider the new Board of Pharmacy regulations in making its decision. Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 518-19 (Ind. 1994). The prescription in question in *Hooks SuperX* was filled prior to the effective date of these regulations. *Id.* at 516.

103. *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 36 (5th ed. 1984) and RESTATEMENT (SECOND) OF TORTS § 285 (1965) (discussing the principle that a standard of conduct may be set by statute or regulation). Not all statutes will, or must, set the standard of conduct, or duty. If the purpose of the statute is something other than establishing conduct, a court may ignore it in determining duty. For example, laws in the 1970s decreasing speed limits may have been enacted for the purpose of saving gasoline rather than to simply decrease speed. Thus, a court could decide not to hold violation of that speed limit to be negligence. For a discussion of this point, see KEETON ET AL., *supra*, at 227. Most OBRA 90 legislation and regulations, however, have indicated that the purpose of the rules was for public safety, thus creating a duty or standard.

104. *See* NATIONAL ASS'N OF BOARDS OF PHARMACY, *supra* note 6, at 50.

105. CONN. GEN. STAT. ANN. 20-185g(c) (West. Supp. 1996).

106. *See* KEETON ET AL., *supra* note 103, § 53 (defining duty as an obligation to conform

Following the lead of *Dooley* and *Lasley*, many plaintiffs will now use a pharmacist expert witness to testify regarding the minimum standard of practice for pharmacists in their community. Should courts follow the reasoning of those decisions, the question of whether a pharmacist can be liable for a failure to warn will be decided by the jury and will turn on the experts' opinions of the pharmacists' minimum standard of practice. That standard has now become the requirement in the prospective drug review section of OBRA 90.[107] The standard of practice of any profession is set by the profession itself.[108] Significantly, even before these requirements became a part of OBRA 90, the concepts were generally accepted by the academic pharmacy community.

Now that OBRA 90 requirements have been codified in most states, expert testimony is more predictable. One test of an applicable standard of care is the minimum standards required by state professional boards. A pharmacist can be disciplined for not meeting a specific professional requirement or for not possessing a minimum standard of knowledge and ability that the pharmacist is expected to meet.[109] While the standard of care is generally based on the custom and conduct of other pharmacists in the community, evidence that the community is careless cannot be used to set the standard of care below that required by the regulations.[110] An expert called to testify about the minimum standard of practice of pharmacists in a given community will be required only to point to the standard required by the regulations.

Even if courts accept the requirements of OBRA 90 as the standard of care and recognize a pharmacist's duty to warn, liability imposed on pharmacists should not go unchecked. As the *Lasley* court noted:

> Once the court determines that a duty exists, the next question is whether the defendant breached the standard of care established pursuant to the duty. . . . In some instances, however, the court may decide as a matter of law that the defendant did not breach the applicable standard of conduct and thus was not negligent. . . . Thus . . . if we can say as a matter of law that [the pharmacy] did not breach its standard of care, we may affirm the trial court's judgment in favor of [the pharmacy].[111]

OBRA 90 requirements impose a duty to warn on either the physician or the pharmacist or both, but do not impose a duty on the pharmacist to prescribe or second guess the physician. It is important that courts recognize that

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to a particular standard of conduct; because the standard of conduct is the minimum, a lower standard is not recognized).

107. 42 U.S.C. § 1396r-8(g)(2)(A)(ii) (1994).

108. *See* KEETON ET AL., *supra* note 103, § 32.

109. *Id.* § 32, at 185-86.

110. *Id.* § 33, at 194-95.

111. Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1132 (Ariz. Ct. App. 1994) (citations omitted).

OBRA 90 establishes only a limited duty. Under OBRA 90, the pharmacist must perform a drug review.[112] The required drug review, however, is limited to a single check for physician errors such as contraindicated drugs or an obvious overdose.[113] Once the pharmacist checks for errors, he or she could then be required to call the physician with questions or to warn of possible dangers or risks. Unless the dose or drugs are completely outside a safe range, once the physician indicates awareness of the possibilities and has taken those factors into his or her risk assessment decision, the pharmacist should be able to dispense the prescription. Any resulting injury to the patient would be proximately caused by the physician's decision rather than the pharmacist's failure to review and warn. OBRA 90 was not designed to require pharmacists to determine what medication the patient should take. It should not be interpreted by courts as requiring pharmacists to perform a risk-benefit test to determine what medication is right for a particular patient. Likewise, dosages are prescribed by the physician after considering specific patient information unavailable to the pharmacist. The pharmacist should question the dose only when the dose is outside a normal range. Under current practice, and with information currently available to the pharmacist in out-patient pharmacy settings, the duty of determining what prescription is appropriate must remain with the physician.

As a part of the duty to warn, pharmacists may also be required to counsel patients on how the medication should be taken. The pharmacist's duties are different from those of the physician. The physician's duty is to determine *what* medication should be taken. The pharmacist's duty is to determine *how* that medication can best be taken for the patient's benefit.[114] While the physician performs risk assessment, the pharmacist performs risk management. The test is whether the decision requires a judgment of what type of medication or how the medication should be taken. OBRA 90 appears to recognize this distinction; hopefully, the courts will recognize it as well.[115]

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112. 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

113. *Id.*

114. The What vs. How test is a restatement of an analysis of respective duties of the physician and the pharmacist developed by David Brushwood, and noted with approval in a footnote in *McKee v. American Home Products*. McKee v. American Home Products, 782 P.2d 1045, 1052 n.7 (Wash. 1989).

115. One case suggests that courts may recognize reasonable limitations on pharmacists' duties. Nichols v. Central Merchandise, Inc., 817 P.2d 1131 (Kan. Ct. App. 1991). *Nichols* involved an allegation that a child was born with bone abnormalities because a pharmacist failed to warn the pregnant mother that Gantanol may cause birth defects. *Id.* at 1132. On a motion for summary judgment, the court held that the pharmacist had no duty to warn of potential side effects of prescribed drugs. *Id.* at 1133. The court held that there was no duty under the facts of the case because there was no obvious error on the face of the prescription; the prescription package insert warning of birth defects was theoretical only. *Id.* at 1133-34. Although *Lasley* cited *Nichols* in a footnote as holding that the pharmacist had no duty to warn, actually the *Nichols* court appears to agree with the *Lasley* court's assessment of upholding a summary judgment when the court can decide as a matter of law the standard was not

The OBRA 90-type regulations in the states appear to establish pharmacists' duty to warn. For prescriptions filled after January 1, 1993, juries rather than courts will decide whether a pharmacist has met this minimum standard to warn. When a claim involves allegations of failure to perform duties mandated by OBRA 90, pharmacists will no longer be able to dispose of a claim through summary judgment. Under OBRA 90, when a pharmacist is dealing with a medicaid recipient, he or she has a duty to maintain a patient record, review each prescription, and counsel each patient.[116] Summary judgment will remain a valuable tool for pharmacists, however, whenever the claim involves duties above and beyond OBRA 90 duties. Once a pharmacist warns a physician of a potential interaction, the final decision of whether or not the prescription is filled falls to the physician. Whether or not a risk associated with the particular treatment in question outweighs the risk of not treating the patient can be the duty of only one professional. Absent extraordinary risk, pharmacists do not, and should not, have the power or duty to veto a physician's decision.

The role of the pharmacy in providing medical care, and thus the pharmacist's duty, is still evolving. The present discussion should not be confused with the current debate over "pharmaceutical care" which involves the pharmacist even more deeply in medication decisions. Pharmaceutical care envisions pharmacists becoming medically responsible for the outcome of medication treatment. The role of pharmacists in such a model would expand to include ensuring patient compliance. Eventually, because of the pharmacist's more extensive training in drugs, pharmacists would acquire prescribing authority while diagnosing authority would remain with the physician, whose training focuses on recognition and diagnosis of diseases. A few states have already granted limited prescribing authority to pharmacists.[117] As new roles for pharmacists become mainstream, the legal duties of the pharmacist and the minimum standards will naturally expand. Currently, expanded roles are above the minimum standard and can be imposed only when a pharmacist holds himself or herself out as practicing above the minimum standard of the profession.[118] The current duty of pharmacists is set by the OBRA 90-type regulations. It is important that courts not lag too far behind or leap too far forward. The standards of any profession are set by the profession; pharmacy has set its minimum standards and they are found in OBRA 90.

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breached. Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1133 (Ariz. Ct. App. 1994).

116. 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

117. *See* NATIONAL ASS'N OF BOARDS OF PHARMACY, *supra* note 6, at 53.

118. For a discussion of imposing an increased duty on those holding themselves out as having greater knowledge and skill than the average practitioner, see KEETON ET AL., *supra* note 103, at § 36.