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ENTERPRISE LIABILITY FOR BAD OUTCOMES FROM DRUG THERAPY: THE DOCTOR, THE HOSPITAL, THE PHARMACY, AND THE DRUG FIRM

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TABLE OF CONTENTS

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I. INTRODUCTION

Drugs are essential tools in the modern medical arsenal with more than seven percent of all health care expenditures spent on medications.[1] More than seventy-five percent of patient visits to physicians result in at least one drug prescription, making drug therapy by far the most common form of medical intervention.[2] Drug use is highest among patients sixty-five and older—a population with chronic ailments accounting for approximately twelve percent of the population but thirty-two percent of all drugs used.[3] An abundance of pharmaceutical products are available to physicians, with thousands of prescription drugs already on the market and new ones introduced every year. These modern drugs offer remarkable results for a variety of illnesses, from ulcers to atrial fibrillation.[4] New drugs, which are more potent than earlier generations, pose increased risks of adverse reactions and are often misprescribed by physicians for a variety of reasons, resulting in harm to the patient.[5] Not only are physicians often too quick to prescribe

1. Stephen B. Soumerai et al., *Improving Drug Prescribing in Primary Care: A Critical Analysis of the Experimental Literature*, 67 MILBANK Q. 268, 269 (1989).

2. *Id.* at 269.

3. *Id.*

4. *Id.*

5. *See* Steven A. Wartman, *Do Prescriptions Adversely Affect Doctor-Patient Interactions?*, 71 AM. J. PUB. HEALTH 1358, 1358 (1981) (discussing prescriptions as a therapeutic action expected as a result of the medical care visit); Jan Koch-Weser, *Fatal Reactions to Drug Therapy*, 291 NEW ENG. J. MED. 302, 303 (1974) (stating that adverse drug effects are commonly caused by inappropriate pharmacology); *see also* Soumerai et al., *supra*

drugs, they frequently do so without providing their patients with much information about potentially dangerous side effects.[6]

Drugs are therefore dangerous as well as pervasive. Patients who experience bad outcomes from other consumer products can sue parties in the chain of distribution. For example, if patient injury is traceable to a product such as forceps, a fetal monitor, or an oximeter, the plaintiff can generally sue those in the chain of distribution for a defect in the product's manufacture, design, or warning.[7] Drugs, by contrast, are an exception to the usual product liability rules.[8] Liability in drug injury cases is characterized by substantial judicial deference to both drug companies and the pharmacies ultimately selling the drugs.[9] Sellers, distributors, and retailers of defective pharmaceutical products are theoretically subject to the same strict liability as other product sellers.[10] In the case of pharmaceutical products, however, the principle of strict liability is qualified by special rules: (1) there is a prescription drug exception for "unavoidably unsafe" products; and (2) the learned intermediary rule places responsibility for warning of potential risks on the treating physician prescribing a prescription drug and exempts both the pharmacist and drug manufacturer from liability for a failure to warn.[11]

The unavoidably unsafe shield was created by the drafters of the Restatement of Torts out of deference to drugs like the polio vaccine and antibiotics like penicillin—drugs that offer substantial public health benefits.[12] This exception for drugs is unique among consumer products in the marketplace—the result of judicial desires to enable the drug industry to innovate unfettered by potential tort liability.[13] William Prosser and the drafters of the Second Restatement of Torts were impressed with drug benefits and the inevitability of side effects, viewing drugs as beneficial but sometimes

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note 1, at 269; ROBERT S. MENDELSOHN, MALE PRACTICE: HOW DOCTORS MANIPULATE WOMEN 36-37 (1982) (arguing that oral contraceptives have been prescribed as if they were no more hazardous than chewing gum).

6. Koch-Weser, *supra* note 5, at 303.

7. *See, e.g.*, Anderson v. Somberg, 338 A.2d 1, 4 (N.J.), *cert. denied*, 423 U.S. 929 (1975).

8. *See* Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 198 (1987).

9. *Id.* at 199-200.

10. Burch v. Sears, Roebuck & Co., 467 A.2d 615, 621 (Pa. Super. Ct. 1983). "Under our products liability law, all suppliers of a defective product in the chain of distribution, whether retailers, partmakers, assemblers, owners, sellers, lessors, or any other relevant category, are potentially liable to the ultimate user injured by the defect." *Id. See also* Vandermark v. Ford Motor Co., 37 Cal. Rptr. 896, 899 (Cal. 1964) (justifying strict liability for retailers on several grounds: the retailer is an integral part of the overall marketing of products; it can easily be sued; and it can exert pressure on the manufacturer to improve risky products).

11. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

12. *Id.*

13. Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 855 (1983).

unavoidably unsafe.[14] The learned intermediary rule was derived from the informational structure of the doctor-patient relationship, with the physician in the best position to decide on a course of drug treatment and to advise the patient of the risks of that treatment in a face-to-face and effective manner.[15]

The drug delivery system is changing as the American health care economy evolves. Tort rules created during a previous era of drug production and marketing are not adequate for a rapidly evolving medical economy. The incentives of liability under the tort system are needed along with the Food and Drug Administration's (FDA) power of drug approval to control the drug industry. Enterprise liability that includes the whole distribution chain—manufacturers, hospitals, physicians, and pharmacists—offers significant advantages for both risk reduction and consumer safety.[16] The time has come to re-examine the old assumptions underlying the allocation of risk for drug mishaps. The protectionism inherent in current tort rules governing drug risk is extraordinary, reflecting effective industry marketing of the need for judicial deference toward the inherent risk of drug use. Courts have accepted the notion that drug firms will stop producing lifesaving products merely because of increased liability risks.[17] An ideal drug distribution system should promote drugs that are both effective and economical. Patients want accurate physician advice as to which drugs to use, for how long, and in what dosages. Patients worry about deadly interactions and want the FDA and drug manufacturers to continue studying side effects and risks from approved drugs and to keep doctors and patients informed. While patients are willing to be partners in monitoring their own drug use up to a point, they also know they lack expertise. Patients do not want to be injured or killed by an unexpected side effect, an interaction, a contaminant, or an incorrect dosage. They would rather not have to face drug side effects if alternative therapies are available. While compensation awarded years after the fact for such harm is some benefit, minimization of such risks is always preferable.

The FDA licenses drugs.[18] Its processes are rigorous, its approvals are careful.[19] Most drug side effects and interactions, however, are discovered after a drug enters the market.[20] If the FDA is the gatekeeper for the entry of new drugs, then tort liability is a risk auditor—tracking drug risks and forcing

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14. *Id.* at 868 n.73.

15. *See* Gibbs & Mackler, *supra* note 8, at 198.

16. *See* Jon Chait, *Continuing the Common Law Response to the New Industrial State: The Extension of Enterprise Liability to Consumer Services*, 22 UCLA L. REV. 401, 431 (1974).

17. James A. Henderson & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1541 (1992).

18. For a good discussion of current FDA procedures, see generally Gibbs & Mackler, *supra* note 8.

19. *Id.*

20. *See, e.g.*, Ellen J. Flannery, *Reporting Foreign ADRs and ADRs in Phase IV Studies, and the Significance of Causality Assessment*, 46 FOOD DRUG COSM. L.J. 43, 44 (1991) (describing problems with FDA standards for reporting foreign adverse drug effects).

manufacturers to internalize the costs of drug injuries.[21] The dual threat of liability judgments and bad publicity should be sufficient to force drug manufacturers into a state of constant awareness regarding the risks of drug use. The threat of liability, however, has not served this function well given the vigor of judicially created defenses and courts' inability to develop a design defect theory flexible enough to include changing product markets, physician failures, pharmacy errors, and consumers' lack of information.[22]

II. MANUFACTURER AND PHYSICIAN LIABILITY: THE SHIELDS OF THE RESTATEMENT

The concept of enterprise liability had its genesis in product liability law, with earlier roots in the debate over workers' compensation acts around the turn of the century.[23] This position viewed compensation as the primary goal of tort litigation, with the enterprise the proper target for internalizing those costs inherent in its production of goods.[24] Injured workers deserving compensation, like capital and materials, were simply additional costs of the industrial enterprise, much like interest charged on loans and costs of maintaining and replacing machinery.[25]

The enterprise grew more complicated with the mass marketing of consumer products such as automobiles in a national market.[26] The more complicated enterprise required not only factories but also elaborate chains of distribution from the factory to the consumer.[27] Dealers stood as a buffer against tort suits.[28] The new consumer was vulnerable: she lacked the ability to evaluate the safety of the consumer product; the seller had exploitative market power; products created a higher level of risk in some cases; and the consumer faced legal barriers to recovery for any injuries suffered.[29] Courts responded in a number of ways to solve these new problems. They developed warranty law to protect consumers and, in order to transmit liability up the chain from retailer to manufacturer, they began to treat the enterprise more broadly as a chain of production and distribution.[30] Over several decades, courts changed their views of the corporate enterprise and the resulting legal consequences. Manufacturers of defective and unreasonably dangerous products were held liable to consumers or users for injury to person or

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21. Gibbs & Mackler, *supra* note 8, at 196.

22. *Id.* at 215-43.

23. Chait, *supra* note 16, at 404-23.

24. *Id.* at 414-22.

25. Lawrence M. Friedman & Jack Ladinsky, *Social Change and the Law of Industrial Accidents*, 67 COLUM. L. REV. 50, 52 (1967).

26. *Id.*

27. *Id.*

28. *Id.* n.11.

29. *See* Steven P. Croley & Jon D. Hanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 MICH. L. REV. 683, 706 (1993) [hereinafter *Rescuing the Revolution*].

30. *See generally id.*

property, even though the product was manufactured with all possible care and the manufacturer did not sell the product to the ultimate user.[31] Strict liability was imposed not only on the manufacturer, but on dealers and retailers as well.[32] Imposition of strict product liability reflected judicial acceptance of a limited version of enterprise liability—attribution to the enterprise of liability for all costs associated with it. This rationale was echoed earlier in the workers' compensation debates. Courts justified imposing liability by arguing that consumers were vulnerable, that the enterprise could better bear the losses and spread them to all consumers, and that a complex industrial society greatly magnified the difficulties in identifying the tortfeasor responsible for the injury.[33] The expansion of product liability law allowed plaintiffs to reach parties participating in the manufacturing, distribution, sales, and installation process, even if they were unrelated.[34] The liability was not true enterprise liability, however, because plaintiffs still had to prove a product defect through a variety of balancing or risk-utility tests that often approximated negligence-based analyses.

A. *Manufacturing Defects: Downstream Liability*

Product defects are generally classified into manufacturing, design, and warning defects.[35] Drugs are an anomaly in products liability litigation—manufacturing defect cases are uncommon in the case law.[36] If a drug firm sells a defectively manufactured drug, the firm, the pharmacist, wholesalers, and retailers will be treated by most courts as part of the chain of distribution of the defective product.[37] The drug in this context is like any other product treated by the law governing manufacturing defects.[38] The pharmacist is

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31. RESTATEMENT (SECOND) OF TORTS § 402A (1965); *see* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 104 (5th ed. 1984); MORRIS & MORRIS, TORTS 237-44 (2d ed. 1980).

32. *See, e.g.*, Burt A. Leete, *Products Liability for Nonmanufacturer Product Sellers: Is It Time to Draw the Line?*, 17 FORUM 1250, 1251 (1982).

33. *See* Guido Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L.J. 499, 500-01 (1961); Howard C. Klemme, *The Enterprise Liability Theory of Torts*, 47 U. COLO. L. REV. 153, 156-58 (1976).

34. Klemme, *supra* note 33, at 158-65.

35. Sheila L. Birnbaum & Barbara Wrubel, *"State of the Art" and Strict Products Liability*, 21 TORT & INS. L.J. 30, 30 (1985).

36. *See* Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76 (1994). According to Cupp: "At least with regard to prescription drugs, defects usually are not related to mistakes in manufacture, but rather center around unwarranted consequences of using the drug." *Id.* at 90.

37. Carole A. Cheney, Comment, *Not Just for Doctors: Applying the Learned Intermediary Doctrine to the Relationship Between Chemical Manufacturers, Industrial Employers, and Employees*, 85 NW. U. L. REV. 562, 564 (1991).

38. *See* Abbott Lab. v. Lapp, 78 F.2d 170, 176 (7th Cir. 1935) (holding a manufacturer liable in negligence for allowing virulent bacteria to contaminate sterilized milk formula);

subject to strict liability as part of the chain of distribution.[39] Manufacturing defects are rarely found in drug product liability litigation, probably due to the stringent FDA quality control requirements in drug production.[40] But such defects do occur and can cause harm if the defects are not discovered or are not reported to the FDA.[41] Investigations of Copley Pharmaceutical drugs, including Brompheril and Albuterol, for example, have focused on incomplete or false data provided by the company indicating inspections for purity that were never performed by employees.[42]

B. *Warning Defects: The Learned Intermediary*

Drug liability cases most often involve errors in warning physicians of drug risks through incomplete or erroneous labeling by the manufacturer.[43] A drug is not considered defective if the warnings about inappropriate uses, contraindications, or interactions are spelled out.[44] Comment k to the Second

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Randall v. Goodrich-Gamble Co., 70 N.W.2d 261, 264 (Minn. 1955) (holding that jury's determination that plaintiff failed to prove the defendant's negligence in a case involving injuries resulting from the use of liniment was not contrary to the evidence); David v. McKesson & Robbins, 300 N.Y.S. 635, 636-37 (App. Div. 1937) (finding a manufacturer liable in negligence for a death caused by sodium bicarbonate found in a soda), *aff'd*, 16 N.E.2d 127 (N.Y. 1938).

39. *See, e.g.*, Burgess v. Sims Drug Co., 86 N.W. 307, 308 (Iowa 1901); Tremblay v. Kimball, 77 A. 405, 407 (Me. 1910). Some exceptions to strict pharmacist liability exist, such as the sealed container exception. *See* Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881, 885 (Ind. Ct. App. 1985) (holding that no liability exists for the failure to warn a customer of possible hazards associated with a drug); Ferguson v. Williams, 374 S.E.2d 438, 440 (N.C. Ct. App. 1988) (holding that there is no liability for an adverse drug reaction unless the pharmacist is aware of a special circumstance and fails to advise the patient); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 274 (N.C. Ct. App.) (holding that no liability exists unless the pharmacist fails to prescribe the proper drug), *review denied*, 233 S.E.2d 921 (N.C. 1977).

40. *See, e.g.*, Judith P. Swazey, *Prescription Drug Safety and Product Liability, in* THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION 291, 305 (Peter W. Huber & Robert E. Litan eds., 1991). For example, the FDA found quality assurance control flaws in the production of Abbott Laboratories' diagnostic kits, including its AIDS testing kit. *See* Thomas M. Burton, *FDA Uncovers Flaws in Abbott Labs' Diagnostic Devices, Including AIDS Kit*, WALL ST. J., Jan. 11, 1995, at B8.

41. For example, the drug Brompheril was allegedly manufactured with faulty coatings, and the company filed false reports to the FDA regarding the coating problems. *See* Joseph Rebello & Joseph Pereira, *Grand Jury Probes Drug Maker Copley on Whether It Withheld Data on Defects*, WALL ST. J., Dec. 23, 1994, at B4. Another Copley drug, Albuterol, allegedly was not properly inspected by employees before they signed off on the drug's purity. Joseph Rebello, *Grand-Jury Probe of Copley Extends to Asthma Drug*, WALL ST. J., Nov. 10, 1994, at A5.

42. *See* Rebello & Pereira, *supra* note 41.

43. *See* Koch-Weser, *supra* note 5, at 302-03.

44. *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965).

Restatement of Torts section 402A provides an "unavoidably unsafe" exception to the strict liability rule for drugs due to risks associated with and inherent in their use.[45] Such drugs are neither defective nor unreasonably unsafe if they are prepared properly and are accompanied by adequate warnings of the risks involved in their use.[46] In most situations, these

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45. RESTATEMENT (SECOND) OF TORTS § 402A comment k provides:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Id. § 402A cmt. k.

46. For example, in *Lareau v. Page*, the plaintiff had Thorotrast residue in her cranium, the result of a craniotomy, which had formed a calcified mass. Lareau v. Page, 840 F. Supp. 920, 933 (D. Mass. 1993), *aff'd*, 39 F.3d 384 (1st Cir. 1994). The court held that the information provided by the drug company was sufficient to put a neurosurgeon on notice of risks of Thorotrast, and that the pharmaceutical companies were not liable for injuries resulting from the use of Thorotrast as a drug because, although harmful, it was not defective given its capacity to avert an otherwise inevitable death. *Id.* In *Hunt v. Hoffman-La Rouche*, the plaintiff sued the defendant for birth defects apparently caused by his mother's ingestion of Accutane. Hunt v. Hoffman-La Rouche, 785 F. Supp. 547, 548 (D. Md. 1992). The plaintiff claimed the defendant failed to provide adequate warnings concerning the drug's dangerous side effects, particularly its potential to cause birth defects. *Id.* The court held that the "learned intermediary" rule protected the manufacturer against suit. *Id.* In *Windham v. Wyeth Lab., Inc.*, the plaintiff sued Wyeth for its conduct in manufacturing and marketing a Phenergan suppository. Windham v. Wyeth Lab., Inc., 786 F. Supp. 607, 608 (S.D. Miss. 1992). The plaintiff's physician prescribed the suppository to the plaintiff for relief from persistent nausea and vomiting. *Id.* The plaintiff was 12-15 weeks pregnant at the time. *Id.* The physician testified he was aware of the drug's adverse effects, but felt it had less potential for

warnings are communicated directly to the physician as learned intermediary rather than to the patient.[47] To fall within the learned intermediary protection,

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side effects than alternative medications. *Id.* at 609. In 1984, when the drug was prescribed, the package insert contained neither a warning of the extrapyramidal symptoms, which the plaintiff experienced, nor a warning that the drug should only be used during pregnancy if the potential benefit outweighed the risk. *Id.* Over three years after the suppository had been prescribed to her, the plaintiff used a remaining suppository and experienced extrapyramidal symptoms. *Id.* The 1987 package insert for the Phenergan suppositories included a statement concerning extrapyramidal symptoms and advised caution when using the suppositories during pregnancy. *Id.* The court held that Wyeth had a duty only to warn the physician, even though the plaintiff argued the that doctor-patient relationship no longer existed. *Id.* at 611. In *Garside v. Osco Drug, Inc.*, the minor plaintiff sued defendants Hoffman-La Rouche and Beecham, Inc. as manufacturers of amoxicillin, McKesson Corp., manufacturer of phenobarbital, and Osco Drug, as the seller of the drugs. Garside v. Osco Drug, Inc., 764 F. Supp. 208, 209 (D. Mass. 1991), *rev'd*, 976 F.2d 77 (1st Cir. 1992). The three-year-old plaintiff was treated at a physician's office for an ear infection and was prescribed amoxicillin. *Id.* On the way to get the prescription filled, the plaintiff suffered a seizure and was rushed to the hospital where she was treated with phenobarbital to control the seizures and amoxicillin for the ear infection. *Id.* She later developed a severe rash and was diagnosed as having toxic epidermal necrolysis (TEN), a condition which results from the poisoning of the skin tissue. *Id.* TEN had a devastating effect on the plaintiff, who was left blind and suffering from severe hearing loss and scars covering the majority of her body. *Id.* Defendant Osco Drug filed a third-party complaint against the doctor who treated the plaintiff at the hospital and who wrote the prescriptions for the phenobarbital and amoxicillin, which were filled at the Osco Drug pharmacy. *Id.* The court granted the defendants' motions for summary judgment for all counts, except the plaintiff's third amended complaint against defendant McKesson as manufacturer. *Id.* at 209-10. The court applied the learned intermediary rule and focused on McKesson's duty to warn the doctor of the risks involved with the drug phenobarbital. *Id.* at 212. The court held that if the treating doctor knew of the potential adverse reactions to phenobarbital then the failure of McKesson to warn the doctor could not have been the proximate cause of plaintiff's injuries. *Id.* The doctor testified he knew of the connection of phenobarbital with TEN and he did not discuss the possible side effects with his patient. *Id.*

47. The phrase learned intermediary—the concept that a manufacturer's duty to warn is satisfied by providing information and warnings to the physician—was first articulated in *Marcus v. Specific Pharmaceuticals, Inc.* Marcus v. Specific Pharmaceuticals, Inc., 77 N.Y.S.2d 508, 509-10 (Sup. Ct. 1948). The rationale of the learned intermediary doctrine was stated by the Washington Supreme Court in *Terhune v. A.H. Robins Co.*

> The reasons for this rule should be obvious. Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. The cases upholding the doctrine are numerous.

a drug manufacturer must have provided a legally adequate warning to the physician.[48] Such warnings, however, can be too complex for a busy doctor to process and pass on to the patient.[49] Exceptions have included contraceptives and mass vaccinations, which require warnings to the patient as well.[50] Manufacturers of drugs with a certain narrow therapeutic index also prepare patient literature to help both the patient and the physician avoid drug and food interactions and other risks from powerful drugs.

The council draft of the Restatement (Third) of Torts preserves the learned intermediary rule, requiring that the drug manufacturer provide adequate warnings to the "prescribing and other health care providers who are in a position to reduce the risk of harm in accordance with the instructions or warnings."[51] The rationale for the rule is that only health care professionals "are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy."[52]

The learned intermediary rule is justified by several arguments. First, physicians as medical professionals are in the best position to decide whether and what drug to prescribe.[53] While this proposition is generally true, drug companies are increasingly advertising directly to consumers, creating patient expectations that physicians may have trouble resisting. Even when the phy-

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Terhune v. A.H. Robins Co., 577 P.2d 975, 978 (Wash. 1978). *See, e.g.*, DeLuryea v. Winthrop Lab., 697 F.2d 222, 224-25 (8th Cir. 1983); Werner v. Upjohn Co., 628 F.2d 858, 860 (4th Cir. 1980), *cert. denied*, 449 U.S. 1080 (1981); Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 91-93 (2d Cir. 1980); Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1363 (4th Cir. 1975); Snawder v. Cohen, 749 F. Supp. 1473, 1483 (W.D. Ky. 1990).

48. *See* Fornoff v. Parke Davis & Co., 434 N.E.2d 793, 802-03 (Ill. App. Ct. 1982).

49. Such a "sensory overload" condition can occur when a physician receives too much drug product information. *See, e.g.*, Dunn v. Lederle Lab., 328 N.W.2d 576, 580 (Mich. Ct. App. 1982) (finding excessive warnings or product labels may be counterproductive).

50. *See* Smith v. E.R. Squibb & Sons, Inc., 273 N.W.2d 476, 479 (Mich. 1979).

51. RESTATEMENT (THIRD) OF TORTS § 8(d)(1) (Tentative Draft No. 2, 1994).

52. *Id.* cmt. b.

53. Reyes v. Wyeth Lab., 498 F.2d 1264, 1276 (5th Cir.) ("As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative."), *cert. denied*, 419 U.S. 1096 (1974); West v. Searle & Co., 806 S.W.2d 608, 613-14 (Ark. 1991) (finding that the provider is the best assessor of risks and benefits); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 549 (Ind. Ct. App. 1979) ("[T]he physician acts as a 'learned intermediary' . . . . It is his duty to inform himself of the qualities and characteristics of these products which he prescribes for, administers to, or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product."); Bichler v. Willing, 397 N.Y.S.2d 57, 59 (App. Div. 1977) ("When a consumer asks a druggist to fill a prescription . . . he does not rely on the druggist's judgment as to whether that particular drug is inherently fit for its intended purpose but rather he places that confidence and reliance in the physician who prescribed the remedy.").

sician is a rational decisionmaker in choosing among therapeutic options, her range of choices is limited to those drugs manufactured.

Second, providing information to the patient outside the traditional doctor-patient relationship—such as through direct-to-consumer advertising—may interfere with that relationship by deterring patients from following their doctors' advice.[54] Direct advertising is already pervasive, and patients are gleaning information from sources such as CD-ROM programs and on-line databases which offer medical information.

Third, it is argued that the cost of providing this information to patients is too high or that the information cannot be adequately conveyed by labeling. Patients may have difficulty processing complex risk-benefit information.[55] While this may be true for patients, it is also often true for physicians, who are notoriously deficient at assessing pharmaceutical risks and choices.[56] This further militates pushing liability back to the manufacturer.

Fourth, it has been argued that physicians must also convey risk and benefit information to patients as required by the doctrine of informed consent, and any such duty on the part of the drug manufacturer to convey such information to patients is duplicative. The reality of informed consent, however, is that physicians do not adequately disclose risks and alternatives.

Physicians rarely appear as defendants in appellate cases. In prescription drug cases prescribing physicians are often named as defendants, but the primary target is usually the drug manufacturer. Very often the claim against the prescribing physician is resolved before trial.[57] One court has recognized the inadequacy of warning only physicians when a drug has been withdrawn from the market.[58] In general, however, the learned intermediary rule does provide at least a first level defense for a drug manufacturer in a drug product liability lawsuit.

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54. *In re* Certified Questions, 358 N.W.2d 873, 883 (Mich. 1984) (Boyle, J., dissenting) (warning that in some cases, a patient "could potentially cause undue interference with the doctor-patient relationship [and] cause patient confusion"); Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 870 (Tex. Civ. App. 1973) ("[The] entire system of drug distribution in America is set up so as to place the responsibility . . . upon professional people.").

55. *See generally* Teresa M. Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 830 (1991).

56. *See generally* Soumerai et al., *supra* note 1.

57. *See, e.g.*, Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 90 (2d Cir. 1980) (claims against prescribing physician settled just prior to trial); Magee v. Wyeth Lab., 29 Cal. Rptr. 322, 324 (Ct. App. 1963) (claims against physicians and nurses settled prior to trial); Formella v. Ciba-Geigy Corp., 300 N.W.2d 356, 357 (Mich. 1980) (claims against physician settled after first day of trial); Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 864 (Tex. Civ. App. 1973) (claims against physicians, anesthetist, and hospital settled prior to trial); *see also* Ortiz v. Allergan Pharmaceuticals, 489 S.W.2d 135, 136 (Tex. Civ. App. 1972) (claims against physician and pharmacy settled during trial).

58. *See, e.g.*, Nichols v. McNeilab, Inc., 850 F. Supp. 562, 565 (E.D. Mich. 1993).

C. *Design Defects: The Comment k Escape*

The design defect is at the heart of the debate over the merits of strict liability. As applied to prescription drugs, strict liability requires proof that a drug is "defective." The meaning of that elusive term in drug cases is hard to articulate, although general product rules conclude that a defective drug is one with a higher risk than the benefits it produces.[59] In general, however, design defects have been conflated into labeling defects. The Restatement (Second) of Torts section 402A governs such design defects and requires the plaintiff to prove the product is in an unreasonably defective condition, dangerous to the consumer.[60] A drug is not defective if warnings about inappropriate uses or other contraindications are spelled out.[61] Strict product liability is unavailable to an injured plaintiff under comment k.[62]

Comment k of the Restatement (Second) of Torts section 402A makes an exception to the strict liability rule for products such as drugs, which are unavoidably unsafe due to risks associated with and inherent in their use.[63] A drug is neither defective nor unreasonably unsafe if it is prepared properly and accompanied by adequate warnings of the risks involved. Comment k, drafted by William Prosser, the Reporter for the Restatement, operates on the assumption that a great many experimental and uncertain drugs are justifiably placed on the market.[64]

Several state courts have held that comment k was intended to exempt all prescription products from strict design defect liability.[65] Comment k states that such products are not defective or unreasonably dangerous, citing

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59. John Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 837-38 (1973) (discussing a number of factors used to weigh the risks of a product against its benefits).

60. Section 402A of the Restatement (Second) of Torts provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

RESTATEMENT (SECOND) OF TORTS § 402A (1965).

61. *Id.* § 402A cmt. k.

62. *See id.*

63. *Id.*

64. *See* MARSHALL S. SHAPO, A NATION OF GUINEA PIGS: THE UNKNOWN RISKS OF CHEMICAL TECHNOLOGY 14-15 (1979).

65. *See, e.g.*, Brown v. Superior Court, 751 P.2d 470, 476 (Cal. 1988).

as specific examples "drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician."[66] States have proved resistant to plaintiffs' arguments that the manufacturer, and the pharmacist as retailer—the end point in the chain of distribution of drugs—should both be held strictly liable.[67] Because comment k is unclear, courts have disagreed about its nature and scope. Most courts have concluded that comment k imposes a negligence standard on product sellers.[68] A few courts retain some vestiges of strict liability in cases discussing comment k.[69] Courts also disagree about the application of comment k to pharmaceutical products, whether it should apply across the board or be decided on a case-by-case basis.[70]

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66. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Comment k was apparently intended to cover all prescription drugs as well as at least some nonprescription medications. To the extent that the language of comment k is unclear as to its scope, the ambiguity may be explained by the lack of knowledge on the part of William Prosser and the drafters of the Restatement regarding the regulatory distinction between prescription and nonprescription medications. *See* Andrew Barrett, Note, *The Past and Future of Comment k: Section (4)(b)(4) of the Tentative Draft Restatement (Third) of Torts—Is It the Beginning of a New Era for Prescription Drugs?*, 45 SYRACUSE L. REV. 1291, 1303 (1995).

67. Several courts have refused to hold a retail pharmacist strictly liable as the retailer of a defective product that is unreasonably dangerous to the consumer due to the absence of adequate warnings. *See, e.g.*, Ramirez v. Richardson-Merrell, Inc., 628 F. Supp. 85, 88 (E.D. Pa. 1986); Murphy v. E.R. Squibb & Sons, Inc., 202 Cal. Rptr. 802, 807 (Ct. App. 1984), *vacated*, 710 P.2d 247 (Cal. 1985); Kinney v. Hutchinson, 449 So. 2d 696 (La. Ct. App. 1984); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 275 (N.C. Ct. App.), *review denied*, 233 S.E.2d 921 (N.C. 1977); *see also* Sidney H. Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 555-62 (1978).

68. *See, e.g.*, Plummer v. Lederle Lab., 819 F.2d 349, 356 (2d Cir.), *cert. denied*, 484 U.S. 898 (1987); Ferrigno v. Eli Lilly & Co., 420 A.2d 1305, 1318 (N.J. Super. Ct. Law Div. 1980); *see also* David A. Fischer, *Products Liability—The Meaning of Defect*, 39 MO. L. REV. 339, 345-46 (1974); Marcia A. Mobilia, *Allergic Reactions to Prescription Drugs: A Proposal for Compensation*, 48 ALB. L. REV. 343, 345 (1984).

69. Graham v. Wyeth Lab., 666 F. Supp. 1483, 1496 (D. Kan. 1987) ("[C]omment k . . . [does not stand] for the rule that all prescription drugs are unavoidably unsafe as a matter of law."); Kearl v. Lederle Lab., 218 Cal. Rptr. 453, 464-65 (Ct. App. 1985) (discussing plaintiff's ability to prosecute her case under a strict liability theory); Toner v. Lederle Lab., 732 P.2d 297, 308 (Idaho 1987) ("We do not believe comment k was intended to provide nor should it provide all ethical drugs with blanket immunity from strict liability . . . ."); Johnson v. American Cyanamid Co., 718 P.2d 1318, 1323 (Kan. 1986).

70. Many courts have held that courts should decide the applicability of comment k on an individual basis. *See, e.g.*, Hill v. Searle Lab., 884 F.2d 1064, 1068-69 (8th Cir. 1989); Toner v. Lederle Lab., 779 F.2d 1429, 1433 (9th Cir. 1986); Feldman v. Lederle Lab., 479 A.2d 374, 383 (N.J. 1984); White v. Wyeth Lab., Inc., 533 N.E.2d 748, 752 (Ohio 1988).

Many courts have held that comment k applies to prescription drugs as a class. *See, e.g.*, McElhaney v. Eli Lilly & Co., 575 F. Supp. 228, 230 (D. S.D. 1983), *aff'd*, 739 F.2d 340 (8th Cir. 1984); Fellows v. USV Pharmaceutical Corp., 502 F. Supp. 297, 300 (D. Md. 1980); Brown v. Superior Court, 751 P.2d 470, 482 n.11 (Cal. 1988).

The proper liability standard imposed on sellers of pharmaceutical products faces similar arguments as those raised against the application of strict liability to pharmacy. First, strict liability rules are best suited to mechanical products rather than chemical or biological products such as pharmaceuticals.[71] Strict liability would have an undesirable adverse effect on the availability of pharmaceutical products.[72] Second, the imposition of such a duty would raise the costs to society—which needs and values the pharmaceutical products sold by druggists—to unduly high and prohibitive levels.[73] In *Brown v. Superior Court*, the California Supreme Court argued that subjecting pharmaceutical companies to strict liability for design defects discourages the development and marketing of new and beneficial drugs.[74] The argument that industries producing potentially dangerous products should compensate injured patients, distribute the loss through liability insurance, and add the cost to the price of the product, is often countered by the phantom fear that drug companies may be deterred from producing and selling useful products, such as penicillin and cortisone, drugs with dangerous side effects. [75]

The Council Draft No. 2 of the proposed Restatement (Third) of Torts makes few changes from previous law.[76] Section 8 of the Council Draft deals with the sale of prescription drugs or medical devices.[77] It proposes that the plaintiff should only recover if (1) "the drug or medical device contains a manufacturing defect . . . ; or (2) the drug or medical device is not reasonably safe due to defective design or because of inadequate instructions or warnings."[78]

Pharmacists and other retail sellers of drugs are subject to liability only upon sale of a product containing a manufacturing defect, or when the retail seller, during the period leading up to the sale or other distribution of the prescription drug or medical device fails to exercise reasonable care and such

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71. *See* George C. Pratt & Fred W. Parson, *Diagnosis of a Legal Headache: Liability for Unforeseeable Defects in Drugs*, 53 ST. JOHN'S L. REV. 517, 519-21 (1978-79) (arguing that differences exist between pharmaceutical products and machines).

72. Richard Epstein, *The Temporal Dimension in Tort Law*, 53 U. CHI. L. REV. 1175, 1204 (1986) (asserting that fear of excessive tort liability caused DTP vaccine manufacturers to withdraw their products from the market).

73. *See* Brown v. Superior Court, 751 P.2d at 479 (discussing society's need for prescription drugs).

74. *Id.* at 484.

75. *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 98, at 661 (5th ed. 1984).

76. I do not intend to explore here the complications of the new Restatement, nor its politics. For an extended discussion, see Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 IOWA L. REV. (forthcoming 1996).

77. RESTATEMENT (THIRD) OF TORTS § 8 (Tentative Draft No. 2, 1995).

78. *Id.* § 8(b)(1)-(2). For an objection to this assessment process, see Howard A. Latin, *The Preliminary Draft of a Proposed Restatement (Third) of Torts: Products Liability—Letter*, 15 J. PROD. & TOXICS LIAB. 169, 172 (1993).

failure causes harm to a consumer.[79] The council draft also recognizes the risks associated with drugs provided directly to consumers: reasonable instructions or warnings must be provided "directly to the patient when the manufacturer knew or had reason to know that no health care provider would be in the position described in subsection (d)(1)."[80]

Design defects in pharmaceutical products have traditionally avoided judicial scrutiny, although a few courts have reviewed these products in terms of alternative safer design tests.[81] Judicial evaluation of these drug design defects has varied from treating drugs as products, with the comment k "unavoidably unsafe" characterization as an affirmative defense, to changing the plaintiff's burden of proof.[82] A few courts have adopted the test preferred by the American Law Institute—instructing the jury that a design defect claim requires proof that if the manufacturer had been aware of the risks, it would not have marketed the drug.[83] Retailers of prescription drugs and devices traditionally have been liable only if they were negligent. Liability of the retailer for design and warning defects has not extended to a

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79. RESTATEMENT (THIRD) OF TORTS § 8(e)(1)-(2) (Tentative Draft No. 2, 1995).

80. *Id.* § 8(d)(2).

81. *See, e.g.*, Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 654 (1st Cir. 1981) (finding design defect claim proper when available alternative design would have provided same benefit at far less risk); Rohrbough v. Wyeth Lab., Inc., 719 F. Supp. 470, 476-77 (N.D. W. Va. 1989) (holding vaccine design subject to risk-utility analysis), *aff'd*, 916 F.2d 970 (4th Cir. 1990); Shanks v. Upjohn Co., 835 P.2d 1189, 1193-94 (Alaska 1992) (holding that policies supporting strict liability for defectively designed products outweigh policies protecting drug companies); West v. Searle & Co., 806 S.W.2d 608, 611-13 (Ark. 1991) (holding that a manufacturer may defend against design defect by showing through risk-utility analysis that product was unavoidably unsafe); Adams v. G.D. Searle & Co., 576 So. 2d 728, 732-33 (Fla. Dist. Ct. App. 1991) (holding that products must pass risk-utility balancing test for reasonable design); Toner v. Lederle Lab., 732 P.2d 297, 308-09 (Idaho 1987) (stating that protection on a case-by-case basis, and "unavoidably unsafe" exemption requires showing that benefits outweigh risks); Feldman v. Lederle Lab., 479 A.2d 374, 382-83 (N.J. 1984) (stating that "drugs, like any other products, may contain defects that could have been avoided by better manufacturing or design"); Davila v. Bodelson, 704 P.2d 1119, 1127-28 (N.M. Ct. App.) (finding "unavoidably unsafe" exemption from strict liability appropriate when useful drug poses certain dangers even when properly prepared and labeled), *cert. denied*, 704 P.2d 431 (N.M. 1985); White v. Wyeth Lab., 533 N.E.2d 748, 752 (Ohio 1988) (determining that drugs do not per se fall within comment k, but require case-by-case determination); Castrignano v. E.R. Squibb & Sons, 546 A.2d 775, 781 (R.I. 1988) (holding that exemption from strict liability based on design defect is only available if drug's apparent benefits outweigh apparent risks).

82. Williams v. Ciba-Geigy Corp., 686 F. Supp. 573, 577-79 (W.D. La.) (using case-by-case analysis, but with a high threshold test), *aff'd*, 864 F.2d 789 (5th Cir. 1988).

83. *See, e.g.*, Tobin v. Astra Pharmaceutical Prods., 993 F.2d 528, 535 (6th Cir.), *cert. denied sub nom.* Duphar v. Tobin, 510 U.S. 914 (1993); Toner v. Lederle Lab., 732 P.2d 306, 312 (Idaho 1987); Savina v. Sterling Drug, Inc., 795 P.2d 915, 924 (Kan. 1990).

strict liability approach.[84] Section 8(c) of the proposed restatement offers a design defect test:

> A prescription drug or medical device is not reasonably safe due to defective design when the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits so that no reasonable health care provider, knowing of such foreseeable risks and therapeutic benefits, would prescribe the drug or medical device for any class of patients.[85]

The test is a balance—requiring the plaintiff to show no net benefit from the use of the drug to any class of patients. If there is any benefit, a warning is sufficient to relieve the manufacturer of liability. The comment notes the usual rationales for this limited liability for design defects: "possible negative effects of judicially imposed liability on the cost and availability of valuable medical technology."[86] The comment also observes that the rigorous regulatory regime will keep dangerous drugs off the market.[87] Prescribing providers can backstop this regulation by insuring the right drugs reach the right patients.[88] In spite of these justifications, the American Law Institute notes that some courts have rejected unqualified deference to the FDA. Section 8(c) reflects this judicial rejection of FDA determinations by imposing on plaintiffs a heavier burden of proof than that applied to products generally, but still allowing the plaintiff to claim and prove that a drug has "so little merit compared with its risk" that no reasonable provider would prescribe it, if he knew of all the risks.[89] The ALI states in comment f:

> The proposed rule in § 8(c) best advances the policies and values explicated in Comment *b*. It shows appropriate deference to the regulated market, where the FDA and learned intermediaries select which drug should be available to the public generally and which drugs should be given to individual patients, respectively. It does not, on the other hand, wholly exempt defendants from liability simply because other institutions have taken steps to improve product safety. . . . Unlike most products, which confer essentially the same benefits to all users, prescription drugs and medical devices have the capacity to do great harm or great good depending on the patient.

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84. *See, e.g.*, Ellsroth v. Johnson & Johnson, 700 F. Supp. 151 (S.D.N.Y. 1988); Leesley v. West, 518 N.E.2d 758 (Ill. App. Ct.), *cert. denied*, 522 N.E.2d 1246 (Ill. 1988); Makripodis v. Merrell-Dow Pharmaceuticals, Inc., 523 A.2d 374 (Pa. Super. Ct. 1987). *See generally* David B. Brushwood & Richard R. Abood, *Strict Liability in Tort: Appropriateness of the Theory for Retail Pharmacists*, 42 FOOD DRUG COSM. L.J. 269 (1987).

85. RESTATEMENT (THIRD) OF TORTS § 8(c) (Tentative Draft No. 2, 1995).

86. *Id.* § 8 cmt. b.

87. *Id.*

88. *Id.*

89. *Id.* § 8 reporters' note, cmt. f.

> Accordingly, liability will attach only if the design cannot be justified for any class of patients.[90]

Critics argue that such a proposal overstates the minority position and adds nothing to a warning-based cause of action.[91] But it does add something—even if a drug design is justified for a particular class of patients, it may often be misprescribed for patients not in that class, either because the physician is not properly informed or ignores the available information. A stronger imposition of liability would distinguish these cases from defective drug product design.[92] Such a test will be discussed later.

III. HOSPITAL LIABILITY FOR DRUG MISHAPS: LITTLE AND LATE[93]

A. *Drug Risk Duties*

A health care institution, whether hospital, nursing home, or clinic is liable to its patients for negligence in maintaining its facilities, providing and maintaining medical equipment, hiring, supervising and retaining nurses and other employees, and for failing to have in place adequate procedures to protect patients.[94] Basic negligence principles govern hospital liability for injuries caused by sources other than negligent acts of the medical staff.[95] Hospitals are generally held to a national standard of care for hospitals of their size and treatment category.[96] When, however, a new technology of proven efficacy has been adopted by some hospitals, the standard may be used to measure the practice in all hospitals.[97] A hospital must provide a safe

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90. *Id.*

91. *See generally* Harvey L. Kaplan et al., *Third Restatement: New Prescription for Makers of Drugs and Medical Devices*, 61 DEF. COUNS. J. 64 (1994).

92. *See* Page, *supra* note 13, at 883 (arguing that in cases of product risks unknown at the time of sale, strict liability should be imposed as an incentive to manufacturers to improve product safety and as a means of satisfying justifiable consumer expectations).

93. For an outline of differing liability models for health care providers, see Table 1 in the Appendix.

94. *See* Lamb v. Candler Gen. Hosp., Inc., 413 S.E.2d 720, 721 (Ga. 1992); HCA Health Services of Georgia, Inc. v. Hampshire, 424 S.E.2d 293, 298 (Ga. Ct. App. 1992).

95. *See, e.g.*, Lamb v. Candler Gen. Hosp., Inc., 413 S.E.2d at 722 (finding hospital negligent in failing to use proper replacement parts in a medical instrument).

96. Wickliffe v. Sunrise Hosp., Inc., 706 P.2d 1383, 1389 (Nev. 1985).

97. In *Washington v. Washington Hospital Center*, the defendant had not yet placed end-tidal carbon dioxide monitors—allowing early detection of insufficient oxygen in time to prevent brain injury—in its operating rooms. Washington v. Washington Hosp. Ctr., 579 A.2d 177, 180 (D.C. 1990). The plaintiff's injuries would have been prevented by the early detection that such monitors make possible. *Id.* at 183. The defendant argued that the use of such devices was only "encouraged," a "developing" standard as of the date of the incident. *Id.* at 182. The court responded: "A standard of due care, however, necessarily embodies what a *reasonably prudent* hospital would do, . . . and hence care and foresight exceeding the minimum required by law or mandatory professional regulation may be necessary to meet that standard."

environment for patient diagnosis, treatment, and recovery. If an unsafe condition of the hospital's premises causes injury to a patient, the hospital has breached its duty.[98] The test is "whether the negligent act occurred in the rendering of services for which the health care provider is licensed."[99]

Hospitals must have minimum facilities and support systems to treat the range of problems and side effects that accompany procedures they offer, must provide inventories of medical equipment and drugs necessary for medical procedures, and must have adequate staffing.[100] A hospital and its contracting physicians may be liable for damages caused by inadequate or defective systems they develop and implement, particularly when emergency care is involved, including in-house pharmacies and drug distribution systems for patient use of drugs.[101] Hospitals must recognize errors in physician drug orders and monitor their practice, when high risk pharmaceuticals such an anticoagulants are involved in patient care.[102]

Id.

The carbon dioxide monitor and its companion, the blood-monitoring pulse oximeter, at issue in *Washington* have become mandatory devices in hospital operating rooms. By 1990 all hospitals used oximeters in their operating rooms; in 1984, no hospital had them. The device beeps when a patient's blood oxygen drops due to breathing problems or overuse of anesthesia. That warning can give a vital three or four minute warning to physicians, allowing them to correct the problem before the patient suffers brain damage. These devices have so improved patient safety that malpractice insurers have lowered premiums for anesthesiologists. *See* Charles R. Appleby, *Pulse Oximeters Pump Up Bottom Lines and Patient Safety, Deflate Malpractice Risk*, HEALTHWEEK, October 9, 1990, at 17.

98. *See, e.g.*, Pearce v. Feinstein, 754 F. Supp. 308, 309 (W.D.N.Y. 1990) (upholding a jury finding that a hospital was negligent in providing a defective catheter to a patient which had been previously recalled by the manufacturer); Murillo v. Good Samaritan Hosp., 160 Cal. Rptr. 33 (Ct. App. 1979) (finding the failure to properly set the bedrails on a patient's bed constituted negligence). Whether the hospital's negligence is characterized as "ordinary" or "professional" negligence is important for the purpose of malpractice reform statutes. For example, California has a $250,000 cap on pain and suffering for injuries resulting from professional malpractice. CAL. CIV. CODE § 3333.2 (Deering 1995). A rape or slip and fall injury to a patient while in an institution would not be considered "professional" malpractice subject to the cap on damages.

99. Andrea N. v. Laurelwood Convalescent Hosp., 18 Cal. App. 2d 894, 906 (Ct. App. 1993).

100. *See, e.g.*, Dixon v. Taylor, 431 S.E.2d 778, 782 (N.C. Ct. App. 1993) (holding that whether the hospital failed to properly stock surgical cart with appropriate laryngoscope blade was a question of fact).

101. Air Shields, Inc. v. Spears, 590 S.W.2d 574, 581 (Tex. Ct. App. 1979) (finding negligently created rules and regulations as to oxygen administration to infants constituted a basis for liability).

102. Thompson v. Nason Hosp., 591 A.2d 703, 707-09 (Pa. 1991) (upholding corporate negligence count against hospital for failing to monitor physician's use of the anticoagulent Coumadin).

B. *Strict Liability*

The doctrine of strict liability has rarely been applied to hospital services, or to the delivery of health care services. Courts distinguish between medicine and other commercial enterprises, even though the distinction is losing its force.[103] Courts view health care, whether provided by a physician or a hospital, as essentially the sale of a service in which the products are merely ancillary, and therefore inappropriate for the application of strict liability.[104] In situations in which a product liability analysis might apply, such as the transfusion of infected blood, most states have declared by statute that blood is not a product.[105] Courts have also been troubled by expanding the liability of health care providers, considering (1) the experimental nature of much medical treatment, (2) factors beyond the control of the physician, and (3) lack of certainty of successful results.[106]

Courts have standard objections to applying strict liability to medical services. As the court in *Hoven v. Kelble*[107] wrote:

> Medical and many other professional services tend often to be experimental in nature, dependent on factors beyond the control of the professional, and devoid of certainty or assurance of results. Medical services are an absolute necessity to society, and they must be readily available to the people. It is said that strict liability will inevitably increase the cost for medical services, which might make them beyond the means of many consumers, and that imposition of strict liability might hamper progress in developing new medicines and medical techniques.[108]

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103. For a collection of cases, see Marc L. Carmichael, Annotation, *Liability of Hospital or Medical Practitioner Under Doctrine of Strict Liability in Tort, or Breach of Warranty, for Harm Caused by Drug, Medical Instrument, or Similar Device Used in Treating Patient*, 54 A.L.R.3d 258, 260 n.11 (1974).

104. Courts have refused to impose strict liability on hospitals for various health care mishaps. *See, e.g.*, Vergott v. Desert Pharmaceutical Co., 463 F.2d 12, 15 (5th Cir. 1972) (defective catheter); Flynn v. Langfitt, 710 F. Supp. 150, 151-52 (E.D. Pa. 1989) (defective tissue graft); Hector v. Cedars-Sinai Medical Ctr., 225 Cal. Rptr. 595, 601 (Ct. App. 1986) (defective pacemaker); Silverhart v. Mount Zion Hosp., 98 Cal. Rptr. 187, 191 (Ct. App. 1971) (defective surgical needle); North Miami Gen. Hosp. v. Goldberg, 520 So. 2d 650, 652 (Fla. Dist. Ct. App. 1988) (defective electro-surgical grounding pad); Perlmutter v. Beth David Hosp., 123 N.E.2d 792, 794 (N.Y. 1954) (impure blood transfusion); Easterly v. HSP of Texas, Inc., 772 S.W.2d 211, 213 (Tex. Ct. App. 1989) (defective catheter); Nevaux v. Park Place Hosp., 656 S.W.2d 923, 926 (Tex. Ct. App. 1983) (radiation burns from cobalt therapy); Shivers v. Good Shepherd Hosp., Inc., 427 S.W.2d 104, 106 (Tex. Ct. App. 1968) (contaminated drugs).

105. *See* Edward R. Wiest, *Pricing Bad Blood: Reassessing Liability for Post-Transfusion Hepatitis*, 15 HARV. J. ON LEGIS. 557, 558 (1978).

106. *See, e.g.*, Hoven v. Kelble, 256 N.W.2d 379, 387 (Wis. 1977).

107. Hoven v. Kelble, 256 N.W.2d 379 (Wis. 1977).

108. *Id.* at 391.

The court also noted the power of the standard strict product liability justifications. The reasons for applying the doctrine to the sale of goods seem equally valid when applied to the provision of medical services. The provider of medical services appears to stand in substantially the same position with respect to the patient as the seller of goods does with the consumer. The typical purchaser of medical services cannot evaluate the quality of care offered because medical services are complex and infrequently bought. The medical care market gives the purchaser little assistance in enabling the purchaser to evaluate what he or she is buying. It is generally the physician—not the patient—who determines the kind of services to be rendered and how often. It is the physician, not the patient, who prescribes other goods and services—drugs, therapy, and hospitalization—that should supplement the physician's services. The physician is in a better position than the patient to determine and improve the quality of the services, and the patient's reliance on the doctor's skill, care, and reputation is perhaps greater than the reliance of the consumer of goods. The difficulties faced by plaintiffs in carrying the burden of proving negligence on the part of a doctor are well known. The hospital and doctor are in a better position than the patient to bear and distribute the risk of loss.

The only exception to the no-strict-liability rule is the occasional use of res ipsa loquitur against hospitals, which is similar to strict liability in its effects. It is typically invoked when medical devices are involved.[109] The various devices that a hospital furnishes its staff and patients, as part of the provision of medical service, must be properly selected, stored, and maintained or replaced when worn. Strict liability arguments imported from product defects litigation have made some inroads in lawsuits against hospitals.[110] Both implied warranty doctrine and section 402A of the Second Restatement have, on rare occasions, been applied to devices used in hospitals.[111] The growth of technological medicine has made physicians increasingly dependent upon diagnostic machinery, computer-assisted tests, and drugs and devices. Many of the res ipsa loquitur cases, for example, involve medical devices that failed during surgery.[112] These devices are

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109. *See, e.g.*, Jackson v. Oklahoma Memorial Hosp., 909 P.2d 765, 770-73 (Okla. 1995) (acknowledging the availability of res ipsa loquitur in cases involving medical devices).

110. *See, e.g.*, Advincula v. United Blood Servs., 654 N.E.2d 644, 650 (Ill. App. Ct. 1995) (strict liability imposed upon hospitals dealing with blood products).

111. *See, e.g.*, Dubin v. Michael Reese Hosp. & Medical Ctr., 393 N.E.2d 588, 597 (Ill. App. Ct. 1979) (holding that x-radiation was a product under § 402A of the Restatement (Second) of Torts so as to render hospital strictly liable), *rev'd*, 415 N.E.2d 350, 352 (Ill. 1980) (holding that x-radiation was not a product subject to the doctrine of strict liability in tort).

112. *See, e.g.*, Holliday v. Peden, 359 So. 2d 640, 642 (La. Ct. App. 1978) (involving a needle which broke during a tonsillectomy and became lodged in the patient's throat); Anderson v. Somberg, 338 A.2d 1, 3 (N.J.) (involving an angulate pituitary rongeur, much like forceps, which broke off in the patient's spinal canal), *cert. denied*, 423 U.S. 929 (1975).

bought by a hospital's purchasing department, subject to the controls imposed by the hospital's administration.

The standard use of drugs and devices implicates the hospital as a middleman in the stream of commerce, as in products liability cases. Consider, for example, *Skelton v. Druid City Hospital Board*,[113] involving a suture needle which broke off in the patient during ventral hernia repair.[114] These needles were re-used several times by the hospital, and there was no way to be sure exactly how many times.[115] Section 2-315 of the Uniform Commercial Code, dealing with implied warranties of fitness for a particular purpose, was applied to this "hybrid" service-product transaction between the hospital and patient.[116] The court held:

> The gist of an action under this section is reliance. Patients are rarely in a position to judge the quality of the medical supplies and other goods sold to them and used in their care; often, those supplies are of an inherently dangerous nature. The complete dependence of patients on the staff of a hospital to choose fit products justifies the imposition of an implied warranty under § []2-315, whether the hospital is a "merchant" or not.[117]

In the hospital setting, the patient is usually administered a variety of drugs as part of treatment and these drugs come from hospital supplies. In *Karibjanian v. Thomas Jefferson University Hospital*,[118] the plaintiff suffered injuries from the use of Thorotrast, a contrast medium with which he was injected during a diagnostic medical procedure.[119] The hospital argued that a hospital could not be liable under section 402A when a defective surgical tool injures a patient during an operation, because it is in the business of supplying services, supplies surgical tools only incidentally, and that the medical service could not be performed without the use of the instrument.[120] The hospital also argued that it was not in the "business of selling" Thorotrast, within the meaning of section 402A, but was rather in the business of providing services.[121]

The federal district court concluded that:

> [S]o long as a hospital *regularly* supplies contrast media to its patients, albeit as an incidental part of its service operations, it seems to fall within § 402A as explained by comment (f). The comment draws no distinction

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113. Skelton v. Druid City Hosp. Bd., 459 So. 2d 818 (Ala. 1984).
114. *Id.* at 819.
115. *Id.* at 820.
116. *Id.* at 823.
117. *Id.*
118. Karibjanian v. Thomas Jefferson Univ. Hosp., 717 F. Supp. 1081 (E.D. Pa. 1989).
119. *Id.* at 1082.
120. *Id.* at 1085.
121. *Id.*

> between suppliers of goods who also supply services, and those suppliers who simply supply goods.[122]

The hospital might be found by the trier of fact to be a seller of such drugs, which are held in inventory until used by patients, even though the use is only incidental to the medical services provided.[123] In *Karibjanian,* the judge noted that while such products may be termed incidental, the product in fact makes the service possible, and the hospital has a duty to ensure the safety of the equipment chosen.[124] Other courts have indicated a willingness to allow a strict liability claim when the product ancillary to the service is in effect sold to the patient.[125]

Enterprise liability for bad hospital-based outcomes—whether caused by drugs, devices, or medical services—makes sense. Hospital administrative and mechanical services have been held to be subject potentially to strict liability,[126] as have hospital operations that are not "integrally related to its primary function of providing medical services."[127] A hospital may also be strictly liable for defective goods and materials that are not directly related to

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122. *Id.*

123. *But cf.* Podrat v. Codman-Shurtleff, 558 A.2d 895 (Pa. Super. Ct.) (involving forceps that broke, leaving piece in patient's disc space), *appeal denied,* 569 A.2d 1368 (Pa. 1989). The court in *Podrat* stressed the hospital's function of providing a service to a patient, noting that the instrument's use is simply incidental to the provision of this service. The court stated:

> In sum, we conclude that the trial court did not err in finding that the hospital could not be liable under a theory of strict liability because the hospital was not in the business of selling this instrument, its use was only incidental to the hospital's primary function of providing medical services and the medical services could not have been rendered without the use of this product.

Id. at 898.

In *Grubb v. Albert Einstein Medical Center,* the court stated in a plurality opinion that a hospital could be held liable under § 402A; however, because four of the seven judges dissented with regard to that issue, the hospital was liable only under a negligence theory. Grubb v. Albert Einstein Medical Ctr., 387 A.2d 480, 490 (Pa. Super. Ct. 1978).

124. Karibjanian v. Thomas Jefferson Univ. Hosp., 717 F. Supp. 1081, 1085-86 (E.D. Pa. 1989). In footnote 5, Judge Lord offers a delicious analogy. He observes: "[A] restaurant patron who enjoys an exquisite souffle values the services of the chef more than the eggs with which it is made, since the eggs could be had for less than a dollar at any store. Nonetheless, if fate has it that the eggs are bad, the restaurant would be liable under § 402A as a supplier of eggs, even though the eggs were but an incidental part of what the patron paid for. And this is not to mention the services of the maitre d' who seats her, and the waiter who serves her." *Id.* at 1086 n.5.

125. *See, e.g.*, Mauran v. Mary Fletcher Hosp., 318 F. Supp. 297, 301 (D. Vt. 1970) (involving anesthetic drugs).

126. *See, e.g.*, Johnson v. Sears, 355 F. Supp. 1065, 1067 (E.D. Wis. 1973).

127. Silverhart v. Mount Zion Hosp., 98 Cal. Rptr. 187, 191 (Ct. App. 1971) (identifying a gift shop as example of such a nonessential hospital function).

medical services.[128] In *Johnson v. Sears*,[129] the court allowed a plaintiff to plead strict liability against a hospital for alleged defects in mechanical and administrative services.[130] Hospitals began as the doctor's workshop, little more than a shell within which health care services were provided.[131] As they have grown in complexity, hospitals' obligations to patients have also grown. The health care institution provides support, equipment, and administration to physicians, and is therefore responsible for both sloppy and careful practice within its walls. Changing judicial perceptions of the responsibility of institutions toward their providers, whether defined as employees or independent contractors, have expanded hospital liability. The hospital industry is pervasively regulated, particularly by the federal government. It makes sense to focus liability on the hospital, whether the negligent acts are done by staff employees or independent contractor physicians. As the doctrine of corporate negligence has developed, courts have grown receptive to expanding the hospital's duty to supervise physicians in drug use, especially with anticoagulant drugs that need careful monitoring.[132]

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128. Thomas v. St. Joseph Hosp., 618 S.W.2d 791, 796 (Tex. Ct. App. 1981) (involving a defective hospital gown that caught fire); Pierson v. Sharp Memorial Hosp., 264 Cal. Rptr. 673, 675 (Ct. App. 1989) (holding that defective carpet was part of a room that was integral to hospital services).

129. Johnson v. Sears, 355 F. Supp. 1065 (E.D. Wis. 1973).

130. *Id.* at 1067. Other courts have extended *Johnson* to cover medical services as well. *See* Grubb v. Albert Einstein Medical Ctr., 387 A.2d 480, 490 (Pa. Super. Ct. 1978) (involving a physician who used a plug cutter to remove a bone plug from the vertebrae of the plaintiff; as a result of a series of errors, the patient was rendered a quadriplegic; the court held that § 402A was applicable to the hospital).

131. ROSEMARY STEVENS, IN SICKNESS AND IN WEALTH 46-51 (1989); PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 24-25 (1982); CHARLES E. ROSENBERG, THE CARE OF STRANGERS, 18-19 (1987).

132. In *Thompson v. Nason Hospital*, plaintiff Linda Thompson was involved in a car accident and taken to Nason Hospital's emergency room. Thompson v. Nason Hosp., 591 A.2d 703, 704 (Pa. 1991). She was taking the anticoagulant Coumadin, had a pacemaker, and took other heart medications, and her husband so advised emergency room personnel. *Id.* Dr. Edward D. Schultz, a general practitioner who enjoyed staff privileges at Nason Hospital, entered the hospital via the emergency room to make his rounds and was asked by a nurse to attend to Mrs. Thompson due to a prior physician-patient relationship. *Id.* He examined her and diagnosed her as suffering from multiple injuries. *Id.* He knew Mrs. Thompson was suffering from rheumatic heart and mitral valve disease and was on anticoagulant therapy. *Id.* at 705. Because he lacked training in establishing dosages for such therapy, he called a cardiologist and spoke with an associate. *Id.* Three days later, another physician treating her eye injuries noted that Mrs. Thompson was suffering from side effects of the anticoagulant drug and approved the withholding of Coumadin and the continued use of Heparin. *Id.* She was transferred to the Hershey Medical Center and was found to have a large intracerebral hematoma in the right frontal temporal and parietal lobes of the brain. *Id.* The plaintiffs argued a corporate negligence theory, alleging that Mrs. Thompson's injuries were caused by the hospital's failure to adequately examine and treat her, in failing to follow its rules relative to consultations, and in failing to monitor her conditions during treatment, including the failure

The hospital is arguably in the best position to monitor conduct within its walls, to enforce adherence to policies, and to provide a source of compensation to injured patients. Expanded liability also encourages a hospital to insure its staff and physicians on the medical staff under the same insurance carrier to reduce its costs,[133] and to turn independent contractor physicians into employees for some hospital functions.[134] Hospitals have come to be viewed as enterprises that can harm as well as cure. As risk producing enterprises, they are capable of distributing the risks of patient injuries as well.

C. *Duty to Monitor Informed Consent*

Pharmaceutical products other than contrast media and other substances used by the hospital are prescribed by physicians with staff privileges. Hospitals are generally not required to monitor the actions of these nonemployee staff physicians in obtaining the informed consent of patients, on the ground that it is the treating physician's responsibility.[135] In *Petriello*

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of Dr. Schultz to consult with a cardiologist with regard to the dosage of anticoagulants. *Id.* The court allowed the corporate negligence count. *Id.* at 706-08.

133. *See* Arthur F. Southwick, *Hospital Liability—Two Theories Have Been Merged*, 4 J. LEGAL MED. 1, 49 (1983).

134. *Id.* Judicial decisions have changed institutional provider behavior in some instances. For example, the decision by the Alaska Supreme Court in *Jackson v. Power*, in which the court held that the defendant hospital had a non-delegable duty to provide non-negligent physician care in its emergency room and, therefore, could be liable, led plaintiffs' attorneys in Alaska to include hospitals in every suit they brought against individual physicians. Jackson v. Power, 743 P.2d 1376, 1385 (Alaska 1987). Some hospitals in Alaska responded to this decision by hiring their own emergency room physicians so the hospital would not need to worry about being joined in suits brought against independent contractor physicians over whom it had less control. *See* Dean Mayer, *Malpractice Standoff Riles Alaska Doctors*, HEALTHWEEK, June 6, 1988, at 1.

135. *See, e.g.*, Moore v. Baker, No. CV 491-93, 1991 WL 578264 (S.D. Ga. Oct. 1, 1991), *aff'd*, 989 F.2d 1129 (11th Cir. 1993); Petriello v. Kalman, 576 A.2d 474 (Conn. 1990); Hammer v. Mount Sinai Hosp., 596 A.2d 1318 (Conn. App. Ct.), *appeal denied*, 599 A.2d 384 (Conn. 1991); Smith v. Gaynor, 591 A.2d 834 (Conn. Super. Ct. 1991); Pickle v. Curns, 435 N.E.2d 877 (Ill. App. Ct. 1982); Pauscher v. Iowa Methodist Medical Ctr., 408 N.W.2d 355 (Iowa 1987); Busalacchi v. Vogel, 429 So. 2d 217 (La. Ct. App. 1983); Beck v. Lovell, 361 So. 2d 245 (La. Ct. App.), *cert. denied*, 362 So. 2d 802 (La. 1978); Lincoln v. Gupta, 370 N.W.2d 312 (Mich. Ct. App. 1985); Wilson v. Lockwood, 711 S.W.2d 545 (Mo. Ct. App. 1986); Baltzell v. Baptist Medical Ctr., 718 S.W.2d 140 (Mo. Ct. App. 1979); Roberson v. Menorah Medical Ctr., 588 S.W.2d 134 (Mo. Ct. App. 1979); Llera v. Wisner, 557 P.2d 805 (Mont. 1976); Cooper v. Curry, 589 P.2d 201 (N.M. Ct. App.), *cert. denied*, 588 P.2d 554 (N.M. 1978); Prooth v. Wallsh, 432 N.Y.S.2d 663 (1980); Fiorentino v. Wenger, 227 N.E.2d 296 (N.Y. 1967); Garzione v. Vassar Bros. Hosp., 320 N.Y.S.2d 830 (App. Div. 1971), *aff'd*, 286 N.E.2d 731 (N.Y. 1972); Gray v. Grunnagle, 223 A.2d 663 (Pa. 1966); Ritter v. Delaney, 790 S.W.2d 29 (Tex. Ct. App. 1990); Alexander v. Gonser, 711 P.2d 347 (Wash. Ct. App. 1985); Belcher v. Charleston Area Medical Ctr., 422 S.E.2d 827 (W. Va. 1992);

v. Kalman[136] the Connecticut Supreme Court held that a hospital had no duty to obtain a patient's consent to surgery, nor to conduct any kind of inquiry.[137] The plaintiff suffered a miscarriage and the treating physician scheduled the plaintiff for a dilation and curettage to remove the fetus.[138] A hospital nurse medicated the plaintiff before the procedure, without obtaining the plaintiff's signature on the consent form—violating hospital policy.[139] Despite the policy violation, the court rejected the argument that the hospital was under any duty to complete such forms.[140] Imposing such a duty is resisted by courts on the basis that the responsibility belongs to the attending physician.[141] The court stated: "This contention is unsound, however, because it equates the signing of the form with the actuality of informed consent, which it is the sole responsibility of the attending physician to obtain."[142]

Drugs are a pervasive feature of hospital care. Emerging case law is finding a duty on the hospital and its staff to ensure that patient consent for the use of pharmaceutical products is properly obtained by attending

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Scaria v. Saint Paul Fire & Marine Ins. Co., 227 N.W.2d 647 (Wis. 1975). The same result has been achieved by statute in Ohio. *See* OHIO REV. CODE ANN. § 2317.54 (Anderson 1991). *See generally* Stephen R. Conlin, Note, *Hospital Corporate Negligence Based upon a Lack of Informed Consent*, 19 SUFFOLK U. L. REV. 835 (1985) (examining what duties a hospital owes with regard to the doctrine of informed consent and the theory of hospital corporate negligence).

136. Petriello v. Kalman, 576 A.2d 474 (Conn. 1990).

137. *Id.* at 478-79.

138. *Id.* at 476.

139. *Id.*

140. *Id.* at 479-80.

141. *Id.*

142. *Id.* at 478; *see also* Johnson v. Sears, Roebuck & Co., 832 P.2d 797, 799 (N.M. Ct. App.), *cert. denied*, 832 P.2d 1223 (N.M. 1992). In *Johnson*, while the patient underwent bladder suspension surgery and a hysterectomy, she received one unit of packed red cells which was transfused by nurses under the attending physician's orders. *Id.* at 798. The physician did not obtain informed consent to the transfusion. *Id.* As a result of the transfusion, the patient contracted hepatitis and ultimately died. *Id.* The court stated that "placing a duty of obtaining a patient's informed consent to procedures ordered by a physician but performed by hospital staff would unnecessarily interfere with the physician-patient relationship." *Id.* at 799; *see also* Pauscher v. Iowa Methodist Medical Ctr., 408 N.W.2d 355, 362 (Iowa 1987) (holding that the responsibility of obtaining informed consent is the duty of the doctor and the hospital should not interfere); Kershaw v. Reichert, 445 N.W.2d 16, 19 (N.D. 1989) (stating that a hospital, unlike a patient's physician, generally has no duty to procure informed consent); Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 822-23 (Wash. 1990) (stating that the doctrine of corporate negligence imposes a duty upon a hospital "to exercise reasonable care in selecting, retraining, and supervising the performance of their medical staff" but that duty does not encompass a claim for failure to obtain informed consent); *cf.* Cross v. Trapp, 294 S.E.2d 446, 459 (W. Va. 1982) (holding that a hospital is generally not liable to a patient whose private physician administered treatment without consent and was not an employee of the hospital at the time of treatment).

physicians.[143] When the hospital is part of a clinical investigation of a drug product, courts also impose liability for obtaining informed consent.[144] Such a duty is justified on several grounds. First, the hospital will work harder to ensure consent is properly obtained if it is subject to liability. Given the possibility that such consent may be overlooked by individual physicians because of scheduling or other conflicts, hospital responsibility for obtaining informed consent increases the likelihood consent will be obtained. Second, in other areas of the law, courts have expanded the responsibilities of the hospital and its corresponding obligations to supervise staff, to establish proper procedures, and to hire qualified and competent staff members.[145] Third, the deference to physician responsibility that has been part of the case law of hospital-physician relationships is diminishing as courts recognize that the delivery of quality health care is a team operation in which hospital support is vital.[146] Fourth, the impetus to complete written records in health care institutions—primarily for reimbursement and monitoring purposes—has increased the responsibility of the institution to guarantee completeness of records. Written consent forms are prevalent in institutional settings given bureaucratic pressures for a complete patient record, a desire to protect against litigation, and a sense that something is better than nothing. Consent forms, however, are often reduced to little more than a bureaucratic formality that the institution hopes will act as a defense against malpractice suits.[147] Such forms, however, can be improved to facilitate doctor-patient conversation and risk disclosure. That task should fall upon the hospital with its multiplicity of administrators. As health care reform moves toward enterprise liability and centrally managed care organizations, it is likely that health care institutions will face expanded duties to obtain informed consent from patients.

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143. *See, e.g.*, Brownfield v. Daniel Freeman Marina Hosp., 256 Cal. Rptr. 240 (Ct. App. 1989); Doctors Memorial Hosp. v. Evans, 543 So. 2d 809 (Fla. Dist. Ct. App. 1989); Magana v. Elie, 439 N.E.2d 1319 (Ill. App. Ct. 1982); Lincoln v. Gupta, 370 N.W.2d 312 (Mich. Ct. App. 1985); Campbell v. Pitt County Memorial Hosp., Inc., 352 S.E.2d 902 (N.C. Ct. App.), *aff'd*, 362 S.E.2d 273 (N.C. 1987).

144. *See, e.g.*, Kus v. Sherman Hosp., 644 N.E.2d 1214 (Ill. App. Ct.), *appeal denied*, 652 N.E.2d 343 (Ill. 1995). In *Kus*, the court held the hospital liable for failing to obtain the patient's informed consent for the implantation of intraocular lenses, an experimental FDA procedure. *Id.* at 1221. The court held that "a hospital, as well as a physician, may be held liable for a patient's defective consent in a case involving experimental intraocular lenses . . . ." *Id.* at 1220.

145. *See, e.g.*, Marrese v. Interqual, Inc., 748 F.2d 373, 390 (7th Cir. 1984), *cert. denied*, 472 U.S. 1027 (1985).

146. *See* Cathy Jones, *Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy*, 47 WASH. & LEE L. REV. 379, 429 (1990).

147. *See* CHARLES W. LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY 318 (1984) (concluding that consent forms in psychiatric settings were largely insignificant, too complex, presented too late in the process to patients, rarely read, and barely understood).

D. *Organizational Liability Proposals*

Organizational enterprise liability for hospitals and other institutional providers has emerged as a strong model for malpractice reform. The American Law Institute (ALI) has proposed a "channeling" model of organizational liability.[148] Organizational liability, as defined by the ALI, would make a hospital liable for physician negligence that injures patients within the hospital:[149]

> [W]e would exculpate doctors from personal liability for negligence (and thus eliminate their need to purchase insurance against such liability), on the condition that the hospital assume such liability and provide the insurance, a change that would leave untouched the patient's present entitlement to recover for injuries caused by the doctor's negligence.[150]

All doctors within an institution would be treated as part of a single enterprise, hospital, or health care organization—treating medical enterprises the same way product liability law now treats other commercial enterprises, such as airlines.[151] Such insurance channeling to the hospital is based on two primary assumptions: (1) that most incidents causing serious patient injury occur within the hospital setting, which is therefore the appropriate locus for liability;[152] and (2) that institution-based quality assurance programs can promote effective safety programs, reducing patient injury.[153]

Channeling of liability to the hospital through organizational liability is justified by several arguments. First, insurers would be able to price insurance effectively, because difficulties in pricing for individual physicians in high-risk specialties would be eliminated. In most other areas of tort law—from environmental to product risks—business enterprises bear the cost of insuring against liability of its members. Second, by eliminating the insurance problems inherent in the area of malpractice, specialties such as obstetrics would no longer face onerous burdens, nor would physicians face premiums that fluctuate excessively from year to year. Third, physicians would be free from the psychological stress inflicted by being named defendants in malpractice suits. Physicians often overestimate the risks of being sued and the size of judgments.[154] Fourth, administrative and litigation costs would also

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148. THE AMERICAN LAW INSTITUTE, 2 REPORTERS' STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 113-19 (1991) [hereinafter ALI STUDY].

149. 2 *id.* at 114.

150. 2 *id.* at 115.

151. 2 *id.* at 118 n.14.

152. 2 *id.* at 114.

153. 1 *id.* at 298-99.

154. Ann G. Lawthers et al., ***Physicians' Perceptions of the Risk of Being Sued***, 17 J. HEALTH POL. POL'Y & L. 463, 468 (1992); *see also* Paul Weiler et al., *Proposal for Medical Liability Reform*, 267 JAMA 2355, 2356 (1992). Ann Lawthers' study concluded that physicians overestimate the rate of suit for malpractice at three times the actual rate. Lawthers et al., *supra*. This perceived risk suggests that physicians do respond to the messages sent by

be reduced by having only one defendant, rather than the multiplicity of providers named in the typical malpractice suit.[155] Fifth, patterns of poor medical practice would be deterred by placing liability on institutions rather than individuals,[156] because organizations have superior data collecting abilities and management tools for controlling risks.[157]

IV. PHARMACIST LIABILITY: EXPANDING THE ROLE, INCREASING THE RISK[158]

The liability of the pharmacist is expanding. The number of drugs available has increased tremendously, as has the level of information about drug risks, interactions, and contraindications as FDA requirements and research have generated more data. The government has determined as a matter of policy that pharmacists should be the front line counselors on drug interactions and risks for Medicaid patients.

A. *Compounder Apothecary*

The simplest and oldest form of pharmacist liability is when the pharmacist introduces a foreign substance into a drug or errs in compounding or dispensing a drug.[159] The test for liability for this type of error is negligence, based on the pharmacist's traditional role in compounding and dispensing prescriptions. For example, in *Huggins v. Longs Drug Stores California, Inc.*,[160] the pharmacy, in filling a prescription for plaintiffs' two-month-old son, wrote directions for five times the dosage ordered by the

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litigation. Similarly, Paul Weiler reported: "[S]everal reasons . . . lead us to believe that the tort system exerts a deterrent effect. First, the self-reported behavior of New York physicians interviewed by us is consistent [with this conclusion]. Second, our finding of increased negligence among the elderly and among the uninsured may be attributed, at least in part, to reduced economic losses in those groups, and therefore, a smaller likelihood of their bringing claims. Finally, there is evidence of fewer workplace injuries because of the workers' compensation program." Weiler et al., *supra* (footnotes omitted).

155. 2 ALI STUDY, *supra* note 148, at 119.

156. *See id.* at 121-26. *See generally* Lewis A. Kornhauser, *An Economic Analysis of the Choice Between Enterprise and Personal Liability for Accidents*, 70 CAL. L. REV. 1345 (1982); Alan O. Sykes, *The Economics of Vicarious Liability*, 93 YALE L.J. 1231 (1984).

157. Physician profiling by insurers and providers has become commonplace in tracking provider behavior. *See* David W. Emmons et al., *Data on Employee Physician Profiling*, 26 J. HEALTH & HOSP. L. 73 (1993); *see also* John H. Eichhorn et al., *Standards for Patient Monitoring During Anesthesia at Harvard Medical School*, 256 JAMA 1017 (1986).

158. For an outline of the pharmacist's roles in the delivery system and the liability imposed, see Table 2 in the Appendix.

159. *See, e.g.*, Adams v. American Druggist Ins. Co., 245 So. 2d 808, 810 (La. Ct. App.) (dealing with prescription for choloasma erroneously compounded by pharmacist—bichloride of mercury was 6.56% rather than 0.5% and salicylic acid was 4.08% rather than 1% specified), *cert. denied*, 247 So. 2d 863 (La. 1971).

160. Huggins v. Long Drug Stores California, Inc., 862 P.2d 148 (Cal. 1993).

doctor.[161] Such errors are usually so obvious, when measured against the standard of practice of pharmacy, that a breach of duty is easily found. Errors of this sort, as well as product confusion, continue to occur because of similar labeling of drugs by manufacturers.[162]

B. *The Gatekeeper Druggist*

Courts have traditionally been reluctant to impose on pharmacists a duty to warn. Courts argue that primary responsibility lies with the physician and imposing such duties on a pharmacist would only "serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability."[163] A few jurisdictions have disagreed, holding that certain

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161. *Id.* at 149. The case involved a claim of emotional distress by the parents of the infant. *Id.* The appellate court concluded that a pharmacist automatically assumes a duty of care toward a patient's closely related caregivers simply by filling a prescription with actual or constructive knowledge that the patient is an infant or is otherwise helpless. *Id.* The "direct victim" label stems from *Molien v. Kaiser Foundation Hospitals*, in which the court found that "a hospital and a doctor owed a duty directly to the husband of a patient, who had been diagnosed incorrectly by the doctor as having syphilis and had been told to so advise her husband in order that he could receive testing and, if necessary, treatment." *Id.* at 151-52 (citing Molien v. Kaiser Found. Hosps., 616 P.2d 813, 821 (Cal. 1980)).

162. *See* Doug Podolshy & Penny Loeb, *Dangerous Drugs*, U.S. NEWS & WORLD REP., Jan. 9, 1995, at 48 (describing a range of drug risks, including confusing packaging).

163. Jones v. Irvin, 602 F. Supp. 399, 402 (S.D. Ill. 1985); *see* Mazur v. Merck & Co., 964 F.2d 1348, 1356-57 (3d Cir.) (suggesting no duty on pharmacist to give warnings), *cert. denied*, 506 U.S. 974 (1992); Ramirez v. Richardson-Merrell, Inc., 628 F. Supp. 85, 88 (E.D. Pa. 1986) (imposing duty to warn would place pharmacist between the prescribing physician and the patient); *cf.* Murphy v. E.R. Squibb & Sons, 710 P.2d 247, 249 (Cal. 1985) (concluding pharmacists using due care in compounding and labeling prescription drugs immune from strict liability); Pysz v. Henry's Drug Store, 457 So. 2d 561, 562 (Fla. Dist. Ct. App. 1984) (finding no duty to warn but noting a situation might exist which would support negligence action against pharmacist who lawfully filled a prescription); Frye v. Medicar-Glaser Corp., 605 N.E.2d 557, 560 (Ill. 1992) (suggesting consumers should look principally to prescribing physicians to convey appropriate drug warnings); Leesley v. West, 518 N.E.2d 758 (Ill. App. Ct.) (holding pharmacist has no duty to warn consumer of drugs' dangerous side effects), *cert. denied*, 522 N.E.2d 1246 (Ill. 1988); Eldridge v. Eli Lilly & Co., 485 N.E.2d 551, 554-55 (Ill. App. Ct. 1985) (suggesting pharmacist has no common law duty to refuse to fill prescription simply because it is for a quantity beyond that normally prescribed or to warn a physician of that fact); Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881, 885 (Ind. Ct. App. 1985) (holding that decision to warn requires knowledge of medical history and other facts about patient; pharmacist has no duty to warn, except those warnings actually contained in physician's prescription); Nichols v. Central Merchandise, 817 P.2d 1131, 1133 (Kan. Ct. App. 1991) (finding no duty to warn patient of potential consequences of drug use under facts of case); Adkins v. Mong, 425 N.W.2d 151, 152 (Mich. Ct. App. 1988) (concluding that pharmacist has no duty to warn when prescription is proper on face, dispensed according to prescription, and neither physician nor manufacturer requested pharmacist give a particular warning; pharmacist has no legal duty to monitor and intervene); Stebbins v. Concord Wrigley

situations impose a duty on a pharmacist, who in their view, should be more than a mere "warehouse for drugs . . . [or] a shipping clerk who must dutifully and unquestioningly obey the written orders of omniscient physicians."[164] These courts expect that at a minimum the pharmacist must notify the prescribing physician of "obvious inadequacies appearing on the face of the prescription which create . . . a substantial risk of serious harm to the plaintiff."[165]

Drugs, Inc., 416 N.W.2d 381, 387 (Mich. Ct. App. 1987) (adopting the rule followed in *Pysz* and *Jones* that pharmacist has no duty to warn when a prescription is proper on its face and neither physician nor manufacturer has required pharmacist to give a warning); Ullman v. Grant, 450 N.Y.S.2d 955, 956 (App. Div. 1982) (suggesting no duty of pharmacy to warn customer of possible side effect in use of drug); Bichler v. Willing, 397 N.Y.S.2d 57, 59 (App. Div. 1977) (declining to hold that a druggist can never be liable for correctly filling a prescription); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 274 (N.C. Ct. App.) (holding that a druggist was not liable on grounds of negligence for alleged failure to warn plaintiff of risks and side effects of drug), *review denied*, 233 S.E.2d 921 (N.C. 1977); Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1386-87 (Pa. 1991) (declining to impose duty upon pharmacists to supply drug risk information; recognizing pharmacists might refuse to fill prescriptions to avoid liability); Makripodis v. Merrell-Dow Pharmaceuticals, 523 A.2d 374, 378-79 (Pa. Super. Ct. 1987) (concluding that pharmacist is not required to provide consumer with same warnings drug manufacturers are required to give physicians); McKee v. American Home Prods. Corp., 782 P.2d 1045, 1055 (Wash. 1989) (finding no duty to warn; although pharmacist should have a duty to be alert for incompatible prescriptions, he or she does not have a duty to provide customers with manufacturers' package insert information or to question judgment made by physician as to propriety of prescription). *But cf.* Kampe v. Howard Stark Professional Pharmacy, 841 S.W.2d 223, 226-27 (Mo. Ct. App. 1992) (absent apparent discrepancy on face of prescription, pharmacist has no duty to warn patient; duty fulfilled by properly filling legal prescription as written).

164. Riff v. Morgan Pharmacy, 508 A.2d 1247, 1251 (Pa. Super. Ct. 1986), *appeal denied*, 524 A.2d 494 (Pa. 1987).

165. *Id.* at 1252. In *McKee v. American Home Products Corp.*, the Washington Supreme Court described the limits of this duty:

> The pharmacist . . . has a duty to accurately fill a prescription . . . and to be alert for clear errors or mistakes in the prescription. The pharmacist does not, however, have a duty to question a judgment made by the physician as to the propriety of a prescription or to warn customers of the hazardous side effects associated with a drug, either orally or by way of the manufacturer's package insert.

McKee v. American Home Prods. Corp., 782 P.2d at 1055-56; *see also* Nichols v. Central Merchandise, 817 P.2d at 1133 (holding that pharmacist has a duty to accurately fill prescriptions and to look for clear errors in the prescription, but no duty to question the judgment of the physician or propriety of the prescription); Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d at 387 (holding that pharmacist has duty to fill prescriptions correctly and is not liable for any damages resulting from a correctly filled prescription); Kampe v. Howard Stark Professional Pharmacy, 841 S.W.2d at 225 (holding that pharmacist has no duty to warn).

This view of the druggist as gatekeeper is reflected in *Lasley v. Shrake's Country Club Pharmacy, Inc.*,[166] in which a duty to advise a customer of the addictive nature of a prescribed drug was found. The treating physician prescribed Doriden and codeine to the plaintiff for ten years, and during this period the pharmacy had filled the prescriptions and mailed one or more of the drugs to the plaintiff's residence in another state.[167] The plaintiff had to be hospitalized for Doriden detoxification and psychiatric treatment for addiction.[168] The pharmacy argued that as a matter of law, a pharmacist has no duty to either warn of a drug's dangerous propensities nor to control or track a customer's reliance on drugs prescribed by a physician.[169] The court rejected the argument, even though it noted that a majority of courts considering the question had held that no duty exists. The court noted three cases—*Dooley v. Everett*,[170] *Hand v. Krakowski*,[171] and *Riff v. Morgan Pharmacy*[172]—in which the courts had allowed a duty to warn theory to proceed to the jury. The *Lasley* court relied on expert testimony that the pharmacy standard of care includes "a responsibility to advise a customer of the addictive nature of a drug, to warn of the hazards of ingesting two or more drugs that adversely interact with one another, and to discuss with the physician the addictive nature of a prescribed drug and the dangers of long-term prescription of the drug."[173] The court admitted excerpts from the American Pharmaceutical Association Standards of Practice for the Profession of Pharmacy as evidence of the standard of care.[174]

C. *Counselor Pharmacist: The New Learned Intermediary*

Congress has been less protective of the pharmacy profession than the courts, passing the Pharmaceutical Access and Prudent Purchasing Act of 1990 to control costs in the Medicaid program.[175] The Act requires

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

167. *Id.* at 1131.

168. *Id.*

169. *Id.*

170. Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990).

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

172. Riff v. Morgan Pharmacy, 508 A.2d 1247 (Pa. Super. Ct. 1986), *appeal denied*, 524 A.2d 494 (Pa. 1987).

173. Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d at 1134.

174. *Id.*

175. 42 U.S.C. § 1396r-8 (1994). Section 4401 of the Omnibus Budget Reconciliation Act of 1990 established expanded standards of pharmacy practice as a condition of participation in the federal/state Medicaid program. The language has been codified as follows:

> (ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following:
>
> (I) The pharmacist must offer to discuss with each individual receiving

pharmacists to offer to discuss with customers matters they deem significant, including directions and precautions for preparation, administration and use, and possible adverse side effects or interactions.[176] The pharmacist must also obtain, record, and maintain "[i]ndividual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices."[177]

Pharmacists are trained to counsel patients about their medications, and are taught to interact with physicians and help choose the most appropriate therapy for the patient.[178] It has been argued that pharmacists should be advocates as well, encouraging "the patient to assume responsibility for drug therapy . . . ."[179] As pharmacists take on a greater role in patient care, they become a new "learned intermediary" along with the treating physician. Patients depend on pharmacists to provide drug information.[180] While physicians are more trained in evaluating the benefits and risks of a given drug for a particular patient, pharmacists are still familiar with disease states in general.

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

Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401(a), 104 Stat. 1388 (1990).

176. *Id.*

177. *Id.*

178. *See generally* David W. Hepplewhite, *A Traditional Legal Analysis of the Roles and Duties of Pharmacists*, 44 DRAKE L. REV. 519 (1996) (discussing pharmacy standards).

179. David B. Brushwood, *The Pharmacist's Duty to Warn: Toward a Knowledge-Based Model of Professional Responsibility*, 40 DRAKE L. REV. 1, 17 (1991).

180. *Id.* at 25.

D. *Pharmacist as Team Member*

The hospital pharmacist is already part of the health care team. The community and chain store pharmacist will be next to join the health care team, given the pharmacy's abilities to store patient records, profile drug use, and track prescriptions. A patient's full record may soon be accessible through the pharmacy computer.[181] This is already true for the hospital pharmacy—which has on-line records at its disposal. The search for interactions, abuse of prescriptions by patients, and other drug risks could easily be automated if patient confidentiality concerns can be overcome. A computer search could be automated through an electronic agent that can travel over data networks and sort through masses of information. Such an agent could identify a problem with a patient's drug use or interactions, triggering an automatic warning by electronic mail or other computer link to the patient's physicians and pharmacists.[182] The integration of the pharmacist into the whole delivery system, including the managed care organization (MCO) and the hospital, strengthens the argument that some version of strict liability should apply to pharmacists as part of the chain of distribution.[183] The courts have resisted this argument, articulating a range of excuses for pharmacists. First, to hold pharmacists strictly liable for their acts would "make the druggist an insurer of the safety of the manufactured drug and would impose on the retail druggist the obligation to test, at its own expense, new drugs."[184] Because the pharmacist is not familiar with the medical history and condition of the patient and is not trained like the physician, such liability would only serve as insurance against drug mishaps.

Second, to hold a druggist liable for the failure to warn, when the manufacturer has no duty to warn the consumer directly, would be "illogical and inequitable."[185] By this, courts have apparently meant that to hold the druggist to a higher obligation to warn than the manufacturer is unfair, because the manufacturer has greater access to risk information.

Third, the doctor is the actual purchaser of the drugs, and the patient is unable to properly assess and weigh the benefits and risks attendant to the use of such drugs. Holding pharmacists liable would intrude on the doctor-

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181. Japan is moving rapidly toward computerized patient records and prescriptions. *See Hospital Hopes*, THE ECONOMIST, Oct. 9, 1993, at 91.

182. Such electronic agents are now in use in academic and other research centers and are attaining commercial feasibility as on-line services look for ways to become more user-friendly. For a discussion of the operation of such agents, see David Bennahum, *Genius Ex Machina: The Scarily Smart New Breed of On-Line Researchers*, 4 LINGUAFRANCA 68 (1994); *see also* G. Christian Hill, *Cyber Servants: Electronic 'Agents' Bring Virtual Shopping a Bit Closer to Reality*, WALL ST. J., Sept. 27, 1994, at A1.

183. *See* Frank J. Vandall, *Applying Strict Liability to Pharmacists*, 18 U. TOL. L. REV. 1 (1986).

184. Ramirez v. Richardson-Merrell Inc., 628 F. Supp. 85, 87 (E.D. Pa. 1986).

185. Leesley v. West, 518 N.E.2d 758, 762 (Ill. App. Ct.), *cert. denied*, 522 N.E.2d 1246 (Ill. 1988).

patient relationship.[186] Drug information, however, is increasingly aimed at the end user, the consumer. Direct-to-consumer advertising, patient information for narrow therapeutic index drugs, and contraceptives are all exceptions that intrude, but have no great effect on the doctor-patient relationship.

Fourth, the pharmacist is not an independent retailer in the chain of distribution of drugs. "A pharmacist cannot dispense such drugs himself but can do so only upon the direction of a physician."[187] Because drugs are no longer compounded by pharmacists but rather packaged for customers pursuant to physician orders, the pharmacist has no power to choose among product lines from different manufacturers. In other words, the pharmacy is not a hardware store, which can be fairly described as part of the chain of distribution.[188]

But as OBRA obligations and state regulations expand the duties on pharmacists to monitor patient records, consult with them about interaction risks and side effects, and override the physician in extreme cases, the pharmacist has taken on substantial independent duties. The pharmacist has joined with the physician in a collaborative prescribing endeavor. By doing so, the pharmacist has gained the kind of power that justifies treating pharmacists as independent retailers—held strictly liable for their acts.

One court has allowed a strict liability count against a pharmacy. In *Heredia v. Johnson*,[189] the plaintiff was treated at the Ruby Mountain Medical Clinic in Elko, Nevada after suffering from pain and numbness in his left ear.[190] The attending doctor diagnosed Mr. Heredia's condition as acute severe left otitis media with bullous myringitis and prescribed three medications.[191] Plaintiff had the three prescriptions filled by the pharmacist on duty, Faris Massis, at Payless Drug Store in Elko, Nevada.[192] The prescription for Pediotic Otic Suspension drug—ear drops—was allegedly not properly labeled, lacking a warning that its use or administration "should be discontinued and the prescribing physician promptly contacted in case of symptoms of tympanic membrane rupture."[193] Plaintiff argued that due to the defective and unreasonably dangerous manner in which the drug was dispensed—without appropriate labeling and warning—he suffered from severe and permanent injuries, including brain damage.[194]

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186. Makripodis v. Merrell-Dow Pharmaceuticals, Inc., 523 A.2d 374, 378 (Pa. Super. Ct. 1987).

187. *Id.* at 379.

188. The case against strict liability for pharmacy is argued by Brushwood & Abood, *supra* note 84; *see also* Leonard J. Nelson & Stanley Susina, *The Case Against Applying Strict Liability to Pharmacists: A Reply to Professor Vandall*, 19 U. TOL. L. REV. 783 (1988).

189. Heredia v. Johnson, 827 F. Supp. 1522 (D. Nev. 1993).

190. *Id.* at 1523.

191. *Id.*

192. *Id.*

193. *Id.* at 1524.

194. *Id.*

On a motion for summary judgment, the court considered the plaintiff's claim that the Pediotic Otic Suspension was in a "defective condition," rendering it "unreasonably dangerous" when it left the control of Payless and was delivered to the plaintiff.[195] The court wrote:

> Strict tort liability may be imposed upon sellers and those in the chain of distribution as well as manufacturers for their role in placing a defective product into the stream of commerce. To the extent that the plaintiff here bases his strict liability count against Defendant Payless on the pharmacy's role in the chain of distribution, standing between the patient and the drug manufacturer and doctor, the claim is valid. For purposes of the strict liability claim, the allegation is not directed at the conduct of the pharmacist but rather the nature of the product as it made way through the stream of commerce. The Nevada Supreme Court has extended the doctrine of strict liability to all types of products. And the Nevada Courts recognize that strict liability may be imposed even though the product is faultlessly made if it is unreasonably dangerous to place the product in the hands of the user without suitable and adequate warning concerning safe and proper use. A failure to warn may constitute a product defect.
>
> This Court cannot find that the Nevada Supreme Court would hold that the strict liability doctrine does not apply to Defendant simply because the subject transaction was a sale by defendant of a prescription drug.[196]

The court properly looked at the drug as a risk-creating product that moved in commerce.

E. *The Merits of Strict Liability for Pharmacy*

The arguments in favor of strict liability for pharmacists invoke the familiar policy justifications found in products litigation generally.[197]

1. *Superior Knowledge*

First, pharmacists possess superior knowledge about the risks and uses of drugs in comparison to patients and probably in comparison to physicians also. Their knowledge is second only to the manufacturer's knowledge—given their training in drug risks and attributes and their direct access to patients at the point of drug purchase. Expanded liability risks for pharmacists may increase the level of discussion with patients, beyond that already mandated by federal law. While this certainly takes more time, and therefore increases costs for the pharmacy, it places incentives where they belong—on the professional with superior knowledge. If, as critics worry,

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195. *Id.*
196. *Id.* at 1524-25 (footnote omitted) (citations omitted).
197. *See* Vandall, *supra* note 183.

pharmacists stop carrying high-risk drugs for fear of liability,[198] then manufacturers will respond with incentives such as indemnity agreements to encourage the sale of such drugs. Insofar as drug manufacturers need pharmacies to sell their drugs, they will find contractual ways to share or absorb risks to keep their distribution channels open.

2. *Control of Risks*

Critics of strict liability for pharmacists argue that pharmacists have little or no power to select and market prescription drugs.[199] Such drugs are, after all, prescribed by physicians, while the pharmacist merely fills the prescription. For this reason, a pharmacy can exert little pressure on the drug manufacturer of a risky drug. Brushwood and Abood argue that a "pharmacist does not induce the purchase of prescription drugs or market them as such. The physician selects the product; it is not chosen by the patient or the pharmacist and there is no comparison shopping for different products by the patient."[200] This lack of influence over the marketing of the drugs weakens the strict liability rationale, which assumes that safety incentives will be provided by retailers pressuring manufacturers. Such criticism of strict liability is unconvincing today, for several reasons. Under OBRA, pharmacists have expanded obligations to discuss drug risks with patients and to take a more aggressive role in detecting drug interaction problems.[201] Also, pharmacists argue that they should have the right to refuse to fill generic prescriptions—at least as to narrow therapeutic index drugs (NTIs) such as Coumadin—given the increased risks to patients. As their professional obligations expand, pharmacists are more able to affect the sales of a given manufacturer's drugs. As a result, they have become a powerful link in the chain of distribution.

Critics warn that strict liability may influence some pharmacists to refuse to stock drugs and fill prescriptions that pose a risk of harm, even though they are beneficial to patients.[202] Of course, all drugs pose some risk of harm, so an argument suggesting that pharmacies will simply close rather than prescribe is an overstatement. Critics also warn that pharmacists will refuse to fill prescriptions for off-label uses.[203] The FDA has expressed concern about off-label uses of drugs;[204] and reluctance on the part of pharmacists to fill off-label prescriptions might be a good result for patients.

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198. *See* Brushwood & Abood, *supra* note 84, at 285.

199. *See* Makripodis v. Merrell-Dow Pharmaceuticals, Inc., 523 A.2d 374, 379 (Pa. Super. Ct. 1987).

200. Brushwood & Abood, *supra* note 84, at 283.

201. *See* 42 U.S.C. § 1396r-8(g) (1994).

202. *See* Brushwood & Abood, *supra* note 84, at 285.

203. *Id.*

204. *See* United States v. Evers, 453 F. Supp. 1141, 1142 (M.D. Ala. 1978), *aff'd*, 643 F.2d 1043 (5th Cir. 1981).

The general fear is that the sale of prescription drugs would be curtailed because of the threat of liability.[205] Manufacturers who need retailers to market their drugs will need to find ways to accommodate the concerns of community pharmacies. The dire scenarios painted by the critics are based on a remarkably rigid view of the marketplace and ignore the ability of economic enterprises to adapt to changing market environments. Changes in tort law are just one example of such market forces. Enterprises adapt or they die in the competitive marketplace. As long as drugs can be sold for a profit, however, channels of distribution will remain open.

3. *Risk Redistribution*

The availability of insurance as a device for risk distribution makes expanded liability appropriate for pharmacies. Critics object that premiums for such policies will fall unevenly on smaller community pharmacies—already disadvantaged by their inability to obtain volume discounts from drug companies—thereby forcing drug prices upward. This argument ignores the fact that pharmacies are an integral link in the chain of distribution. Drug manufacturers rely on a variety of vehicles for drug sales, from hospital pharmacies to small community pharmacies. Small pharmacies may have to associate to procure affordable policies, or may have to negotiate contracts that distribute the risk between themselves and the manufacturer. Like Adam Smith's invisible hand expressed through the price mechanism in the marketplace, the threat of liability is as likely to spur innovative responses to ensure continued drug distribution as it is to destroy community pharmacies. The dire predictions of the critics assume that none of the players will respond constructively—an unlikely assumption considering the highly profitable nature of these socially desirable consumer products.

V. ENTERPRISE (STRICT) LIABILITY FOR DRUG DISTRIBUTION: SEARCHING FOR THE OPTIMAL LIABILITY REGIME

Starting in the 1970s, motivated by Guido Calabresi's book *The Costs of Accidents*[206] and the application of economic analysis to tort doctrine, legal commentators turned their attention to medical accidents. The 1970s medical malpractice "crisis" provided the political energy that motivated such intellectual explorations as the search for a "fix" to the claimed defects of the malpractice system.[207] Law and economics theorists argued that

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205. For a discussion of such fears, see Nelson & Susina, *supra* note 188, at 793-95.

206. GUIDO CALABRESI, THE COSTS OF ACCIDENTS (1970).

207. *See* INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES, BEYOND MALPRACTICE: COMPENSATION FOR MEDICAL INJURIES (1978); John H. Campbell, *Enterprise Liability—An Adjustment of Priorities*, 10 FORUM 1231 (1975); Robert E. Keeton, *Compensation for Medical Accidents*, 121 U. PA. L. REV. 590 (1973); Jeffery O'Connell, *Expanding No-Fault Beyond Auto Insurance: Some Proposals*, 59 VA. L. REV. 749 (1973); Jon Chait, Comment, *Continuing the Common Law Response to the New Industrial State: The Extension of Enterprise Liability to Consumer Services*, 22 UCLA L. REV. 401 (1974).

enterprises were better than courts at identifying responsible actors and altering their conduct.[208] The theory relies on the claim that the accident history of an agent of an enterprise should be much more important than the details of any particular accident in assessing liability. Enterprise liability also makes it much easier for plaintiffs to identify the cause of injuries, simply by attributing the cause to the enterprise.[209] It also allows for a range of actions to deter future accidents. Since the enterprise must bear the costs of liability, it is motivated to reduce those costs. Rather than focusing on the fault of the individual agent, as courts must do under the fault system, the enterprise can penalize the agent's whole work group, restructure the work environment, or take other steps that transcend the responsibility of an individual agent.[210] The enterprise is also a superior fund for compensation, and a superior risk-spreading instrument.[211]

The health care field is evolving toward integrated corporate enterprises that manage thousands of employees and complex systems. In response to this evolution, courts have, in several doctrinal areas, channeled liability toward health care institutions such as hospitals and HMOs. Although the results have been piecemeal and erratic, serious proposals for enterprise liability for hospitals and other institutional providers have surfaced during

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208. *See, e.g.*, Kornhauser, *supra* note 156, at 1351.

209. *Id.* at 1370.

> [S]hifting from agent to enterprise liability will lead to a greater level of care if first, the principal can affect the probability of injury by her arrangement of the work environment; second, the principal may, at some cost, screen agents on the basis of carefulness; or third, the principal can identify the causally responsible agent more readily than courts can.

Id.

210. *Id.* Other commentators have expanded on this concept:

> To the extent that the goal is "general deterrence"—seeking not to eliminate a particular activity or outcome altogether, but to constrict it consonant with market-valued benefits and burdens—entrusting the investors and managers to put their own house in order finds support in familiar arguments for market superiority. Those tied to the enterprise's economic well-being are presumed to have the motivation and expertise to devise and implement the most cost-effective arrangements for avoiding legal penalties, just as they are presumed most capable of avoiding market penalties. Firms that fail to shape up will suffer competitive disadvantage and, rightly, decline.

Christopher D. Stone, *The Place of Enterprise Liability in the Control of Corporate Conduct*, 90 YALE L.J. 1, 13 (1980).

211. The case against strict or enterprise liability is based upon the assumption that consumers would prefer a free contract regime in the marketplace, so long as risk disclosures are made to ensure informed choice or that deterrence is not affected by the tort system's unpredictable awards. *See, e.g.*, Alan Schwartz, *The Case Against Strict Liability*, 60 FORDHAM L. REV. 819, 837-40 (1992).

the debate over health care reform—driven by both legal trends and the corporatization of medicine.[212]

Although drugs are consumer products, marketed for the ultimate purchase and use of individuals, they are unlike most consumer products in that they are highly regulated, are typically selected by physicians as agents for consumers, and are sold to consumers by retail pharmacists with specialized knowledge about the uses and risks of the drugs. This multi-layered system of product selection and distribution explains why normal strict liability analysis is rarely applied in drug injury cases. This distribution enterprise has not been subjected to an enterprise liability analysis similar to that applied to other products and malpractice. The ALI, in its new draft of the Restatement of Torts, continues to treat drug liability as though drug production, marketing, and distribution is static.[213] The new forces altering the distribution of liability for drug outcomes are also coming from market pressures driving drug companies into mergers, acquisitions, and searches for new markets. An examination of these changes points to the need to change the current law.

A. *Arguments Against Drug Enterprise Liability: Regulation and Innovation*

Judicial resistance to strict liability traverses the landscape of drug distribution. The halo of the drug industry extends to the professionals—the physicians and pharmacists—who are in the chain of distribution. Drug distribution, however, cannot be readily distinguished from distribution of other consumer products, such as bakery goods or automobiles. A chain saw has risks inherent to its design; the hardware store as retailer is jointly liable with the manufacturer; the saw selection is a culling out from a larger universe of saws the store chooses to carry, either because of price, quality, or both. No group of product sellers should be subjected to a lesser standard of liability simply because of the products they sell. Consumers of pharmaceutical products are entitled to the same legal protection as consumers of any other product.[214]

Doctors may find themselves in an awkward position in the middle of this chain of distribution. Doctors assess patient risks when prescribing a given drug, but also act as the consumer of the drug, as the agent of the patient consumer, as the MCO formulary consumer, and as the user of the hospital pharmacy. The ability to insure and pass risks along, spreading out

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212. *See generally* Barry R. Furrow, *Enterprise Liability and Health Care Reform: Managing Care and Managing Risk*, 39 ST. LOUIS U. L.J. 79 (1994); Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evaluation of the American Health Care System*, 108 HARVARD L. REV. 381 (1994).

213. *See* RESTATEMENT (THIRD) OF TORTS (Tentative Draft No. 2, 1994).

214. Justice Traynor put it well in a law review article written three decades ago: "Thus ill health offers adventure; no one has a better chance to live dangerously than the ill who must take their medicine." Roger J. Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 368 (1965).

liability in the process, is what made strict liability possible as to mass-produced consumer goods generally. Merck, CVS, RiteAid, and Dr. Kildare all can insure and then allocate their risks through contract and indemnity agreements. The more integrated the drug production and delivery system becomes, the more compelling the argument that no deference is owed and that stronger versions of strict or enterprise liability are necessary to control risks.

1. *Regulation Controls of Drug Risks*

The central role of the Food and Drug Administration (FDA) in approving new drugs and in regulating their marketing and labeling has diverted liability concerns about pharmaceuticals. Strong government regulation, the argument goes, provides sufficient incentives for risk reduction, so that stronger forms of product liability are hardly necessary. To the contrary, these critics continue, compliance with FDA requirements should constitute an affirmative defense in a tort suit.[215] Drugs are more heavily regulated than other consumer products, even more than toys or chain saws—products not subject to pre-approval requirements or strenuous testing.

The regulatory compliance defense has been forcefully argued as necessary to drug law.[216] It is argued that so long as certain conditions of regulatory intensity are satisfied, the defense should be available.[217] The underlying assumption is that regulation is more effective than tort liability in controlling risks, while still allowing productive products to be marketed.[218] Given the FDA's regulatory status as arguably the best government agency,[219] the argument is an attractive one. The FDA regulation, however, is just the starting point, not the end point, of drug risk controls.

2. *Liability Chills Innovation*

The judicially created protections of the Restatement of Torts and case law are based on the value of drug innovation. The prospect of a miracle cure

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215. *See, e.g.*, W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1438 (1994) (concluding that "tort liability is generally inappropriate in cases when manufacturers have complied with the FDCA").

216. *See* 2 ALI STUDY, *supra* note 148, at 90-93. *But see* Margaret Gilhooley, *Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice*, 24 SETON HALL L. REV. 1481 (1994).

217. *See* 2 ALI STUDY, *supra* note 148, at 110.

218. *See* Viscusi et al., *supra* note 215; Alan Schwartz, *The Case Against Strict Liability*, 60 FORDHAM L. REV. 819 (1992). For an earlier discussion of strict liability for prescription drugs, see Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1 (1973).

219. *See generally* Charles J. Walsh & Alissa Pyrick, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 SETON HALL L. REV. 1325 (1994).

foregone or a vaccine undeveloped has haunted courts, justifying a continuing doctrinal subsidy of drug manufacturers. Expanded pharmacist liability, following this line of reasoning, would deter new drug development,[220] while doing little to promote safer drug development.[221] The uncertainty in the common law litigation process, with its flexible standards, has deterred the courts from further expansion of liability rules—out of concern for continuing innovation in the drug industry.[222]

The fear of overdeterrence has constrained drug products law. Even the drafters of the new Restatement have accepted the new conventional wisdom, observing that "there is a widespread sense that the growing product liability burden has discouraged innovation and damaged the competitiveness of American industry."[223] Yet little hard evidence can be mustered to show that the general level of product litigation, or the threat of such litigation, has any negative impact on drug product development.[224] As one study concluded: "[T]he direction of causality from the innovation environment to the costs of liability is theoretically ambiguous. . . . Higher liability costs create incentives for safety that will stimulate efforts to improve product safety, provided the costs are not so great that the products are withdrawn from the market."[225] To the contrary, industry surveys have found that the threat of litigation has induced companies generally to improve their product lines.[226] In the pharmaceutical industry, little evidence exists showing a chilling effect on innovation, and some industry insiders have observed little effect of any kind from the threat of litigation.[227] Potential profitability and the size of the drug market are the real sources of drug development decisions.

Vaccines are a common example used to justify these exceptions. The specter of children made ill as the result of the lack of a vaccine is used to inflate perceptions of a chilling effect of liability law. Vaccines are, however, a poor example of negative effects of product liability law for several reasons. First, the market for vaccines is small and nonrecurring when contrasted with other drugs such as antidepressants, cholesterol reducers, or sedatives.

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220. *See, e.g.*, Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, *in* THE LIABILITY MAZE, *supra* note 40, at 336-47; W. Kip Viscusi, *Toward a Diminished Role for Torts Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety*, 6 YALE J. ON REG. 65, 75 (1989).

221. *See, e.g.*, Judith Swazey, *Prescription Drug Safety and Product Liability*, *in* THE LIABILITY MAZE, *supra* note 40, at 291, 327-28 (stating that liability has "only a marginal effect on the development of safer drugs").

222. *See* Brown v. Superior Court, 751 P.2d 470 (Cal. 1988); Teresa M. Schwartz, *Product Liability Reform by the Judiciary*, 27 GONZ. L. REV. 303, 324-30 (1991).

223. 1 ALI STUDY, *supra* note 148, at 266.

224. *See* Schwartz, *supra* note 222, at 314 ("The central problem with these claims is the lack of reliable data to confirm that such adverse [e]ffects are caused by the product liability system.").

225. *See* W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability and Innovation*, *in* THE LIABILITY MAZE, *supra* note 40, at 107.

226. *See generally* Swazey, *supra* note 221, at 294-98.

227. *Id.*

Second, because profitability is lower, a drug company might well cease research or product development of a vaccine simply because it is not as attractive a product as other drugs that are purchased repeatedly by patients. While expensive to develop, vaccines produce much less income because they do not require refills. As commodities, vaccines do not meet the test of a reusable product.[228] They are also not a useful example because vaccine production is now protected by federal legislation which takes vaccine risks out of the tort system altogether.[229] Because it is a special case, vaccine production and innovation is no longer appropriately part of the argument against expanded drug product liability.

For most products, particularly drug products, under-deterrence rather than over-deterrence is the most likely situation.[230] One author surveyed drug company in-house counsel as to the effects of the threat of tort liability.[231] The lawyers, speaking off-the-record, believed that the threat of litigation is a myth and that the threat of liability did not affect much except labeling in the pharmaceutical industry.[232] Another analyst concluded that the liability "tax"—the costs imposed on manufacturers through increased premiums for liability insurance—is at most two percent.[233] Given the relatively low liability

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228. *See* Gary Stix, *Immuno-Logistics*, 270 SCI. AM. 102, 105 (June 1994).

> Vaccines may never prove as enticing as drugs for pharmaceutical makers. They can be more expensive to develop, and they may produce less income—repeated refills not required. Governments and international aid agencies . . . cannot afford pharmacy prices.
>
> By one estimate, the annual world-wide vaccine market is about $2 billion. At $1.2 billion . . . Prozac . . . might overtake the sale of potions that save the lives of millions of children every year.

Id.

229. The National Childhood Vaccine Injury Act of 1986 covers solely those individuals injured or killed by vaccines. 42 U.S.C. § 300aa-11 (1994). It became effective October 1, 1988. The program requires a petition to the U.S. Claims Court and an adjudication by that court for injuries or deaths allegedly caused by vaccines. *Id.* § 300aa-11(a)(1). The petitioner must elect to accept or reject the judgment of the court. Acceptance bars any tort suit against the manufacturer. *Id.* § 300aa-21(a). The federal government will pay compensation to those who develop specified symptoms or reactions to a vaccine within specified periods of time and suffer a vaccine-related injury that lasts for at least six months. *Id.* § 300aa-14. For an account of the program, and its current operation, by a Special Master who handles petitions filed under the Act, see Denis J. Hauptly & Mary Mason, *The National Childhood Vaccine Injury Act: The Federal No-Fault Compensation Program that Gives a Booster for Tort Reform*, 37 FED. BAR NEWS & J. 452, 453 (1990). *See also* Jenelle C. Prins-Stairs, *The National Childhood Vaccine Injury Act of 1986: Can Congressional Intent Survive Judicial Sympathy for the Injured?*, 10 J. LEGAL MED. 703 (1989); Mary Beth Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149 (1988).

230. Swazey, *supra* note 221, at 295-96.

231. *Id.* at 296-97.

232. *Id.*

233. Robert E. Litan, *The Liability Explosion and American Trade Performance: Myths and Realities*, *in* TORT LAW AND THE PUBLIC INTEREST 127, 149 (Peter H. Schuck ed., 1991).

risks, the current deferential tort rules hardly provide strong incentives for drug manufacturers to increase safety. As one consumer advocate said, "[p]harmaceutical companies are really dumb if they haven't learned some lessons, but you also have to recognize that marketing divisions are the tail that wags the company dog."[234] In other words, marketing pays little attention to the risk of tort judgments, which are currently too low to affect marketing decisionmaking as to highly profitable drug products. More incentives are needed, in order to provide effective market deterrence for drug manufacturers, which supports the argument that courts should expand rather than contract liability.

B. *Justifications for Enterprise Liability*

The justifications for some version of expanded liability for drug products rest on several arguments.[235] First, regulation by the FDA is a necessary but insufficient force for minimizing drug risks. Expanded liability through an enterprise liability theory improves the deterrent effect by creating increased pressure for attention to safety and effectiveness before and after FDA approval—leaving to the FDA the threshold issues of approval. Second, an enterprise liability theory makes more sense as the industry integrates distribution. The market for drugs is changing as new modes of distribution are sought by the drug industry. The relationships of drug manufacturer, prescription benefit firm, managed care organization (MCO), physician, and patient are changing in complex ways. The integration of the drug industry—with increased control over the prescription of drugs—supports focusing liability through enterprise liability. Third, the risks imposed by the use of prescription drugs do not lend themselves to governance by risk contracts, such as those implicitly created by labeling warnings. The free market contract model, in which risk disclosures to consumers and physicians as their agents are sufficient to maximize utility and promote safety, is flawed with drug products for the same reason that malpractice risks are not governed by pure contract theory.

1. *The Limits of Regulation: The Risk Landscape*

The regulation argument for limited drug liability has limits. The FDA regulates, through its pre-approval process, only those risks detected by testing over a relatively short period of time with limited numbers. After the

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234. Swazey, *supra* note 221, at 298.

235. *See generally Rescuing the Revolution*, *supra* note 29; Stephen P. Croley & Jon D. Hanson, *What Liability Crisis? An Alternative Explanation for Recent Events in Products Liability*, 8 YALE J. ON REG. 1 (1991) [hereinafter *What Liability Crisis?*]; Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199 (1992); Neil K. Komisar, *Injuries and Institutions: Tort Reform, Tort Theory, and Beyond*, 65 N.Y.U. L. REV. 23 (1990); Robert A. Prentice & Mark E. Roszkowski, *"Tort Reform" and the Liability "Revolution": Defending Strict Liability in Tort for Defective Products*, 27 GONZ. L. REV. 251 (1991).

drug is marketed, the FDA tracks side effects and can impose requirements of notification or even withdraw a drug from the market. The FDA has also pressured drug companies not to advertise off-label uses of their products. Drug companies can be slow to comply, however, allowing products to circulate in the marketplace longer than the FDA desires. The FDA is also under attack in a political climate increasingly hostile to government regulation, accused of slowing the marketing of innovative products and harassing manufacturers.[236] A new medical innovation project organized by members of the Republican party and funded by drug companies is proposing a replacement for the FDA that would increase the role of the private sector in testing and certification of prescription drugs while shrinking the government's role in the process.[237] While it is unlikely that the FDA will be dismantled, it may face budgetary and other constraints limiting its power as a regulator.[238] Whatever the future shape of the FDA, the threat provided by the possibility of litigation is a vital component of market deterrence.

The world of Prosser and the Restatement of Torts is one in which drug risks represent an irreducible minimum that the manufacturer has achieved through relentless and brilliant research and study. Even with FDA regulation and competitive forces, however, drugs create categories of risks that could be reduced further or managed in order to limit the ultimate harm to users.

2. *Risks at the Time of Sale*

Drugs that copy successful products already on the market may have clear costs compared to existing drugs, offering in some cases a poorer cost-benefit ratio. In such cases, it is possible that patient injury could have been avoided by choosing another product. The language of the Third Restatement is aimed at risks in which an alternative may exist.[239] In making this assessment, the risk calculus must also compare a drug's risks to other therapeutic alternatives, including no treatment at all.

3. *Post-Approval Risks*

The FDA approval process, while strenuous, cannot detect every risk and contraindication of a new drug. Clinical trials, the primary source of information about new drugs, often fail to provide much of the information needed for therapeutic decisions.[240] The FDA requires neither comparisons

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236. For a conservative position on reducing the FDA's power, see James Bovard, *First Step to an FDA Cure: Dump Kessler*, WALL ST. J., Dec. 8, 1994, at A18.

237. *See* Laurie McGinley, *GOP Takes Aim at FDA, Seeking to Ease Way for Approval of New Drugs, Medical Products*, WALL ST. J., Dec. 12, 1994, at A16.

238. *See* Anthony Lewis, *Reform or Wreck?*, N.Y. TIMES, Jan. 27, 1995, at A27, A27 (lamenting "uncommonly brutal" right-wing attacks on the FDA, with the goal of destroying many of its important functions).

239. *See* RESTATEMENT (THIRD) OF TORTS § 8(c) (Tentative Draft No. 2, 1995).

240. *See* Wayne A. Ray et al., *Sounding Board: Evaluating Drugs After Their Approval for Clinical Use*, 329 NEW ENG. J. MED. 2029, 2031 (1993) (proposing a new center for the

of a new drug with alternative treatments before approval, nor controlled studies after approval to track the rates and costs of adverse effects. Relative data on efficacy, toxicity, cost, and the consequences of sub-optimal use is not available for most drugs, neither is a program to collect such data post approval.[241] Many risks materialize only after enough years on the market and use by enough people to show the side effects.[242] In such cases, the defect is not discovered at the time of sale, and under current law the risk is covered by the law of warning defects.[243] A risk, however, may be "undiscovered" yet "discoverable." It is a question of the time and the money spent in researching the side effects of a new drug. This tradeoff in testing—between better knowledge of risks and speed in getting drugs into the marketplace—is a constant struggle with pharmaceutical companies, given public hopes of constantly improving treatments. Neither the FDA nor the drug companies want a process that takes too long. Testing, therefore, continues indirectly with the general public as experimental subjects. The drug is disseminated widely into use by physicians in their treatment of patients, with various options such as notification and wholesale withdrawal of products as new risks emerge in the population exposed to the drug. The questions become: Did the manufacturer properly warn physicians of the newly discovered side effects or interactions? And will such warnings be efficacious?

One court has been troubled by the problem of drug withdrawals from the marketplace, finding a warning to physicians insufficient to immunize a manufacturer from liability. In *Nichols v. McNeilab, Inc.*,[244] the decedent died from a severe anaphylactic reaction to the ingestion of Zomax, a prescription drug manufactured and marketed by McNeilab.[245] The court refused to apply the learned intermediary rule, holding that on the facts of the case a manufacturer's duty to warn as a matter of law was not discharged by reliance upon a warning to a learned intermediary.[246] According to the court, when a consumer uses a drug intermittently, a warning to a physician of a recall or withdrawal of a prescription drug from the market is insufficient to protect a patient.[247] In such cases, a warning to the general public or directly to the consumer, in combination with a warning to physicians, may be

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assessment of pharmaceutical effectiveness).

241. *Id.* at 2030.

242. *See, e.g., Carter-Wallace Sued by Epilepsy Patients Who Used Felbatol*, WALL ST. J., Sept. 30, 1994, at B5 (describing cases of aplastic anemia and liver failure produced by Felbatol, an epilepsy drug). For example, the drug, Felbatol, introduced in August of 1993, has now been subject to an FDA notice urging physicians to stop prescribing the drug, and to keep it in use only for severe epileptics for whom the benefits outweigh the risks. *Id.*

243. *See* Page, *supra* note 13 (arguing that in cases of product risks unknown at the time of sale, strict liability should be imposed as an incentive to manufacturers to improve product safety and as a means of satisfying justifiable consumer expectations).

244. Nichols v. McNeilab, Inc., 850 F. Supp. 562 (E.D. Mich. 1993).

245. *Id.* at 563.

246. *Id.* at 565.

247. *Id.*

necessary.[248] The inadequacy of a warning given only to a physician was apparent in *Nichols*, in which the decedent was prescribed Zomax by an emergency room physician.[249] If the obligation fell only on the physician, it would create a heavy record-keeping burden upon hospitals to inform all patients to whom the drug was previously prescribed.[250] As the court noted, "reliance upon the learned intermediary doctrine would not provide any warning to patients in a situation where a doctor's records have been destroyed by fire or flood, or if the doctor herself has died since prescribing the withdrawn medication."[251] The court stated that "the learned intermediary doctrine does not apply where a manufacturer of a prescription drug that previously has marketed its product for intermittent use withdraws its product from the market wholesale."[252]

4. *Off-Label Uses*

Physicians increasingly prescribe approved drugs for "off-label" uses—those not approved by the FDA—particularly with desperate cancer patients.[253] One survey found that oncologists' prescription patterns were often for off-label uses.[254] Such off-label uses sometimes produce important new uses later approved by the FDA. More often, however, the experimental off-label use fails to justify itself. Questionable off-label uses include silicone injections for breast augmentation and lip enlargement; the use of Retin-A to treat wrinkles, actinic keratosis, and skin lesions; and collagen injections for lip enlargement.[255] Some of these uses are encouraged by the manufacturer as a way of selling more of its product.[256]

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248. In *Nichols*, the court claimed that the manufacturer had a "duty to warn by means that are reasonably calculated to reach all consumers of their defective product." *Id.*

249. *Id.*

250. *Id.*

251. *Id.*

252. *Id.*

253. William L. Christopher, *Off-Label Prescription: Filling the Regulatory Vacuum*, 48 FOOD & DRUG L.J. 247, 247-50 (1993).

254. Thomas Laetz & George Silberman, *Reimbursement Policies Constrain the Practice of Oncology*, 266 JAMA 2996, 2997 (1991).

255. *See* Donald M. Payne, *Consumers at Risk: Off-Label Uses of Medical Drugs and Devices*, 29 TRIAL 26 (1993).

256. Johnson & Johnson touted Retin-A as a wrinkle cream through television appearances and press interviews given by researchers, after a small study suggested that the drug was effective against wrinkles and other skin damage. Such promotional efforts might violate FDA marketing rules regarding cross-over uses. Johnson & Johnson ended up shredding thousands of documents related to a federal investigation of this promotional effort on behalf of Retin-A. *See* Elyse Tanouye, *J&J to Admit to Shredding Retin-A Papers*, WALL ST. J., Jan. 11, 1995, at B1, B6.

C. *Prescribing Practices: The Physician as Drug Spigot*

Physicians can misprescribe drugs. Inappropriate medication use contributes to avoidable mortality in patients, particularly the elderly.[257] Often, physicians prescribe drugs when the drug is not effective, or simply use prescriptions as a way to provide treatment for problems with no medical solution, and avoid pressure from other health care workers and patients. Further, physicians may fail to prescribe valuable drugs because they have not kept up with new pharmacological developments. The risks discussed in this article involve problems associated with overprescription. If physicians are poorly informed about drugs and risks, they can be viewed more as a spigot in the drug distribution stream: opened by patient demand, drug company advertising, and vague familiarity with products. This creates risks without awareness. While the characterization as spigot may overstate the physician role in the doctor-patient relationship, it is too often the case with many drug prescriptions. Physicians often write voluminous prescriptions for drugs such as Prozac without a clear understanding of its comparative efficacy to other drugs.[258] Physicians are aggressively wooed by drug manufacturers using mailings, advertising campaigns, and such devices as "seeding trials"—which involve company sponsored trials of approved drugs with little scientific purpose—aimed at enticing physicians to try a new or competing drug and prescribe it for their patients.[259] Physicians are not always rational cost-benefit decision-makers in their choices of drugs for patients and in their prescription patterns.

1. *Market Power: New Patterns of Drug Distribution*

A powerful justification for imposing strict product liability is the market power of the manufacturer. Possessing inside information on risks, the ability to advertise to increase consumer hazard awareness, and the ability to muster a good defense to any tort suit, the large corporation has power superior to that of any consumer. Is the drug distribution system different? Drug companies spend heavily on promotion in many different ways, backed by their tremendous market power and their assets. But they also have a legal duty to warn physicians about a drug's risks and side effects. Why should that not be enough, leaving the physician in the center as the learned intermediary?

Drug companies can hype, overpersuade, and even bribe physicians to use their products.[260] Marketing departments spend time and talent thinking

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257. Soumerai et al., *supra* note 1, at 270.

258. Lars F. Gram, *Fluoxetine*, 331 NEW ENG. J. MED. 1354, 1359 (1994) (analyzing the clinical effects of fluoxetine (Prozac), concluding that the "published data on the antidepressant effect of fluoxetine does not fully explain its popularity. . . . [and o]ne may speculate that fluoxetine has psychobiologic effects not strictly related to the biology of depression and that it acts primarily as a mood- or affect-modulating agent").

259. *See generally* Kessler et al., *infra* note 277, at 1351.

260. *See* Mary-Margaret Chren & Seth Landefeld, *Physicians' Behavior and Their*

about how to attract both physician and patient. Physicians are often influential agents in their role as purchasers of drugs on behalf of patients. This conflict is explicit in Japan, where doctors get a percent of drug sales for their prescriptions, constituting a large portion of their income. French doctors also prescribe medications at high levels because doctors face no financial constraints on prescribing drugs and because patients want drugs.[261] The selection of drugs for therapeutic use had traditionally been relegated to physician decision-making. The power of comment k and the learned intermediary rule reflects an era when drug firms employ armies trying to convince physicians to use their prescription products over their competitors' products. More prescription drugs are becoming over-the-counter drugs, turning the consumer into the decision-maker; managed care organizations are constraining physician prescription choices; and physicians are continuing to use drugs for off-label purposes.

2. *Managed Care Formularies*

The competitive forces of health care are now driving the growth of MCOs. Such organizations centralize decisions, including drug formularies, in committees and restrict choices of individual physicians.[262] Such MCOs also restrict drug companies' access to physicians.[263] If an MCO limits the choice of prescription drugs it covers for subscribers, the physician's ability to prescribe is also limited. The physician's role as the learned intermediary, at least in selecting from among alternative treatments, is limited although not preempted by the MCO. The choices of available drugs must represent drugs that are generally medically acceptable as standard treatments because the MCO and the physician might both be liable if they refuse to prescribe certain useful drugs to patients.

Drug companies are searching for ways to stay profitable in the changing health care economy. Acquisition of prescription-benefit firms is one strategy; acquisition of stakes in MCOs is another. Such minority ownership interests give drug companies access to MCO formularies, guaranteeing a growing market for their drugs.[264] With such vertical

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Interactions with Drug Companies: A Controlled Study of Physicians Who Requested Additions to a Hospital Drug Formulary, 271 JAMA 684, 684-88 (1994) (finding that requests by physicians that drugs be added to a hospital formulary were strongly and specifically associated with the physicians' interactions with the companies manufacturing the drugs).

261. *See* Jonathan E. Fielding & Pierre-Jean Lancry, *Lessons from France—'Vive la Différence,'* 270 JAMA 748, 755 (1993).

262. Richard M. Cooper, *Some Effects of the Clinton Health Care Reform Proposals on Regulated Aspects of the Pharmaceutical Industry*, 24 SETON HALL L. REV. 1260, 1264 (1993).

263. *See* Michael A. Weber, *Impact on the Pharmaceutical Industry of Changes in the American Health Care System: A Physician's Perspective*, 24 SETON HALL L. REV. 1290, 1294 (1993).

264. *See* Elyse Tanouye & Greg Steinmetz, *Managed-Care Feeding Frenzy Probably Hasn't Ended*, WALL ST. J., July 13, 1994, at B3, B8 (predicting drug companies are likely to seek "tie-ups with HMOs to remain competitive").

integration comes a greater ability of manufacturers to control drug choices and risks associated with drug use.

3. *Patient-Driven Markets: Risks Direct to the Patient*

The rules for drug liability have long recognized two exceptions to the learned intermediary doctrine: mass vaccinations and contraceptives.[265] In both situations, the role of the physician as prescriber and decision-maker is subordinate to the patient. The movement toward patient-driven marketing is apparent in other aspects of drug distribution. Such marketing makes the patient the consumer of the drug and strengthens an argument that drugs, like consumer goods generally, should be subject to strict liability rules. Two examples of increased emphasis on the patient as consumer are direct-to-consumer advertising and over-the-counter drugs.

In the 1980s, direct-to-consumer advertising began as the FDA lifted its moratorium on such advertising. By the 1990s drug companies were pumping millions of dollars into such advertising.[266] Early advertising was educational, informing the public of a health problem and stressing the need to see their doctor. Such advertising was sponsored by companies with products that might serve this health need.[267] The Upjohn Company was the first manufacturer to use product-specific direct-to-consumer advertising in the United States to promote Rogaine, for hair loss treatment.[268] Rogaine was ideally suited for such advertising as a cosmetic product with few risks; the physician only needed to be contacted to discuss the patient's eligibility for the drug and to get a prescription. Several other firms conducted similar campaigns. Campaigns have been conducted for Seldane[269] and Hismanal,[270] two nonsedating antihistamines; for the antismoking patch transdermal nicotine delivery systems; for Mevacor, a cholesterol-lowering drug produced by Merck;[271] and for Premarin, estrogren therapy for menopause side effects

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265. Schwartz, *supra* note 55, at 832-34.

266. Patricia Winters, *Prescription Drug Ads Up*, ADVERTISING AGE, Jan. 18, 1993, at 10, 10.

267. For example, an advertisement by Merck described the prostate, its functions, and the symptoms of prostate enlargement. TIME, Jan. 25, 1993, at 20-21.

268. In 1992, following the introduction of Proscar, a "ground-breaking" new prostate cancer treatment, Merck spent $10 million on a campaign to "promote awareness of prostate disease." Winters, *supra* note 266. These ads are not universally well-received. *See, e.g.*, *Miracle Drugs or Media Drugs?*, CONSUMER REP., Mar. 1992, at 142 ("[P]romoting drugs in the guise of public education allows the promoters to publicize uses for the drug that have not received FDA approval, and to disregard a drug's side effects . . . ."); *see also* Amy Bernstein, *Prescription Drugs: Pitching Directly to the Patient*, U.S. NEWS & WORLD REP., Jan. 15, 1990, at 46 (concluding that some ads appearing prior to the Rogaine campaign were criticized for crossing the line between information and product-specific selling).

269. *See* TIME, Aug. 12, 1991, at 7-8.

270. *See* NEWSWEEK, July 15, 1991, at 10-12.

271. *See* TIME, Jan. 25, 1993, at 41-42; N.Y. TIMES, Sept. 15, 1994, at A24 (showing advertisement for Mevacor); *see also* TIME, Mar. 15, 1993, at 42-43 (displaying an

and osteoporosis.[272] The drug Relafen is advertised by SmithKline Beecham as an alternative to other anti-inflammatory drugs for arthritis.[273] Cognex is advertised for Alzheimer's disease by Parke-Davis, with a suggestion that readers should contact their physicians about the product.[274]

Such direct advertising is motivated by drug company determinations that they can reach potential customers more rapidly than by waiting for physicians to pass the information to consumers.[275] The advertising attempts to induce consumers to become salespeople who will pressure their physicians to prescribe such drugs for their problems. The FDA has had little to say about such advertising.[276] This drug promotion is driven by manufacturers' needs to distinguish their drugs from other similar therapeutic class drugs in a crowded marketplace.[277] The advertising is effective, creating conflicts for managed care physicians at times when the drug is not in an MCO formulary or is more expensive than alternatives. The campaigns can be quite elaborate, using patient videotapes, interactive computer programs, and programs with patient groups.[278]

Some direct information may be intended to inform rather than generate demand. Some drugs, however, have narrow therapeutic uses and are risky if the patient abuses them or has an interaction with another drug. A drug like Coumadin, for example, is both highly effective for preventing strokes in certain classes of patients and also dangerous if it interacts with certain foods or other drugs. Drug companies selling such drugs often prepare copious literature for both physician and patient in order to reduce

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advertisement for Norplant System contraceptive implants); *id.* at 50 (showing an advertisement for Cardizem CD, touted as a cheaper alternative to Cardizem).

272. *See* TIME, Jan. 9, 1995, at 74.

273. Wayne Kuznar, *A Future Epidemic in Need of Better Therapy*, 4 MANAGED HEALTHCARE 534 (1994).

274. N.Y. TIMES, Nov. 27, 1994, § 1, at 59.

275. *See* Tim S. Hall, Note, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL'Y 449, 450 (1993).

276. *See* Elisabeth Rosenthal, *Drug Makers Set Off Bitter Debate with Ads Aimed Directly at Patients*, N.Y. TIMES, Mar. 3, 1991, at I34, I34 (stating that "[a]lthough the law now governs all prescription drug advertising, it was written at a time when doctors were the only audience"). The FDA, however, has moved to control statements made about prescription drugs in educational settings. *See generally* Charles J. Walsh & Alissa Pyrich, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 SETON HALL L. REV. 1325, 1355-68 (1994) (discussing FDA regulation of advertising generally).

277. David A. Kessler et al., *Therapeutic-Class Wars—Drug Promotion in a Competitive Marketplace*, 331 NEW ENG. J. MED. 1350, 1350-51 (1994).

278. Bristol-Myers launched a complex attack on the patient market for Serzone, a competitor for Prozac, by not only sending brochures and samples to doctors, but also targeting videotapes, computer programs, and specialty educational programs at patients. *See* Elyse Tanouye, *Bristol-Myers to Market Antidepressant By Claiming Less Sexual Dysfunction*, WALL ST. J., Jan. 6, 1995, at B2.

the risks of bad outcomes by increasing patient understanding and compliance. The collaborative enterprise created by such information brings the patient into the monitoring and decision-making process, therefore reducing the role of the physician.

Over-the-counter drugs (OTC) are becoming a growing consumer product, as more prescription drugs go off-patent and into the community pharmacy.[279] These "switch-overs" include former prescription products moved to OTC status, as well as low-dose versions of prescription chemicals. Self-medication, or self-care, is a trend in modern medicine. The consumer is more sophisticated and more interested in OTC medicines.[280] Alternative medicines and fitness concerns reflect a desire for self-managed health care. Higher health care costs, due to copayment and deductibles on health insurance, push consumers toward self-treatment. According to the FDA, 500,000 OTC drugs are currently on the market in the United States.[281] The growth of the OTC drug market has been projected to result in "$73 billion in gross savings by the year 2000, with a net benefit to the economy of $34 billion."[282] One example of an OTC switch-over is the drug hydrocortisone, used to treat many dermatologic disorders and now sold over-the-counter in concentrations up to 0.5%.[283]

Every drug has a unique risk-benefit profile. Some OTC products offer substantial benefits with relatively few risks, justifying their direct sale to consumers. Some prescription drugs, on the other hand, have less qualitative or quantitative benefit than their OTC cousins, but may involve significantly greater risks or are indicated for more complex pathologies necessitating medical supervision and thus prescription status. In both cases, the marketing classification distinction does not directly turn on drug benefits. Indeed, even the risk factor is playing a less important role in marketing decisions as demand for over-the-counter medications increases.

The drug industry in the future will respond with greater integration of drug manufacturer and delivery. A pharmaceutical firm is well advised not only to develop drugs and manufacture them, but to provide services with drugs in the new marketplace, as the Merck acquisition of Medco demonstrates. Only in this way can drug manufacturers continue to guarantee their market share. The next step is to become involved in the actual provision of health care by bundling the entire product line. Such bundling allows drug manufacturers to offer preferential treatment to large health plans. A more ambitious form of integration is to form relationships with major health plans by acquiring equity interests to guarantee their products will be used.[284] The final entity might be an integrated health care business,

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279. *See generally* Thomas M. Moore & Scott L. Hengsbach, *Comment k: A Prescription for the Over-the-Counter Drug Industry*, 22 PAC. L.J. 43 (1990).

280. *Id.* at 69-73.

281. *Id.* at 84.

282. *Id.* at 85.

283. *Id.* at 84-85.

284. *See American Drug Firms Kicking the Habit*, THE ECONOMIST, Dec. 25, 1993, at 90.

with a drug firm, HMOs, and insurance combined into one firm.[285] Such integration is not likely to proceed smoothly, but offers advantages to the respective parties in a health care economy of mergers and growing concentration. It also creates a true enterprise in which the decisions as to drug manufacture and purchase are more closely integrated. The more integration, the stronger the case for enterprise liability with only limited tort defenses.

D. *Maximizing Deterrence*

The primary justification for relying on tort law, along with market forces and federal regulation, is that it promotes a greater deterrence of harm. It creates added economic incentives for manufacturers to search for risk reduction, product improvement, and more careful marketing and promotion of risky drugs. Because the tort system is admittedly an inefficient and expensive compensation mechanism, its value lies in the blend of compensation of patient injury and deterrence pressures created by the threat and imposition of judgments.[286] The law and economics literature proposes that an efficient product liability system has two goals: deterrence—impelling parties to prevent all those accidents that can be efficiently prevented; and insurance—efficiently allocating the risks of unprevented accident costs.[287]

Recent analyses have concluded that the doctrinal expansion of product liability law in the 1970s and 1980s produced effective market deterrence. Injured consumers recovered more often from manufacturers, who then increased their investments in safety, driving up their product prices.[288] As economic theory predicted, "[o]nce price increases forced consumers to internalize the full costs of product accidents, consumption patterns changed, and the market for some products disappeared altogether."[289] As Steven P. Croley and Jon D. Hanson argue, "where products liability law has shifted toward enterprise liability, the changes brought about by that shift have been

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285. *See The Birth of Universal Health, Inc*, THE ECONOMIST, Mar. 26, 1994, at 73. An early step in this direction is the acquisition by Zeneca Group PLC of Salick Health Care, Inc. Salick provides cancer treatment and other health care services. Zeneca's purchase bolsters its product line, including Nolvadex, a breast cancer drug, and Zoladex, a prostate cancer drug, by giving it direct access to patients through Salick. *See* Ron Winslow, *Zeneca Sets Purchase of 50% of Salick for $195 Million; Treatment Data Cited*, WALL ST. J., Dec. 23, 1994, at B5.

286. Deterrence and insurance are considered the two primary goals of product liability litigation. *See* Alan Schwartz, *Proposals for Products Liability Reform: A Theoretical Synthesis*, 97 YALE L.J. 353, 368-69 (1988). For a critical review of strict product liability and a proposal for enterprise liability, see *What Liability Crisis?*, *supra* note 235.

287. *See, e.g.*, PATRICIA M. DANZON, MEDICAL MALPRACTICE 3 (1985).

288. Even critics of tort litigation acknowledge the rational market responses to expanded product liability risks. Viscusi observes that "[d]ecisions to discontinue products that are the subject of litigation are rational responses to changing economic circumstances." Viscusi, *supra* note 220, at 82.

289. *What Liability Crisis?*, *supra* note 235, at 9.

efficient."[290] If effective deterrence has been achieved through product redesigns and withdrawals, then the tort system is doing exactly what it should—flushing out risky products and forcing their alteration or elimination. The problem with strict product liability under the current liability system is that it is little more than a modified negligence standard, forcing the trier of fact to balance risks and utilities under a reasonableness standard. What is needed is absolute enterprise liability—simplifying the proof process in litigation, providing greater certainty for all parties by reducing the areas of proof at trial, and tilting the balance back toward the consumer where it belongs in a world of overprescribed, overmarketed, risky drug products.

E. *Forced Insurance*

The contract model, so popular with the current generation of tort reformers, returns risks to the consumer.[291] In this world, risk disclosures through warnings and proper labeling are sufficient to maximize utility and promote safety. Given adequate disclosures to the physician and the consumer, liability is transferred to the consumer. Such a position is inapplicable with drugs, for the same reason that malpractice risks are not left to pure contract law theories. Drug purchases are complicated by the role of the physician as intermediary—until now, the real consumer of prescription drugs was the physician, in the sense that the physician ordered the drug purchase as an agent for the patient.[292] The patient is the consumer-user of drugs and the accompanying risks. Patient-consumers and physician-consumers are dependent on the manufacturer and the FDA for drug information, although in the future access to on-line databases and CD-ROM services may expand access to information for a computer-savvy patient. The physician in many cases may be the best source of information regarding choices and risks, and the pharmacist is an essential partner in follow-up warnings.[293] Is the physician-consumer a perfect consumer? Given physician training and skill, the assumption underpinning comment k and the learned

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290. *Id.* at 11.

291. *See generally* PETER W. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES 224-27 (1989) (advocating the replacement of tort law principles with contract principles).

292. Physicians are also the indirect agent of the drug firm, because their purchase orders through prescriptions generate the revenues for the firms. Firms, therefore, have worked to influence physician purchase decisions, with substantial success. *See* Chren & Landefeld, *supra* note 260, at 684 (finding that requests by physicians that drugs be added to a hospital formulary were strongly and specifically associated with the physicians' interactions with the companies manufacturing the drugs).

293. Margaret Gilhooley argues that risk information should be furnished directly to patients, and written patient labeling furnished when the drug is prescribed is more effective than physician disclosures or other alternatives. *See generally* Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633, 653-68 (1984) [hereinafter *Learned Intermediaries*]; Gilhooley, *supra* note 216, at 1488-98.

intermediary rule is that physician expertise will be used to process risk information on behalf of the patient. But the risk disclosure issue may turn on the manufacturer's disclosures and the adequacy of such disclosures.[294] Because the patient still relies on the physician's expertise in deciding on drug use and dosages, his recommendations will determine the extent to which the patient is aware of or ignores a drug's risks and side effects. Physicians are highly sensitive to marketing claims of effectiveness for drugs. At the same time, examples such as the withdrawal of zomepirac from the market after reported deaths demonstrate that physician prescription practices may be hard to alter even if warning letters are distributed.[295] Consumers treat drugs as saviors, the primary mechanism to achieve symptom relief and cure.[296] Busy physicians, however, may not pay sufficient attention to drug risks and follow-up warnings about newly discovered side effects of approved drugs.

It is unreasonable to shift the risks of drug use to patients: their exposure to drugs is limited to occasional use unless they experience chronic disease; they lack training in assessing drug side effects; and they are anxious to use drugs in search of magic bullets to cure their ailments.[297] Some courts argue that consumers can never be sophisticated enough to process risk information conveyed to them by pharmacists, so it is best to leave such discussion to the physician and patient.[298] Other critics argue that the more information that is available to the patient, the better, regardless of the source.[299] While the FDA and the courts should promote patient decisionmaking and access to information, the profound limitations on the consumer's ability to read, understand, and follow drug warnings should mitigate against the availability of strong defenses for manufacturers.

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294. *See* Merrill, *supra* note 218, at 22-23 (noting that the manufacturers of MER/29 allegedly misled consumers and the FDA about the risks associated with the use of their product).

295. *See* Dennis Ross-Degnan et al., *Examining Product Risk in Context: Market Withdrawal of Zomepirac as a Case Study*, 270 JAMA 1937, 1940 (1993). The authors found that McNeil's advertising campaign was very effective, leading to rapid acceptance and a large market share for Zomax. *Id.* After several users died, McNeil sent out over 200,000 letters to physicians warning them of the side effects. *Id.* at 1937. These mailed warnings had "no detectable effect on zomepirac use." *Id.* at 1940.

296. *See* Page, *supra* note 13, at 853-59. Page argues that in cases of product risks unknown at the time of sale, strict liability should be imposed as an incentive to manufacturers to improve product safety and as a means of satisfying justifiable consumer expectations. *Id.*

297. *See* Howard Latin, *"Good" Warnings, Bad Products, and Cognitive Limitations*, 41 UCLA L. REV. 1193, 1270-72 (1994) (discussing cases involving OTC drugs such as acetaminophen and the risks of kidney damage from sustained use). Latin asks: "Why should the presence of a good warning, no matter how explicit, prevent courts from considering the value of alternative marketing strategies in light of the common tendency of people to overuse over-the-counter drugs that provide relief from chronic ailments?" *Id.* at 1271.

298. *See supra* note 163 and accompanying text.

299. *See Learned Intermediaries*, *supra* note 293.

Expanded liability operates as forced insurance carried by the manufacturer.[300] Critics contend that product producers are poor insurers because they cannot monitor consumer use of their products, cannot discipline consumers to use the product properly, and cannot observe the accident. Tort law is "a poor vehicle for delivering insurance services. There are high administrative costs and long delays in processing claims, and there is a strong likelihood that a victim will receive nothing or be undercompensated."[301] Critics argue that enterprise liability, an absolute version of strict liability, simply raises the price of drugs and deters manufacturer drug development and innovation.[302] The debate in academic circles regarding the role of liability turns on the relative merits of consumer insurance versus manufacturer insurance. George Priest argues that manufacturer-provided insurance is less efficient than first-party consumer insurance because it forces companies to provide consumers with unneeded insurance (since most consumers have their own health and disability insurance to cover injuries); manufacturer-provided insurance also weakens commercial insurance markets.[303] Croley and Hanson argue in response to Priest that expanded product liability has improved the operation of the insurance mechanism and pure enterprise liability will do even better.[304] Croley and Hanson offer a strong prescription for a renewal of enterprise liability: "[C]ourts should move toward enterprise liability, unashamedly. On both deterrence and insurance grounds, enterprise liability appears to be the superior products liability regime."[305]

F. *The Test for Drug Enterprise Liability*

Proposals expanding liability for prescription drug injuries are not new. Richard Merrill argued powerfully over twenty years ago that bad drug outcomes are an inevitable result of the availability of such drugs, and that the tort rules for assigning liability are inefficient.[306] He wrote: "Most reactions are the by-product of what amounts to government approved medical experimentation, conducted ostensibly to advance society's interest in having available a broad range of prescription medications."[307] Drug manufacturers,

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300. The insurance function is one of the two goals of products liability law. *See generally Rescuing the Revolution*, *supra* note 29.

301. 2 ALI STUDY, *supra* note 148, at 50.

302. George Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1553-55 (1987).

303. *Id.* at 1537; *see also* George Priest, *The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law*, 14 J. LEGAL STUD. 461, 520 (1985).

304. *See What Liability Crisis?*, *supra* note 235, at 59-67; *Rescuing the Revolution*, *supra* note 29, at 685; Jon D. Hanson and Kyle D. Logue, *The First-Party Insurance Externality: An Economic Justification for Enterprise Liability*, 76 CORNELL L. REV. 129, 137-59 (1990).

305. *What Liability Crisis?*, *supra* note 235, at 111.

306. Merrill, *supra* note 218.

307. *Id.* at 87-88.

physicians, and the FDA all have greater power than consumers and patients to reduce these drug risks. Consumers are unable to process risk information needed for safe drug use.[308] Even if they could, as Merrill writes, "once having submitted to treatment, the consumer is virtually helpless against most severe or sudden injuries as well as those progressive reactions that he cannot discern until too late."[309]

The economic justifications for imposing enterprise liability on drug manufacturers are based upon the concept of internalization of the costs imposed by drugs. Such costs, absorbed by the manufacturer, can be absorbed through self-insurance or third party insurance and passed on to consumers through higher prices. The most likely outcome, and the strongest argument in favor of enterprise liability, is a mix in which the higher liability costs are split between pass-through costs, absorbed costs, and higher insurance premiums. An accelerated research effort into risk reduction is the probable outcome of such economic incentives, given the generous profit margins that the industry enjoys and the increased scrutiny on cost effectiveness demanded by drug purchasers such as MCOs.

1. *Presuming Liability from Bad Patient Outcomes*

Consumers lack the ability to bargain with the drug industry, pharmacies, or MCOs about drug risks. The transaction costs for such bargaining are too high. In Merrill's words, "[r]epetitive purchases and identifiable reasons for disappointment are more likely to galvanize concern about shoddy quality, rising prices, or product hazards. The risks of prescription drugs, unlike those of many household items, ordinarily are not visible or palpable."[310] Bargaining over price is not possible, given laws allowing pharmacists to substitute generic drugs for brand name drugs. But as to the class of drug prescribed, only physicians have traditionally been able to exercise market choice to affect manufacturer behavior. Although it is now possible to shop for lower priced drugs, there is still little evidence that manufacturers want to compete based on market safety.[311]

Drug liabilities should be assigned to both the manufacturers and also MCOs if physicians prescribing the causal drug operate in such networks. The manufacturer sets the boundaries of risk for drugs, and also the information about that risk, while MCOs increasingly limit physician drug options through their formularies. The relevant variables physicians must

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308. *Id.* at 93.

309. *Id.* at 94.

310. *Id.* at 95.

311. *See id.* at 97. A look at current advertising for prescription drugs reveals little movement toward safety-based marketing over the intervening two decades since the publication of Merrill's article. The drug Coumadin, marketed by Dupont Pharma, may be one example of a narrow therapeutic index drug in which safety-based marketing is occurring. The drug is marketed with a bundle of services and monitoring information that link physician, patient, and manufacturer in tracking use, interactions, and risk. For prescription drugs generally, such bundled marketing has not yet occurred.

take into account in evaluating drug choices are defined by the drug manufacturer and the MCO.

The test should be as follows: the manufacturer of a drug is liable for all drug reactions not the result of physician negligence, pharmacist negligence, or patient carelessness.[312] Manufacturer liability would be presumed for bad patient outcomes unless the outcome was caused by one of the reasons listed above. Allergic reactions would be included within the ambit of the presumption. This test creates absolute strict liability with limited affirmative defenses. It has the advantage of certainty, countering the objections made by critics to the risk-utility balancing tests so common to defective product analysis.[313] A categorical enterprise liability approach, abandoning all multi-factor balancing, will avoid "meaningless semantic disputes" so characteristic of case law in the product liability area.[314]

2. *Excusing Defenses*

a. Patient Comparative Fault. Only patient carelessness in drug use should provide a defense to a bad drug outcome. Neither the environment in which doctors write prescriptions nor the warnings given are sufficient to put consumers on notice of risks in most cases. It is rare that patients will negotiate with their physicians for different drugs or refuse drug treatment at all. Patients do not bargain over drug risks with doctors. A patient-based defense should therefore be limited only to carelessness in compliance with physician instructions as to dosage or other restrictions on use—conduct rising to the level of assumption of the risk.[315]

b. Physician Error. Physician fault should be narrowly construed to include a failure to follow clear warnings and instructions accompanying the product, or readily accessible through the PDR or other standard source. Because physicians do not perform as well as drug prescribers—often overprescribing and often ignoring drug warnings and contraindicated uses—new methods of providing information to physicians may be needed.

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312. *See id.* at 107-08 for Merrill's version of this manufacturer-based strict liability test.

313. *See generally* Viscusi et al., *supra* note 215, at 1461 (noting that current liability rules do not yield predictable results, increasing the cost and complexity of litigation).

314. *See* Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Tort*, 81 YALE L.J. 1055, 1056 (1972) (discussing courts' attempts at limiting strict product liability, the authors note that "the questions posed in strict liability cases seem in many cases to degenerate into . . . meaningless semantic disputes").

315. A finding of contributory negligence was upheld in *Ray v. Wagner* when the physician performed a pap smear on the plaintiff, received a positive test result indicating a problem, and was unable to reach the plaintiff by telephone for five months. Ray v. Wagner, 176 N.W.2d 101, 104 (Minn. 1970). The court noted that the patient had no phone where she lived. *Id. See also* Harlow v. Chin, 545 N.E.2d 602, 608-10 (Mass. 1989) (holding plaintiff who failed to return for further treatment when pain got worse was 13% comparatively negligent).

c. Pharmacist Capacity to Avoid Harm. The pharmacist has a capacity to monitor and detect drug interaction problems or other risks, which will improve further as patient records are integrated on computer databases. As medical record databases develop, a manufacturer can argue that pharmacist failures to detect a problem should provide for shared responsibility, or in rare cases, superseding responsibility. In general, however, the pharmacy should be treated as part of the chain of distribution, allocating the relative share of liability by contract indemnity principles to the greatest extent possible.

d. Managed Care Formularies. The increasing location of the physician within MCOs, using drug formularies that limit prescription choices, allows the MCO to devise new methods for monitoring physician and nurse drug orders to better protect against drug interactions, emerging risks, and other side effects. They are not only part of the distributional chain for drugs, they are key partners and decisionmakers in determining which drugs their physicians will be permitted to prescribe. MCOs are focusing on cost-effectiveness, safety, and the best outcomes among competing drugs. Their incentives to search for the best and safest drugs are enhanced by sweeping them within the reach of enterprise liability. Large MCOs will then negotiate risk-sharing contracts with manufacturers that include risks of bad patient outcomes and resulting liability exposure.[316] MCOs, like hospitals, should be part of the drug enterprise for purposes of both deterrence and insurance, leaving it to the various players to devise their own allocation of risks within the enterprise by means of indemnification.

VI. CONCLUSION

The burgeoning use of outcomes measurement in marketing comparative differences in health plans is likely in the near future.[317] Hospitals and MCOs are beginning to compete not only on price but also on quality. Safety and good drug outcomes are becoming a part of the sales pitch for health care providers. This means that FDA approval by itself will not be sufficient to distinguish among competing therapeutic drug choices. Advantages in safety, effectiveness, and ease of patient compliance may be required before a drug is admitted to the managed care or hospital formulary. The MCO as consumer will promote higher levels of drug effectiveness, marketing quality as well as price to their purchasers. Integration of drug manufacture and delivery to patients is already occurring in the health care industry. This transmutation of the drug enterprise, into an interwoven system sharing financial risks and marketing of effectiveness and price, underscores the value in a move to absolute enterprise liability. The current formulations of strict product liability, with its risk-utility formulas that resemble negligence balancing, impose high litigation and uncertainty costs on all sides. Enterprise liability, by contrast, reduces the costs of litigation and uncertainty to a level that would make even an actuary smile. Predictable

316. *See* Cooper, *supra* note 262, at 1266.

317. *See id.* at 1265-66.

liability for bad patient outcomes generates powerful incentives up and down the drug distribution chain—the manufacturer will consider improvements in research and development and post-marketing monitoring of risks; the pharmacist will be more careful to monitor patient interactions and sensitivities; and the physician will be more attentive to drug uses and contraindications. The blend of deterrence and insurance provided by tort liability will improve the safety of drugs, a goal that all parties in the chain of distribution want.

APPENDIX

Table 1
HOSPITAL LIABILITY MODELS[318]

Approach	Status Quo: Erratic Evolution	Organizational Liability		
		Fault-Based		Cause-Based Accelerated-Compensation Events
		Provider as Big HMO	Neo-no-fault	
Features	Fault-based liability determination; Jury as trier of fact, settlement in shadow of jury; Causal link required to specific physician; Damages include wages, medical expenses, pain and suffering (subject only to state statutory limits, such as caps).	Liability "channeled" to enterprise: hospital, HMO, rather than left on each provider; Can be achieved by legislation or by unilateral action, such as hospital excess coverage policy.	Institutional tender of offer to settle claim for an injury, on fixed schedule, in exchange for patient giving up right to sue.	List of compensable events, avoidable outcome; Patient with such an outcome automatically compensated for certain expenses and losses, and foreclosed from any other recovery for those outcomes; Litigation or arbitration for uncovered outcomes; Prompt payment from insurer for claims on list.
Advantages	Evolutionary response to changes in environment of providers, as evidenced by doctrinal expansions of liability, damages, causal tests; Moral judgment as to individual physician error.	Firm is better choice for managing risk, doing statistical analyses of risks, and providing feedback and incentives for risk reduction; Relieves physicians of defendant status; Lower administrative costs.	Reduces administrative costs by reducing litigation; Compensates more injuries, including small ones; Provides incentives for provider to monitor patient injury, due to direct financial impact.	No fault, rather a list of bad outcomes; Easy determination in many cases; Quick payout, enhancing compensation of smaller claims; Reduced administrative costs.
Drawbacks	Fails to identify and compensate small injuries; Angers and terrifies physicians; Places deterrent focus on wrong pressure point.	Possibility of firm seeking to adversely select against higher risk patients; Firm might overreact, reducing physician autonomy by "over-managing" their care, as HMO physicians sometimes have complained.	Incentive to tender likely to focus on litigious patients with serious injuries; Provider likely to cover up or avoid small claims, for which suits are not now filed, to minimize costs; One-sided, coercive of patients; Quid pro quo suspect, given possibility that injuries will be concealed.	Costs in generating and constantly reforming the lists of compensable events; Disputes in close cases end up in courts or arbitration.
Sources	Fifty state court systems, plus federal system, with overlay of legislative reforms at the margins.	ALI STUDY, *supra* note 148; PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE 122-51 (1993).	H.R. 3084, 99th Cong., 1st Sess. (1985) ("Moore-Gephardt bill"); PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE 151 (1993).	Laurence R. Tancredi & Randall R. Bovbjerg, *Creating Outcomes-Based Systems for Quality and Malpractice Reform: Methodology of Accelerated Compensation Events (ACEs)*, 70 Milbank Q. 183 (1992).

318. This table is borrowed from another article of mine. *See* Barry R. Furrow, *Enterprise Liability and Health Care Reform: Managing Care and Managing Risk*, 39 ST. LOUIS U. L.J. 79, 133 (1994) (alterations made from original). For an extended discussion of enterprise liability in the health care setting, see generally *id.*

Table 2

Pharmacist Role	Compounder Apothecary	Gatekeeper Druggist	Counselor Pharmacist	Team Clinical Pharmacist
Nature of Liability	Liability for misdispensing drug, typically by introducing a foreign substance into prescription.	Liability for failing to check for drug interactions with other drugs, patient allergies; improper labeling. Limited duties to warn of adverse effects. Duty to inquire of physician in unusual cases.	Expanded duties to: 1) maintain patient profile; 2) perform a screen prior to prescribing. Prospective drug utilization review (DUR) requires better access to patient records. Risk management model driven by Medicaid and state rules.	Enhanced role of hospital pharmacist and pharmacist as member of health team. Result of cost pressures, desire to allow pharmacist to prescribe as part of cost containment pressures within systems.
Advantages	Simple test for liability, limited exposure.	Expands liability to match the knowledge and power of modern pharmacy. Based on informational capabilities and improved education.	Expanded liability assumes knowledge superiority of pharmacist as to drug outcome management. Recognizes reality of Medicaid mills and sloppy physician prescription practices.	Promotes coordination of health care delivery, improving quality of care and efficiency. Pharmacist serves as consultant and provider.
Drawbacks	Relegates pharmacist to clerk and an extension of drug manufacturer. Too much deference to physician power.	Fails to protect patient against range of bad outcomes that pharmacist is capable of detecting. Too much deference to physician power.	May conflict with pressures to put out high volumes of prescriptions in drug store chains. Requires good patient records and time to engage in DUR.	Physicians hostile to loss of autonomy to other health professionals. Continued expansion of liability exposure.
Sources	Cody v. Toller Drug Co., 5 N.W.2d 824 (Iowa 1942).	Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990); Ferguson v. Williams, 374 S.E.2d 438 (N.C. Ct. App. 1988); Nevada State Board of Pharmacy v. Garrigus, 496 P.2d 748 (Nev. 1972).	Griffin v. Phar-Mor, Inc., 790 F. Supp. 1115 (S.D. Ala. 1992); OBRA 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388. Forty states have extended counseling to all prescription customers of pharmacies. Kentucky has integrated DUR with therapeutic algorithms in treating diseases as well as prescribing.	Riff v. Morgan Pharmacy, 508 A.2d 1247, 1253 (Pa. Super. 1986) (discussing "the other professionals and support personnel in the health care team"), *appeal denied*, 524 A.2d 494 (Pa. 1987); State regulations, new Medicaid rules.