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A PHARMACIST'S DUTY TO WARN: SOUND ECONOMICS, EFFECTIVE MEDICINE, AND CONSISTENT WITH DRUG REGULATION THEORY

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I. Introduction

Imagine that you are sick. You go to your doctor who prescribes to you the antibiotic Flagyl. On the way home from the doctor's office, you make a stop at the drug store to get the prescription filled. While you wait for the pharmacist to complete his service, you purchase some cough syrup to ease your discomfort. Unfortunately, that evening your illness may turn into a violent episode of nausea and vomiting. It is only later, after hours of sickness, that you recover your senses, read the package insert that came with the cough syrup, and recall the hurried words of your doctor: combining Flagyl with even a minimal amount of alcohol severely poisons your system. Putting two and two together, but much too late, you notice that your cough syrup contains 3.5% alcohol. Would that you knew.

The above scenario is neither difficult to imagine nor uncommon. The FDA estimates that 30 to 55% of American patients fail to comply with their prescription drug instructions.¹ Given that American doctors write over 1.5 billion prescriptions every year,² we should not be surprised by the high number of adverse reactions to prescription drugs.³ Violent nausea and vomiting is only

¹Ken Rankin, *Pharmacists Get Consultation Wake Up Call*, Drug Store News, May 18, 1992 at s17.

²David A. Kessler, *Communicating With Patients About Their Medications*, 325 *New Eng. J. Med.* 1650 (1991)

³Terence C. Green, *Licking, Sticking, Counting, and Pouring—Is That All Pharmacists*

a mild example of the dangers associated with misuse of prescription drugs. One report finds that prescription drug misuse results in approximately 125,000 patient deaths every year.⁴ Though no price can be placed on human life, hard economics often drives the considerations behind drug regulation in America. Accordingly, turning to quantitative terms, studies show that patient misuse of prescription drugs has resulted in over 4.5 billion dollars in extra hospital costs⁵ and countless more billions in lost working hours and other opportunity costs.⁶

These dire ramifications of patient misuse, both human and economic, beg for a more effective mechanism of drug warning. According to David Kessler, Commissioner of the FDA, a primary cause of this patient misuse is the wide communication gap that has long existed between the health care provider and the patient.⁷ Often overlooked in this health care dynamic is the critical role of the pharmacist. Their proximity to actual drug consumption help pharmacists maintain a unique position in the chain of health care provision. This position enables pharmacists to reach out to patients toward safer, more effective prescription drug treatment.

This paper argues in favor of a duty to warn on the part of the pharmacist. In the next section, I begin with a discussion of two common regulatory approaches to warning patients of prescription drug hazards and flesh out their inadequacies. In section three, I will discuss the legal status of

Do?, 24 Creighton L. Rev. 1449 (1991).

⁴David E. Smith & John C. West, *A Prescription For Liability: The Pharmacy Mandate of the Omnibus Budget Reconciliation Act of 1990 and Its Impact Upon Pharmacists' Common Law Duties*, 2 J. Pharmacy & L. 127, 129 (1994).

⁵Green, 24 Creighton L. Rev. at 1449.

⁶Smith & West, 2 J. Pharmacy & L. at 129.

⁷1991: *Retail Pharmacy in Mid Life Crisis*, Drug Store News, April 20, 1992 at 30A.

the pharmacist's duty to warn and the negative reaction to the current trends in that doctrine. Then, in section four, I will go on to propose an alternative model for the duty to warn, explore arguments in support of this model, and finally attempt to reconcile the proposed duty to warn scheme with the primary theoretical underpinnings of drug regulation in the United States.

II. Coon Approaches to Prescription Drug Warning

Leaving aside the role of the pharmacist for the moment, the regulatory scheme for warning patients of prescription drug hazards consists of the learned intermediary doctrine and patient package inserts. It is obvious from the widespread misuse of prescription drugs that this approach fails to sufficiently warn the public of the hazards associated with prescription drugs.

A. The Learned Intermediary Doctrine

Traditionally, the law's attempt to disclose to patients the hazards of prescription drugs has operated through a two-pronged duty. First, the manufacturer has a duty to inform the physician about the uses and hazards of its drug; second, the physician has a duty to relate to each of her patients the dangers of using that prescription drug.⁸ In other words, the physician is the learned intermediary between the drug manufacturer and the patient. Advocates of the learned intermediary doctrine reason that since the physician is closely familiar with the patient's medical history, she is in the best position to discern what risks may affect her patient and to assess the need to inform the patient of those risks.⁹ Because of the unique relationship between doctor and

⁸Green, 24 Creighton L. Rev, at 1459.

⁹Id. at 1459-60.

patient, supporters argue, the legal duty to warn is best placed on the physician, not the pharmacist.

Too many patients suffer from avoidable injury for the learned intermediary doctrine to claim success. In part, the doctrine's malfunction may derive from a misplaced assumption regarding the flow of information in the physician-patient relationship. Another explanation of its failure to adequately protect the public focuses on the fact that 68% of physicians decide against full disclosure of hazards to their patients.¹⁰ Further, the courts and FDA agree, that for certain types of drugs, the learned intermediary doctrine will fail to protect the consumer. In *MacDonald v. Ortho Pharmaceutical Corp.*,¹¹ for example, the court noted that the learned intermediary doctrine does not apply to drugs with particular characteristics – where the role of the prescribing physician is passive, the warnings concerning the drug are complex, or in the presence of a high likelihood of side effects, the learned intermediary doctrine fails. That the doctrine is not effective for all drugs, along with its failure to adequately inform the public of the hazards of prescription drugs points up the inability of the learned intermediary doctrine to serve as the chief implement in the law's attempt to warn patients of prescription drug hazards.

B. Patient Package Inserts

Section 502(f) of the Federal Food, Drug, & Cosmetic Act calls upon the FDA to outlaw any drug unless its labeling bears such adequate warnings against use in those pathological conditions or by children where its use

¹⁰David B. Brushwood, *The Pharmacist's Duty to Warn: Toward a Knowledge-Based Model of Professional Responsibility*, 40 Drake L. Rev. 1, 12 n. 56 (1990-91).

¹¹394 Mass. 131, 475 N.E.2d 65 (1985).

may be dangerous to health, or against unsafe dosage or methods or duration of administration or application as are necessary for the protection of users.¹²

Charged with this responsibility and cognizant of the need to supply the public with adequate warnings regarding their prescription drugs, the FDA in 1979 proposed a scheme of patient package inserts (PPIs).¹³ In addition to supplying information to physicians, the regulation would require that a PPI accompany each prescription drug dispensed to a consumer. Modeled after the physician inserts, these PPIs would include warnings of the common hazards associated with the use of a certain drug. Patient labeling, according to the FDA, would help solve the problem of a public underwarned of drug hazards.

Citing voluntary action on the part of the pharmaceutical industry, the FDA revoked the PPI regulation three years after its conception.¹⁴ Today, the FDA requires PPIs for only a handful of special drugs.¹⁵ Beneath this apparent lack of political viability lie additional shortcomings which render unsatisfactory a PPI scheme of regulation. Under a PPI warning scheme, a patient may treat the insert as medical authority and substitute it for the directions of his health care provider. For example, rather than following his doctor's orders, the patient may discontinue usage of the drug when symptoms disappear but before completing the required sequence.¹⁶ An insert listing hazards associated with the drug may frighten the patient and contribute to unhealthy

¹²21 U.S.C. 352 (1992).

¹³44 Fed. Reg. 40,016 (July 6, 1979).

¹⁴47 Fed. Reg. 7200 (Feb 17, 1982); 47 Fed Reg 39,147 (Sept 7, 1982).

¹⁵21 C.F.R. S310.5016516 (1990).

¹⁶Demnkovich, *FDA in Hot Water Again Over Cost of Proposed Drug Labeling Rule*, National Journal, Sept 22, 1979 at 1568.

self-diagnosis.¹⁷ Finally, PPIs may serve only to inundate the patient with written warnings. Lengthy warnings (in small print) will go unread by the patient, further inhibiting the effectiveness of PPIs. In terms of a better informed public, the costs of a PPI regulatory scheme may well outweigh any benefits¹⁸.

Before 1993, this was the legal regime in place to protect and inform the public against the hazards of prescription drugs. Persistent drug misuse and avoidable injury, however, continue to obviate the regime's insufficiency. The public needs more than the learned intermediary doctrine or PPIs. An enhanced role for the pharmacist as a member of the health care team may provide the additional security. Significantly, pharmacists themselves want to play a more active role.¹⁹ One viable method of improving patient awareness to the potential hazards of prescription drugs is a regulatory scheme which includes a duty to warn on the part of the pharmacist.

III. The Duty to Warn On The Part Of Pharmacists

A. Common Law Tradition

A court will almost always hold liable a pharmacist who makes an error in dispensing the prescription drug. Considered a mechanistic task, filling a prescription is given no latitude for error.²⁰ Slightly more restless is the doctrine governing the plight of a pharmacist who correctly fills a prescription, but does not warn the patient of potential side effects of the drug.

The general thrust of the case law finds a pharmacist without a

¹⁷Id.

¹⁸Id.

¹⁹Id at 1569; Rankin, Drug Store News, May 18, 1992 at s17.

²⁰Brushwood 40 Drake L. Rev, at 18-19.

substantial duty to warn the patient of drug side effects. Some courts, however, have held pharmacist to a higher standard. For example, the court in *Hand v. Krakowski*²¹ found negligent a pharmacist who correctly filled a prescription for a psychotropic drug, but dispensed it to an alcoholic patient. The court held that the pharmacist had actual knowledge of the customer's alcoholism and knew or should have known that the prescribed drug and alcohol are contraindicated.²² Since he nevertheless continued to refill the prescription for six years, the court held the pharmacist liable for his actions. Though this case seems to suggest a duty to warn principle on the part of pharmacists, its relatively narrow factual scenario precludes any significant precedential effect. It is rare for a pharmacist to have such clear and personal knowledge concerning a customer. Moreover, in such situations, where there is virtually no added cost of acquiring information of a potential hazard, a duty to warn the patients seems to be a well-founded moral obligation; no legal prod is necessary.

In *Rift v. Morgan Pharmacy*, the pharmacist also filled the prescription as written by the physician but this time failed to inform the customer or the physician of an obvious error in the prescription itself.²³ While the physician's order instructed the patient to administer one suppository every four hours to ease a headache, the patient went unwarned that no more than two suppositories should be used per headache and no more than five used in a single week. Ignorant of these hazards, the patient misused the drug and sustained

²¹453 N.Y.5.2d 121 (1982).

²²The pharmacist had previously made a note of the patient's alcoholism in his personal records. *Hand*, 453 N.Y.5.2d at 123.

²³30 A.2d 1247 (pa. 1986).

permanent nerve damage. In support of a safety net of overlapping responsibilities where each member of the health care team is, in part, his brother's keeper,²⁴ the court held the pharmacist liable for his failure to correct the obvious error in the prescription. Here again, however, the pharmacist's duty to warn rests on a narrow factual scenario in which the physician's prescription was clearly erroneous in light of a toxicity well known among pharmacists.

At most, *Hand* and *Rift* establish an extremely limited duty to warn for pharmacists. Far more representative of the courts' position is the recent Washington State Supreme Court ruling in *McKee v. American Home Products Corp.*²⁵ There the court refused to attach liability to a pharmacist who had accurately filled a prescription but had not warned the patient of the potential side effects associated with extended use of the prescription drug. In a lengthy discussion of the issue, the court confirmed that under the learned intermediary doctrine the duty to warn falls only on the shoulders of the physician; the pharmacist bears no responsibility to convey to the patient nonjudgmental information regarding potential hazards of drug use. Consistent with *Hand* and *Rift*, the court held that the pharmacist still has a duty to accurately fill a prescription...and to be alert for clear errors or mistakes in the prescription. A pharmacist, however, does not...have a duty to...warn customers of the hazardous side effects associated with a drug.²⁶ The *McKee* court crystallized the position of many other state courts and reaffirmed the general common law principle – pharmacists do not have a broad duty to warn their customers of

²⁴Id. at 1253654.

²⁵113 Wash.2d 701, 782 F.2d 1045 (1989).

²⁶Id at 1055656.

the potential dangers of prescription drug use.²⁷

B. Statutory Regulation

In a significant departure from the established case law, Congress created a positive duty to warn for pharmacists in the Omnibus Budget Reconciliation Act of 1990. As an amendment to the Social Security Act, OBRA ordered states to implement regulatory programs consistent with its pharmacy mandate that:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter...matters which...the pharmacist deems significant including the following:

... (dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered

A more controversial provision follows:

...(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

...(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.²⁸

Some commentators have argued that OBRA's pharmacy mandate merely codifies existing common law principles.²⁹ The more prevalent interpre-

²⁷Id at 1049652.

²⁸42 U.S.C. S1396r08(g)(2)(A)(ii).

²⁹2 J. Pharmacy & L. 127 at 138.

tation, and the one supported by the Act's legislative history,³⁰ reads OBRA as creating a duty to warn on the part of pharmacists beyond any standard established by state courts. Though OBRA did not become effective until January 1, 1993, many states adopted the pharmacy mandate almost immediately.³¹

C. Negative Reaction Against The Duty To Warn

Given OBRA's unsettling effect upon the duty to warn doctrine for prescription drugs, it is not surprising that many commentators view this change as an unsound shift in the law. Much of the criticism of the pharmacy mandate stems from one of two arguments. First, some claim that the high costs of implementing a duty to warn does not justify a change in the legal scheme. A second group fears that a duty to warn on the part of pharmacists will interfere with and reduce the effectiveness of the physician-patient relationship.

Members of the first school of critics call attention to the costly nature of a changed doctrine. One study approximates the costs of a duty to warn regime to be between \$70 and \$140 million per year.³² Such considerable cost derives from two sources. At the most basic level, OBRA will demand more work-hours from pharmacists. In order to comply with the Act, pharmacists must take the extra time to investigate prescription drug hazards, counsel patients about potential side effects, and create and update patient medical history.³³ Pharmacies will have to hire more professionals and employ larger

³⁰In the Senate debate over the Act, Senator Pryor expressed his view that the purpose of the act was to enhance the role of pharmacists in providing quality medical care 136 Cong. Rec. S5982-04 (daily ed. May 10, 1990).

³¹Kessler, 325 New. Eng. J. Med. at 1650. As an amendment to the Social Security Act, OBRA only applies to Medicaid patients. Probably in a move to ensure equal protection, states have ordered that pharmacists counsel all patients, not just those on Medicaid. Id.

³²5th & West, 2 J. Pharmacy & L. at 141.

³³Michael J. Holleran, *The Pharmaceutical Access and Prudent Purchasing Act of 1990*:

technical support teams. Some commentators note that the mandate requires pharmacies to install new computer hardware and software, and furnish clinics with designated counseling areas to provide the type of counseling OBRA requires.³⁴ These increased operational costs, of course, mean higher prices for prescription drugs and pharmaceutical services.

Along with higher operational costs, liability costs, including litigation costs and insurance costs, will force pharmacies to further raise the price of their prescription drug products. Small pharmacies in competition with diversified megadrug stores, unable to absorb the barrage of cost increases, may be driven out of business.³⁵ Such a reduction in competition will only exacerbate price inflation, pricing out less affluent, and maybe more needy, prescription drug consumers. Thus, this cost-conscious school argues that the increase in prices resulting from implementation of a duty to warn will hurt consumers.

Those worried about the affect on the physician-patient relationship comprise the second group of OBRA critics. Not surprisingly, the leader of this charge is the American Medical Association.³⁶ Reflective of the rationale behind the learned intermediary doctrine, the AMA fears that mandatory pharmacist counseling will adversely interfere with the traditional tie between physician and patient.³⁷ Doctors argue that intrusion by pharmacists into the health care dynamic attenuates the control physicians have over their patients'

Federal Law Shifts the Duty to Warn From the Physician to the Pharmacist, 26 Akron L. Rev. 77, 97 (1992).

³⁴Angelo J. Patane, *OBRA '90 and Developing Case Law: Will the New Revolution Live Up To Its Underlying Goals?*, 1 J. Pharmacy & L. 177, 185 (1992-93).

³⁵Id. at 186.

³⁶Smith & West, 2 J. Pharmacy & L. at 140.

³⁷Id.

drug therapy, reducing the effectiveness of treatment. Though highly competent professionals, pharmacists should not engage in physician-like duties,³⁸ and the legal regime should not foster an environment of second-guessing.³⁹ Moreover, proper treatment requires a relationship of trust between patient and health care provider. The physician-patient, not the pharmacist-patient, relationship most closely reaches this ideal. Indeed, many individuals are uncomfortable with inquiries into medical history made by pharmacists.⁴⁰ In order to insure the most effective treatment of patients, this school concludes, the legal rules must preserve the sanctity of the physician-patient relationship.

IV. The Case For A Duty To Warn

A. An Alternative Proposal

In its current form, the duty to warn may well merit the negative reaction which has followed OBRA. For the sake of public safety, however, the duty to warn deserves implementation. A careful reworking of the duty to warn doctrine, including a reform of OBRA'S pharmacy mandate, will return benefits to society in terms of saved costs and effective treatment.

What is problematic in OBRA's pharmacy mandate is its flirtation with holding pharmacists liable qua physicians. A more effective approach would capitalize on separate areas of expertise of physicians and pharmacists. Specifically, the law must tap pharmacists' knowledge of drug characteristics without intruding into the physician-patient relationship. To this end, lawmakers must repeal or severely limit that part of OBRA's pharmacy mandate which requires

³⁸Patane, 1 J. Pharmacy & L. at 188.

³⁹Smith & West, 2 J. Pharmacy & L. at 139.

⁴⁰Id at 142.

pharmacists to maintain individual patient histories for the purposes of drug counseling.⁴¹ The reasoning behind both the learned intermediary doctrine and the AMA argument against OBRA finds its basis on a sound principle – personal physicians are in the best position to maintain detailed information regarding the patient’s medical history. It should remain the physician’s responsibility to warn patients about adverse drug reactions related to a particular medical condition. Beyond a quick inquiry into major allergies and reactions, pharmacists should not delve into a patient’s individual medical history. Such counseling should remain outside the province of a pharmacist’s responsibilities and should not be an element of his duty to warn.

Instead, the duty to warn for pharmacists should focus on their ability to provide customers full information regarding the characteristics of prescription drugs. Based on the manufacturers’ drug insert, this warning should revolve around nonjudgmental information. That is, the law should require pharmacists to warn customers of the hazards commonly related to the drug, but should not expect the pharmacist to alert patients to side effects linked to the customer’s personal medical history. That obligation to provide patient-specific warnings rests with the physician. However, where a pharmacist has actual knowledge of a contraindicatory condition on the part of the customer, or of an obvious error in the physician’s instructions, the law should require action. The rulings in *Hand* and *Rift*, therefore, deserve crystallization at the federal level. Such a system of risk management,⁴² would enable pharmacists

⁴¹Id.

⁴²Greeri, 24 Creighton L. Rev, at 1476.

to exercise their considerable knowledge and expertise as professionals without intruding into or detracting from the role and effectiveness of the physician.

B. Responding To The Critics

Opponents of OBRA are right to look to the costs of the program in assessing its merit. A similar analysis of the alternative model outlined above indicates that the economic benefits outweigh its costs. Safer drug use represents an obvious and direct effect of implementing an enhanced role for pharmacists in the health care systems' warning mechanism. A duty to warn will strengthen the pharmacists' link in the communication chain leading to the patient. The logic is straightforward: safer use of prescription drugs results in fewer injuries from misuse, leading to reduced hospital costs, and ultimately returning savings to society. Put simply, when patients are more informed of the potential hazards of prescription drug use, they are able to avoid injury and minimize medical costs for society.

Critics of OBRA ascribe much of the program's cost increases to that portion of the pharmacy mandate that requires pharmacists to maintain individual patient medical histories. The proposed model of the duty to warn removes this obligation from pharmacists. Instead, pharmacists must only warn customers of drug-specific hazards. Pharmacists will be held responsible for patient-specific hazards only where the cost of acquiring that actual knowledge of the patient's condition is minimal.⁴³ To fulfill their obligation, pharmacists must only maintain and convey nonjudgmental information regarding hazards

⁴³ *eq. Hand*, 453 N.Y.S.2d 121 (1982).

associated with prescription drugs (knowledge readily obtainable through information provided to pharmacists by manufacturers). Indeed, given that pharmacists receive extensive education in counseling patients,⁴⁴ any rule that does not include such drug counseling among the pharmacists' responsibilities aggravates the underutilization of that professional's training. The benefits in terms of saved lives and medical costs far outweigh any added costs of conveying this information to customers.

To further curtail costs, the alternative regime should incorporate elements limiting pharmacists' liability. To keep liability costs down, the doctrine could include a cap on recovery or a short statute of limitations. Since the alternative scheme aims to keep both operational and liability costs to a minimum, returns to society in economic terms alone should far outweigh any added costs.

The alternative duty to warn scheme will also avoid interjecting the pharmacist into the physician-patient relationship. Instead of forcing pharmacists to usurp the physicians traditional role, the proposed regime builds toward a cooperative model of health care.⁴⁵ While physicians will prescribe drugs in light of the individual medical condition of their patient, pharmacists will dispense drugs to their customers along with information regarding the potential hazards particular to that drug. Thus, without unwanted interference, both the physician can utilize her patient-specific knowledge and the pharmacist can employ his drug-specific expertise. Further, when operating efficiently,

⁴⁴Green 24 Creighton L. Rev, at 1468, 1475; Brushwood, 40 Drake L. Rev, at 6-7 n. 22, 23; Victor Fuchs, *Who Shall Live?* (1975).

⁴⁵Smith & West, 2 J. Pharmacy & L. at 1416142.

this alternative liability scheme will relieve physicians of the obligation to inform patients of drug hazards that pharmacist may be better suited to convey.⁴⁶ With some of their responsibility shifted to lower cost professionals (i.e. pharmacists), doctors can make more efficient use of their time and training. A health care system in which physicians and pharmacists efficiently employ their expertise, unplagued by charges of professional interference, promises patients more effective drug treatment.

C.The Duty to Warn and Drug Regulation Theory

In addition to its cost-effectiveness and efficient utilization of medical professional expertise, the proposed duty to warn regime also fits squarely with the theoretical objectives of drug regulation in America. The government aims its regulation of drug products in this country toward five ends: full information, safety, effectiveness, minimal administrative costs, and the preservation of market incentives. To justify implementation, the alternative model for the pharmacist's duty to warn outlined above, must pass muster when measured against these objectives.

First, placing a duty to warn on pharmacists will provide more complete information to the public regarding their prescription drugs. Drawing from free market theory, full or perfect information stands as a prerequisite to maximized consumer choice. An informed choice is only possible when the consumer is aware of the characteristics of a product, including its potential hazards as well as its benefits. Because of the enhanced role of the pharma-

⁴⁶Pharmacists' expertise of drug characteristics and the close proximity to drug consumption of their position along the communications timeline may render them better suited to warn patients of prescription drug hazards than physicians.

cist, the proposed model affords consumers a more thorough assessment of a drug's characteristics. By exalting complete understanding of the consumption product, the scheme facilitates the exercise of consumer choice, a large step toward maximizing consumer welfare.

Second, as discussed above, the proposed duty to warn regime creates an environment of heightened safety. In the example at the start of this paper, the sufficiently forewarned patient will know better than to take cough syrup while undergoing treatment with Flagyl. For that hypothetical patient, like millions of real patients, the additional warning means protection from injury.

Third, a duty to warn enables consumers to maximize the effectiveness of their prescription drug treatment. A public that is more fully informed of prescription drug hazards will be better equipped to manage their treatment. Not only will patients know what toxic combinations to avoid, they will be cognizant of the most effective means to administer the drug (time of day, before or after meal, etc.). Through this mechanism, the duty to warn will promote the most effective treatment possible.

Fourth, a duty to warn on the part of pharmacists will not burden the FDA or other government agencies with any additional administrative costs. Enforcement of the duty falls on the shoulders of the liability system, not the government. As discussed above, liability and operational costs are inevitable, yet they are minimal in comparison to the economic promises of this legal rule. Unlike labeling, good manufacturing practices, and other regulatory require-

ments of prescription drugs, a duty to warn will not deplete FDA resources.

Fifth, market incentives to invent and manufacture prescription drugs remain intact under the proposed duty to warn regime. By providing an additional source of warning to the consumer, the proposed legal regime will result in fewer injuries from prescription drugs. Fewer injuries not only translate into less liability for drug manufacturers, but also build public trust in the products of these companies. Both of these factors will bolster the economic strength of drug producers. Rather than deter manufacturers, this will encourage drug innovation and production. Moreover, to the benefit of drug companies and consumers, the strengthened warning system may accelerate the marketing of some dangerous yet potentially life-saving drugs. Total risk of a prescription drug is comprised of its intrinsic risk and that risk associated with underwarning. By reducing the later component, a duty to warn will lower total risk. Drugs previously too dangerous to market, may then fall below the market-safe threshold. This will help needy patients and at the same time enhance the profit opportunities of drug companies. Beyond the mere preservation of efficient incentives for drug manufacturers, the proposed duty to warn model may well serve as a boon to many needy patients.

V. CONCLUSION

The hypothetical that began this paper is a far too common reality in America today. Such potential for injury demands action. In the search for a system which will sufficiently warn the public of prescription drug hazards, we must keep in mind the many concerns that are fundamental to a successful

legal regime. Moreover, it is essential that the final set of legal rules comprise a holistically coherent model. The regime proposed in this paper aspires to this end. It promotes sound economics and effective medicine, but most importantly, the proposed model presents a system that is consistent with modern drug regulation theory.