Pharmaceutical Overpromotion Liability: The Legal Battle Over Rural Prescription Drug Abuse

Phillip J. Wininger
University of Kentucky

Follow this and additional works at: https://uknowledge.uky.edu/klj
Part of the Food and Drug Law Commons
Click here to let us know how access to this document benefits you.

Recommended Citation
Kentucky Law Journal: Vol. 93 : Iss. 1 , Article 7.
Available at: https://uknowledge.uky.edu/klj/vol93/iss1/7

This Note is brought to you for free and open access by the Law Journals at UKnowledge. It has been accepted for inclusion in Kentucky Law Journal by an authorized editor of UKnowledge. For more information, please contact UKnowledges@lsv.uky.edu.
Pharmaceutical Overpromotion Liability: The Legal Battle Over Rural Prescription Drug Abuse

BY PHILLIP J. WININGER*

INTRODUCTION

Providing hope to thousands of pain sufferers, Purdue Pharma introduced OxyContin in 1996, heralding the new drug as a great advancement in the science of pain medication. However, in the years since, the story did not unfold as planned. Instead of achieving wonder-drug status, OxyContin became tainted by illegal abuse and widespread addiction. Today, antagonism overshadows fanfare for the drug as its opponents wage an intense legal battle against the manufacturer. Purdue Pharma currently faces over 290 lawsuits, including seven Kentucky suits. One of the most noteworthy of these cases was filed in Ohio, where a court recently certified a class action that may spell trouble for the company.

Citing the $500 million that Purdue Pharma spent to promote OxyContin, plaintiffs claim that the company's marketing efforts...
constitute overpromotion. They consider the company’s promotional campaign a cause of the widespread addiction in eastern Kentucky and other rural areas. Purdue Pharma, however, steadfastly denies all charges of wrongdoing. As a result of what commentators call Purdue Pharma’s “no-compromise stance,” courts in various jurisdictions have dismissed more than thirty-six suits. In fact, Purdue Pharma has been so successful to date that the company boasts it has never lost or even settled a case.

The OxyContin controversy presents unique questions regarding overpromotion liability as applied to rural prescription drug abuse, and particularly highlights the impact of intentional or illegal drug abuse. Consequently, this note outlines and examines theories of overpromotion liability, specifically applying these theories to rural prescription drug abuse. Part I provides a general overview of the OxyContin controversy and highlights the allegations of overpromotion asserted against Purdue Pharma. Part II examines the relationship between the theories of negligent failure to warn and overpromotion liability. It then applies these traditional concepts to Purdue Pharma’s sales campaign and the OxyContin debate. Part III analyzes how traditional overpromotion theory is inapplicable in the context of illegal drug diversion and argues that this form of liability must be altered to fit criminal misuse by utilizing the much broader negligent marketing standard. It then details the main arguments surrounding negligent marketing jurisprudence and analyzes these arguments in the context of rural prescription drug abuse.

---

5 See Camp, supra note 1.
7 See Camp, supra note 1. According to Robin Hogen, Purdue’s vice president for public affairs, the “claims of overly aggressive selling are groundless.” He claims that “no one has ever accused the company of criminal activity or collected a dime by suing.” Id.
8 Camp, supra note 3.
10 Camp, supra note 3.
11 See infra notes 14–30 and accompanying text.
12 See infra notes 31–82 and accompanying text.
13 See infra notes 83–170 and accompanying text.
I. THE OXYCONTIN DEBATE

The correlation between Purdue Pharma’s aggressive sales campaign and the rise of OxyContin addiction has generated allegations that the company overpromoted its product. The Food and Drug Administration (FDA) has designated OxyContin as a Schedule II narcotic, due to the drug’s highly addictive nature and the likelihood of abuse. As a result, the FDA regulations forbid its direct marketing to the general public, and the product’s warning indicates that doctors should only prescribe the drug for “moderate to severe pain.”

In 2002, the Drug Enforcement Agency (DEA) publicized that OxyContin use may have contributed to as many as 464 fatal overdoses in the prior two years. Additionally, news sources called it the “drug of choice” for addicts across the rural South and Midwest, where the medication fuels regional patterns of illegal drug diversion. In February 2001, for example, Kentucky law enforcement officers arrested 207 OxyContin dealers and users in “Operation OxyFest,” the largest drug sweep in the state’s history.

Despite bad press and the dangers of addiction and illegal diversion, Purdue Pharma runs an energetic marketing campaign. The company’s primary strategy involves a delegation of sales representatives, called “detail reps,” who market OxyContin to doctors in various localities. Because of its established history of painkiller use, the Appalachian region has been particularly receptive to OxyContin sales representatives. Federal data confirms that the region currently receives the greatest per capita share of the drug in the nation. In 2000, for example, over 9.7 million pills were sold in Kentucky alone.

---

14 See Camp, supra note 3.
17 Id. at 499–500. (“[T]he DEA . . . verified OxyContin as having directly caused or played a role in as many as 146 death reports,” and it suspects that the drug played a role in up to 464 fatal overdoses.).
18 Id. at 499.
19 Id.
20 Camp, supra note 3.
21 Id. The Appalachian region includes parts of southwestern Virginia, eastern Kentucky, and West Virginia.
22 Id.
23 Id.
Purdue Pharma argues that the allegations of overpromotion are groundless, claiming that the company markets OxyContin like any other drug. However, the sales strategy employed by the company is traditionally associated with less regulated drugs, not Schedule II narcotics. The FDA warned Purdue Pharma twice that it considered OxyContin ads downplaying the drug's risks "egregious and alarming." Additionally, the DEA stated that widespread misuse may have resulted, at least partly, from the company's promotion and distribution methods.

Government reprimands coincide with stories of sales representatives allegedly downplaying the risks of OxyContin. News reports, for example, have focused on the habits of one OxyContin sales representative, who pushed doctors to more readily prescribe the drug, despite the doctors' and pharmacists' concerns about addiction. Reports also reveal that sales representatives disproportionately promoted the drug to small-scale family practitioners who have less expertise with pain medication than more specialized pain management doctors. Plaintiffs assert such reports as evidence that Purdue Pharma engaged in a scheme designed to overpromote the drug, increase sales, and, as a result, create higher levels of dependency due to overprescription.

II. NEGLIGENT FAILURE TO WARN AND OVERPROMOTION LIABILITY

Overpromotion liability arises when a court finds that a manufacturer has negligently failed in its duty to warn users of a product's hazards. Many courts apply a strict liability standard to inadequate warning cases. However, some argue that a negligence standard best applies to overpromotion claims because such cases concern a supplier's conduct rather than the defects of the product itself. This section provides a

---

25 *Id.* See also *Camp*, supra note 1.
29 *Camp, supra* note 1.
30 *Id.*
33 See SPEISER ET AL., 5 THE AMERICAN LAW OF TORTS § 18:105, at 1033–36 (1988). The commentary suggests there is little practical difference between negligence and strict
description of negligent-failure-to-warn theory and presents cases that illustrate this legal standard. The theory is then used to address manufacturer liability for rural prescription drug abuse.

A. Tenets of Negligent Failure to Warn

Like all negligence actions, failure-to-warn cases include the standard elements of duty, breach of duty, cause-in-fact, proximate cause, and damages. The Restatement (Second) of Torts establishes a supplier's duty to warn when the use of a product entails risks a user may not recognize. Most of the analysis, however, concerns whether the supplier breached its duty by "failing to exercise reasonable care" in warning of a product's foreseeable dangers. The product does not have to be defectively designed or manufactured. In fact, even if a product is reasonably produced, a supplier may fail the objective reasonable person standard if it does not adequately warn of foreseeable harms.

With regard to prescription drugs such as OxyContin, most courts apply the learned intermediary rule. Under this doctrine, a doctor

liability causes of action in the context of failure-to-warn claims. Thus, strict liability analysis seemingly entails a similar standard in such cases. See id.

34 See id.

35 See RESTATEMENT (SECOND) OF TORTS § 388 (1965). The section provides the following test for establishing negligent failure to warn:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Id.

36 Id. The comments to § 388 report that the persons to whom a product supplier shall be liable for failure to give a reasonable warning include not only the direct recipients of the product, "but also all those who are members of a class whom the supplier should expect to use it or occupy it or share in its use with the consent of such person, irrespective of whether the supplier has any particular person in mind." Id. cmt. a (emphasis added). This statement suggests that prescription drug suppliers will be liable to patients for failure to warn, even though they do not purchase drugs directly from the manufacturer and may not receive the manufacturer's direct warning.

37 Id; see also Incollingo v. Ewing, 282 A.2d 206, 219–20 (Pa. 1971) (determining that negligent failure to warn and overpromotion apply in cases where a product is not unreasonably designed or manufactured).

38 SPEISER ET AL., supra note 33, § 18:100, at 997–99.
presumably acts as a “learned intermediary” between the manufacturer and the patient, passing along the manufacturer’s warnings when prescribing the drugs. Thus, a pharmaceutical manufacturer fulfills its duty of reasonable care by adequately warning the doctor of a drug’s dangers and, in turn, expecting the doctor to correctly prescribe the drug to patients. However, if the manufacturer fails to properly warn the doctor, the manufacturer will be directly liable to the patient for any resulting injuries. Despite criticism of the learned intermediary doctrine by legal academics, courts generally have followed it.

Determining the reasonableness of a manufacturer’s warning to physicians is a fact-specific inquiry that creates diverse results. The Restatement (Second) of Torts outlines the following general standard for judging reasonable care: “the act is negligent if the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.” This means that the fact-finder must assess the magnitude and likelihood of a drug’s harm as compared to the burden of providing the warning. As the magnitude and possibility of harm increases, the likelihood that one will be deemed negligent for failure to warn also increases.

B. Overpromotion Liability

Overpromotion liability is derived from negligent-failure-to-warn theory because a company’s aggressive or misleading promotional

---

39 Id. When properly informed, the doctor is assumed to be a learned intermediary by “evaluating the patient’s needs, assessing the risk and benefits of available drugs, prescribing one, and supervising its use” in a manner that avoids injury to the patient. Id.

40 Id.

41 Richard C. Ausness, Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers? 37 WAKE FOREST L. REV. 97, 113–14 (2002). The author notes the following public policy arguments supporting rejection of the learned intermediary rule: (1) erosion of the physician patient relationship through the introduction of internet drug sales and the interference of managed care companies in the prescribing process and (2) direct advertising of prescription drugs to the public, which should force pharmaceutical manufacturers to incur the same duties as other sellers. Professor Ausness also notes the argument that drug companies’ aggressive promotion practices justify abolition of the learned intermediary rule as well as the imposition of greater overpromotion liability. The policy underlying both legal movements concerns the desire to force drug manufacturers to more carefully regulate warnings and promotions. Id. at 136–37.

42 RESTATEMENT (SECOND) OF TORTS § 291 (1965).

43 Id.
activities "erode the effectiveness of otherwise adequate warnings."\textsuperscript{44} An ordinarily adequate and reasonable warning to doctors becomes inadequate and unreasonable when a company's promotion of a drug overshadows the initial warning.\textsuperscript{45} Consequently, overpromotion makes the warning unreasonable in light of all communication. Literature that explains overpromotion liability cites two landmark cases as illustrations:\textsuperscript{46} \textit{Love v. Wolf}\textsuperscript{47} and \textit{Salmon v. Parke, Davis & Co.}\textsuperscript{48}

\textbf{1. Love v. Wolf}

\textit{Love}, the first case to uphold overpromotion liability in the pharmaceutical context, involved prescriptions of the antibiotic Chloromycetin.\textsuperscript{49} Following administration of the drug by a doctor, the plaintiff became severely anemic.\textsuperscript{50} This event coincided with research indicating that anemia was one of the harmful side effects of the drug.\textsuperscript{51} The drug manufacturer had already complied with an FDA directive by distributing nearly 200,000 letters to physicians, warning of the potentially fatal side effect.\textsuperscript{52} Other announcements to the medical community, such as drug package inserts and advertisements in medical journals, supplemented the letters.\textsuperscript{53} The warnings in these various announcements advised against "indiscriminate therapy for minor infections" and informed doctors of the "calculated risk."\textsuperscript{54}

The court determined that the physician who negligently prescribed the drug had both read and understood the published warnings.\textsuperscript{55} The warnings, however, were allegedly marginalized and counteracted by company advertisements that downplayed the drug's side effects.\textsuperscript{56} Additionally, the doctor claimed that the company's pharmaceutical representatives "extolled the virtues of [C]hloromycetin, and minimized

\textsuperscript{44} 28 C.J.S. Drugs and Narcotics § 62 (2004).
\textsuperscript{45} See id.
\textsuperscript{46} See Fairchild, supra note 31.
\textsuperscript{48} Salmon v. Parke, Davis & Co., 520 F.2d 1359 (4th Cir. 1975).
\textsuperscript{49} Love, 38 Cal. Rptr. at 184.
\textsuperscript{50} Id.
\textsuperscript{51} See id. at 184–85.
\textsuperscript{52} Id. at 185.
\textsuperscript{53} Id.
\textsuperscript{54} Id.
\textsuperscript{55} Id. at 191, 193.
\textsuperscript{56} Id. at 195.
its dangers.'\textsuperscript{57} The representatives, detail men, were allegedly instructed to tell physicians that the drug had been "officially cleared by the FDA and the National Research Council with no restrictions on the number or the range of diseases for which Chloromycetin may be administered."\textsuperscript{58} The representatives were not told to alter their sales pitch, and the company knew that doctors prescribed the drug for less serious conditions.\textsuperscript{59} The court decided that, in light of the FDA directives, such statements did not represent the "whole truth" as required in a fair and proper warning.\textsuperscript{60} It instructed the jury that "[p]roof of [the company's] sales . . . [is] relevant to show a motive or reason for the alleged overpromotion of the drug."\textsuperscript{61} The court also identified the standard used to judge the company's actions:

\begin{quote}
If the overpromotion can reasonably be said to have induced the doctor to disregard the warnings previously given, the warning given is thereby withdrawn or cancelled and if, furthermore, the jury could have found that the doctor here actually prescribed the drug to cure an infection for which the company's advertising or its detail men had actually recommended its use, then the pharmaceutical company's negligence remains as an inducing cause coinciding with the negligence of the doctor to produce the result.\textsuperscript{62}
\end{quote}

In other words, this standard analyzes whether misleading promotional statements induced the doctor to mistakenly overprescribe the drug. If so, then such promotion constitutes unreasonable cancellation of a warning's effectiveness and becomes a cause-in-fact of the resulting harm.

The doctor in \textit{Love} indicated that he had at least "partly" relied upon promotional statements by company representatives.\textsuperscript{63} Based on this evidence, the court held that the company should remand as a defendant on reversal to the lower court.\textsuperscript{64} This ruling empowered the jury to

\begin{footnotes}
\item[57] Id.
\item[58] Id.
\item[59] Id.
\item[60] Id.
\item[61] Id.
\item[62] Id. at 189.
\item[63] Id. at 196.
\item[64] Id. at 197.
\end{footnotes}
factually analyze the company’s sales campaign and potentially impose liability for the campaign’s effects upon the negligent physician. 

2. *Salmon v. Parke, Davis and Co.*

*Salmon* involved a child who became “permanently and seriously disabled” after taking Chloromycetin. The guardian *ad litem* representing the disabled child targeted the manufacturer’s promotional activities. He argued that the promotion downplayed adequate warnings, lead to overprescription, and increased the risk of death.

The primary evidence was the company’s advertisement calendar, which contained no warnings and was located on the prescribing doctor’s desk. Based on this, the court made the following determination:

> It is foreseeable that a calendar might remain on a physician’s desk as a constant reminder to prescribe a drug long after the sample and its warning had been removed. A jury could infer, therefore, that the absence of a warning on an advertisement for the use of a drug as potentially dangerous as [C]hloromycetin was a form of overpromotion which nullified the effect of even a valid warning on the package.

Although slight, this evidence led to reversal of the lower court’s summary judgment in favor of the defendant company and submission of the overpromotion issue to a jury.

3. *The Effect of Doctor Negligence*

The courts in *Love* and *Salmon* analyzed whether physician negligence could be employed to hold the manufacturer liable. As the Restatement (Third) of Torts suggests, negligence lies within the “scope of risk” created by overpromotion, because it is foreseeable that a doctor may negligently prescribe drugs based upon a manufacturer’s aggressive and misleading sales campaign. Therefore, with regard to proximate cause,

---

65 See id.
67 Id. at 1360.
68 Id. at 1363.
69 Id.
70 Id. at 1363–64. There was also a dispute concerning the drug warning that the company issued to doctors. It did not unequivocally confirm the causal link between Chloromycetin and anemia, and only announced that the drug *could* cause the disease. Id. at 1363.
71 See *Restatement (Third) of Torts* § 29 (2003).
physician negligence does not supersede or restrict manufacturer liability for overpromotion.\textsuperscript{72} In other words, it is foreseeable that a doctor may negligently prescribe drugs based upon a manufacturer's aggressive and misleading sales campaign.

Conversely, a showing that a physician did \textit{not} act negligently \textit{defeats} overpromotion claims. In \textit{Tunnell v. Parke, Davis & Co.}, the court held that the fulfillment of a physician's duty of care in prescribing a drug countered all evidence that sales promotion nullified the warnings and caused overprescription.\textsuperscript{73} This means that prescriptions written by a doctor who relied upon a company's statements demonstrate that overpromotion is a cause-in-fact of the resulting harm.

\textbf{C. Application to Rural Prescription Drug Abuse}

Many of the claims and attacks against Purdue Pharma may actually misrepresent or exaggerate the truth. After all, isolated stories of wrongdoing do not amount to an overall scheme to downplay the risks of the drug. However, to the extent that plaintiffs can substantiate such claims, overpromotion may provide a feasible method of sanction for OxyContin's potentially harmful consequences.

First, the aforementioned allegations in the OxyContin disputes replicate the fact patterns of historical cases applying overpromotion liability. Similar to \textit{Love}, OxyContin plaintiffs support their overpromotion claims with evidence of sales representatives' communications to physicians that downplay the drug's risks, and medical journal advertisements that counteract warnings.\textsuperscript{74} If courts apply a standard similar to \textit{Love}, the sales campaign may serve as "proof or motive" regarding overpromotion. Individual juries would have to determine that physicians responded to these sales efforts by overprescribing, which serves as proof that sales promotion "cancelled" the effectiveness of adequate and reasonable warnings.\textsuperscript{75} The overall warning to physicians would then be deemed unreasonable in light of the foreseeable dangers and the magnitude of harm.\textsuperscript{76}

Second, widespread physician negligence illustrates and supports the alleged effect of overpromotion. As previously discussed, negligence by

\textsuperscript{72} See \textit{Salmon}, 520 F.2d at 1363.
\textsuperscript{73} See \textit{Fairchild}, \textit{supra} note 31 (citing \textit{Tunnell v. Parke, Davis & Co.}, Prod. Liab. Rep. (CCH) \textsection 8039 (Tenn. App. 1977)).
\textsuperscript{74} See \textit{supra} notes 20–30 and accompanying text.
\textsuperscript{75} See \textit{supra} notes 61–62 and accompanying text.
\textsuperscript{76} See \textit{RESTATEMENT (SECOND) OF TORTS} \textsection 388 (1965).
doctors propels, rather than restricts, such claims.\textsuperscript{77} Reports indicate that
many doctors, especially those with less expertise, prescribed the drug
for conditions other than "moderate to severe pain" as required by the
warning.\textsuperscript{78} Many of these negligent prescriptions have led to patterns of
addiction that form the basis of class action suits.\textsuperscript{79}

Plaintiffs must meet a high threshold of proof in order to prevail in
OxyContin suits. Past attempts demonstrate that it is a daunting task to
establish a link between the sales campaign, the counteraction of a drug's
warning information, physician negligence, and the resulting harm.\textsuperscript{80} In
\textit{Foister v. Purdue Pharma},\textsuperscript{81} a Kentucky court ruled that "[t]he plaintiffs
failed to produce any evidence showing that the defendant's marketing,
promotional, or distribution practices have ever caused even one tablet of
OxyContin to be inappropriately prescribed or diverted."\textsuperscript{82} This clear
statement may foreshadow the demise of other cases due to inadequate
evidence.

III. THE NEGLIGENT MARKET STANDARD AND ILLEGAL DRUG
DIVERSION

Traditional concepts of overpromotion liability best apply to
addiction resulting from illegal drug prescriptions. However, incidents of
intentional abuse of OxyContin often accompany or derive from legal
prescriptions. Consequently, the difficulty of legally addressing
intentional drug diversion and, in turn, why traditional overpromotion
concepts offer weak grounds for plaintiffs in such cases will be explored
in this section. Also, the much broader negligent marketing theory,
which is specifically designed for cases involving illegality or intentional
product misuse, will be examined and applied.

\textit{A. Problems Posed by Illegal Drug Abuse}

Illegal drug use creates major problems for lawyers handling
overpromotion class action suits. In West Virginia, for example, one
court has already prohibited overpromotion claims by plaintiffs who have

\textsuperscript{77} See \textit{supra} notes 71–73 and accompanying text.
\textsuperscript{78} Camp, \textit{supra} note 1.
\textsuperscript{79} Camp, \textit{supra} note 28.
\textsuperscript{80} \textit{Advertising Restriction on Promotion of OxyContin Denied,} 2 No. 1
\textsuperscript{81} \textit{Foister v. Purdue Pharma L.P.,} No. 01–268–JBC 2001 \textit{U.S. Dist. LEXIS} 23765
\textsuperscript{82} See \textit{id}. 
illegally or intentionally abused the drug. The court cited "the established legal principle that a plaintiff cannot recover when his own unlawful or immoral act caused the injuries in question." Essentially, allowing illegal drug abusers to recover would amount to a public policy violation.

The West Virginia court's analysis coincides with principles of proximate cause which consider wrongful and intentional violations of a warning's direct instructions to be supervening events. Unlike mere negligence, supervening events break the chain of liability linking the wrongdoer with the manufacturer. Since the overpromotion foreseeably leads to physician negligence, such actions are within the "scope of risk." However, it is difficult to argue that promotional activities counteract drug warnings in an illegal manner. These intentional acts seemingly occur in spite of reasonable and adequate warnings.

Attorneys pursuing class action lawsuits in various states have attempted, without success, to exclude illegal drug abusers from their subject class. For example, a class action suit initiated in Butler County, Ohio, includes a former nurse's assistant, a long-time preacher, and a seventy-nine-year-old retired plant worker among its class of plaintiffs. Despite attempts at building a class without illicit users, lawyers soon discovered that the nurse's assistant had an extensive police record that included illegal drug abuse. This example illustrates the difficult task that plaintiffs' attorneys face in fashioning a clean and effective lawsuit.

---

83 OxyContin: W.Va. State Court Enters First Merits Based Dismissal of OxyContin Suit, 18 No. 5 ANDREWS PHARM. LITIG. REP. 12 (2002).

84 Id.

85 Id.


87 See RESTATEMENT (THIRD) OF TORTS § 29 (2003). The section sets forth the following test for proximate cause: "An actor is not liable for harm different from the harms whose risks made the actor's conduct tortious." Id; see also RESTATEMENT (SECOND) OF TORTS § 442 (1965). This section notes that the following factors, among others, may transform an intervening act into a superseding act that limits a manufacturer's liability: the intervening act "operate[s] independently" of the manufacturer's negligence; the intervening forces results from a third-party act; and wrongful intervening act of a third-party exhibits a high degree of culpability. Id.

88 Camp, supra note 3.

89 Id.
B. Explanation of the Negligent Marketing Standard

Some jurisdictions have attempted to develop a broader overpromotion standard through negligent marketing theory. This concept offers support by more significant judicial precedent and is used for deciding cases involving intentional drug diversion. Instead of examining whether a company's overall promotional scheme renders warnings unreasonable, the negligent marketing standard looks directly at the promotional and distributional activities themselves. This theory states that sellers have a duty to market and distribute products in a manner that helps prevent product misuse and other inherent risks.

Courts have addressed negligent marketing liability primarily within the context of handgun sales. Cases dealing with gun sales have created three categories of negligent marketing: (1) product designs attracting criminal users; (2) unreasonable advertising and promotion; and (3) distribution practices targeting "vulnerable or unsuitable buyers." The distributional element of the negligent marketing standard holds manufacturers liable for retail efforts that facilitate unauthorized sales or illegal use. In regard to the second category concerning advertising and promotion, a seller may be liable for promotional activities that foreseeably entice illegal or dangerous consumers. Legal academics typically use two cases—Hamilton v. Accu-Tek and Merrill v. Navegar, Inc.—to explain negligent marketing theory.

---

90 See generally Richard C. Ausness, Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing, 53 S.C. L. REV. 907 (2002). The author notes that negligent marketing is a relatively new and untested theory of liability. Since its inception, the theory has both received support and been rejected. In response to considerable judicial uncertainty, appellate courts have recently overturned several cases that initially elucidated and applied the tenets of negligent marketing. See id. at 909.

91 See id.

92 Id. at 908.

93 Id. at 912–17.

94 See id. at 915.

95 Id. at 914. For purposes of this note, only the distributional and promotional aspects of negligent marketing will be discussed in the context of rural prescription drug abuse. The first category, claims based upon product design, entails circumstances where the features of the product itself render it highly attractive to criminals. Id. at 912–13.


98 Ausness, supra note 90, at 909.
1. *Hamilton v. Accu-Tek*

In *Hamilton*, a federal district court in New York applied negligent marketing theory to guns that ended up in the hands of illegal users. The plaintiffs, acting on behalf of shooting victims, claimed that a handgun manufacturer promoted and distributed its product in a manner that furthered criminal misuse. Specifically, the plaintiffs alleged that the defendant handgun manufacturer supplied a disproportionate amount of guns to the Southeast, which has less gun regulation than other areas of the country. They further argued that the manufacturer knew these guns were often diverted to other regions and sold illegally, as extensive literature had previously detailed the problem.

The court held that, under New York law, a supplier “is negligent when it breaches its duty of care by engaging in conduct, posing unreasonable risk of harm to others.” This means manufacturers must “exercise reasonable care in marketing and distributing their products so as to guard against risk of its criminal misuse.” Although the court noted that manufacturers may market and distribute dangerous, though non-defective, products, they have a legal duty to “reduce the possibility that these instruments will fall into the hands of those likely to misuse them.”

The court then recited the following factors for a jury to consider when determining a defendant manufacturer’s breach of duty: “the foreseeable likelihood that [conduct] will result in harm, the foreseeable severity of harm that may ensue and the burden that would be borne by the [defendant] and others if the [defendant] takes precautions that eliminate or reduce possibility of harm.” To a considerable extent, this analysis replicates the standard applied in negligent-failure-to-warn cases. However, *Hamilton* removes product warnings from consideration and focuses directly upon specific promotional marketing

---

100 *Id.* at 830.
101 *Id.*
102 *Id.* at 827.
103 *Id.* at 824.
104 *Id.* at 825. When imposing this duty on manufacturers, the court noted several public policy concerns, including the degree of danger posed by guns, the availability of such guns in underground markets, and the heightened concern for public safety. *See id.* at 827.
105 *Id.* at 828.
106 *See supra* notes 34–42 and accompanying text.
and distribution practices. This approach bases liability upon whether such marketing efforts reasonably guard against the potential of illegality, regardless of the warnings issued.  

The Hamilton opinion also specifically addresses the proximate cause issue. As previously discussed, failure-to-warn cases often treat illegality as a supervening event that breaks the chain of liability; but in negligent marketing theory, intentional criminal misuse is not a supervening event. As the standard rests upon a manufacturer's obligation to guard against illegal diversion, it logically follows that such actions fall within the scope of risk and thus cannot break the causal chain.

The expert testimony in Hamilton established that most guns used in crimes were not stolen; rather, the guns originated from federally licensed sellers. As a result, the court determined that the manufacturer could have reduced this risk by prohibiting gun sales to known unscrupulous dealers and by restricting distribution in areas where underground markets operated. To this end, evidence proved the gun industry's awareness of both the underground markets and the wrongdoing of various retail sources. The court held that the manufacturer should have foreseen the effects of its marketing practices; thus, it stood in the best position to effectively deter crime. Consequently, it was reasonable for a jury to find the manufacturer liable.

2. Merrill v. Navegar

In Merrill, a California court applied the negligent marketing standard to a manufacturer of semiautomatic weapons. An individual

---

108 See id. at 833–34.
109 See supra notes 86–87 and accompanying text.
111 Id. at 834.
112 Id. at 825.
113 See id. at 826, 831–832.
114 Id. at 829–31. The court strongly relied upon a 1994 promotional pamphlet introduced into evidence which provided a strong inference of industry knowledge about the illegal handgun market and its associated retail outlets. Id. at 830.
115 Id. at 827.
116 See id.
used the weapons to kill or wound fourteen people.\footnote{118} As in \emph{Hamilton}, the plaintiffs argued that the manufacturer marketed the guns in a manner that increased their appeal to criminals and, thus, failed in its duty to guard against foreseeable illegality.\footnote{119} In this regard, the court noted that "an actor may assume others will act lawfully and carefully."\footnote{120} However, this "assumption does not always correspond to the facts," especially where the law is commonly disobeyed or where a product is specifically directed toward individuals "with violent propensities."\footnote{121}

While \emph{Hamilton} focused on distribution practices, the \emph{Merrill} court specifically addressed the defendant manufacturer's promotional activities. Plaintiffs noted that the company's advertisements, often placed in survivalist magazines, emphasized the guns' "paramilitary nature" and their resistance to fingerprints.\footnote{122} Links were established between this method of advertising and the targeting of criminal users.\footnote{123} The court recognized the rule that, without the presence of a "special relationship," an actor generally garners no liability for third-party acts.\footnote{124} However, in this case the defendant's promotional practices were "grounded upon an affirmative act of [the] defendant which created an undue risk of harm."\footnote{125} As a result, the court held that such promotion, which "invited or enticed" persons likely to so misuse the weapon to acquire it, constituted misfeasance that increased the risk of illegality enough to potentially impose liability upon the company.\footnote{126}

It should be noted that both \emph{Hamilton} and \emph{Merrill} were later overturned, as higher courts refused to accept the negligent marketing standard.\footnote{127} The opinions faltered on whether courts should impose a duty of care on enterprises for the intentional, illegal acts of third

\begin{itemize}
\item \footnote{118} \textit{id.} at 152.
\item \footnote{119} \textit{id.} at 162, 166.
\item \footnote{120} \textit{id.} at 167.
\item \footnote{121} \textit{id.}
\item \footnote{122} \textit{see id.} at 156–57, 188.
\item \footnote{123} \textit{id.} at 188.
\item \footnote{124} \textit{id.} at 164–65.
\item \footnote{125} \textit{id.} at 168 (citing \textit{Weirum v. RKO Gen., Inc.}, 539 P.2d 36, 41 (Cal. 1975)).
\item \footnote{126} \textit{id.} at 168–69. The court also discussed \textit{Merrill}'s relationship to \textit{Avis Rent A Car System, Inc. v. Superior Court}, 12 Cal. App. 4th 221 (1993), which held that a defendant who left an unlocked car unattended had no duty to protect a plaintiff from a thief's negligent driving. \textit{Merrill} is distinguishable from cases like \textit{Avis} because the defendant gun company had substantial reason to foresee the criminal misuse due to its targeted marketing. Such conduct is more suitable for the imposition of a legal duty. \textit{See Merrill}, 89 Cal. Rptr. 2d at 168–69.
\item \footnote{127} \textit{Ausness, supra} note 90, at 939.
\end{itemize}
parties. Hamilton foreshadowed this result by admitting that the judiciary feared "crushing liability" for industries that provide societal benefits. Due to judicial reluctance to accept such an expansive theory of liability, the future of the negligent marketing standard remains questionable. However, to the extent that future courts are willing to use the standard, it may provide the only effective tool for imposing tort liability in the context of illegal diversion.

C. Parallels Between Guns and Drugs

A comparison of Hamilton and Merrill with the OxyContin controversy reveals some parallels that might support a plaintiff's use of negligent marketing theory in the prescription drug context. With regard to Hamilton, similarities exist between OxyContin and the distribution of guns. As already discussed, the Appalachian region has been a fertile ground for painkiller use and associated drug abuse. A disproportionate amount of OxyContin sales promotion occurred within the region and arguably increased the risk of diversion. A court could certainly find that Purdue Pharma fully understood the increased risk inherent in its marketing strategy and did not act reasonably when it energetically promoted the drug in a region already plagued by drug abuse.

The Hamilton court also held that the manufacturers should have prohibited sales to unscrupulous dealers. Similarly, a court could find that Purdue Pharma unreasonably promoted and distributed the drug to doctors who were foreseeably connected with drug diversion. If plaintiffs can establish that the company was careless in its promotion, despite its awareness of possible product misuse, a court could hold that the company failed in its duty to guard against such risks.

In accordance with Merrill, a court may specifically look at the nature of promotion itself, rather than just the targeted regions and physicians. Merrill analyzed advertisements in magazines that appealed

128 See Daniel L. Feldman, Not Quite High Noon for Gunmakers, but it's Coming: Why Hamilton Still Means Negligence Liability in Their Future, 67 BROOK. L. REV. 293, 293–301 (2001). The author argues that the historical status of guns in American society stymied efforts by courts to impose higher duties on gun manufacturers. However, as a policy matter, this tide may be turning in the wake of the Columbine school tragedy and other events that have illustrated the harmful consequences of gun use. Id. at 301–02. In a similar manner, one may argue that the mounting concerns about rural prescription drug abuse facilitates judicial action.


130 See supra notes 17–23 and accompanying text.

to illegal gun consumers, the end users in that case. The OxyContin controversy concerns sales representatives who promoted and sold the drug directly to doctors who then distributed the product to end users. Notice that, in contrast to guns, OxyContin was not advertised to the end users who ultimately engaged in intentional abuse. Further, any evidence of promotional language geared toward criminality by physicians rests within the one-on-one sales campaign, leaving the manufacturer free of promotional incrimination. Advertisements are easily identifiable because hard copies provide proof of unscrupulous promotional methods. However, pitches by sales representatives are necessarily individualized and, hence, not easily discoverable. This difference may create an evidentiary hurdle for plaintiffs to overcome.

D. Challenges to Negligent Marketing Jurisprudence

Given the unstable status of negligent marketing liability, a future court must determine whether the standard falls within the realm of acceptable jurisprudence before applying it to a fact situation. As discussed, the negligent marketing standard offers a new method for evaluating a company's promotional activities that correlate with illegal drug diversion. Critics, however, challenge negligent marketing jurisprudence on at least two grounds: (1) the efficacy of the enabling tort, and (2) the jury's overly broad discretion and subjectivity. This section analyzes both arguments in connection with rural prescription drug abuse.

133 See supra notes 20–30 and accompanying text.
134 See supra notes 28–30 and accompanying text.
135 See generally Jean Macchiaroli Eggen & John G. Culhane, Gun Tort: Defining a Cause of Action for Victims in Suits Against Gun Manufacturers, 81 N.C. L. Rev. 115, 206–07 (2002) (describing enabling tort as a theory under which "the enterprise may bear the ultimate responsibility for making possible, or enabling, the direct tortfeasor's actions.

136 See Ausness, supra note 41, at 138. Professor Ausness states the following: Another disadvantage from the defendant's point of view is that the liability standard for negligent marking is essentially meaningless. There is no objective way to determine when a particular marketing practice is appropriate and when it can be characterized as negligent . . . [N]egligent marketing claims are predominantly factual in nature and, therefore, will ultimately be determined by lay juries.

Id.
1. The Enabling Tort

A primary source of criticism concerns the efficacy of the enabling tort. This emerging theory holds a manufacturer liable for actions by a third-party tortfeasor or criminal wrongdoer. Negligent marketing theory as applied to gun sales rests within this broader area of developing tort law. As the aforementioned gun cases highlight, marketing techniques employed by gun companies allegedly increased the risk of third-party criminality. Under enabling theory, producers should be liable for enhancing these foreseeable risks.

Legal commentators, upholding the enabling tort's efficacy, assert that large enterprises like gun manufacturers can market their products in a manner that reduces the risk of illegal diversion. This form of liability minimizes reliance upon law enforcement and promotes less expensive deterrence of criminal activity. This fulfills the efficiency goal of tort liability: to discover the "cheapest cost avoider" and to then place liability on that party. This analysis also coincides with the Hamilton court's determination that, due to public policy considerations regarding the most efficient risk bearer, gun manufacturers have a duty to prevent criminal conduct.

The court's opinion in Merrill also supports this public policy argument by pointing out that enabling tort liability deters both morally
blameworthy conduct and future harm. The court argues that such liability does not proscribe a product’s marketing altogether, or serve to bar the product itself. Rather, it forces manufacturers to internalize associated societal costs. Where a defendant’s conduct exhibits “little or no social utility” in comparison to the aforementioned harms, the imposition of a duty remains appropriate in order to deter adverse social consequences.

The court also rejected the argument that establishing such a duty for manufacturers invades the legislature’s prerogative. Without completely banning a product with some social value, courts have long instructed juries to examine the propriety of conduct through the lens of the “reasonable person standard” to determine whether plaintiffs deserve protection from the affirmative risks created by others. While such jury determinations require value judgments, juries play a time-tested role in representing the “general level of community intelligence and perception” and gauging the not-easily-quantifiable social value of certain activities.

---

145 Id.
146 Id.
147 Id. at 171. In a footnote to its decision, the court supported this argument with a recitation from the Restatement: “Where an act is one which a reasonable man would recognize as involving risk of harm to another, the risk is unreasonable and the act is negligent if the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.” Id. at 171 n.14 (quoting RESTATEMENT (SECOND) OF TORTS § 291 (1965)). The court also cited another Restatement provision, which holds that balancing the utility and risk involves a determination of “the social value which the law attaches to the interests which are imperiled.” See id. (quoting RESTATEMENT (SECOND) OF TORTS § 293 (1965)).
148 Merrill, 89 Cal. Rptr. 2d at 179.
149 See id. at 179–80. In reference to this argument, the court stated the following: Our decision that there is a legal duty is not a statement that the [firearm] should not be manufactured, or made available to the public or should not be marketed in such a way as to make it particularly desirable to a criminal class. It simply reflects the view that there is a question about reasonableness of the risk created by [the manufacturer’s] activities, that public access to the [firearm] and the manner in which that weapon is marketed are not of such overriding social importance that they are entitled to absolute protection as a matter of law, and that it is therefore for a jury to make the ultimate determination whether [the manufacturer’s] conduct was or was not reasonably prudent in the circumstances.

Id.

The court also relied upon traditional overpromotion cases as grounds for holding that these decisions properly belong to the judiciary. Id. at 184–85.
150 Id. at 180.
Commentators have also noted that, in the past, other large enterprises have been held liable for third-party acts: commercial alcohol vendors have been accountable for reckless, injurious actions of patrons, and property owners have been penalized for permitting conditions that enhance the risk of criminal violence against tenants. As a whole, these examples show that enabling tort theory rests on precedent that may expand into other areas. In fact, the *Hamilton* court used this precedent as grounds for expanding enabling tort liability, stating that such liability is appropriate when the "third party wrongdoer provides the defendant with ability to minimize the risk."  

Many courts, however, are reluctant to impose a duty upon manufacturers to prevent criminal acts associated with their products, including acts that injure innocent bystanders. By overturning both *Hamilton* and *Merrill*, higher courts have created barriers for establishing enabling tort liability against the gun industry. Such decisions arguably reflect politically charged policy efforts regarding gun control, including organizations such as the National Rifle Association (NRA) that advocate for a constitutional right of gun ownership. From a legal standpoint, *Hamilton* foreshadowed the rejection of enabling tort liability in the gun context. The court noted its reluctance to impose "crushing liability" for criminal acts "that may destroy [the manufacturer's] ability to deliver socially useful services."  

---


152 *Hamilton v. Accu–Tek*, 62 F. Supp. 2d 802, 820 (E.D.N.Y. 1999), vacated by 264 F.3d 21 (2d Cir. 2001). It should be noted, however, that most of the authority cited in *Hamilton* regarding enabling tort liability involved circumstances where a special protective or economic relationship existed, such as passenger–carrier, tavern owner–patron, or landlord–tenant. *Id.*

153 See Ausness, *supra* note 90, at 953–54. Professor Ausness notes that courts often consider negligent marketing a matter of nonfeasance, whereby a special relationship must usually exist in order for a manufacturer to incur a duty of reasonable care. *Id.* However, the *Merrill* court more adequately stated that negligent marketing entails an affirmative creation of risk that automatically imposes a duty of reasonable care under tort law. See *Merrill*, 89 Cal. Rptr. 2d at 168. Nonetheless, courts reluctantly impose a duty because of the public policy concerns discussed herein.

154 See Ausness *supra* note 90, at 939.


156 *Hamilton*, 62 F. Supp. 2d at 819. The court cited the following two cases in support of this public policy concern: *Waters v. New York City Hous. Auth.*, 505 N.E.2d 922, 924 (N.Y. 1987) (finding that the prospect of limitless liability militated against imposing a duty on city housing projects to protect a passersby from third–party criminal acts) and *Einhorn v. Seely*, 136 A.2d 122, 127 (E.D.N.Y. 1988) (holding that a locksmith
Prescription drugs and guns are similar with respect to policy issues regarding enabling tort theory. Both products contain inherent traits that attract criminal users, and both are manufactured by large enterprises that arguably should have foreseen and curtailed the consequences. Further, just as gun control is enveloped in a divisive policy debate, negligent marketing theory regarding pharmaceuticals faces considerable political challenges. Potentially the most fatal issue concerns the propriety of addressing illicit drug use. Negligent marketing, at least theoretically, transforms a form of liability that violates public policy (by allowing drug abusers to benefit from their own wrongdoing) into a form of liability that upholds public policy (by making manufacturers accountable for foreseeable abuse associated with their products). As the court stated in Hamilton, the foundation of negligent marketing theory rests upon the foreseeability of product misuse. Likewise, in the prescription drug context, courts may use drug diversion as a gateway to imposing tort liability.

However, because courts often prohibit recovery for harms associated with wrongful conduct, the same public policy concerns may apply to both negligent marketing and traditional overpromotion claims. A new, more expansive tort theory may not erase firmly held principles opposing recovery for an “unlawful or immoral act.” It should be noted that the plaintiffs in Hamilton and Merrill were innocent gun victims and family members. Thus, the only chance of recovery in the prescription drug context may rest with innocent family members of illicit drug users, and not with the drug users themselves.

As an additional public policy concern, companies faced with expansive liability may greatly restrict distribution and access and, as a result, harm legitimate patients who use OxyContin for its intended purpose. As many commentators argue, the price of protecting “irresponsible physicians and illegitimate users from their own bad judgment” is too high. The American Pain Society reports data supporting this argument. The report indicates that 50 million people suffer chronic pain each year, but only one-fourth receives satisfactory treatment. This statistic grants credence to the argument that the

installing a defective lock should not be responsible for rape by an intruder, because such a ruling would enlarge legal obligations “beyond sound public policy”).

157 See supra notes 102–04 and accompanying text.
158 ANDREWS PHARM. LITIG. REP., supra note 83.
161 Weinman, supra note 16, at 502–03.
legitimate benefits of OxyContin should not be destroyed in order to eliminate inherent dangers—an argument indicating that the social utility associated with OxyContin greatly outweighs the social detriments. In an attempt to protect the interests of pain sufferers, the DEA has already issued a statement advising against interference with legitimate OxyContin use for the sake of battling illegality. Efforts by plaintiffs to apply negligent marketing theory to rural prescription drug abuse may, therefore, prove futile as courts contemplate these negative policy implications.

2. Jury Discretion and Subjectivity

The courts in both Merrill and Hamilton held that, ultimately, imposition of liability for negligent marketing rests within the province of the jury. As the Hamilton court expressed, the fact-specific determinations required by negligent marketing, like other negligence cases, are ideally suited for a jury. It is improper for judges to impose standards of conduct and override the community-imposed perceptions of the reasonable person standard, which a jury provides.

Some critics complain, however, that the negligent marketing standard is too vague for juries, and that it fails to promote an objective determination of whether a promotional practice is negligent. Therefore, these critics maintain that juries retain complete discretion without reference to any objective analysis. Additionally, the standard arguably grants disproportionate power to plaintiffs' attorneys who may prejudice juries by portraying defendants as unethical wrongdoers.

In order to overcome these legitimate concerns, juries and courts will have to develop and use tools that better objectify their decision-making procedures. Within the context of pharmaceutical overpromotion, and particularly the OxyContin controversy, courts may employ the framework of the regulatory drug categories. Under tort law, government regulation does not usually dictate the standard of care; however, it provides support for such determinations. Thus, judges and juries could use regulatory descriptions of a drug when assessing the

---

162 Noah, supra note 160, at 63.
163 Hamilton, 62 F. Supp. 2d at 828; Merrill, 89 Cal. Rptr. 2d at 180.
165 Ausness, supra note 41, at 138.
166 Id.
167 See, e.g., Merrill, 89 Cal. Rptr. 2d at 177 (iterating that gun statutes in California do not define the scope of a manufacturer's duty under tort law, but rather, they lend support and guidance for rigorous enforcement by the courts).
reasonableness of promotional activities. Such a regulatory system could track the federal classification system already in place.\footnote{168}{Federal law categorizes drugs as follows: \textit{Schedule I}: Drugs with a high potential of abuse and no accepted medical use, such as LSD. \textit{Schedule II}: Drugs with a high potential for abuse that exhibit some medicinal benefits. This category includes cocaine and \textit{oxycodone} (the active ingredient in OxyContin). \textit{Schedule III}: Drugs, such as Lorca and Vicodin, with some potential for abuse. \textit{Schedule IV}: Drugs with a low potential for abuse. This category includes Darvon, Xanax and Valium. \textit{Schedule V}: Drugs with a low potential for abuse. This category is primarily comprised of over-the-counter medicines. Johnson, \textit{supra} note 15.}

The current federal classification reflects both the medicinal benefits and the potentially abusive qualities of a drug. In the case of OxyContin, its status as a Schedule II narcotic indicates that, while it serves a medicinal purpose, it is also very addictive and prone to abuse. Therefore, a court or a jury could use this information as a reference point to aid an objective analysis of a manufacturer's promotional activities.

With this framework, the fact-finder may better determine the type of promotion appropriate for different types of drugs. In each circumstance, the traditional reasonable person standard applies. However, the same types of promotional activities will not be reasonable when marketing Schedule II narcotics versus less dangerous pharmaceuticals. When the foreseeability of crime and the magnitude of harm increase in comparison to the burden imposed, the manufacturer will be liable for its marketing and distribution practices.\footnote{169}{See \textit{RESTATEMENT (SECOND) OF TORTS} \S 291 (1965).}

In reference to OxyContin, one may argue that its status as a Schedule II narcotic heightens the foreseeability and magnitude of crime associated with aggressive drug promotion and thus supports imposition of overpromotion liability. Further, Purdue Pharma might not have acted reasonably in marketing OxyContin in the same way as less addictive drugs.\footnote{170}{See \textit{supra} notes 20-27 and accompanying text.} However, the use of drug categories does not fully correct for juries' wide discretion and subjectivity. A comparative analysis of pharmaceutical dangers illustrates that more addictive drugs may necessitate restricted marketing efforts, but fails to detail the proper nature of such promotion. This question will ultimately be left within the discretion of the fact-finder.
IV. CONCLUSION

In light of the increasing number of lawsuits filed against Purdue Pharma, one can easily visualize the potential impact of overpromotion liability. The theory, however, remains relatively untested for drug addiction intertwined with illegal diversion. Current and future plaintiffs must surpass high thresholds of proof when persuading the court to adopt and apply the theory in the prescription drug context.

Federal and state courts in regions confronted with widespread OxyContin addiction may more readily accept traditional overpromotion theory; but, as previously discussed, this theory does not account for the illicit drug abuse that requires the greatest and most urgent societal response. Since traditional overpromotion theory inadequately handles such cases, courts should re-analyze old precedent and determine whether a broader enabling tort theory warrants acceptance. The application of enabling tort liability in other contexts proves that it would not be unreasonable to apply it in cases of rural prescription drug abuse.

On the other hand, skepticism regarding negligent marketing theory, as evidenced in both the California and New York gun cases ostensibly foreshadows the same handling of prescription drug cases—especially cases in the hands of more conservative courts. To the credit of such courts, an expansive form of liability should not be applied without careful scrutiny of the potential consequences. Abuse of OxyContin is a societal detriment, but the benefit of eliminating the drug must be weighed against other policy concerns. Thus, the debate regarding whether the law should protect drug abusers and the impact that decision will have upon legitimate users is both productive and necessary.

Ultimately, judicial acceptance of the negligent marketing standard may depend upon whether courts will voluntarily undertake a divisive policy issue or will rather defer to legislatures and regulatory agencies. Because of the minimal regulatory movement to date, courts have considerable room to act on the rural prescription drug abuse issue. The

---

171 See generally Noah, supra note 160. The author explains that regulatory agencies have been both reluctant and unable to restrict the marketing practices for OxyContin: The FDA generally does not have the authority to restrict the distribution of drugs that it approves. Although the DEA clearly enjoys the power to limit the channels of distribution for controlled substances by virtue of its scheduling decisions, it does not usually impose more precise restrictions tailored to a particular drug. Either agency could attempt to persuade a manufacturer to accept nominally voluntary limitations that they could not mandate directly, but that did not happen at the time of OxyContin’s approval.

Id. at 63.
high level of subjectivity and the potential for excessive liability, however, may persuade courts to refrain from testing this form of liability in the near future.