

WEST VIRGINIA’S PAINFUL SETTLEMENT: HOW THE OXYCONTIN PHENOMENON AND UNCONVENTIONAL THEORIES OF TORT LIABILITY MAY MAKE PHARMACEUTICAL COMPANIES LIABLE FOR BLACK MARKETS

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I. INTRODUCTION.....	1409
II. BACKGROUND.....	1412
A. <i>OxyContin: A Prescription Narcotic Backed by Deep Pockets</i>	1412
B. <i>Illicit Diversion of OxyContin</i>	1414
III. INJURED ABUSER AS PLAINTIFF: THE DIFFICULTY OF ESTABLISHING LIABILITY .	1417
A. <i>Drug Abusers as the Primary Source of OxyContin Injuries</i>	1417
B. <i>Suits Brought by Patients and Abusers</i>	1418
IV. PUBLIC ENTITY AS CLAIMANT: WHEN DRUG ABUSE HARMS THE BROADER COMMUNITY	1420
A. <i>Unconventional Tort Theories and Public Entities Generally</i>	1420
B. <i>West Virginia’s Public Entity Suit Against Purdue</i>	1424
C. <i>West Virginia’s Negligent Marketing Claims Conflated Promotion with Distribution</i>	1430
V. POTENTIAL IMPACT OF WEST VIRGINIA’S SETTLEMENT	1433
A. <i>Understanding the Settlement: Why It Happened, and Why It Increases the Threat of Future Legal Action Against Drug Manufacturers</i>	1433
B. <i>Culture: Making Manufacturers Liable for the Failures of Communities</i>	1435
C. <i>Chilling Effects on the Treatment of Chronic Pain</i>	1436
VI. CONCLUSION.....	1437

I. INTRODUCTION

Since the discovery of a veritable goldmine in the now-notorious waves of tobacco and asbestos litigation, many plaintiffs’ attorneys have been searching relentlessly for the “next big thing”¹ in products liability litigation: a new source of tort claims capable of providing a massive sup-

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¹ Huhnsik Chang, *Legal—Litigation—Getting to the Point*, REINSURANCE, Oct. 1, 2003, at 43.

ply of legal fees.² Unfortunately for defendants and for the public, the hunt for mass torts seems often to focus less on the merits and more on the “mass,” either by eschewing well-established yet conventional tort doctrines in favor of less conventional yet more flexible ones,³ or by simply attempting to draw questionable analogies to past plaintiff-side success stories.⁴

This Comment focuses on the potential policy pitfalls posed by unbounded application of the first strategy—that which seeks to establish liability through “unconventional” tort theories—in the context of the harms caused by the use and abuse of prescription narcotics. The controversy concerning the abuse of, and addiction to, the prescription painkiller OxyContin and the ensuing public entity litigation⁵ present a unique opportunity to explore the threats that overly liberal application of “unconventional” tort liability to manufacturers of prescription narcotics may have on pain sufferers.⁶ Specifically, this Comment focuses on the recent settlement of a suit levied against Purdue Pharma (“Purdue”), the manufacturer of OxyContin, by the state of West Virginia. That suit asserted causes of action including, inter alia, negligent marketing and public nuisance,⁷ and ultimately settled in November 2004, with Purdue agreeing to pay \$10 million to the state of West Virginia.⁸

Purdue’s settlement with West Virginia is notable primarily because of the tenuous chain of causation between the design and marketing of OxyContin and the harms associated with its use. In the simplest tort action, *A*

² Scott A. Smith, *Turning Lead into Asbestos and Tobacco: Litigation Alchemy Gone Wrong*, 71 DEF. COUNS. J. 119 (2004).

³ See, e.g., 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) [hereinafter Ausness, *Non-Defective Products*]; Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 123–26 (2002) [hereinafter Ausness, *Aggressive Marketing*] (describing the “relatively new legal theory of ‘negligent marketing,’” which does not require that a plaintiff “prove that the product in question is defective”); see also Doug Morgan, Comment, *What in the Wide, Wide World of Torts Is Going on? First Tobacco, Now Guns: An Examination of Hamilton v. Accu-Tek and the Cities’ Lawsuits Against the Gun Industry*, 69 MISS. L.J. 521 (1999) (discussing claims levied against tobacco companies and gun manufacturers under negligent marketing and negligent distribution theories).

⁴ See, e.g., Smith, *supra* note 2, at 120 (“More than one observer has referred to litigation against former manufacturers of lead pigment and lead paint as ‘the next tobacco’ or ‘the next asbestos.’”).

⁵ Tim O’Brien, *OxyContin Suits Coming up Empty: Purdue Pharma’s Litigation Strategy Costly, but Effective*, CONN. L. TRIB., Oct. 27, 2003, at 3.

⁶ See Beth Packman Weinman, *Freedom from Pain: Establishing a Constitutional Right to Pain Relief*, 24 J. LEGAL MED. 495 (2003) (discussing abuse of prescription narcotics generally, and OxyContin in particular, in relation to the “chronic undertreatment of pain”).

⁷ See Complaint at 16–19, 23–26, *West Virginia ex rel. McGraw v. Purdue Pharma L.P.* (W. Va. Cir. Ct. filed June 21, 2001) (No. 01-C-137-S), available at <http://www.cmht.com/pdfs/oxycontin-cmpl.pdf> [hereinafter *West Virginia Complaint*].

⁸ *OxyContin Lawsuit Is Settled: Purdue Pharma to Pay State \$10 Million*, CHARLESTON GAZETTE, Nov. 6, 2004, at 1A [hereinafter *OxyContin Lawsuit Is Settled*].

negligently or intentionally causes harm to *B*. With the presence of an intervening force, the direct chain of causation from *A* to *B* is broken. An actor or action, *C*, has facilitated the transaction and thus becomes a necessary force in the chain of causation and, arguably, the source most directly responsible for the harm caused. Such an extended chain of causation poses a challenge to plaintiffs, and often frustrates their ability to demonstrate liability. Thus, it is more difficult to hold a manufacturer liable when another party or action has more directly caused the harm.

This Comment focuses only on litigation concerning the most salient harms associated with OxyContin, caused by those who deliberately misuse the drug, as opposed to the more minor threats presented by those who hold prescriptions and administer the drug with legitimate intentions. Proving liability for these indirect harms necessarily involves an extended chain of causation. Users are not patients prescribed OxyContin but instead individuals who came upon the drug through illicit means. Yet even with these barriers to demonstrating causation and liability, West Virginia prevailed. In effectuating its \$10 million settlement with Purdue, West Virginia was able to recover for social harms caused by drug abusers who illegally obtained OxyContin via black markets and knowingly misused the drug for recreation.

Part I of this Comment discusses the history of the drug OxyContin and its sole active ingredient, oxycodone. Contrary to popular misunderstanding, OxyContin is not a revolutionary drug at the chemical level but, rather, a new means of administering a decades-old painkiller. Part I goes on to discuss the means by which OxyContin users and dealers fuel black markets via drug diversion and takes note of the marked geographic concentration of illegal OxyContin trade and abuse.

Part II argues that the harms caused by OxyContin stem primarily from deliberate misuse of the drug, rather than its proper use by “legitimate” patients. Legitimate patients are defined as those who hold valid prescriptions and administer the drug with legitimate intentions, i.e., use as directed. By contrast, abusers are defined as those who have obtained OxyContin on the black market or through an illegal prescription and seek to use the drug for recreation. Part II argues that the active role that OxyContin abusers play in harming themselves is precisely the reason that they have been so unsuccessful as plaintiffs.

However, one OxyContin suit *has* met with success—that brought by West Virginia. Part IV discusses the unique role that public entities can play as plaintiffs in litigating cases with extended causation complications. Specifically, it notes that public entities are in a unique position, insofar as they can assert liability for the harms that a product’s marketing and distribution bring to bear on an entire community. Part IV briefly sketches the jurisprudential history of negligent marketing and public nuisance, two

theories that public entities have applied in novel ways through asbestos,⁹ tobacco,¹⁰ and, especially, firearms litigation.¹¹ First, Part IV argues that, by effectively ignoring the buffering role that physicians play in the marketing of controlled substances and by failing to differentiate between the harms caused by the “legitimate” use of prescription narcotics and their intentional abuse, West Virginia’s negligent marketing and public nuisance claims against Purdue effectively sought to establish liability where there should have been none.¹² Second, Part IV argues that this circumstance is driven as much by the need for public revenues¹³ as it is by the temptation to use tort law as a surrogate where proper legislative regulation is lacking.¹⁴

Part V concludes by stressing that it is precisely in the context of a public entity suit that such “questionable” claims have real force. Economic incentives—such as the avoidance of legal fees and, of particular relevance in the public entity context, negative media coverage—may lead even the most aggressively defensive companies to fold early in litigation, and thus implicitly consent to bear some degree of liability for regulatory failure.¹⁵ The ultimate result is that litigation may have a chilling effect on the treatment of chronic pain, insofar as it makes pharmaceutical companies liable for black markets that they may neither condone nor control.

II. BACKGROUND

A. *OxyContin: A Prescription Narcotic Backed by Deep Pockets*

OxyContin is a brand-name, time-release formulation of oxycodone hydrochloride (“oxycodone”), first launched in 1996 by Purdue.¹⁶ Pharmacologically, oxycodone is an opiate agonist produced synthetically and is capable of producing effects similar to heroin if abused.¹⁷ Because of its

⁹ See Joseph W. Cleary, Comment, *Municipalities Versus Gun Manufacturers: Why Public Nuisance Claims Just Do Not Work*, 31 U. BALT. L. REV. 273, 280–88 (2002).

¹⁰ *Id.* at 282 & n.109.

¹¹ See, e.g., Ausness, *Non-Defective Products*, *supra* note 3, at 917–36; Morgan, *supra* note 3.

¹² See West Virginia Complaint, *supra* note 7.

¹³ See, e.g., Cleary, *supra* note 9, at 273; Laura L. Gavioli, Comment, *Who Should Pay: Obstacles to Cities in Using Affirmative Litigation as a Source of Revenue*, 78 TUL. L. REV. 941 (2004).

¹⁴ See Michael I. Krauss, *Regulation Masquerading as Judgment: Chaos Masquerading as Tort Law*, 71 MISS. L.J. 631 (2001); Philip C. Patterson & Jennifer M. Philpott, Note, *In Search of a Smoking Gun: A Comparison of Public Entity Tobacco and Gun Litigation*, 66 BROOK. L. REV. 549 (2000).

¹⁵ Patterson and Philpott discuss the role that “public entity” suits against tobacco and firearms manufacturers have played in acting as an effective surrogate for litigation, despite the weaknesses of the underlying claims. See Patterson & Philpott, *supra* note 14, at 551 (“Despite the questionable merits of the public entity tobacco lawsuits, the tobacco companies agreed to settle without trying a single case to verdict.” (citation omitted)).

¹⁶ DOMESTIC STRATEGIC INTELLIGENCE UNIT, U.S. DEP’T OF JUSTICE, OXYCONTIN: PHARMACEUTICAL DIVERSION (2002), available at <http://www.avitarinc.com/pdf/Drug-Intelligence-Brief-Oxycotone-Facts.pdf> [hereinafter DOJ INTELLIGENCE BRIEF].

¹⁷ *Id.*

“high potential for abuse,” which “may lead to severe psychological or physical dependence,” OxyContin is categorized as a Schedule II narcotic, the most restrictive schedule available for legal pharmaceuticals.¹⁸

For Purdue—a privately held company¹⁹—OxyContin has provided an enormous financial success. OxyContin generated over \$1.5 billion in sales in 2002 alone, accounting for more than seventy-five percent of Purdue’s total annual revenues.²⁰ That year, OxyContin was the “number-one prescribed Schedule II narcotic in the United States,” according to the U.S. Department of Justice (“DOJ”).²¹ Despite its revolutionary financial success, OxyContin is not an especially revolutionary drug at the chemical level.²² Indeed, the drug’s sole active ingredient, oxycodone, was first synthesized in 1916²³ and has been widely prescribed for decades under brand names including Percocet²⁴ and Percodan.²⁵ These older formulations, however, contain smaller doses of oxycodone in immediate-release formulations and, as a result, provide pain relief of relatively short duration.²⁶ OxyContin is unique in that its time-release mechanism allows for a single pill to slowly release a large amount of oxycodone over time, eliminating the need for repeated dosing. Whereas most oxycodone formulations typically provide only four to six hours of pain relief, OxyContin is effective for up to twelve hours,²⁷ providing not only a convenience to pain patients but, far more importantly, a reduced risk of experiencing pain between doses.²⁸

As a result, a single dose of OxyContin contains far more oxycodone than immediate-release formulations, and this feature has facilitated its abuse. Swallowing OxyContin pills whole, as directed, allows for a steady release of oxycodone over time. Crushing pills prior to ingestion, however, defeats that time-release mechanism and causes all of the active ingredient

¹⁸ 21 U.S.C. § 812(b)(2)(A), (C) (2000). Schedule I, the most restrictive schedule available for *any* substance, is reserved for “drug[s] or other substance[s]” that have “no currently accepted medical use in treatment in the United States” and, thus, includes only drugs that are outlawed entirely. *Id.* § 812(b)(1)(A), (B).

¹⁹ See Press Release, Purdue Pharma, *Purdue Pharma Supports Task Force Recommendations* (Feb. 12, 2004), available at http://www.purdue.ca/about/purdue_pharma_press_release_021204.pdf.

²⁰ Cf. O’Brien, *supra* note 5.

²¹ DOJ INTELLIGENCE BRIEF, *supra* note 16, at 2.

²² Cf. *id.* at 1–2.

²³ Paul Tough, *The Alchemy of OxyContin: From Pain Relief to Drug*, N.Y. TIMES, July 29, 2001, § 6 (Magazine), at 32.

²⁴ See Prescription Drug Information for Consumers and Professionals: Percocet, <http://www.drugs.com/percocet.html> (last visited Feb. 1, 2006). Unlike OxyContin, Percocet is a “dual entity” drug, containing both oxycodone and acetaminophen. *Id.*

²⁵ See Prescription Drug Information for Consumers and Professionals: Percodan, <http://www.drugs.com/percodan.html> (last visited Feb. 1, 2006). Percodan, like Percocet, is a “dual entity” drug, containing a mixture of oxycodone and aspirin. *Id.*

²⁶ DOJ INTELLIGENCE BRIEF, *supra* note 16, at 1.

²⁷ *Id.*

²⁸ BARRY MEIER, PAIN KILLER 84 (2003).

to become immediately available for absorption. A tablet so ingested produces a heroin-like high and, although some regular abusers do swallow the pills whole, most abusers (and, in particular, the most hard-core abusers) simply crush the tablets in order to defeat the time-release mechanism.²⁹ Most abusers crush the tablets and either swallow the resulting powder or, for a more intense effect, snort it like powdered cocaine.³⁰ The ultimate result is that—once crushed—an OxyContin tablet is nothing more than a large dose of oxycodone. As such, one commentator has described OxyContin as “old wine in a new bottle.”³¹ More bluntly, one “long time drug user and dealer” is said to have described it as “the same old shit.”³² Thus, OxyContin is not exactly a “new” phenomenon, and this mischaracterization has served to unnecessarily increase media overreaction to the abuse situation and, in turn, serves to muddy the issue of the potential harms that OxyContin use and abuse may have caused.³³

B. *Illicit Diversion of OxyContin*

OxyContin abuse has been sufficiently concentrated both geographically and socioeconomically that it is now commonly referred to as “hillbilly heroin”³⁴ and “poor man’s heroin.”³⁵ It was relatively poor, rural areas such as Appalachia and rural New England that were hit first and hit hardest by OxyContin abuse and related crimes.³⁶ However, OxyContin abuse and addiction is not categorically limited to rural, impoverished areas: more recently, OxyContin abuse has spread to urban areas,³⁷ and even some of the wealthiest members of society have experienced addiction to the drug, as the recent high-profile scandal involving political commentator Rush Lim-

²⁹ See Kevin Irwin & Mark Kinzly, *Oxy-mania: Still Going Strong*, HARM REDUCTION COMM., Winter 2003, <http://www.harmreduction.org/pubs/news/winter03/win03KinzlyIrwin.htm>; see also MEIER, *supra* note 28, at 13 (noting that it doesn’t “take long for even novice drug abusers” to learn how to crush an OxyContin tablet, thus “releasing its oversized narcotic trove for their immediate pleasure”).

³⁰ See MEIER, *supra* note 28, at 15; Irwin & Kinzly, *supra* note 29, at 13.

³¹ MEIER, *supra* note 28, at 81. Notwithstanding this characterization of OxyContin, Meier is—to say the least—highly critical of OxyContin itself as well as Purdue’s marketing of the drug and its response to early reports of abuse. See *id.* at 311–13.

³² Irwin & Kinzly, *supra* note 29. Although this characterization of OxyContin is humorous, it is also quite illuminating: it reveals that at least some users and dealers are perfectly aware of the fact that OxyContin is little more than a decades-old standby among drugs of abuse.

³³ For a highly critical view of the media coverage of OxyContin abuse, see *id.* (describing the public reaction to OxyContin abuse as “Oxy-Mania”).

³⁴ See Office of Nat’l Drug Control Policy, *Street Terms: Drugs and the Drug Trade*, <http://www.whitehousedrugpolicy.gov/streetterms/ByType.asp?intTypeID=58> (last visited Feb. 1, 2006); see also MEIER, *supra* note 28, at 46 (noting that “[s]ome newspaper writers had started calling [OxyContin] ‘hillbilly heroin’”).

³⁵ NAT’L DRUG INTELLIGENCE CTR., DEP’T OF JUSTICE, *OXYCONTIN DIVERSION AND ABUSE 3* (2001) [hereinafter DOJ BULLETIN].

³⁶ *Id.* at 2.

³⁷ Ausness, *Non-Defective Products*, *supra* note 3, at 915–16.

baugh illustrates.³⁸ The most important factor, perhaps, in the spread of OxyContin abuse is that it was available in every American community well before potential abusers were even aware of its existence. Thus, every town and city effectively harbored a preexisting supply of OxyContin ready for the black market; so long as there was a user or dealer sufficiently clever and motivated to “divert” the drug, a black market was one dubious prescription away.³⁹

“Drug diversion” refers to all of the processes by which legal prescription drugs are ultimately placed in the hands of those for whom the drug has not been *legitimately* prescribed, whether directly by the end user or through a black-market stream of commerce.⁴⁰ Drug diversion is fueled both by physicians who knowingly or unknowingly prescribe scheduled drugs to persons who do not actually need them, and by legitimate patients who forgo one or more doses in order to later sell or simply share with friends. The Department of Justice identifies a number of primary sources for the diversion of OxyContin, which are by no means peculiar to this drug, specifically: “doctor shopping,” “improper prescribing practices,” and “pharmacy diversion.”⁴¹

First, the Department of Justice notes that “[t]he most widely used diversion technique at the street level is doctor shopping,” the practice of visiting large numbers of physicians and convincing them that there is a legitimate need for a prescription.⁴² This technique is not only effective at the level of the individual abuser, but is also available to black market dealers seeking to obtain large amounts of narcotics. Indeed, such charades are often conducted on a large scale, with some drug seekers going so far as to visit doctors in multiple states.⁴³

Second, illegal prescribing practices have facilitated significant drug diversion.⁴⁴ Unscrupulous physicians—who are fully aware that the “patient” has no legitimate need for prescription narcotics—may nonetheless prescribe controlled substances on demand, in order to reap a profit.⁴⁵ Sometimes these activities encompass a doctor’s entire practice, rendering it nothing more than a vehicle for generating revenues from sales of illicit

³⁸ Mark Whitaker, *Top of the Week; The Editor's Desk*, NEWSWEEK, Oct. 20, 2003, at 4 (“Limbaugh admitted to his 20 million listeners that he was ‘addicted to prescription pain medication’ and would check into a 30-day rehab program. The announcement came a week after Limbaugh’s former housekeeper disclosed that she had illegally purchased thousands of OxyContin pills for him over a four-year period, and was cooperating in an official probe.”).

³⁹ *See id.* at 4–5.

⁴⁰ *Id.* at 4.

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Tough, *supra* note 23.

⁴⁵ *See, e.g.*, MEIER, *supra* note 28, at 298–303.

prescriptions. Such operations are often referred to as “pill mills”⁴⁶ and are quite common in areas where OxyContin abuse is high.

Finally, “pharmacy diversion” occurs where workers or thieves divert OxyContin by removing the physician from the picture altogether. Pharmacy diversion may be effectuated either by forging prescriptions or by simply stealing drugs from the pharmacy’s shelves.⁴⁷ Demand for OxyContin has surged so much that a number of pharmacies “have stopped carrying the drug for fear of break-ins.”⁴⁸ Additionally, foreign pharmacies located in countries with relatively lax or ineffective controls on the sale of prescription narcotics have long fueled “pharmacy diversion,” supplying U.S. black markets with ample quantities of prescription pharmaceuticals—and OxyContin is no exception.⁴⁹ One commentator on the underground trade in prescription pharmaceuticals generally has noted that “[t]here are approximately ten times as many pharmacies in Tijuana” as in San Diego, though both are “cities of roughly equal population.”⁵⁰ This imbalance is common among Mexican cities along the U.S. border, due to a robust cross-border trade in prescription drugs for both personal use and illicit resale.⁵¹ While much of this trade is attributable to nonrecreational prescription drug users⁵² seeking a cheaper alternative to the domestic market,⁵³ the cross-border pharmaceutical trade has become a boon for illicit suppliers of scheduled narcotics.⁵⁴ In 1998, two years after OxyContin’s launch, only about 5000 grams of OxyContin were shipped to Mexico.⁵⁵ This number, however, increased to approximately 26,500 grams in 1999 and a staggering 89,000 grams in 2000.⁵⁶

⁴⁶ *Id.* at 302.

⁴⁷ *Id.* at 298–302.

⁴⁸ O’Brien, *supra* note 5, at 3.

⁴⁹ See Donald E. deKieffer, *The Mexican Drug Connection: How Trade in Pharmaceuticals Has Wrecked the FDA*, 9 SW. J.L. & TRADE AM. 321 (2003).

⁵⁰ *Id.* at 322.

⁵¹ *Id.* at 323.

⁵² This group includes both “legitimate” users of scheduled drugs, as well as those seeking drugs with no potential for abuse (such as antibiotics).

⁵³ For a brief discussion of the economic factors that result in lower prescription drug prices in many foreign markets, such as Mexico, see deKieffer, *supra* note 49, at 325–27 (attributing these price differentials to less rigorous regulatory schemes, less stringent patent protection and, in turn, drug counterfeiting).

⁵⁴ DOJ INTELLIGENCE BRIEF, *supra* note 16, at 7–8.

⁵⁵ *Id.* at 7.

⁵⁶ *Id.*

III. INJURED ABUSER AS PLAINTIFF: THE DIFFICULTY OF ESTABLISHING LIABILITY

A. Drug Abusers as the Primary Source of OxyContin Injuries

The media storm created by the abuse of OxyContin has resulted in increased scrutiny of “legitimate” uses of the drug, including increased fear of accidental patient overdoses as well as “iatrogenic” addiction, a term that describes addiction resulting from legitimate use of a drug to combat pain.⁵⁷ Distinguishing between the harms caused by legitimate use of OxyContin and those caused by its intentional abuse is crucial. By confounding the harms caused by “well-intentioned” OxyContin over-prescription with those caused by deliberate diversion and abuse of OxyContin, we confuse the harms that can and cannot be caused by aggressively marketing narcotics to physicians.

Some commentators have accused OxyContin of presenting serious risks to pain patients, and, in turn, there have been a large number of (mostly “conventional”) lawsuits against Purdue alleging, inter alia, negligence⁵⁸ and design defect.⁵⁹ For instance, some patients allege harm or addiction to OxyContin resulting from use of the drug as prescribed, where those prescriptions were well within the confines of uses clearly approved by the FDA.⁶⁰ These suits, however, have been unsuccessful, perhaps in part because of increasing agreement that the drug’s benefits outweigh its risks when it is appropriately prescribed.

More commentators are showing concern that the drug is not as dangerous to legitimate patients as some would urge, and fears that many OxyContin addicts started out as legitimate patients using the drug as prescribed have largely subsided.⁶¹ Recent data suggest that most OxyContin addiction does not result from indiscriminate, “off-label” overprescribing of the drug but, rather, existing drug abusers who were simply trying out a new product.⁶² Additionally, regarding the risk of fatal overdose, a recent study showed that, of all deaths involving oxycodone (and not necessarily OxyContin, specifically), most involved the concomitant use of illicit drugs, other prescription narcotics, alcohol, or a combination of these substances.⁶³

⁵⁷ The term “iatrogenic” means, literally, “physician-induced.” See What Does the Word “Iatrogenic” Mean?, Am. Iatrogenic Ass’n, <http://www.iatrogenic.org/define.html> (last visited Jan. 21, 2006).

⁵⁸ See, e.g., Labzda v. Purdue Pharma L.P., 292 F. Supp. 2d 1346, 1356 (S.D. Fla. 2003).

⁵⁹ See Cornelius v. Cain, No. CACE 01-020213(02), 2004 WL 48102 (Fla. Cir. Ct. Jan. 5, 2004).

⁶⁰ See, e.g., Howland v. Purdue Pharma, L.P., 2003 Prod. Liab. Rep. (CCH) ¶ 16,694 (Ohio Ct. App. July 14, 2003).

⁶¹ See, e.g., Sally Satel, *Painful Correction: OxyContin’s Bad Rap*, FORBES, Sept. 6, 2004, at 48.

⁶² Edward J. Cone et al., *Oxycodone Involvement in Drug Abuse Deaths: A DAWN-Based Classification Scheme Applied to an Oxycodone Postmortem Database Containing over 1,000 Cases*, 27 J. ANALYTICAL TOXICOLOGY 57, 64–66 (2003).

⁶³ *Id.* at 66.

That study found that, although “[a] total of 919 deaths were classified as either being induced by or related to drug abuse[,] . . . only 30 deaths were identified that solely involved abuse of oxycodone” and, of those, only “12 deaths could be identified involving the specific drug product OxyContin.”⁶⁴ However, even on the assumption that OxyContin is acceptably safe when used within FDA guidelines, the drug nonetheless presents *some* degree of substantial risk to “legitimate” pain patients. As a Schedule II narcotic, it should not surprise reasonable observers that the drug poses inherent risks, including at least some risk of iatrogenic addiction.

Regardless of whether harm through prescription use is prevalent, liability may be reasonable for harms caused to patients prescribed OxyContin by doctors who were confused or misled by Purdue’s aggressive marketing. Those patients might have potential claims against Purdue in a direct sense, such as for negligent marketing to physicians. Liability does not seem justified for harms that have befallen those who purchased OxyContin from drug dealers or those who deceived well-meaning physicians into writing a prescription. For them, it was neither Purdue’s marketing nor the design of the pills that caused drug abusers harm but rather their own decisions to intentionally misuse the pills for recreational purposes. Thus, drug abuse as the source of injury appears to be a losing case. However, as the West Virginia suit demonstrates, room for litigation may still exist for harm resulting from this second category of use. While the former group of plaintiffs is more characteristic of those bringing conventional tort suits, the West Virginia suit demonstrates that the indirect harms caused to the community by the latter category of users allow for a unique sort of plaintiff: the public entity.

B. Suits Brought by Patients and Abusers

By late 2003, OxyContin was the source of nearly 300 state and federal lawsuits against Purdue, including a number of class-action complaints.⁶⁵ Plaintiffs have asserted claims against Purdue under a number of “traditional” tort theories, including negligence, defective design, and failure to warn,⁶⁶ as well as under theories relating to Purdue’s marketing and promotion of OxyContin.⁶⁷ In response, Purdue has taken an aggressive stance in

⁶⁴ *Id.*

⁶⁵ See O’Brien, *supra* note 5.

⁶⁶ See, e.g., Howland v. Purdue Pharma, L.P., [2003] Prod. Liab. Rep. (CCH) ¶ 16,694 (Ohio Ct. App. July 14, 2003), available at 2003 WL 21637968; Ohler v. Purdue Pharma, L.P., No. 01-3061, 2002 WL 88945 (E.D. La. Jan. 22, 2002).

⁶⁷ See, e.g., McCauley v. Purdue Pharma L.P., 331 F. Supp. 2d 449 (W.D. Va. 2004) (granting defendant Purdue Pharma’s motion for summary judgment on claim that “Purdue marketed the drug to the plaintiffs’ physicians by falsely representing in written promotional materials and in oral claims made by its sales representatives that OxyContin was safer, less addictive, and less prone to abuse than other oxycodone-based pain medications”).

order to avoid “pay[ing] a dime to a plaintiff” in these cases, and has so far incurred tens of millions of dollars in legal fees.⁶⁸

Design defect claims against Purdue are founded on the notion that OxyContin’s time-release mechanism did not work as it should, and thus resulted in overdose or addiction.⁶⁹ In some of these design defect cases, plaintiffs have alleged that the design of the OxyContin tablets increased the risk of overdose, but these suits have not been successful.⁷⁰ And, where plaintiffs were illegal users, who often intentionally defeated the time-release mechanism, the extent of their deliberate misuse tended to render any sort of claim impracticable.⁷¹

Courts have been reluctant to find causation not only in “conventional” tort claims alleging defective design of OxyContin tablets but also in other doctrinal contexts. The common thread between courts’ rejection of nearly all of these claims is the difficulty in establishing causation and duty between conduct and injury.⁷² First, courts in most jurisdictions will distinguish between the mere *negligent* misuse and the *intentional* misuse of prescription drugs. Foreseeably negligent misuse of a drug does not bar a finding of proximate causation in such jurisdictions, but a court will apply the doctrine of “sole proximate cause” where a drug user “intentionally misuses a product to his detriment.”⁷³ For example, in a wrongful death action brought against Purdue by an OxyContin abuser, a district court granted summary judgment for Purdue on the ground that “intentional misuse of an intoxicating product is the sole proximate cause of the [plaintiff’s] injury” due to the fact that he had “*intentionally* . . . misused the product by crushing and inhaling it.”⁷⁴ Second, courts have not been receptive to plaintiffs’ contentions that drug manufacturers have an “affirmative duty to police their product in the stream of commerce.”⁷⁵ Those courts have referred not only to applicable law specific to the jurisdiction, but to the broader common law concepts espoused by the *Restatement (Second) of Torts* in rejecting the existence of such a duty.⁷⁶

⁶⁸ O’Brien, *supra* note 5, at 3. For cases in which Purdue challenged the class certification instead of settling, *see, e.g., Howland*, [2003] Prod. Liab. Rep. (CCH) ¶ 16,694; *Ohler*, 2002 WL 88945.

⁶⁹ *See, e.g., Wethington v. Purdue Pharma L.P.*, 218 F.R.D. 577, 586–87 (S.D. Ohio 2003) (denying class certification to a group of plaintiffs arguing, *inter alia*, that Purdue was “liable for manufacturing a defective, highly addictive product that lacks an antagonist agent to prevent its euphoric effects when crushed and ingested”).

⁷⁰ *See Cornelius v. Cain*, No. CACE 01-020213(02), 2004 WL 48102 (Fla. Cir. Ct. Jan. 5, 2004).

⁷¹ *See, e.g., Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346, 1355–56 (S.D. Fla. 2003).

⁷² *See generally* Ausness, *Non-Defective Products*, *supra* note 3.

⁷³ *Labzda*, 292 F. Supp. 2d at 1356 (applying Florida law).

⁷⁴ *Id.* (emphasis added).

⁷⁵ *Id.* at 1353. *See also infra* Part IV.A.1 for a more detailed discussion of negligent marketing generally, as well as the alleged “duty” to supervise distribution of potentially harmful products specifically.

⁷⁶ *Labzda*, 292 F. Supp. 2d at 1353–55 (“There is not now, nor has there ever been, any common law duty for either a private person or a governmental entity to enforce the law for the benefit of an individual or a specific group of individuals.” (quoting *Trianon Park Condo. Ass’n, Inc. v. City of Hialeah*, 468

In addition, it is noteworthy that a court's consideration of causation in a case involving drug abuse can often carry moral overtones. In some jurisdictions, the fact that the abuser committed an illegal and ostensibly immoral act in helping to bring about her injury can influence a court's decision of whether to apply a contributory negligence doctrine in lieu of a comparative fault doctrine.⁷⁷ Generally speaking, the application of a contributory negligence doctrine serves to bar a plaintiff's claim altogether, whereas the application of a comparative fault doctrine serves only to *mitigate* damages.⁷⁸ As a result, courts have held illegal abuse of a drug to bar recovery in many jurisdictions, including Kentucky,⁷⁹ Michigan,⁸⁰ and, interestingly, West Virginia.⁸¹

Courts' considerations in cases brought by drug abusers should apply to suits brought by public entities suing on behalf of drug abusers, to the extent that these entities seek compensation for the havoc that intentional abusers have wrought on the community.⁸² Seemingly, claims of mere negligence or a design defect in the time-release mechanism brought by drug abusers have been rejected because of the drug user's own intervening illegal act. This basis for harm still exists even for communities indirectly affected by the drug abuse. Just as intentional abuse of a prescription narcotic eviscerates the causal link between that drug and an abuser's injury in a conventional suit, abuse frustrates causation in a claim based on the *aggregate* harm caused by a great many intentional abusers.

IV. PUBLIC ENTITY AS CLAIMANT: WHEN DRUG ABUSE HARMS THE BROADER COMMUNITY

A. *Unconventional Tort Theories and Public Entities Generally*

Causation problems make it difficult for drug addicts—and especially those drug addicts who have intentionally misused a product for recreation—to assert liability against a prescription narcotics manufacturer. Public entity suits provide a unique method to circumvent these causation problems by alleging that a pharmaceuticals manufacturer has harmed the community as a whole through its product marketing, distribution practices, or both. To illustrate, note the difference between an OxyContin abuser al-

So. 2d 912, 918 (Fla. 1985) (citing RESTATEMENT (SECOND) OF TORTS § 315 (1965) in applying Florida law)).

⁷⁷ See, e.g., *Labzda*, 292 F. Supp. 2d at 1355–56.

⁷⁸ See also *id.* Compare RESTATEMENT (SECOND) OF TORTS § 465 cmt. b, with *id.* § 433A.

⁷⁹ *Foister*, 295 F. Supp. 2d at 704–05 (discussing such a bar in the context of “public policy”).

⁸⁰ *Orzel v. Scott Drug Co.*, 537 N.W.2d 208, 212–15 (Mich. 1995).

⁸¹ Mark A. Ford, Note, *Another Use of OxyContin: The Case for Enhancing Liability for Off-Label Drug Marketing*, 83 B.U. L. REV. 429, 437 (2003) (citing *West Virginia Judge Dismisses OxyContin Case Against Purdue Pharma*, DRUG WK., Oct. 4, 2002, at 30).

⁸² See generally *West Virginia Complaint*, *supra* note 7.

leging that Purdue's marketing practices caused *her* harms and the state alleging that those same practices negligently facilitated her rampant drug abuse, which, in turn, caused harms to *the public*.

In spite of courts' reluctance to accept the novel doctrines advanced during the recent surge of public entity suits against gun manufacturers,⁸³ these suits nonetheless provide a means of pursuing revenue.⁸⁴ Even a few plaintiffs' success stories may render these doctrines increasingly attractive to public entities in need of revenues and, though unpredictable and prone to dismissal, such suits remain tempting sources of income.⁸⁵ As West Virginia's \$10 million settlement demonstrates, such strategies may sometimes prove lucrative.⁸⁶

Public entities have filed high-profile lawsuits not only against gun manufacturers,⁸⁷ but also against tobacco companies and manufacturers of lead paint products.⁸⁸ While a *city* has yet to file suit against a pharmaceutical manufacturer, the state of West Virginia has already pursued such "'social issue' tort litigation"⁸⁹ successfully in the context of OxyContin. States face similar revenue problems as cities and are likewise incentivized to file suit in pursuit of revenue.⁹⁰ Additionally, other states that have faced the highest rates of OxyContin abuse are, for the most part, similarly situated.⁹¹ Therefore, it is unsurprising that West Virginia chose this route when the opportunity arose. In return, West Virginia generated a substantial amount of revenue from its \$10 million settlement with Purdue.⁹²

In its suit, West Virginia relied upon two basic types of novel product liability theories: negligent marketing⁹³ and public nuisance.⁹⁴ This section provides a brief sketch of the characteristics and history of these "unconventional" tort doctrines and discusses the crucial role that public entities have played—as plaintiffs—in spawning these unconventional doctrinal vehicles.

⁸³ See, e.g., *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055 (N.Y. 2001).

⁸⁴ See, e.g., Cleary, *supra* note 9; Gavioli, *supra* note 13; cf. Patterson & Philpott, *supra* note 14.

⁸⁵ Cleary, *supra* note 9; Gavioli, *supra* note 13.

⁸⁶ *OxyContin Lawsuit Is Settled*, *supra* note 8.

⁸⁷ See, e.g., *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004).

⁸⁸ Gavioli, *supra* note 13, at 946–51.

⁸⁹ *Id.* at 951.

⁹⁰ It is notable that the states that have been hit the hardest by the OxyContin epidemic are largely poor and rural, such as West Virginia and the contiguous "Appalachian" states. As such, West Virginia's settlement may motivate similarly situated states to respond to the lawsuit in kind.

⁹¹ *Id.*

⁹² *OxyContin Lawsuit Is Settled*, *supra* note 8.

⁹³ See West Virginia Complaint, *supra* note 7, at 16–19, 23–26. Note that West Virginia was asserting negligent marketing claims based on *both* the promotion *and* distribution of OxyContin.

⁹⁴ See *id.*

1. *Negligent Marketing*.—Negligent marketing is a relatively new theory of liability, first conceived in the context of the sale and manufacture of firearms and first recognized by a court in the 1999 case *Hamilton v. Accu-Tek*.⁹⁵ This theory “assumes that [manufacturers and sellers] have a duty to market their products in a manner that will not affirmatively increase a product’s inherent risk to consumers and third parties.”⁹⁶ Support for negligent marketing gained momentum when a later California court recognized the theory in *Merrill v. Navegar, Inc.*⁹⁷ In both cases, however, the theory was rejected on appeal,⁹⁸ leading one noted commentator on negligent marketing, Professor Richard Ausness, to opine that “the status of negligent marketing claims remains very much in doubt.”⁹⁹ Nonetheless, West Virginia’s settlement suggests that negligent marketing claims (and product public nuisance claims) nonetheless pose a real threat.

Professor Ausness delineates three broad categories of negligent marketing claims: first, claims based on a product’s design; second, claims based on advertising and promotional activities; and, finally, claims based on negligent distribution practices.¹⁰⁰ As West Virginia’s suit highlights, negligence claims based on promotional and distributional practices are of particular interest to pharmaceutical manufacturers.¹⁰¹ Specifically, Ausness notes that liability may arise from pharmaceutical companies’ efforts to “pressure or bribe doctors to prescribe [drugs] . . . in excessive dosages or to persons who do not really need them.”¹⁰² Ausness terms such activity “overpromotion,” and opines that “[r]ecent experience involving the painkiller OxyContin illustrates the potential applicability of [the overpromotion] form of negligent marketing to prescription drug sellers,” because of Purdue’s alleged attempts to promote the drug for inappropriate uses.¹⁰³

Distribution-centered strains of negligent marketing stem not from the advertising or promotion of a product per se but, rather, on the actual distribution of the product.¹⁰⁴ Professor Ausness explicitly defines negligent distribution claims as a “form of negligent marketing” that focus on the notion that a product’s distribution may allow inappropriate users to “more easily obtain access to it at the retail level.”¹⁰⁵ In its OxyContin suit, West Vir-

⁹⁵ 62 F. Supp. 2d 802 (E.D.N.Y. 1999); see Ausness, *Non-Defective Products*, supra note 3, at 909.

⁹⁶ Ausness, *Non-Defective Products*, supra note 3, at 908–09.

⁹⁷ 89 Cal. Rptr. 2d 146 (Ct. App. 1999); see Ausness, *Non-Defective Products*, supra note 3, at 909.

⁹⁸ *Merrill v. Navegar, Inc.*, 28 P.3d 116 (Cal. 2001), rev’g 89 Cal. Rptr. 2d 146; *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055 (N.Y. 2001) (rejecting negligent marketing as a viable theory under New York law on a certification of the issue from Second Circuit Court of Appeals).

⁹⁹ Ausness, *Non-Defective Products*, supra note 3, at 909.

¹⁰⁰ *Id.* at 912–17.

¹⁰¹ Ausness, *Aggressive Marketing Practices*, supra note 3, at 133–35.

¹⁰² *Id.* at 133.

¹⁰³ *Id.*

¹⁰⁴ Ausness, *Non-Defective Products*, supra note 3, at 915.

¹⁰⁵ *Id.*

ginia relied on this type of a claim in its allegation that Purdue's practice of supplying Mexican pharmacies "facilitate[ed] the inappropriate use of OxyContin" simply because "members of the public [could] obtain OxyContin from these pharmacies without a prescription."¹⁰⁶ Ausness notes that this charge "resembles one of the negligent marketing claims brought against handgun manufacturers in *Hamilton v. Accu-Tek*," in that it comprises a negligent failure to supervise retailers claim.¹⁰⁷

2. *Public Nuisance in the Products Arena.*—An additional (yet still emerging and uncertain) vehicle has grown from the more traditional theory of public nuisance, and similarly poses a threat to pharmaceutical manufacturers.¹⁰⁸ Public nuisance is an unconventional avenue in the context of products liability litigation.¹⁰⁹ The *Restatement (Second) of Torts* identifies public nuisance as "an unreasonable interference with a right common to the general public,"¹¹⁰ and the doctrine has roots extending far back into the English common law.¹¹¹ More recently, plaintiffs have attempted to stretch its boundaries to cover product liability for the manufacture, marketing, and sale of asbestos,¹¹² firearms,¹¹³ tobacco,¹¹⁴ and—most recently with West Virginia's suit—OxyContin.¹¹⁵

At first glance, stretching public nuisance into the products realm may not seem entirely unreasonable. The Restatement speaks of "interference with a public right"¹¹⁶ and looks to whether the "actor knows or has reason to know" that her actions "ha[ve] a significant effect upon the public right."¹¹⁷ As such, the doctrine can be so extended by simply framing the negative societal impacts of dangerous products in terms of interference with a "public right."¹¹⁸ Expansion of the doctrine, however, has engendered much academic criticism,¹¹⁹ and attempts to extend the doctrine to

¹⁰⁶ West Virginia Complaint, *supra* note 7, at 9; see Ausness, *Non-Defective Products*, *supra* note 3, at 915–16.

¹⁰⁷ Ausness, *Aggressive Marketing Practices*, *supra* note 3, at 135 (discussing *Hamilton v. Accu-Tek*, 62 F. Supp. 2d 802 (E.D.N.Y. 1999)).

¹⁰⁸ West Virginia Complaint, *supra* note 7, at 16–19.

¹⁰⁹ See Cleary, *supra* note 9, at 278–88.

¹¹⁰ RESTATEMENT (SECOND) OF TORTS § 821B (1965).

¹¹¹ See Cleary, *supra* note 9, at 276–78.

¹¹² See *id.* at 280–82 (discussing the failures of numerous attempts to establish liability for the production and sale of asbestos under a public nuisance theory).

¹¹³ See, e.g., *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055 (N.Y. 2001); see also Cleary, *supra* note 9, at 282–88; Morgan, *supra* note 3, at 521.

¹¹⁴ See Patterson & Philpott, *supra* note 14, at 549.

¹¹⁵ See West Virginia Complaint, *supra* note 7, at 16–19.

¹¹⁶ RESTATEMENT (SECOND) OF TORTS § 821B(2) (1965).

¹¹⁷ *Id.* § 821B(2)(c).

¹¹⁸ See, e.g., Cleary, *supra* note 9, at 280.

¹¹⁹ *Id.*

cover products liability in the context of asbestos have failed outright.¹²⁰ Similarly, expansion in the context of firearms has achieved mixed results in convincing courts to allow such claims to go to trial.¹²¹ As time wears on, however, courts have been increasingly reluctant to recognize the merits of public nuisance claims in the context of public entity firearms litigation.¹²²

In a recent decision, the Supreme Court of Illinois granted a defendant-firearms manufacturer's motion to dismiss a public nuisance claim levied by the city of Chicago.¹²³ There, the court penned a fifty-page opinion criticizing the plaintiff's proposed extension of public nuisance doctrine, specifically noting that firearms are "product[s] that may be possessed legally by some persons, in some parts of the state."¹²⁴ The court's dismissal was based on two primary considerations. First, the court took issue with the plaintiff's attempts to establish causation, noting that "the alleged public nuisance is not so foreseeable to the dealer defendants that their conduct can be deemed the legal cause of a nuisance that is the result of the aggregate of the criminal acts of many individuals over whom they have no control."¹²⁵ Second, the court stressed its "reluctance to expand nuisance liability in an area highly regulated by both state and federal law" in such a way as to "creat[e] an entirely new species of public nuisance liability."¹²⁶ Such drastic action, it concluded, "must be the work of the legislature, brought about by the political process."¹²⁷

B. *West Virginia's Public Entity Suit Against Purdue*

The success of Purdue's aggressive litigation strategy established that more traditional avenues of tort liability would not be effective in targeting the real source of the OxyContin problem—its abuse.¹²⁸ In 2001, the Attorney General of West Virginia, Darrell McGraw, Jr., filed suit against Purdue in an attempt to establish liability on the basis of Purdue's production, promotion, marketing, and distribution of OxyContin.¹²⁹ In total, the com-

¹²⁰ *Id.* at 280–82.

¹²¹ *Id.* at 282–88.

¹²² *See, e.g., id.* at 280.

¹²³ *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004).

¹²⁴ *Id.* at 1121.

¹²⁵ *Id.* at 1138.

¹²⁶ *Id.* at 1148.

¹²⁷ *Id.*

¹²⁸ *See* Tim O'Brien, *Suits Abound by Users Claiming Addiction to Painkiller OxyContin*, N.J.L.J., Oct. 21, 2003, at 1, available at <http://www.law.com/jsp/article.jsp?id=1066605407030>.

¹²⁹ West Virginia Complaint, *supra* note 7, at 1. Specifically, the complaint named as defendants Purdue Pharma, L.P., Purdue Pharma, Inc., Purdue Frederick Company, Inc., Abbott Laboratories, and Abbott Laboratories, Inc. *Id.* Purdue has an agreement with Abbott Laboratories making in a "co-promoter" of OxyContin, and "Purdue allegedly agreed to indemnify Abbott Laboratories for all liabili-

plaint set forth seven causes of action: violation of the West Virginia Consumer Credit Protection Act, continuing public nuisance, unjust enrichment/restitution, indemnity, negligence, medical monitoring, and, finally, violation of West Virginia's antitrust statutes.¹³⁰ Despite Purdue's otherwise aggressive, "no-settle" stance taken in other litigation¹³¹—which has cost it approximately \$250 million to sustain for three long years¹³²—it finally settled with West Virginia for the sum of \$10 million, money which "will finance doctor continuing-education programs, law enforcement drug-prevention programs and community drug-rehabilitation programs."¹³³

West Virginia alleged that its state agencies incurred some \$30.5 million in OxyContin related expenditures between 1996 and 2003.¹³⁴ Its complaint struggled to tie Purdue's aggressive marketing of OxyContin to the costs that the state had borne out because of OxyContin abuse, alleging that Purdue's marketing led to "excessive, inappropriate [sic] and unnecessary prescriptions of OxyContin" and, thus, that "citizens and consumers of West Virginia, who have legitimately and legally paid for OxyContin, have incurred actual damages and excessive costs."¹³⁵ Thus, West Virginia sought, inter alia, "restitution and reimbursement sufficient to cover all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including but not limited to addiction due to defendants' wrongful conduct," as well as "restitution and reimbursement sufficient to cover all prescription costs the State has incurred related to OxyContin due to defendants' wrongful conduct."¹³⁶ The "wrongful conduct" presumably relates to Purdue's marketing and distribution practices.

I. West Virginia Effectively Sought to Recover for Harms Caused by OxyContin Abuse.—

On its face, the complaint simply sought to gain reimbursement for costs to the state caused by the unnecessary prescription of OxyContin: first, the direct costs associated with the state payment for patients' prescriptions and, second, for the indirect expenses related to overprescribing, such as state efforts to treat iatrogenic addiction.¹³⁷ Tellingly, however, the

ties . . . in relation to OxyContin." *1st Imp: Defense Costs Not Damages in Policy*, CONN. L. TRIB., Sept. 27, 2004, at 219.

¹³⁰ West Virginia Complaint, *supra* note 7, at 12–30.

¹³¹ See, e.g., Heather Smith, *The Pain Continues*, AM. LAW., Jan. 2004, at 29.

¹³² *1st Imp: Defense Costs Not Damages in Policy*, *supra* note 129. This figure includes all legal defense fees for both Purdue and its codefendant Abbott Laboratories, which it contracted to help promote OxyContin. *Id.*

¹³³ *OxyContin Lawsuit Is Settled*, *supra* note 8.

¹³⁴ *Id.*

¹³⁵ West Virginia Complaint, *supra* note 7, at 12.

¹³⁶ *Id.* at 18.

¹³⁷ Although West Virginia never specified the amount sought to compensate it for the costs of treating addiction, it specifically sought \$30.5 million for costs associated with the overprescription of

complaint alleged that “ten of the 55 counties in West Virginia, all in the southern part of the state, accounted for approximately 48% of the total prescriptions paid for by” the West Virginia Department of Health and Human Resources.¹³⁸ This disparity in the geographic source of claims betrays the real nature of West Virginia’s suit, exposing it as a vehicle by which to conflate the harms caused by the legitimate—albeit potentially medically unnecessary—use of OxyContin with the harms caused by blatant abusers who obtained the drug via purposeful diversion and related black markets.

Although it is conceivable that a higher number of pain patients would be concentrated in these areas, or that doctors working in these areas would be less informed and, thus, more susceptible to Purdue’s marketing claims, these factors do not offer a persuasive explanation for the geographical disparity. This inconsistency can be better explained by considering that the more concentrated locations are the very areas of West Virginia where black markets for OxyContin were most flourishing.¹³⁹ The harm is more likely to have resulted from increased doctor shopping and the operation of so-called pill mills, i.e., criminal activity perpetrated by drug seekers and often intentionally aided by physicians, as opposed to random chance. This notion is supported by two distinct propositions.

First, to be blunt, doctors are not stupid. As this Comment has already stressed, OxyContin contains but one active ingredient, oxycodone, which has been in common use for longer than the vast majority of physicians have been alive.¹⁴⁰ Moreover, OxyContin is a Schedule II drug, and all physicians prescribing it are acutely aware of that fact and its implications.¹⁴¹ Indeed, OxyContin received the most restrictive classification available for a prescription drug due to its “high potential for abuse.”¹⁴² While it is true that OxyContin’s marketing may have increased well-intentioned prescriptions of the drug, a marketing strategy that would have equal impact in all markets is unlikely to explain the geographical disparities in the prescribing volume of the drug. This geographic concentration of addiction speaks more of a *culture* of abusers seeking the drug for recreational purposes. Cultural and educational disparities, among other factors, could account for some increase in iatrogenic addiction from region to region.¹⁴³ Such factors

OxyContin. Associated Press, *West Virginia, OxyContin Manufacturer Settle Suit*, NAT’L L.J., Nov. 15, 2004, at 10.

¹³⁸ *Id.* at 11.

¹³⁹ See DOJ INTELLIGENCE BRIEF, *supra* note 16, at 2–3; DOJ BULLETIN, *supra* note 35, at 1–2. Southern West Virginia borders on Kentucky and Virginia, and is near the geographical center of Appalachian OxyContin black markets.

¹⁴⁰ Tough, *supra* note 23, at 34.

¹⁴¹ Moreover, OxyContin’s status as a Schedule II drug is not only mentioned but displayed prominently in its ads. See, e.g., November 2002 OxyContin Advertisement, <http://www.fda.gov/cder/warn/2003/JamaAdNov02.pdf> (last visited Feb. 1, 2006).

¹⁴² 21 U.S.C. § 812(b)(2)(A) (2000).

¹⁴³ See DOJ INTELLIGENCE BRIEF, *supra* note 16, at 2–3; DOJ BULLETIN, *supra* note 35, at 1–2.

cannot account for *all* of the regional variances, however, given the degree to which the concentration of OxyContin abuse varies between socio-economically comparable states.¹⁴⁴

Second, West Virginia alleged that Purdue's practice of supplying Mexican pharmacies "facilitate[ed] the inappropriate use of OxyContin," because Purdue was "aware that members of the public [could] obtain OxyContin from these pharmacies without a prescription."¹⁴⁵ This allegation clearly sought to establish liability for OxyContin abuse resulting not from innocent albeit unnecessary prescriptions but, rather, from the illicit diversion of OxyContin. The claim evidences the weak causal link between Purdue's actions and West Virginia's harms because it underscores the important causal role played by drug abusers and addicts who were purchasing the drug through black markets.

2. *The Primary Basis of West Virginia's Suit: Purdue's Controversial Marketing.*—

Although Purdue has never engaged in direct-to-consumer marketing of OxyContin, it does promote the drug to physicians, a ubiquitous practice in which virtually all prescription drug companies engage.¹⁴⁶ Purdue has utilized several methods of promoting OxyContin to physicians, including print advertising in medical journals,¹⁴⁷ "promotional giveaways" such as stuffed animals and compact discs,¹⁴⁸ as well as "seminars on pain management in resort locations like Arizona, California, and Florida."¹⁴⁹ Internal documents disclosed during a Florida investigation of Purdue's marketing described a "communication objective[] [to] . . . convince health care professionals . . . to aggressively treat both non-cancer pain and cancer pain"

¹⁴⁴ See, e.g., DOJ BULLETIN, *supra* note 35, at 1–2.

¹⁴⁵ West Virginia Complaint, *supra* note 7, at 9.

¹⁴⁶ *OxyContin Ads Pulled*, AM. MED. NEWS, Mar. 10, 2003, at 1, available at <http://www.ama-assn.org/amednews/2004/02/16/prsa0216.htm>. But see *Ohler v. Purdue Pharma, L.P.*, No. Civ. A 02-3061, 2002 WL 88945, at *2 (E.D. La. Jan. 22, 2002) (involving plaintiffs' allegations that Purdue promoted and marketed "OxyContin directly to consumers utilizing multimedia and the internet and otherwise facilitat[ed] the inappropriate unsafe use of the drug to increase its market").

¹⁴⁷ *OxyContin Ads Pulled*, *supra* note 146.

¹⁴⁸ MEIER, *supra* note 28, at 33.

¹⁴⁹ *Id.* at 96–97. Regarding these seminars, Meier argues:

Officials of the drugmaker always insisted when asked by reporters that the talks were generic in nature, intended only to raise medical awareness about the inadequacy of pain treatment rather than to market OxyContin. But any program promoting the use of long-acting narcotics also promoted OxyContin. The reason: the number of competing products could be counted on a few fingers.

Id. at 97.

In all fairness to Purdue, however, it is worth mentioning that Meier—who is cited rather extensively in this Comment—is one of Purdue's most outspoken critics, penning not only *Pain Killer* but also a large number of newspaper articles on OxyContin. See Trevor Butterworth, *The Great OxyContin Correction Controversy: Did Slate Correct Its Way into Error?*, STATS, Apr. 27, 2004, at 2–3, available at <http://www.stats.org/files/upld-news469pdf?.pdf>.

with OxyContin, stressing that “[t]he positive use of opioids, and OxyContin tablets in particular, will be emphasized.”¹⁵⁰

Purdue’s marketing first caught the attention of the Food and Drug Administration (“FDA”) in 2000, when the FDA sent a warning letter to Purdue “regarding a journal advertisement that appeared in the *New England Journal of Medicine* that promoted OxyContin in a manner that was false or misleading.”¹⁵¹ This letter charged that

the advertisement implied OxyContin had been studied in all types of arthritis and can be used as first-line therapy for the treatment of osteoarthritis, failed to include important limitations to claims presented from an osteoarthritis study; and promoted OxyContin in a selected class of patients without presenting risk information especially applicable to that selected class of patients.¹⁵²

Ultimately, Purdue ceased dissemination of the advertisement.¹⁵³

In January 2003, the FDA issued another warning letter to Purdue’s Executive Vice President and Chief Operating Officer, Michael Friedman, regarding two other advertisements for OxyContin that Purdue had published in respected medical journals, such as the *Journal of the American Medical Association* (“JAMA”).¹⁵⁴ In it, the FDA charged that Purdue’s “advertisements omit[ted] and minimize[d] the serious safety risks associated with OxyContin, and promote[d] it for uses beyond which [sic] have been proven safe and effective.”¹⁵⁵ In response to the FDA warning, Purdue discontinued the ads permanently.¹⁵⁶ It would appear that both of these print advertisements were similarly aimed at furthering Purdue’s objective of “convinc[ing] health care professionals . . . to aggressively treat both non-cancer pain and cancer pain.”¹⁵⁷ The FDA certainly thought so, including an entire section in its warning letter entitled “Overbroadening of Indi-

¹⁵⁰ MEIER, *supra* note 28, at 97–98.

¹⁵¹ *OxyContin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor, and Pensions*, 107th Cong. 18 (2002) (statement by John K. Jenkins, M.D., Director, Office of New Drugs, Food and Drug Administration) [hereinafter *OxyContin Hearing*].

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ Warning Letter from Thomas W. Abrams, Food & Drug Admin., to Michael Friedman, Executive Vice President and Chief Operating Officer, Purdue Pharma L.P. (Jan. 17, 2003), available at http://www.fda.gov/foi/warning_letters/g3797d.htm [hereinafter FDA Warning Letter]. Both the October ad and the November ad are available on the FDA’s website. October 2002 OxyContin Advertisement, <http://www.fda.gov/cder/warn/2003/JamaAdOct02.jpg> (last visited Feb. 1, 2006); November 2002 OxyContin Advertisement, <http://www.fda.gov/cder/warn/2003/JamaAdNov02.pdf> (last visited Feb. 1, 2006). Interestingly, the November ad included the following text, which the earlier October ad did not: “Purdue is firmly committed to maintaining the highest standards of marketing practices in the industry while continuing to advance the proper treatment of pain in America. If Purdue’s marketing and sales practices fail to meet this standard, we urge you to contact us at 1-888-690-9211.” *Id.*

¹⁵⁵ FDA Warning Letter, *supra* note 154, at 1.

¹⁵⁶ *OxyContin Ads Pulled*, *supra* note 146.

¹⁵⁷ MEIER, *supra* note 28, at 97–98.

cation,¹⁵⁸ which asserted that by “portray[ing] a seemingly healthy, unimpaired man out fishing and taking care of a child, rather than . . . a more typical person with persistent, moderate to severe pain,” Purdue was suggesting the use of OxyContin “for pain relief in a much broader range of patients than indicated.”¹⁵⁹ Ultimately, the FDA concluded that the advertisements were “misleading because they ma[de] prominent claims of effectiveness for pain relief, but omit[ed] from the body of the advertisements crucial facts related to the serious, potentially fatal safety risks associated with the use of OxyContin, the potential for OxyContin to be abused, and the limitations on its appropriate indicated use.”¹⁶⁰ Thus, the FDA concluded that both ads were in violation of print advertising regulations, and demanded that Purdue pull the ads immediately.¹⁶¹

3. *Purdue's Efforts to Combat OxyContin Abuse and Black Markets.*—Purdue has undertaken at least some response measures to rein in OxyContin black markets. Purdue's actions may very well make financial sense for the company: despite increased revenues from narcotic abuse and addiction, this is not a situation that a drug manufacturer wants to confront. Although diversion necessarily bolsters sales, black markets produce substantial costs in the form of bad publicity,¹⁶² as well as the costs incurred in defending tort actions¹⁶³ and coping with increased regulatory pressures.¹⁶⁴ Notably, one of Purdue's most outspoken critics has opined that “[t]here is no reason to believe that Purdue executives ever foresaw the catastrophe that OxyContin would create,” and that “[s]imilar disasters have befallen other drugmakers and every pharmaceutical company lives with the dread that it might be next.”¹⁶⁵

First, Purdue has spent a considerable sum on researching means by which abuse of OxyContin may be thwarted. As of October 2003, it had spent roughly \$200 million on preventing abuse of the drug, the bulk of which went toward “the development of an ‘antagonistic’ substance that would make it difficult for users to get the heroin-like rush if [abusers] crushed and then snorted or injected the tablet.”¹⁶⁶ Approximately \$50 mil-

¹⁵⁸ Translated into plain English, “overbroadening of indication” simply refers to an unjustifiable increase in the number of situations in which a drug is thought to be sufficiently safe and effective to warrant its use.

¹⁵⁹ FDA Warning Letter, *supra* note 154, at 5.

¹⁶⁰ *Id.* at 3.

¹⁶¹ *Id.* at 4–6.

¹⁶² *See, e.g., id.*

¹⁶³ O'Brien, *supra* note 5, at 3.

¹⁶⁴ *See* Associated Press, *Lawmakers: OxyContin Maker Failing to Curb Abuse*, USA TODAY, Dec. 20, 2001, <http://www.usatoday.com/news/health/addiction/2001-12-12-oxycontin.htm>.

¹⁶⁵ MEIER, *supra* note 28, at 293.

¹⁶⁶ O'Brien, *supra* note 5, at 3. Because OxyContin abusers must crush the tablets in order to thwart the time-release mechanism, it is conceivable that an opioid antagonist—a compound which would effectively negate the effects of the drug's active ingredient, oxycodone—could be incorporated

lion of those expenditures has gone toward “educating the public and medical community about the dangers of prescription drug abuse, as well as security efforts to combat thefts and illegal trafficking of OxyContin.”¹⁶⁷

Additionally, Purdue has certainly not ignored foreign distribution problems entirely. In direct response to concerns about illicit diversion, Purdue initially “restrict[ed] shipments of certain dosage strengths” to Mexico and “change[d] the indicium on tablets destined for the Mexican market” in order “to help identify tablets seized in the United States that are diverted from Mexico.”¹⁶⁸ Ultimately, Purdue ceased all shipments to Mexico following an armed robbery in December of 2001, in which nine thieves stole over 30,000 bottles of the drug from a Mexico City distributor.¹⁶⁹ Such precautions establish that Purdue was, at the very least, taking substantial action to mitigate the diversion of OxyContin.

C. *West Virginia’s Negligent Marketing Claims Conflated Promotion with Distribution*

There are two distinct aspects to West Virginia’s negligent marketing and public nuisance claims: one that inheres in Purdue’s promotional activities, and one that inheres in its distribution practices. It is crucial to distinguish between “direct-to-consumer” marketing of prescription pharmaceuticals and marketing that is directed at the prescribing physician. Pharmaceutical companies’ use of direct-to-consumer marketing has surged in recent years,¹⁷⁰ and—as a number of commentators have noted—such marketing may ultimately serve to expose drug manufacturers to increased liability.¹⁷¹ However, there is no reason to think that direct-to-consumer marketing has played a substantial role in Purdue’s marketing of OxyContin, generally.¹⁷² Rather, most charges that Purdue negligently marketed

such that crushing the tablet would activate or release the antagonist. Thus, the antagonist would not be of concern to “legitimate” oxycodone users, but would render the tablets wholly ineffective once crushed or otherwise altered so as to facilitate abuse. MEIER, *supra* note 28, at 303–06 (discussing Purdue’s inquiries into the possibility of incorporating naloxone—an opiate antagonist—into OxyContin tablets).

¹⁶⁷ O’Brien, *supra* note 5, at 3.

¹⁶⁸ DOJ INTELLIGENCE BRIEF, *supra* note 16, at 7.

¹⁶⁹ *Id.* at 7–8.

¹⁷⁰ Linda C. Fentiman, *Internet Pharmacies and the Need for a New Federalism: Protecting Consumers While Increasing Access to Prescription Drugs*, 56 RUTGERS L. REV. 119, 135–36 (2003).

¹⁷¹ See, e.g., Ausness, *Aggressive Marketing*, *supra* note 3, at 97; Fentiman, *supra* note 170, at 135–36.

¹⁷² *But see*, e.g., *Ohler v. Purdue Pharma L.P.*, No. Civ. A 01-3061, 2002 WL 88945, at *2 (E.D. La. Jan. 22, 2002) (granting motion to remand to state court). Plaintiffs alleged that Purdue was, inter alia, “marketing/promoting OxyContin directly to consumers utilizing multimedia and the internet and otherwise facilitating the inappropriate unsafe use of the drug to increase its market.” *Id.*

The accusations in this incarnation of *Ohler*—that OxyContin had been marketed directly to consumers—were based on information contained on the website “Partners Against Pain,” which offered information about chronic pain and its treatments to the general public. In such cases, the Partners

OxyContin have primarily focused instead on its promotion of “off-label” uses of the drug to *physicians*¹⁷³ to prescribe the drug as a “first-line” treatment against a broad range of pain.¹⁷⁴

“Overpromotion” is an apt descriptor of the theoretical basis of claims alleging that a physician inappropriately prescribed OxyContin to a plaintiff as a result of overly aggressive or even wholly off-label marketing.¹⁷⁵ In considering the close relation between distribution and marketing, however, it is important to note that there is a distinction between negligent advertising and negligent distribution.¹⁷⁶ This is most clearly illustrated by contrasting allegations that Purdue was acting negligently *simply because it supplied* OxyContin to Mexican distributors with allegations that its aggressive advertising to physicians led to overprescribing. West Virginia’s complaint contains both types of allegations.¹⁷⁷

Under Ausness’s framework, both the simple distribution to Mexican pharmacies and the alleged “overpromotion” may constitute negligent marketing, albeit for different reasons.¹⁷⁸ There is, however, an important distinction between “overpromotion” that leads physicians to simply prescribe OxyContin to the wrong patients and distribution practices that have the ancillary effect of facilitating diversion. But, there is also a connection between the two: by increasing the total number of prescriptions, “overpromotion” may facilitate diversion. The more often the drug is prescribed, the greater the total production and, in turn, more pills are available for diversion. An increase in the total number of prescriptions facilitates illicit diversion and, in so doing, fuels black markets. It is error, however, to categorize such impact as the result of “marketing,” at least for legal purposes. Admittedly, it is conceivable that marketing the drug to physicians increased its black-market availability. This, however, would be true of *any* marketing of a prescription narcotic, negligent or otherwise. In other words, the more of the drug there is in the stream of legitimate commerce, the more easily criminals can divert it into the black market.

Against Pain website was itself named as a defendant. *Id.* at *1–2; *see, e.g.*, Little v. Purdue Pharma, L.P., 227 F. Supp. 2d 838, 839, 842 (S.D. Ohio 2002) (sustaining grant of plaintiffs’ motion to remand to state court in class action against, inter alia, Purdue Pharma, L.P. and Partners against Pain). Because of the relatively minor role of this alleged marketing, and the tenuous connection that it would bear to a public entity suit such as West Virginia’s, this Comment operates under the assumption that OxyContin has never been marketed to consumers. Indeed, the most salient criticisms of Purdue’s marketing strategies have focused on its marketing to physicians through the use of journal advertisements, seminars, and the like, marketing which was unquestionably undertaken on a large scale and conceivably could have had a large impact on the volume of OxyContin prescriptions.

¹⁷³ *See* Ford, *supra* note 81, at 431–32, 445.

¹⁷⁴ *OxyContin Hearing*, *supra* note 151.

¹⁷⁵ Ausness, *Non-Defective Products*, *supra* note 3, at 913–14.

¹⁷⁶ *Id.* at 913–16.

¹⁷⁷ West Virginia Complaint, *supra* note 7, at 23–26.

¹⁷⁸ Ausness, *Non-Defective Products*, *supra* note 3, at 915–16.

One critic of Purdue's marketing notes that, "[i]nstead of limiting the drug's promotion to doctors who specialize in treatment of patients with severe and chronic pain and who regularly monitor those patients, OxyContin was promoted to general practitioners who would not closely monitor the effects of the drug on their patients."¹⁷⁹ Interestingly, this observation goes not to the question of *availability* to black-market users but simply to the overprescribing of the drug for seemingly legitimate patients. It is important to stress again that, for purposes of liability, Purdue's marketing practices were only relevant to the extent that they lead to iatrogenic addiction and "legitimate" patient overdose *or* to the extent that they increased the availability of black-market OxyContin. In evaluating a claim that focuses on the harms caused by black-market sales and abuse of a drug, marketing to physicians is only relevant to the extent that it bolsters distribution of the drug. As egregious as such marketing may seem in the context of increasing prescriptions, it is clear that the causal connection between such marketing and black markets is far less direct and, indeed, even tenuous.

Tellingly, this inherently weak causal link between the sale of a legal product and the establishment of black markets has already led a number of jurisdictions to refuse to apply unconventional tort theories in the firearms context. Those courts have held that the causal connection between the supply of a legal product to the general population and the social harms created by firearms crime was simply too tenuous to establish liability.¹⁸⁰

Most notable is *City of Chicago v. Beretta U.S.A. Corp.*, a case in which the Supreme Court of Illinois vigorously rejected a public entity's attempt to render a gun manufacturer liable for the "alleged fostering of an underground handgun market."¹⁸¹ Because the legal strategy effectively translates into an attempt to establish liability on the grounds that the legal sale of a legal product was ultimately feeding a black market, *Beretta* is especially relevant to analysis of the merits of West Virginia's claim.¹⁸² Moreover, the *Beretta* court cited the opinions of numerous jurisdictions in reaching its conclusions, indicating that the causal weaknesses inherent in negligent marketing and distribution claims largely transcend jurisdictional peculiarities.¹⁸³

Second, notwithstanding problems of causation, the *Beretta* court was especially reluctant to allow "judicial intervention" in an area where there is comprehensive regulatory legislation, stressing that "[l]itigation should not be used to achieve legislative goals."¹⁸⁴ Academic commentators have ex-

¹⁷⁹ Ford, *supra* note 81, at 447.

¹⁸⁰ See, e.g., *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004); *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055, 1056 (N.Y. 2001).

¹⁸¹ *City of Chicago*, 821 N.E.2d at 1122.

¹⁸² *Id.*

¹⁸³ *Id.* at 1119–20.

¹⁸⁴ *Id.* at 1123.

pressed this same concern,¹⁸⁵ a concern which ultimately led the court to conclude that “[a]ny change of this magnitude in the law affecting a highly regulated industry must be the work of the legislature, . . . not the work of the courts.”¹⁸⁶ To say that the manufacture and sale of OxyContin is *at least* as heavily regulated as the manufacture and sale of firearms is truly an understatement. As a Schedule II narcotic,¹⁸⁷ OxyContin is heavily regulated even among controlled substances with a high potential for abuse. As such, the *Beretta* court’s reasoning, here, is readily applicable to unconventional tort theories in the context of OxyContin, as well as in the context of firearms.

V. POTENTIAL IMPACT OF WEST VIRGINIA’S SETTLEMENT

A. *Understanding the Settlement: Why It Happened, and Why It Increases the Threat of Future Legal Action Against Drug Manufacturers*

It is important to note that, among the literally hundreds of lawsuits filed against Purdue, this is the *only* case to date that has not been either dismissed or withdrawn.¹⁸⁸ Although Purdue officially admitted no wrongdoing, the settlement was undoubtedly a blow to its corporate ego, in that it was the first OxyContin lawsuit that Purdue had settled, and the company was known to “boast[] that it had never settled or lost a case.”¹⁸⁹ This record certainly provided not only a source of institutional pride but also helped buttress Purdue’s claims that its marketing practices were not negligent. Thus, the question is presented: Why did Purdue settle *this* case?

There are a number of plausible explanations for Purdue’s decision to settle this case wholly unrelated to the merits of its underlying claims. First, West Virginia’s suit was “one of the earliest [OxyContin] suits” against Purdue, filed in 2001.¹⁹⁰ As time wore on, Purdue may have had an increasing incentive to end the suit, so as to cut losses and avoid the uncertainties associated with a jury trial. Second, the unconventional nature of the action may have led Purdue to reason that a settlement in this particular context would not necessarily signal a willingness to settle the hundreds of other suits pending against it.¹⁹¹ Settlement of the West Virginia case would free up resources to pursue further dismissals in those cases. Although a settlement might risk emboldening other public entities to follow suit, Purdue may have been willing to take that risk so as to focus its resources on fighting the gales of lawsuits filed by individual citizens. Finally, the Oxy-

¹⁸⁵ See, e.g., Cleary, *supra* note 9, at 280.

¹⁸⁶ *City of Chicago*, 821 N.E.2d at 1148.

¹⁸⁷ DOJ INTELLIGENCE BRIEF, *supra* note 16, at 1–2.

¹⁸⁸ *Court Downgrades OxyContin Suit*, LEXINGTON HERALD-LEADER, Dec. 16, 2004, at B3.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ O’Brien, *supra* note 5, at 3.

Contin phenomenon had drawn much attention in the media, and a long, high-profile trial would only have drawn further negative exposure.¹⁹² This exposure could have severely harmed Purdue's reputation and perhaps even encouraged more individual citizens to either file suit themselves, participate in class actions, or both.¹⁹³ A plaintiff's perceived stature and motivations are likely to influence public perception of the merits of that plaintiff's suit. Thus, the public is likely to perceive a legal battle with private citizens—many drug addicted, no less—very differently than it would perceive a legal battle with a public entity. Regardless of the *actual* merits, the general public is skeptical of trial lawyers generally and tort claims in particular.¹⁹⁴ This is especially true where the plaintiff appears to be at least partially at fault.¹⁹⁵ On the other hand, a public entity suit is not likely to be viewed as skeptically by the public. There is an enormous difference between an action initiated by a private litigator and one initiated by a duly appointed state attorney general. As a result, the public is far less likely to discount West Virginia's suit as trivial, incentivizing Purdue to keep the whole matter as far away from the public spotlight as possible.

With respect to the potential impact of West Virginia's suit, it is worth noting that the amount of the settlement—\$10 million—is a substantial sum. It thus presents a credible threat not only to Purdue but to all similarly situated manufacturers of scheduled prescription drugs. This sum is just under one third of the amount that West Virginia health care agencies had spent on OxyContin between 1996 and 2003, \$30.5 million.¹⁹⁶ Moreover, such a high-profile case is likely to generate even more suits, including large class actions,¹⁹⁷ as well as generate even more bad press for narcotic painkillers generally.¹⁹⁸

Finally, should the promise of revenues encourage additional public entities to follow West Virginia's lead, by suing Purdue, other manufacturers of scheduled narcotics, or both, the degree of negative fallout from the settlement would multiply greatly. Although it is too early to know for certain whether other public entities will indeed follow, OxyContin opponents in some states are already urging their attorneys general to consider pursuing similar claims.¹⁹⁹ More troubling, the rapid succession of public entity

¹⁹² See generally MEIER, *supra* note 28.

¹⁹³ See, e.g., *DaWalt v. Purdue Pharma L.P.*, 397 F.3d 392 (6th Cir. 2005) (involving a class of plaintiffs alleging personal injuries caused by use of OxyContin).

¹⁹⁴ Robert A. Clifford, *Popular Media Paints Unrealistic Portrait of Lawyers (. . . and What We Can Do About It)*, CHI. B. ASS'N REC., Jan. 2005, at 44, 45.

¹⁹⁵ *Id.*

¹⁹⁶ Associated Press, *supra* note 137.

¹⁹⁷ See, e.g., *DaWalt*, 397 F.3d at 392.

¹⁹⁸ See generally MEIER, *supra* note 28.

¹⁹⁹ See, e.g., Shamus McGillicuddy, *A Loud Voice of OxyContin Concern*, PATRIOT LEDGER (Quincy, Mass.), Feb. 17, 2005, at 16.

suits against firearms manufacturers suggests the possibility of a similar phenomenon in the context of scheduled narcotics.²⁰⁰

B. Culture: Making Manufacturers Liable for the Failures of Communities

The ultimate settlement of West Virginia's case against Purdue presents the risk of making pharmaceutical manufacturers absolutely liable for prescription narcotic black markets, markets which have existed as long as there have been recreational drug users demanding the high that these narcotics can offer. The problem with West Virginia's claims—and any other claims that may be levied by any sort of “public entity”²⁰¹—is that the harms caused by OxyContin do not appear to have resulted from well-intentioned overprescription to legitimate, honest patients but, rather, from the black markets created by crafty suppliers and buyers who were not legitimately prescribed the drug.²⁰² Thus, the causal connection between Purdue's marketing, even if it were indeed negligent in some sense, and these black markets is indirect, and reveals the tenuous relation between Purdue's marketing practices and the black-market use of drugs.

In making Purdue so liable, the West Virginia settlement raises the specter of drug manufacturer responsibility for the regulatory and law-enforcement failures at all levels of government, which have allowed these black markets to flourish.²⁰³ Indeed, Purdue executives noted a possible connection between the cultural and socioeconomic conditions of those regions hit hardest by the OxyContin phenomenon and prescription drug abuse, generally.²⁰⁴ Many of these regions have “high unemployment rates and a long history of using narcotic painkillers to treat injuries caused by regional occupations like farming, mining, and logging,”²⁰⁵ as well as a history of prescription narcotic black markets long predating the release of OxyContin.²⁰⁶

Were there a greater connection between Purdue's marketing—which was aggressive nationally, and not limited to regional promotions—and black markets, one would certainly expect to see a less pronounced concentration of OxyContin diversion and abuse. Rather, despite the fact that OxyContin abuse has spread to more urban areas,²⁰⁷ its abuse has nonethe-

²⁰⁰ Cf. Patterson & Philpott, *supra* note 14, at 549.

²⁰¹ *Id.* at 549–50 (citation omitted).

²⁰² See, e.g., Satel, *supra* note 61.

²⁰³ Cf. Patterson & Philpott, *supra* note 14, at 551 (“The most likely result in the public entity gun litigation is . . . a settlement, thus achieving the type of industry-wide reform through litigation that has not been achieved through legislation.” (citation omitted)).

²⁰⁴ MEIER, *supra* note 28, at 47.

²⁰⁵ *Id.*

²⁰⁶ See, e.g., Irwin & Kinzly, *supra* note 29; cf. Satel, *supra* note 61.

²⁰⁷ Ausness, *Non-Defective Products*, *supra* note 3, at 915–16.

less remained highly concentrated geographically.²⁰⁸ Moreover, these are the regions where public entities are most incentivized to file suit due to the same fiscal shortcomings that allow black markets to flourish in the first place.²⁰⁹ Thus, in attempting to hold Purdue (or similarly situated pharmaceutical companies, for that matter) liable for this extreme abuse, plaintiffs are effectively making them liable for the failures not only of an imperfect system of narcotics control on a national level but, more disconcertingly, for the failures of a community to police physician prescribing and to keep local black markets in check.

C. *Chilling Effects on the Treatment of Chronic Pain*

Increased litigation could serve to further chill pharmaceutical companies' development and promotion of narcotic painkillers and, in turn, further the "chronic undertreatment of pain."²¹⁰ Morphine consumption rose by seventy-five percent between 1990 and 1994 as a result of the so-called pain management movement, a trend which promoted the use of prescription narcotics to combat chronic pain and fight what many saw as the widespread failure of physicians to use strong, narcotic painkillers often enough and in sufficient dosages.²¹¹ In 1994, the Department of Health and Human Services updated its clinical guidelines to more aggressively encourage the use of opioids for treatment of cancer pain.²¹² Clearly, these events were taken by many supporters of the pain management movement as significant advancements in fighting what some perceive as the chronic undertreatment of pain.²¹³ However, a trend toward holding pharmaceutical manufacturers liable for black markets could lead to a retrenchment of hard-won gains on the pain management front.²¹⁴ Prior to its settlement, Purdue's attorneys threatened in a memorandum that such a negative outcome might lead it to discontinue sales of OxyContin in West Virginia altogether.²¹⁵

Moreover, overreaction to the OxyContin phenomenon has already led some state legislators to propose a bill banning OxyContin and, possibly, all oxycodone-containing drugs.²¹⁶ Purdue's settlement could very well add to the hysteria, influencing the prescribing practices of the most scrupulous pain management physicians and contributing to doctors' general fear of

²⁰⁸ See DOJ BULLETIN, *supra* note 35, at 1–2.

²⁰⁹ See, e.g., Cleary, *supra* note 9, at 273; Gavioli, *supra* note 13, at 941–46.

²¹⁰ Weinman, *supra* note 6, at 496.

²¹¹ Tough, *supra* note 23, at 36.

²¹² *Id.*

²¹³ See, e.g., Weinman, *supra* note 6, at 495–96.

²¹⁴ See, e.g., Kent Durning, Note, *No Pain No Gain?!: Who Will Make the Greatest Sacrifices in Curbing Opioid Analgesic Diversion and Abuse?*, 93 KY. L.J. 199, 234–35 (2004).

²¹⁵ Tobey Coleman, *OxyContin Marketing Tactics Go on Trial Today*, CHARLESTON GAZETTE, Nov. 1, 2004, at 1A.

²¹⁶ West Virginia Bill Sought to Ban OxyContin, http://www.pharmacist.com/articles/d_dn_0009.cfm (last visited Feb. 1, 2006).

litigation and criminal liability associated with the use of opiate painkillers. Indeed, the vigorous criminal prosecution of doctors (often in questionably criminal circumstances) has already been decried as creating a “chilling effect” on the “willingness of doctors to prescribe powerful prescription narcotics, which many [pain management physicians] think is the only way to relieve chronic pain.”²¹⁷

VI. CONCLUSION

West Virginia's success, even if limited, is an instance of a questionable claim surviving long enough to induce settlement and, in so doing, an attempt to regulate a broad social problem through the courts—here, the black-market trade in prescription narcotics. However, regulation of social problems is a task better suited to a legislature, a conclusion that courts have reached in the context of other highly regulated yet legal products. The causal link between Purdue's advertising and deliberate OxyContin *abuse* is limited simply to the fueling of drug diversion via an increase in the total amount of pills available to divert; this link is, at best, weak. Such a theory of liability thus offers a very slender reed on which to rest a new chapter in the law of products liability, particularly when the well-being of so many patients in need of effective treatment for chronic pain hangs in the balance.

²¹⁷ Jerry Markon, *Drug Trial of Former Pain Doctor Opens Today*, WASH. POST, Nov. 4, 2004, at B8.

