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Weaning Drug Manufacturers Off Their Painkiller: Creating an Exception to the Learned Intermediary Doctrine in Light of the Opioid Crisis

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**WEANING DRUG MANUFACTURERS OFF
THEIR PAINKILLER:
CREATING AN EXCEPTION TO THE
LEARNED INTERMEDIARY DOCTRINE IN
LIGHT OF THE OPIOID CRISIS**

*Max Roberts**

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INTRODUCTION

Beginning in the twentieth century, a shift in tort law allowed consumers to hold manufacturers of goods, rather than just sellers, liable for injuries caused by said goods.¹ However, a notable exception to this rule still exists for pharmaceuticals through the “learned intermediary” doctrine. The learned intermediary doctrine provides that a drug manufacturer may evade liability for injuries caused to a patient when the manufacturer warns the prescribing physician of the dangers associated with the drug.² For many years, drug manufacturers have relied on this doctrine as a shield from liability. But should manufacturers continue to be allowed to do so?

Since the 1990s, an epidemic has been brewing in the United States: the opioid crisis. In 2017 alone, opioid overdoses — either caused by prescription opioids or illicit opioids such as heroin — caused 47,600 deaths in the United States,³ and the opioid crisis has cost the United States over \$1 trillion from 2001 to 2017, according to

1. *See generally* MacPherson v. Buick Motor Co., 111 N.E. 1050 (N.Y. 1916).
2. *See* Porterfield v. Ethicon, Inc., 183 F.3d 464, 467–68 (5th Cir. 1999).
3. *Drug Overdose Deaths*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 19, 2018), <https://www.cdc.gov/drugoverdose/data/statedeaths.html> [https://perma.cc/LJF2-RECF].

estimates.⁴ In light of these alarming figures, President Trump declared the opioid crisis a “national emergency.”⁵

As with any crisis, a question of liability arises and becomes especially relevant to any legal action taken by aggrieved parties.⁶ Yet, when the spotlight has been pointed at pharmaceutical manufacturers — already under fire in a number of lawsuits⁷ — these companies have attempted to shield themselves from liability using the aforementioned learned intermediary doctrine.⁸ This Note argues that opioid drug manufacturers should not be able to hide behind the learned intermediary doctrine.

This Note does not intend to place the burden of the opioid crisis solely on the shoulders of drug manufacturers. “Pill mill” doctors and heroin dealers also contributed to the opioid crisis, and doctors, government regulators, law enforcement, and insurance companies, in addition to drug manufacturers, all have a role to play in curbing the epidemic. Rather, this Note proposes that deterring drug manufacturers by removing a barrier to liability will create the ripple effects necessary to help alleviate the crisis.

Part I of this Note chronicles the scale and tragedy of the opioid crisis in the United States, and how opioid manufacturers were a direct cause of the problem. Part I then explains the learned intermediary doctrine, which drug manufacturers are currently able to rely on to avoid liability for harm caused by opioids. Part II proposes

4. *Economic Toll of Opioid Crisis Exceeded \$1 Trillion Since 2001*, ALTARUM (Feb. 13, 2018), <https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001> [<https://perma.cc/7GXB-7WY4>].

5. Ali Vitali & Corky Siemaszko, *Trump Declares Opioid Crisis National Emergency*, NBC NEWS (Aug. 10, 2017, 5:38 PM), <https://www.nbcnews.com/storyline/americas-heroin-epidemic/trump-declares-opioid-crisis-national-emergency-n791576> [<https://perma.cc/EM7R-ZSCT>].

6. Compare Patrick Radden Keefe, *The Family that Built an Empire of Pain*, NEW YORKER (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain> [<https://perma.cc/6BC3-NQ7E>] (blaming the marketing tactics created by Arthur Sackler), with Dan Merica, *Trump Declares Opioid Epidemic a National Public Health Emergency*, CNN (Oct. 26, 2017, 5:59 PM), <https://www.cnn.com/2017/10/26/politics/donald-trump-opioid-epidemic/index.html> [<https://perma.cc/QHG3-K6JM>] (reporting on a speech by President Trump in which Trump put at least part of the blame on Mexican heroin dealers).

7. Jerry Mitchell, *Opioid Makers Face Hundreds of Lawsuits for Misleading Doctors About Drug's Addictive Nature*, USA TODAY (Jan. 29, 2018, 8:33 AM), <https://www.usatoday.com/story/news/nation-now/2018/01/29/judge-stop-legal-fights-and-curb-opioid-epidemic/1072798001/> [<https://perma.cc/79W3-Y894>].

8. *See, e.g.*, *Foister v. Purdue Pharma*, L.P., 295 F. Supp. 2d 693, 708 (E.D. Ky. 2003) (holding plaintiffs' failure to warn claims against Purdue over OxyContin labeling were barred by the learned intermediary doctrine).

that an exception to the learned intermediary doctrine should be carved out for prescription opioids. This exception is based on the collective practices of drug manufacturers in over-marketing opioids, which helped create the crisis. The exception is also based on opioids not being “unavoidably unsafe,” as the learned intermediary doctrine relies upon, in their most common use. Finally, Part III assesses the effects of creating this exception on the health care industry. Although exposing drug manufacturers to increased liability will carry some negative ramifications, this Note argues that the exception should still be instituted because those negative effects can be alleviated by realistic changes to the treatment of pain.

I. THE OPIOID CRISIS AND THE LEARNED INTERMEDIARY DOCTRINE

In providing an overview of the opioid crisis and the learned intermediary doctrine, this Part discusses how the opioid crisis transpired, specifically examining the role of prescription opioids and drug manufacturers in causing the crisis. Next, this Part discusses the application of the learned intermediary doctrine, the policy underlying the doctrine, and certain exceptions to the doctrine that have been carved out previously.

A. The Opioid Crisis

Opioids are a class of drugs derived from the opium poppy that are typically used to treat pain.⁹ These drugs also react strongly with pleasure receptors in humans and can be very addictive with debilitating withdrawal effects.¹⁰ Opioids come in a number of forms, with three in particular contributing to the opioid crisis. The first and most recent contributor is fentanyl. Fentanyl is a synthetic opioid most often used for treating severe pain (such as advanced cancer pain) that is fifty times more potent than morphine.¹¹ In many cases,

9. Josh Katz, *Short Answers to Hard Questions About the Opioid Crisis*, N.Y. TIMES: THE UPSHOT (Aug. 10, 2017), <https://www.nytimes.com/interactive/2017/08/03/upshot/opioid-drug-overdose-epidemic.html> [<https://perma.cc/K8PL-76DX>].

10. See SAM QUINONES, DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC 38–39 (2015) (“[N]o other molecule in nature provided such merciful pain relief, then hooked humans so completely, and punished them so mercilessly for wanting their freedom from it.”).

11. *Fentanyl*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 19, 2018), <https://www.cdc.gov/drugoverdose/opioids/fentanyl.html> [<https://perma.cc/2C8B-AQPP>].

fentanyl is being laced into heroin and into counterfeit pills without the user's knowledge, causing users to intake far stronger opioids than intended, leading to overdoses.¹² The second contributor is heroin, a Schedule I drug.¹³ While heroin has been around for over a century,¹⁴ more potent forms sold more cheaply and conveniently by dealers from Xalisco, Mexico have led to an increase in usage.¹⁵

The third contributor, and most relevant for this Note, is prescription opioids. For much of the twentieth century, doctors were hesitant to prescribe opioids to patients because of the fear of addiction.¹⁶ This attitude gradually changed in the 1970s as doctors began prescribing opioids for cancer and terminally ill patients.¹⁷ By the 1980s, however, the floodgates began to open. In 1980, *The New England Journal of Medicine* published a letter to the editor authored by Jane Porter and Dr. Hershel Jick.¹⁸ The letter claimed that of the nearly 12,000 patients treated with opioids at a hospital, only four had become addicted.¹⁹ The letter did not provide any data on which opioids were given or the dosages prescribed,²⁰ and the fact that these patients were carefully overseen by their treating doctors was overlooked.²¹ The letter was not even a formal scientific study.²² Nevertheless, the letter was cited in a number of influential scientific studies on pain treatment,²³ which helped reinforce by the 1990s the

12. Katz, *supra* note 9.

13. *Drug Scheduling*, U.S. DRUG ENF'T ADMIN., <https://www.dea.gov/drug-scheduling> [<https://perma.cc/888F-TSNZ>]. "Schedule I" refers to drugs that have "no currently accepted medical use and a high potential for abuse." *Id.*

14. *Heroin Overview: Origin and History*, UNIV. OF ARIZ.: METHOIDE, <https://methoide.fcm.arizona.edu/infocenter/index.cfm?stid=174> [<https://perma.cc/M2G4-KP4Z>] (noting that heroin was first synthesized in 1874 and produced commercially in 1898).

15. See QUINONES, *supra* note 10, at 19, 43–45 (describing the black tar heroin being sold as more potent than other forms of heroin, and a "fast food-like" delivery system that made heroin easy to acquire at a low cost).

16. *Id.* at 80.

17. *Id.*

18. Jane Porter & Hershel Jick, *Correspondence: Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123, 123 (1980).

19. *Id.*

20. QUINONES, *supra* note 10, at 16.

21. *Id.* at 107.

22. *Id.* at 108.

23. See, e.g., Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 PAIN 171, 183 n.38 (1986) (citing Porter & Jick to support the claim that opioids could be prescribed with little risk of addiction); see also QUINONES, *supra* note 10, at 107 ("Everybody heard it everywhere. It was Porter and Jick. We [referring to the medical community] all used it. We all thought it was gospel."). In 2001, *Time* magazine called Porter & Jick

claim that opioids were non-addictive.²⁴ In fact, this “pain revolution” helped swing the pendulum far to the other side, suggesting to physicians the idea that not only might opioids be safe to treat chronic pain patients, but also that doctors had been previously “undertreating” pain patients.²⁵ This shift in thinking led to the emergence of blockbuster painkillers like OxyContin, which was heavily promoted and prescribed²⁶ chiefly because it was thought to not be addictive.²⁷

From these origins, the opioid crisis was born. Backed by the aforementioned research, drug manufacturers such as Purdue Pharma (“Purdue”), Cephalon, Inc. (“Cephalon”), Janssen Pharmaceuticals (“Janssen”), Endo Health Solutions (“Endo”), and Insys Therapeutics (“Insys”) began heavily manufacturing opioids.²⁸ To foster sales of these drugs, manufacturers contributed substantial funds to patient advocacy groups and professional societies including the Academy of Integrative Pain Management and the National Pain Foundation, groups which focused on chronic pain and opioid-related issues.²⁹ For instance, from 2012 to 2017, Purdue, Janssen, Mylan N.V., Depomed, Inc., and Insys contributed \$9 million in total to opioid-related advocacy groups.³⁰ In turn, these advocacy organizations heavily promoted the use of prescription opioids.³¹ Manufacturers also relied on large pharmaceutical distributors, including McKesson Corporation, Amerisource Bergen Corporation, and Cardinal Health, Inc. to distribute their drugs.³² As a result of these marketing and distribution efforts by manufacturers, by 2015,

“a landmark study” that helped eliminate the “myth” of opioid addiction. See QUINONES, *supra* note 10, at 108.

24. *Id.* at 109.

25. *Id.* at 95.

26. Mark A. Ford, *Another Use of OxyContin: The Case for Enhancing Liability for Off-Label Drug Marketing*, 83 B.U. L. REV. 429, 430 (2003) (noting that Purdue spent over \$200 million marketing OxyContin in 1998, and that the drug became the most prescribed painkiller in the nation soon after).

27. See QUINONES, *supra* note 10, at 132.

28. Complaint at 45–46, *Rutherford County v. Purdue Pharma L.P.*, No. 18-cv-00238 (M.D. Tenn. Feb. 26, 2018) (showing table of opioid manufacturers and the opioid drug they manufactured).

29. U.S. SENATE HOMELAND SEC. & GOV'T AFFAIRS COMM., FUELING AN EPIDEMIC: EXPOSING THE FINANCIAL TIES BETWEEN OPIOID MANUFACTURERS AND THIRD PARTY ADVOCACY GROUPS 3–4 (2018).

30. *Id.* at 1.

31. *Id.* at 12.

32. U.S. SENATE HOMELAND SEC. & GOV'T AFFAIRS COMM., FUELING AN EPIDEMIC: A FLOOD OF 1.6 BILLION DOSES OF OPIOIDS INTO MISSOURI AND THE NEED FOR STRONGER DEA ENFORCEMENT 1 (2018).

the number of opioids prescribed was enough for every American to be medicated around the clock for three weeks.³³

Concurrently, because opioids were addictive despite “studies” to the contrary, this surge in use was coupled with an increase in misuse and tragedy.³⁴ Of the 97.5 million people who used painkillers in 2015, 12.5 million people misused them.³⁵ Further, drug distributors often failed to meet their reporting obligations under the Controlled Substances Act to “monitor and report suspicious orders under the controlled substances act to the Drug Enforcement Agency.”³⁶ This resulted in massive amounts of opioids being diverted — given from the person to whom it was prescribed or from the pharmacy it was sold to another person for illicit use — contributing to the crisis.³⁷ Other users simply switched from prescription opioids to heroin because heroin was cheaper.³⁸ Regardless of the form, this misuse of opioids exacted both a human and financial toll. Over 47,000 people died from an opioid overdose in 2017,³⁹ and the opioid crisis could claim a projected one million lives by 2020.⁴⁰ The crisis has cost the United States over \$500 billion per year attributable to criminal justice measures, treating patients in intensive care wards in hospitals, and lost productivity in businesses.⁴¹

33. *Opioid Prescribing*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 6, 2017), <https://www.cdc.gov/vitalsigns/opioids/infographic.html#infographic> [https://perma.cc/3VQC-V364]. Prescribing hit a peak in 2012, with 255 million prescriptions issued at a rate of 81.3 prescriptions per 100 people. *U.S. Prescribing Rate Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 3, 2018), <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> [https://perma.cc/8NNW-VLGJ].

34. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 223 (2009).

35. Arthur Hughes et al., *Prescription Drug Use and Misuse in the United States: Results from the 2015 National Survey on Drug Use and Health*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Sept. 2016), <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.htm> [https://perma.cc/M9XA-VNWX].

36. FUELING AN EPIDEMIC: A FLOOD OF 1.6 BILLION DOSES OF OPIOIDS INTO MISSOURI AND THE NEED FOR STRONGER DEA ENFORCEMENT, *supra* note 32, at 1.

37. *Id.* at 4.

38. QUINONES, *supra* note 10, at 6.

39. *Drug Overdose Deaths*, *supra* note 3.

40. Jerry Mitchell, *With 175 Americans Dying a Day, What Are the Solutions to the Opioid Epidemic?*, USA TODAY (Jan. 29, 2018, 10:29 AM), <https://www.usatoday.com/story/news/nation-now/2018/01/29/175-americans-dying-day-what-solutions-opioid-epidemic/1074336001/> [https://perma.cc/NR5Z-2453].

41. Maria LaMagna, *More Evidence that the Opioid Epidemic Is Only Getting Worse*, MARKETWATCH (Aug. 16, 2018, 10:34 AM),

Although the opioid crisis has hit rural communities the hardest, it has not left urban communities untouched.⁴² On the contrary, the opioid crisis has increasingly affected urban communities, with the highest rate of increases in opioid overdoses between July 2016 and September 2017 occurring in large metro areas (areas with a population of 1 million or more and covering a major city).⁴³ In Philadelphia, for instance, opioids caused 1,217 overdose deaths in 2017.⁴⁴ Philadelphia Health Commissioner Thomas Farley described Philadelphia as “[a]n entire city floating on opioids.”⁴⁵ The rise of the urban opioid crisis has been driven by heroin, and particularly heroin cut with fentanyl, as both are more prevalent in urban markets than prescription opioids.⁴⁶

The urban opioid crisis has especially taken a toll on black communities in urban environments, who are now dying at a faster rate than in suburban and rural areas.⁴⁷ The CDC found that overdose deaths among black urbanites rose by 41% in 2016,⁴⁸ while the Office of the Medical Examiner in Washington, D.C. found that opioid overdose deaths among black men between the ages of forty-nine and sixty-nine increased by a whopping 245% between 2014 and 2017.⁴⁹ Whereas overdose deaths per 100,000 among blacks in rural areas was 6.7% in 2016, it was 22.7% among blacks in urban areas, which represented a drastic increase.⁵⁰ This is as compared to whites,

<https://www.marketwatch.com/story/how-much-the-opioid-epidemic-costs-the-us-2017-10-27> [<https://perma.cc/634M-7XBZ>].

42. Ahlshia Shipley, *Opioid Crisis Affects All Americans, Rural and Urban*, USDA: BLOG (Jan. 11, 2018), <https://www.usda.gov/media/blog/2018/01/11/opioid-crisis-affects-all-americans-rural-and-urban> [<https://perma.cc/K2Z4-FR2N>].

43. Corky Siemaszko, *Large U.S. Cities See Big Jump in Deadly Opioid Overdoses, CDC Data Shows*, NBC NEWS (Mar. 6, 2018, 2:12 PM), <https://www.nbcnews.com/storyline/americas-heroin-epidemic/large-u-s-cities-see-big-jump-deadly-opioid-overdoses-n854041> [<https://perma.cc/YL5D-YYWG>].

44. Larry Eichel & Meagan Pharis, *‘No Silver Bullet’ for Opioid Crisis in Philadelphia, Other Urban Areas*, PEW CHARITABLE TRUSTS (May 10, 2018), <https://www.pewtrusts.org/en/research-and-analysis/articles/2018/05/10/no-silver-bullet-for-opioid-crisis-in-philadelphia-other-urban-areas> [<https://perma.cc/9Q4G-3E6V>].

45. *Id.*

46. Siemaszko, *supra* note 43.

47. Marisa Peñaloza, *The Opioid Crisis Is Surging in Black, Urban Communities*, NAT’L PUB. RADIO (Mar. 8, 2018, 5:00 AM), <https://www.npr.org/2018/03/08/579193399/the-opioid-crisis-frightening-jump-to-black-urban-areas> [<https://perma.cc/28UK-5BJJ>].

48. *Id.*

49. *Id.*

50. *Id.* (citing charts).

whose overdose deaths per 100,000 for urban and rural areas were much closer (25.6% for urban, 19.6% for rural).⁵¹

While most opioid-related deaths are now caused by heroin and fentanyl, more than 40% of opioid overdose deaths in 2016 involved a prescription opioid,⁵² and experts agree that curbing the amount of prescription opioids available is necessary to stopping the crisis.⁵³ This Note proposes to do exactly that by removing the learned intermediary barrier to drug manufacturer liability, which will lead to fewer prescription opioids being manufactured and distributed.

B. The Learned Intermediary Doctrine

In tort law, manufacturers are typically held liable for any harms caused by their products. However, the learned intermediary doctrine is a noteworthy exception to this general rule.⁵⁴ Considered by some to have been first applied in 1948 in *Marcus v. Specific Pharmaceuticals*,⁵⁵ the doctrine holds that a drug manufacturer may escape liability for injuries caused to a patient by the drug when the manufacturer warns the prescribing physician of the dangers associated with the drug.⁵⁶ In other words, the duty of the manufacturer to warn in cases involving pharmaceuticals extends only to the prescribing physician, not the patient.⁵⁷

The doctrine is rooted in two fundamental principles.⁵⁸ The first principle is that because drug warnings are often complex and the risks and benefits of a given medication are hard to gauge for each individual patient, physicians are best suited to evaluate whether to prescribe a given drug.⁵⁹ The rationale is that a patient's physician,

51. *Id.* (citing charts).

52. *Prescription Opioid Data*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 19, 2018), <https://www.cdc.gov/drugoverdose/data/overdose.html> [<https://perma.cc/SS7P-RV7S>].

53. Katz, *supra* note 9.

54. Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5th § 2[a] (1998).

55. *Marcus v. Specific Pharms., Inc.*, 77 N.Y.S.2d 508, 508 (Sup. Ct. 1948); *see also* Mark P. Robinson, Jr. & Kevin F. Calcagnie, *Vioxx and the "Learned Intermediary" Defense*, 8 ANDREWS DRUG RECALL LITIG. REP. 7 1, Jan. 2005, at 2 (citing *Marcus* as the first application of the learned intermediary doctrine).

56. *See* *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467–68 (5th Cir. 1999).

57. Kane, *supra* note 54, at Introduction.

58. Other principles have been put forth, such as a reluctance by the courts to intrude upon the doctor-patient relationship and an inability of drug manufacturers to adequately communicate with patients. *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1255 (N.J. 1999).

59. Kane, *supra* note 54, § 2[a].

unlike a drug manufacturer, is aware of a patient's particular "needs and susceptibilities."⁶⁰ Thus, the physician is deemed to be the "learned intermediary" between a drug manufacturer and a patient,⁶¹ and the physician is tasked with informing a patient of the various risks and benefits associated with the drug so that the patient can exercise informed consent.⁶²

The second principle is that prescription drugs are considered "unavoidably unsafe."⁶³ The premise here is that many drugs are incapable of being made completely safe given the current state of scientific knowledge.⁶⁴ However, because the benefits of a drug are deemed to outweigh the risks associated with a drug, the drug is not considered defective or unreasonably dangerous when accompanied by proper warnings.⁶⁵ An example of this would be the Pasteur treatment for rabies, which pairs the rather serious side effects of the remedy with the substantial risk of death from the disease itself.⁶⁶ Thus, the use and marketing of this treatment is justified, notwithstanding the concomitant side effects and risks.

Although the learned intermediary doctrine is absolute in most states,⁶⁷ some states have carved out limited exceptions. One exception was created for direct-to-consumer advertising by the New Jersey Supreme Court in *Perez v. Wyeth Laboratories, Inc.*⁶⁸ In *Perez*, the court found that the principles underlying the learned intermediary doctrine were absent in direct-to-consumer advertising.⁶⁹ Specifically, the court reasoned that (1) doctors had less time to see patients and thus could not provide a thorough risk-

60. *Id.*

61. *Id.*

62. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b (AM. LAW INST. 1998).

63. Kane, *supra* note 54, § 2[a].

64. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

65. Kane, *supra* note 54, § 2[a].

66. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

67. DAVID G. OWEN & MARY J. DAVIS, OWEN & DAVIS ON PRODUCTS LIABILITY § 9:25 (4th ed. 2014).

68. *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1260 (N.J. 1999). The Third Restatement of Torts has also suggested such an exception might apply. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b (AM. LAW INST. 1998) ("In certain limited therapeutic relationships the physician or other health-care provider has a much-diminished role as an evaluator or decisionmaker. In these instances, it may be appropriate to impose on the manufacturer the duty to warn the patient directly.").

69. *Perez*, 734 A.2d at 1255.

benefit analysis for prescribing drugs,⁷⁰ (2) the multi-billion dollar advertising budget of drug manufacturers undermined any claims that drug manufacturers could not effectively communicate with patients,⁷¹ (3) patients “now enter physicians’ offices with preconceived expectations about treatment because of information obtained from DTC [direct-to-consumer] advertisements,”⁷² and (4) a policy protecting “the patient’s interest in reliable information predominates over a policy that would insulate manufacturers.”⁷³ For these reasons, the *Perez* court held that drug manufacturers had a duty to warn patients when they directly marketed their products to consumers.⁷⁴

Some courts have also recognized an exception when a drug manufacturer excessively promotes a product. In these circumstances, the marketing for the drug is so extensive that the warnings given by the manufacturer to physicians are rendered meaningless, causing a physician to prescribe a drug when it would otherwise be unwarranted.⁷⁵ For example, in *Stevens v. Parke, Davis & Co.*,⁷⁶ Parke, Davis was required to warn physicians that an antibiotic carried a serious risk of causing bone marrow disease.⁷⁷ Despite this, Parke, Davis attempted to circumvent these warnings through marketing, such as by placing ads in physicians’ magazines, distributing calendars that mentioned the benefits of the drug without noting the serious side-effects, and having salespeople directly visit physicians to promote the drug.⁷⁸ These marketing techniques caused physicians to prescribe the antibiotic when they otherwise may not have,⁷⁹ leading to Parke, Davis being held liable to the patient because the warnings it had given physicians were nullified by its marketing tactics.⁸⁰

70. *Id.*

71. *Id.* at 1255–56.

72. *Id.* at 1260.

73. *Id.* at 1262.

74. *Id.* at 1263.

75. *See Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018, 1030 (S.D. Ill. 2001).

76. 507 P.2d 653 (Cal. 1973).

77. *Id.* at 655.

78. *Id.* at 662.

79. *Id.*

80. *Id.* at 664.

II. FASHIONING AN OPIOID EXCEPTION TO THE LEARNED INTERMEDIARY DOCTRINE

Part II argues that an exception to the learned intermediary doctrine should be created for prescription opioids. This would allow patients to hold drug manufacturers liable when a prescription opioid causes an injury to the patient unless the manufacturer directly warns the patient of the dangers of the drug. The exception should be created because the opioid crisis has demonstrated the flaws inherent in the learned intermediary doctrine. First, drug manufacturers did not adequately warn physicians about the dangers of opioids, and even if they had, concerted over-promotion of opioids diluted those warnings. Second, prescription opioids are not “unavoidably unsafe” for treating chronic, non-cancer pain because their risks outweigh their benefits.

A. Drug Manufacturers Engaged in an Industry-Wide Practice of Failing to Adequately Warn Physicians About Opioid Dangers, and Rendered Warnings Were Made Moot Through Over-Promotion of Opioids

As noted above, one principle underlying the learned intermediary doctrine is that only physicians can adequately wade through the complex warnings accompanying a drug to decide whether to prescribe the drug to a patient.⁸¹ However, this principle assumes that the drug manufacturer gives physicians adequate warnings in the first place.⁸² In the case of opioids, drug manufacturers failed to properly apprise physicians of the dangers associated with opioids, and the manufacturers’ excessive marketing of these drugs rendered any warnings that were given meaningless. Further, because these tactics constituted an industry-wide practice, a more expansive remedy in the form of an opioid exception to the learned intermediary doctrine is justified.

1. Drug Manufacturers Failed to Warn Physicians about the Risks of Opioids

While the learned intermediary doctrine protects drug manufacturers if they adequately warn a prescribing physician of the

81. Kane, *supra* note 54, § 2[a].

82. *See, e.g.,* Boehm v. Eli Lilly & Co., 747 F.3d 501, 505 (8th Cir. 2014) (“[T]he manufacturer of an ‘unavoidably unsafe’ but beneficial prescription must make ‘an adequate warning’ to prescribing physicians of the risks of adverse side effects.”).

risks associated with a drug,⁸³ the marketing of OxyContin by Purdue Pharma illustrates how drug manufacturers failed to adequately warn physicians of the dangers of addiction linked to opioid painkillers. Underlying Purdue's marketing strategy were claims that OxyContin was virtually non-addictive,⁸⁴ despite these claims not being accurate.⁸⁵ Part of the training for Purdue's sales representatives consisted of teaching them that the risk of addiction was "less than one percent," per the Porter and Jick⁸⁶ study.⁸⁷ Purdue also focused on marketing to primary care physicians with little pain-management training, who were functioning in the time-strapped world of managed care.⁸⁸ Thus, not only did these practitioners have negligible experience to counteract the claims by Purdue, but pills were also a particularly appealing solution for doctors who could only devote only a few minutes to each patient.⁸⁹

2. *Drug Manufacturers Over-Promoted Opioid Painkillers, Rendering any Warnings Meaningless*

Compounding this lack of warning, Purdue undermined any cautions given by over-promoting OxyContin.⁹⁰ To prove over-

83. See *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1365–66 (S.D. Fla. 2007).

84. *Van Zee*, *supra* note 34, at 223.

85. QUINONES, *supra* note 10, at 127 (quoting a former Purdue sales manager, who said: "They told us to say things like it is 'virtually' non-addicting. That's what we were instructed to do. It's not right, but that's what they told us to say . . . You'd tell the doctor there is a study, but you wouldn't show it to him."); First Amended Complaint at 14, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, No. 1884-cv-01808 (Mass. Super. Ct. Jan. 31, 2019), <https://www.documentcloud.org/documents/5715954-Massachusetts-AGO-Amended-Complaint-2019-01-31.html> [<https://perma.cc/5CUL-N7PT>] ("Purdue always knew that its opioids carry grave risks of addiction and death. Instead of being honest about these risks, Purdue obscured them, including by falsely stating and implying that 'appropriate' patients won't get addicted.").

86. Porter & Jick, *supra* note 18, at 123.

87. *Id.*; *Van Zee*, *supra* note 34, at 223.

88. QUINONES, *supra* note 10, at 97; *Van Zee*, *supra* note 34, at 222.

89. QUINONES, *supra* note 10, at 97–98 (noting doctors had increasingly less time with their patients, that doctors were "making their money by churning patients through their offices at a thirteen-minute clip," and that "opioids helped a harried doctor with what was now the largest drain on his time: chronic-pain patients").

90. Typically, independent knowledge by a physician of dangers associated with a drug can alleviate a manufacturer of liability as well. *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007). However, a drug manufacturer can still be held liable even if a physician knows of the dangers associated with a drug if the marketing of the drug could foreseeably induce a physician to prescribe the drug when it was otherwise not warranted. *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 664 (Cal. 1973). As will be described more thoroughly in the main text, this is exactly what

promotion, a plaintiff must present “individualized proof that such over-promotion caused the physician to initiate or maintain the prescription at issue.”⁹¹ As noted earlier, over-promotion was found in *Stevens*, where the court determined that Parke, Davis used giveaways such as calendars, physicians’ reference articles, and personal visits by salesmen that ignored the side effects caused by the drug to undermine any warnings Parke, Davis was required to give.⁹²

Purdue engaged in similar and even more aggressive tactics. First, Purdue provided giveaways, such as OxyContin-branded “fishing hats, stuffed toys, golf balls, pens with charts converting a patient’s dosage in other pills to OxyContin,” message paper pads, and even a swing jazz CD that “urged listeners to ‘Swing in the Right Direction with OxyContin.’”⁹³ According to the DEA, no company had ever used branded merchandise as extensively to market a Schedule II⁹⁴ drug.⁹⁵

Second, Purdue hosted more than forty all-expenses paid national pain-management and speaker training conferences attended by some 5000 physicians, pharmacists, and nurses recruited and trained to be speakers for Purdue and OxyContin.⁹⁶ These types of conferences have been shown to influence the prescribing patterns of physicians.⁹⁷ Purdue also focused on Continuing Medical Education (CME) programs, funding more than 20,000 CME programs that promoted the benefits of OxyContin.⁹⁸ CMEs essentially became marketing tools, with drug manufacturers wining and dining physicians, and featuring speakers picked by drug manufacturers to promote specific drugs.⁹⁹ The influence of drug manufacturers on CMEs became so problematic that new rules were established to stymie this behavior.¹⁰⁰

occurred with the marketing of opioids. QUINONES, *supra* note 10, at 132 (“[Purdue gave] a very effective presentation . . . It really did make you doubt your feelings about what you’d been taught [about opioids] in medical school.”).

91. *Patterson v. AstraZeneca, L.P.*, 876 F. Supp. 2d 27, 35 (D.D.C. 2012).

92. *Stevens*, 507 P.2d at 662.

93. QUINONES, *supra* note 10, at 134.

94. *Id.* at 135 (“Schedule II is a federal designation for drugs with accepted medical uses, but a high potential for abuse resulting in dependency.”).

95. *Id.*

96. *See id.* at 135; Van Zee, *supra* note 34, at 221.

97. *See Van Zee, supra* note 34, at 221.

98. QUINONES, *supra* note 10, at 135–36.

99. *Id.* at 135.

100. *Id.*

Third, Purdue made extensive use of video marketing. In 1998, Purdue sent out a non-FDA video to doctors, entitled: *I Got My Life Back: Patients in Pain Tell Their Story*, which not only showed patients claiming that OxyContin had greatly benefited them, but also reinforced the “less than one percent” claim about opioid addiction.¹⁰¹ The claims about quality of life improvement were completely unsubstantiated.¹⁰² In fact, three of the seven patients featured in *I Got My Life Back* became opioid addicts, two of whom died as active opioid abusers.¹⁰³ The video did not portray these users as addicts, however. On the contrary, *I Got My Life Back* made the bold claim that patients who appeared to be addicted were suffering from “pseudoaddiction.”¹⁰⁴ “Pseudoaddiction is relief seeking behavior mistaken as drug addiction”¹⁰⁵ and helped embed in physicians the idea that there was no limit to how many opioids they could prescribe because the patient could never really become addicted.¹⁰⁶ These marketing strategies reinforced the idea that OxyContin should be “prescribed ‘for everything,’” rather than only for the specific uses on its FDA-approved label.¹⁰⁷

Purdue’s marketing did not stop with doctors. Purdue also sent out a video, *From One Pain Patient to Another: Advice from Patients Who Have Found Relief*, which was intended for doctors’ waiting rooms.¹⁰⁸ The video urged patients to discuss their pain with their doctors and aimed to assuage patient concerns about taking opioids, again citing the “less than one percent” addiction rate claim.¹⁰⁹ These videos also came at a time when patients were becoming more

101. *Id.* at 136.

102. *Id.*

103. See John Fauber & Ellen Gabler, *What Happened to the Poster Children of OxyContin?*, MILWAUKEE J. SENTINEL, Sept. 8, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/what-happened-to-the-poster-children-of-oxycontin-r65r0lo-169056206.html/> [<https://perma.cc/5ASQ-V86H>].

104. *Last Week Tonight with John Oliver: Opioids*, YOUTUBE (HBO television broadcast Oct. 23, 2016), <https://youtu.be/5pdPrQFjo2o?t=10m40s> [<https://perma.cc/EV4A-6KPQ>] (showing footage from *I Got My Life Back* in which a doctor discusses the concept of “pseudoaddiction”).

105. *Id.* (quoting Dr. Alan Spanos from *I Got My Life Back*); see also QUINONES, *supra* note 10, at 109 (“Usually, a patient demanding ever-higher doses of a drug would be proof that the drug wasn’t working. But in opiate pain treatment, it was taken as proof that the doctor hadn’t yet prescribed enough.”).

106. QUINONES, *supra* note 10, at 110.

107. Ford, *supra* note 26, at 444–45.

108. QUINONES, *supra* note 10, at 136–37.

109. *Id.*

comfortable demanding drugs for treatment.¹¹⁰ Purdue's marketing program additionally included targeting doctors who prescribed opioids at the highest rate, paying large bonuses to sales representatives based on sales of OxyContin, and a coupon program that provided patients with a free seven to thirty-day supply of OxyContin.¹¹¹

In 2001 alone, Purdue spent \$200 million on an extensive marketing campaign,¹¹² which spurred OxyContin sales from \$44 million in 1996 to approximately \$3 billion between 2001 and 2002.¹¹³ This record of corporate behavior constitutes the "individualized proof" required to satisfy the over-promotion exception to the learned intermediary doctrine that would normally preclude liability for drug manufacturers when a doctor is prescribing the medication. Moreover, the video intended for physicians' waiting rooms arguably fulfills the direct-to-consumer exception established by *Perez*.¹¹⁴ Specifically, the videos demonstrated that drug manufacturers could directly reach consumers¹¹⁵ and that patients would enter their doctor's office with preconceived notions of the treatment they should receive, thus undermining the doctor-patient relationship.¹¹⁶

While Purdue's OxyContin campaign is the most publicized example of opioid over-promotion, it is not the only example. In 2008, Cephalon agreed to a \$425 million settlement to resolve claims of off-label marketing¹¹⁷ for its drug, Actiq, in violation of the Food, Drug and Cosmetics Act.¹¹⁸ Actiq is a "transmucosal immediate-release fentanyl" ("TIRF") opioid¹¹⁹ that had been approved for

110. *Id.* at 96.

111. *Id.* at 133–34 (noting that Purdue paid \$40 million in bonuses related to OxyContin sales in 2001); Van Zee, *supra* note 34, at 222.

112. Van Zee, *supra* note 34, at 221.

113. *Id.* at 223.

114. *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1263 (N.J. 1999).

115. *Id.* at 1255–56.

116. *Id.* at 1260.

117. *Understanding Unapproved Use of Approved Drugs "Off Label"*, U.S. FOOD & DRUG ADMIN. (Feb. 5, 2018), <https://www.fda.gov/forpatients/other/offlabel/default.htm> [<https://perma.cc/7RT5-2WHG>] (defining "off label use" as "using an FDA-approved drug for an unapproved use"). Hence, "off label marketing" would be marketing approved drugs for unapproved uses.

118. Press Release, Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million and Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> [<https://perma.cc/4DAA-BU7R>] [hereinafter DOJ Press Release].

119. Thomas Sullivan, *FDA: Transmucosal Immediate-Release Fentanyl (TIRF) REMS*, POL'Y & MED. (May 6, 2018), <http://www.policymed.com/2012/01/fda->

treating pain in opioid-tolerant cancer patients.¹²⁰ However, between 2001 and 2006, Actiq was marketed for treating other ailments, such as migraines and generic injuries, even in those patients who were not opioid-tolerant.¹²¹ Cephalon did this by specifically targeting physicians other than oncologists (including general practitioners, much like Purdue)¹²² and training its sales force to stress that “pain is pain” in contravention of an FDA label restriction limiting usage to only treating cancer pain.¹²³ Cephalon also utilized direct physician-to-salesperson contact and funded CME programs.¹²⁴

Another more recent example is that of Insys and its drug, Subsys, which like Actiq is a TIRF opioid approved for treating breakthrough pain (severe pain that occurs in patients already medicated with painkillers) in cancer patients.¹²⁵ The Subsys marketing plan had several features. First, starting with the launch of Subsys in 2012, Insys spent \$10 million funding speaker programs.¹²⁶ Insys paid doctors hundreds of thousands of dollars to speak at these engagements on the condition that they would prescribe or continue prescribing Subsys, with the highest paid speakers each being paid more than \$200,000.¹²⁷ Insys even attracted one doctor to be a speaker by hiring an exotic dancer to woo him; this doctor ended up accounting for 58% of Subsys’s prescriptions in Illinois over a three-year period.¹²⁸ As a result of this arrangement, Subsys sales increased

transmucosal-immediate-release-fentanyl-tirf-rems.html [https://perma.cc/P5VH-SZSE]. These fentanyl-based opioids are different than OxyContin, which contains large doses of oxycodone, which is molecularly similar to heroin. QUINONES, *supra* note 10, at 124. This is further contrasted with other types of opioids such as Vicodin and Percocet, which combine small doses of oxycodone with acetaminophen (the pain-killing ingredient in Tylenol). *Id.* at 125.

120. DOJ Press Release, *supra* note 118.

121. *Id.*

122. *See supra* Section II.A.1 (“Purdue also focused on marketing to primary care physicians with little pain-management training . . .”).

123. DOJ Press Release, *supra* note 118.

124. *Id.*; *see also supra* Section II.A.2 (“CMEs essentially became marketing tools, with drug manufacturers wining and dining physicians, and featuring speakers picked by drug manufacturers to promote specific drugs.”).

125. Evan Hughes, *The Pain Hustlers*, N.Y. TIMES: THE MONEY ISSUE (May 2, 2018), <https://www.nytimes.com/interactive/2018/05/02/magazine/money-issue-insys-opioids-kickbacks.html> [https://perma.cc/D6PT-VGCD].

126. *Id.*

127. *Id.*; *see also* Nate Raymond, *North Carolina Accuses Drugmaker Insys of Scheme to Push Opioid*, REUTERS (Dec. 21, 2017, 11:40 AM), <https://www.reuters.com/article/us-insys-opioids/north-carolina-accuses-drugmaker-insys-of-scheme-to-push-opioid-idUSKBN1EF292> [https://perma.cc/GK7Z-KA8M].

128. Hughes, *supra* note 125.

by more than 1,000% between 2012 and 2013.¹²⁹ According to federal prosecutors, all of this amounted to a kickback scheme,¹³⁰ a charge to which one former Subsyst speaker from Rhode Island recently pled guilty.¹³¹

Second, Insys specifically targeted doctors who wrote the most prescriptions.¹³² At the top of Insys's list — the “highest decile” — were doctors that did not specialize in cancer pain. This strategy resembles Purdue's and Cephalon's targeting of primary care physicians. It was common knowledge in the industry that sales representatives should target pain doctors and other non-oncologists,¹³³ because doctors can write prescriptions for off-label usage at their own discretion,¹³⁴ and doctors lacking much experience with these types of medications¹³⁵ are presumably more easily influenced to do so. As a result of these efforts, as of September 2016, only 4% of Subsyst prescriptions were written by oncologists, and only about 20% of patients receiving Subsyst actually suffered from breakthrough cancer pain — the only pain Subsyst was approved to treat.¹³⁶

Finally, Insys fraudulently obtained insurance reimbursement for Subsyst. Due to the risks associated with the drug, coverage reimbursement required prior authorization and insurers would only pay for Subsyst when it was used to treat breakthrough cancer pain.¹³⁷ Using a team of “prior authorization specialists,” Insys representatives would call insurers, pretend to be from a doctor's office (with blocked caller ID to disguise their true identities), and tell the insurer that the patient had breakthrough cancer pain when the patient in fact did not.¹³⁸ These tactics caused the approval rate of

129. *See id.*

130. *Id.*

131. Nate Raymond, *Rhode Island Doctor Pleads Guilty to Opioid Kickback Scheme Related to Insys*, REUTERS (Oct. 25, 2017, 2:48 PM), <https://www.reuters.com/article/us-insys-opioids/rhode-island-doctor-pleads-guilty-to-opioid-kickback-scheme-related-to-insys-idUSKBN1CU2SA> [<https://perma.cc/HS4G-SQ78>].

132. Hughes, *supra* note 125.

133. *Id.*

134. *Id.*

135. QUINONES, *supra* note 10, at 97.

136. Hughes, *supra* note 125.

137. *Id.*

138. *Id.*; *see also* U.S. SENATE HOMELAND SEC. & GOV'T AFFAIRS COMM., FUELING AN EPIDEMIC: INSYS THERAPEUTICS AND THE SYSTEMATIC MANIPULATION OF PRIOR AUTHORIZATION 8–10 (2017) (analyzing the transcript of such a call from an Insys sales representative to an insurance company representative).

Subsys to surge to 87% by 2013.¹³⁹ All of these tactics, taken together, constitute over-promotion by Insys.¹⁴⁰

3. *Drug Manufacturers' Engagement in Industry-Wide Marketing Practices Justifies the Creation of an Opioid Exception to the Learned Intermediary Doctrine*

Although the actions of Purdue, Cephalon, Insys, and other opioid manufacturers would be sufficient to prevent each *individually* from asserting the learned intermediary doctrine on failure to warn or over-promotion grounds, these sales tactics constituted an *industry-wide practice*, which warrants the establishment of an opioid exception to the learned intermediary doctrine. This position is supported by the reasoning behind the joint liability doctrine, which allows multiple tortfeasors to be held liable for the full amount of damages caused by their conduct.¹⁴¹

In the seminal case of *Hall v. E.I. Du Pont De Nemours & Co.*,¹⁴² Judge Jack Weinstein discussed the concept of joint liability in finding that the manufacturers of blasting caps could be tried together on the issue of joint liability.¹⁴³ First, Judge Weinstein outlined the elements of joint liability: “(1) causing harm (2) by cooperative or concerted activities (3) which violated a legal standard of care.”¹⁴⁴ Next, the decision described three major policy reasons underlying joint liability:

The first is the problem of joint or group control of risk: the need to deter hazardous behavior by groups or multiple defendants as well as by individuals. The second is the problem of enterprise liability: the policy of assigning the foreseeable costs of an activity to those in the most strategic position to reduce them. The third is the problem of fairness with respect to burden of proof: the desire to avoid denying recovery to an innocent injured plaintiff because proof of

139. Hughes, *supra* note 125.

140. Markland v. Insys Therapeutics, Inc., 270 F. Supp. 3d 1318, 1322 (M.D. Fla. 2017) (citing plaintiff's argument that the learned intermediary doctrine should not “be applied in this case due to Insys' aggressive over promotion of Subsys”). The Court did not reach this issue because it found plaintiff's claims to be preempted by federal law. *Id.* at 1331 n.6.

141. See *Tilcon Capaldi, Inc., v. Feldman*, 249 F.3d 54, 62 (1st Cir. 2001) (defining “joint liability”).

142. 345 F. Supp. 353 (E.D.N.Y. 1972).

143. *Id.* at 381.

144. *Id.* at 371.

causation may be within defendants' control or entirely unavailable.¹⁴⁵

Judge Weinstein also delved into what is considered “cooperative or concerted activities.” The decision held that “cooperative or concerted” activity does not mean that an express business venture must exist; “all that is required is that there shall be a common design or understanding.”¹⁴⁶ Indeed, “The variety of business and property relationships in which joint control of risk has been found demonstrates the flexibility of the doctrine. Liability is not limited to particular formal modes of cooperation, nor to illegal or grossly negligent activities.”¹⁴⁷ To this end, plaintiffs can show that defendants jointly controlled a risk by “submit[ing] evidence that defendants, acting independently, adhered to an industry-wide standard or custom.”¹⁴⁸ Finally, although Judge Weinstein also stated that “the existence of industry-wide standards or practices alone will not support, in all circumstances, the imposition of joint liability,”¹⁴⁹ he also articulated, “[T]he point [of joint liability] is not only that the damage is caused by multiple actors, but that the sole feasible way of anticipating costs or damages and devising practical remedies is to consider the activities of a group.”¹⁵⁰

These principles offer a theory of joint liability that may be applied to opioid drug manufacturers. Per the foregoing analysis,¹⁵¹ the marketing practices of Purdue, Cephalon, and Insys considerably overlap. First, all three companies targeted non-oncologist physicians, especially primary care and pain doctors and particularly those doctors known for heavy prescribing practices.¹⁵² Second, each of these companies marketed off-label uses for their drugs.¹⁵³ Finally, each company made extensive use of educational seminar-type engagements, such as CMEs and speaker series.¹⁵⁴ The confluence and intention of these three strategies indicate that these types of actions were “industry-wide standards and practices.”

145. *Id.*

146. *Id.*

147. *Id.* at 374.

148. *Id.*

149. *Id.*

150. *Id.* at 378.

151. *See supra* Section II.A.1 and II.A.2.

152. *See supra* Section II.A.1 and II.A.2.

153. *See supra* Section II.A.1 and II.A.2.

154. *See supra* Section II.A.1 and II.A.2.

Further, a finding of joint liability based on the marketing practices of Purdue, Cephalon, and Insys (among others) fulfills the three policy goals of the joint liability doctrine. As previously explained, joint control of risk is “the need to deter hazardous behavior by groups or multiple defendants as well as by individuals.”¹⁵⁵ It is necessary to deter drug manufacturers from excessively marketing opioids, thereby reducing the number of opioids in circulation. The second consideration is enterprise liability, which is “the policy of assigning the foreseeable costs of an activity to those in the most strategic position to reduce them.”¹⁵⁶ Drug manufacturers are not only the entities most in control of producing and distributing opioids but are also the only entities in control of their marketing protocols. As drug companies have previously circumvented government limits on marketing,¹⁵⁷ drug companies are thus in the most strategic position to reduce the foreseeable costs of their activities. Finally, as to fairness with respect to the burden of proof, patients were never intended to see the majority of marketing materials distributed by drug companies. The proof of causation, therefore, is largely within the control of drug manufacturers because patients must rely largely on materials within drug manufacturers’ possession to prove their cases.

It may be true that data showing which types of patients were prescribed opioids may disclose which drug manufacturers are responsible for specific injuries.¹⁵⁸ Thus, unlike the fact pattern in *Hall*, the drug manufacturers here are not unidentifiable parties. However, the purpose of joint liability is to reduce the possibility of risk and spread costs by considering the activities of individuals as a group.¹⁵⁹ Going after only one drug manufacturer will not end the opioid crisis. To illustrate, the conduct of Insys occurred five years after Purdue pled guilty in 2007 to criminal charges about

155. *Hall*, 345 F. Supp. at 371.

156. *Id.*

157. DOJ Press Release, *supra* note 118 (describing how Cephalon circumvented FDA limits on off-label marketing); Hughes, *supra* note 125 (describing how Insys circumvented FDA limits on off-label prescribing).

158. *What Information Does an Electronic Health Record (EHR) Contain?*, HEALTHIT.GOV (Mar. 17, 2013), <https://www.healthit.gov/faq/what-information-does-electronic-health-record-ehr-contain> [<https://perma.cc/8AUN-QBJB>].

159. *See Hall*, 345 F. Supp. at 378 (holding that joint liability “would represent rather the law’s traditional function of reviewing the risk and cost decisions inherent in industry-wide safety practices”).

misrepresenting the abusive potential of OxyContin.¹⁶⁰ In other words, even if one drug manufacturer is held liable for opioid-related conduct, another may spring up, and the conduct of each company only worsens the opioid crisis. Further, despite criminal penalties, Purdue has continued to peddle opioids.¹⁶¹ Since a 2007 Massachusetts judgment against it, Purdue has sold “more than 70,000,000 [70 million] doses of opioids in Massachusetts,” collecting “a revenue of \$500,000,000 [\$500 million].”¹⁶² Only by considering the actions of drug manufacturers as a group and imposing liability on industry-wide practices collectively can proper deterrence be achieved.¹⁶³ Accordingly, the policy justifications for joint liability mandate the creation of an opioid exception to the learned intermediary doctrine.

B. Prescription Opioids Are Not “Unavoidably Unsafe” for Treating Chronic, Non-Cancer Pain

The other major principle underlying the learned intermediary doctrine is that prescription drugs are “unavoidably unsafe” — that is, the drugs are *not* considered unreasonably dangerous when accompanied by proper warnings because the benefits associated with these drugs outweigh the costs.¹⁶⁴ As far as prescription opioids are concerned, this premise may be true when the drugs are used to treat acute temporary pain or pain in cancer patients.¹⁶⁵ The efficacy of treating chronic, non-cancer pain with opioids, however, is far less certain.¹⁶⁶ Because non-cancer patients make up the overwhelming majority of opioid users, as discussed *infra*, the inquiry should be whether opioids are unavoidably unsafe when treating chronic, non-cancer pain.

160. Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <https://www.nytimes.com/2007/05/10/business/11drug-web.html> [<https://perma.cc/6ED9-PJ6L>].

161. First Amended Complaint at 12, *Commonwealth v. Purdue Pharma L.P.*, No. 1884-cv-01808 (Mass. Super. Ct. Jan. 31, 2019) (alleging that since a 2007 judgment against it, Purdue visited Massachusetts prescribers and pharmacists “more than 150,000 times”).

162. *Id.* at 8.

163. *Hall*, 345 F. Supp. at 378 (holding that in certain circumstances, joint liability is “the only feasible method of ascertaining risks, imposing safeguards and spreading costs is through joint liability or other methods of joint risk control”).

164. Kane, *supra* note 54, § 2[a].

165. Van Zee, *supra* note 34, at 223 (noting that the science supporting treating acute and cancer pain with opioids is “robust”).

166. *Id.* (noting “there is still much controversy in medicine about the use of opioids for chronic non-cancer-related pain”).

Some courts have held that comment k to section 402 of the Second Restatement of Torts¹⁶⁷ – which gave birth to the concept of “unavoidably unsafe” – should always apply to prescription drugs so long as they are accompanied by proper warnings.¹⁶⁸ Other courts have suggested a case-by-case inquiry as to whether a prescription drug is unavoidably unsafe.¹⁶⁹ In *Toner v. Lederle Laboratories*,¹⁷⁰ for example, the Idaho Supreme Court noted that “[comment k] contemplates a weighing of the benefit of the product against the risk,” and that “this weighing process should consider the value of the benefit, the seriousness of the risk, and the likelihood of both.”¹⁷¹ Similarly, the Colorado Supreme Court in *Belle Bonfils Memorial Blood Bank v. Hansen*¹⁷² held that for a drug to be classified as “unavoidably unsafe,” “the product’s utility must greatly outweigh the risk created by its use; the risk must be a known one; the product’s benefits must not be achievable in another manner; and the risk must be unavoidable under the present state of knowledge.”¹⁷³ The *Hansen* court also held that the “benefit should extend to the vast majority of the users of the product.”¹⁷⁴

Even the Third Restatement of Torts seems to have walked back the approach of comment k. In section 6, the Third Restatement states the following:

(c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.¹⁷⁵

Under these frameworks, prescription opioids fail to meet the definition of unavoidably unsafe for treating chronic, non-cancer pain. Under the *Toner* standard, “the value” of a drug’s benefits are

167. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

168. *See, e.g.*, *Brown v. Superior Court*, 751 P.2d 470, 482–83 (Cal. 1988) (holding a drug manufacturer “is not strictly liable for injuries caused by a prescription drug so long as the drug was . . . accompanied by warnings of its dangerous propensities”).

169. *See, e.g.*, *Feldman v. Lederle Laboratories*, 479 A.2d 374, 383 (N.J. 1984) (“[W]e perceive no justification for giving all prescription drug manufacturers a blanket immunity from strict liability and design defect claims under comment k.”).

170. 732 P.2d 297 (Idaho 1987).

171. *Id.* at 306.

172. 665 P.2d 118 (Colo. 1983).

173. *Id.* at 122.

174. *Id.* at 123.

175. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (AM. LAW INST. 1998).

weighed against “the seriousness” of its risks and “the likelihood of both” occurring to determine whether the drug is “unavoidably unsafe.”¹⁷⁶ Prescription opioids theoretically provide the benefit of pain relief.¹⁷⁷ However, whether opioids in fact provide pain relief is contestable. Four-week studies concerning opioid treatment have shown patients to have “statistically significant but small to modest improvement in pain relief with no consistent improvement in physical functioning.”¹⁷⁸ Longer-term pain relief is even more unclear,¹⁷⁹ as are the effects of these drugs on quality of life.¹⁸⁰ Further, these benefits do not outweigh the serious side effects caused by opioids, including hyperalgesia (increased susceptibility to pain), respiratory depression, constipation, hormonal effects (e.g., decreased libido), effects on the immune system (at least in immunocompromised persons, such as HIV patients), and addiction.¹⁸¹ Although a number of side effects caused by opioids disappear with continued use, constipation and hormonal effects can persist indefinitely.¹⁸² The risk of opioid abuse has also been measured to be as high as 45%, while the risk of opioid addiction¹⁸³ has been assessed to reach as high as 50%, depending on the patient population studied.¹⁸⁴ Prescription opioids have also been linked to more overdose deaths than illicit drugs such as cocaine¹⁸⁵ and are the most common types of prescription drugs that are diverted.¹⁸⁶ The risk of prescription opioid abuse has also been coupled with the use of heroin. Studies have shown that, between 2008 and 2010, among

176. *Toner*, 732 P.2d at 306.

177. Jane C. Ballantyne, *Opioids for Chronic Nonterminal Pain*, 99 S. MED. J. 1245, 1246 (2006) (“[C]linical observation suggests that chronic pain states are, in fact, relieved by opioid treatment.”).

178. Van Zee, *supra* note 34, at 223 (citing various studies).

179. *Id.*; see also Ballantyne, *supra* note 177, at 1246 (“The question of whether analgesic efficacy and other benefits of chronic opioid therapy can be maintained over years rather than months remains unanswered.”).

180. Ballantyne, *supra* note 177, at 1248.

181. *Id.* at 1248–49.

182. *Id.*

183. “Drug abuse” is the overuse of a drug without becoming physically dependent on it. “Drug addiction” requires physical dependence. See *What Is the Difference Between Abuse and Addiction?*, EVERYDAY HEALTH (Aug. 13, 2012), <https://www.everydayhealth.com/addiction/experts-difference-between-substance-abuse-and-drug-addiction.aspx> [<https://perma.cc/RQY7-B8E9>].

184. Van Zee, *supra* note 34, at 223.

185. See U.S. DEP’T OF JUSTICE DRUG ENF’T ADMIN., 2017 NATIONAL DRUG THREAT ASSESSMENT 25 (2017), https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf [<https://perma.cc/7YQU-YQ57>].

186. *Id.* at 33.

people who used both prescription opioids and heroin, 77.4% reported using prescription opioids before transitioning to heroin.¹⁸⁷

The prevalence of negative side effects coupled with the risks of addiction, abuse, and transitioning to heroin outweigh the arguable efficacy of using opioids to treat long-term chronic pain. This balancing is further supported by the FDA's recent decision to remove Opana ER, an extended-release opioid,¹⁸⁸ from the market because "the benefits of the drug may no longer outweigh its costs."¹⁸⁹ Based on this evidence, opioid painkillers fail to meet the *Toner* standard for being unavoidably unsafe because their side effects outweigh the alleged benefits.

Under the *Hansen* standard, prescription opioids would also not be considered unavoidably unsafe. *Hansen*, also weighs the costs and benefits of a drug, focusing on (1) whether "the product's utility greatly outweigh[s]" its risks; (2) whether "the risk is a known one"; (3) whether the product's benefits are "achievable in another manner"; (4) whether the risk is "unavoidable under the present state of knowledge"; and (5) whether the benefit "extend[s] to the vast majority of the users of the product."¹⁹⁰ As demonstrated *supra*, the risks associated with prescription opioids outweigh the benefits for the treatment of long-term chronic pain. Bolstering this assertion, opioids are not a first-line treatment for chronic pain, and there are non-opioid treatments that can provide relief while being demonstrably safer.¹⁹¹ In other words, the benefits of opioid treatment are achievable in another manner without the dangerous

187. Wilson M. Compton et al., *Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use*, 374 NEW ENG. J. MED. 154, 156 (2016) (citing studies).

188. There are various types of opioid painkillers. The class Opana ER (as well as OxyContin) belongs to is called "long-acting" or "extended release" opioids. These opioids slowly send the drug into the body over several hours, as opposed to all at once. QUINONES, *supra* note 10, at 124. In theory, this made extended release opioids less addictive. *Id.* at 85. Ironically, it has been shown that extended release opioids are more prone to abuse and overdose. Leonard J. Paulozzi et al., *Vital Signs: Variation Among States in Prescribing Opioid Pain Relievers and Benzodiazepines – United States, 2012*, 63 MORBIDITY & MORTALITY WKLY. REP. 563, 563 (2014).

189. Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm> [<https://perma.cc/299B-945M>].

190. *Belle Bonfils Memorial Blood Bank v. Hansen*, 665 P.2d 118, 122–23 (Colo. 1983).

191. CTRS. FOR DISEASE CONTROL & PREVENTION, NON-OPIOID TREATMENTS FOR CHRONIC PAIN 1–2 (2016), https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf [<https://perma.cc/87WB-W4BK>].

side effects. Furthermore, as non-cancer patients made up 86% of the total opioid market in 1999,¹⁹² the majority of prescription opioid users take a drug whose costs outweigh its benefits. Even if the risk involving opioids is known and unavoidable, opioids would still fail to meet the *Hansen* standard.

Finally, opioids fail to classify as unavoidably unsafe under the Third Restatement approach. The Third Restatement asks if “the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits” such that reasonable healthcare providers would not prescribe the drug.¹⁹³

Again, as noted above, the risks of opioids outweigh the benefits in terms of treating long-term, chronic pain. Moreover, it is true that cancer patients and those with acute pain do benefit from opioid treatment, which means doctors would prescribe opioids for at least two classes of patients, satisfying an aspect of the Third Restatement approach. However, as explained *supra*, this group represents a minority of the opioid market, and “[i]t does not serve society that an unavoidably unsafe product, which has occasional or factious benefit, should enjoy insulation from strict liability in tort when the product’s predominant effects are detrimental to individual and public safety.”¹⁹⁴ Thus, opioids are not unavoidably unsafe under the Third Restatement approach.

In treating long-term, chronic patients with opioid painkillers, the risks outweigh the benefits for most patients. As a result, opioids fail to meet the standards of several accepted balancing tests for determining which drugs are unavoidably unsafe. Accordingly, because opioids are not unavoidably unsafe for treating long-term, chronic pain, an exception to the learned intermediary doctrine should be created for opioids.

III. THE EFFECTS OF CREATING THE OPIOID EXCEPTION TO THE LEARNED INTERMEDIARY DOCTRINE

By exposing drug manufacturers to more liability, creating the opioid exception will impose a higher level of accountability on said manufacturers, which will, in turn, increase the cost of opioid drugs

192. See Van Zee, *supra* note 34, at 223.

193. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (AM. LAW INST. 1998).

194. Sidney H. Willig, *The Comment K Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 545 (1978).

and decrease their availability.¹⁹⁵ Drug manufacturers would also be required to directly and adequately warn patients about the dangers of opioids.¹⁹⁶ Drug manufacturers could do this by clearly stating the risks of addiction on drug labels and in marketing materials addressed to patients.¹⁹⁷ In theory, restricting the flow of prescription opioids would help alleviate the crisis. However, restricting the flow of prescription opioids might create additional problems.

A. The Problem of Pre-Existing Chronic, Non-Cancer Pain Patients

First, restricting the flow of opioids will not stop patients who have already become dependent on opioids from being addicted; that is to say, a lack of opioids will not cure pre-existing addiction. Rather, restricting the flow may deter future addiction, but pre-existing addicts, with fewer prescription opioids available and those that are available becoming more expensive than before¹⁹⁸ will be pushed towards cheaper opiates such as heroin.¹⁹⁹ However, many of these people resorted to opioids in the first place because they had no other way to deal with their pain.²⁰⁰ In the case of chronic, non-cancer pain, that scenario does not have to be.

One promising approach to treating chronic pain without relying on opioids involves multi-disciplinary treatment. As an illustration, the Center for Pain Relief at the University of Washington Medical

195. Kent Durning, *No Pain No Gain?! Who Will Make the Greatest Sacrifices in Curbing Opioid Analgesic Diversion and Abuse?*, 93 KY. L.J. 199, 234 (2004).

196. Jennifer A. Guidea & Shana E. Russo, *The Learned Intermediary Doctrine: A Retrospective Review to the Present*, REED SMITH LIFE SCIENCES INDUSTRY GROUP PRESENTATION 22, <https://www.reedsmith.com/-/media/files/events/2014/02/reed-smith-teleseminar/files/presentation-materials/fileattachment/the-learned-intermediary-doctrine-22714-presenta.pdf> [<https://perma.cc/NPA5-Z849>].

197. The current OxyContin label, for instance, refers patients to a “Medication Guide.” See, e.g., *OxyContin*, DRUGS LIBRARY, http://www.drugs-library.com/drugs/oxycontin_bfdfe235.html [<https://perma.cc/KCB4-QKZZ>] (featuring labels). A more effective warning would be to actually note the risk of addiction and other negative effects of OxyContin directly on the package in large, clear font, much like with cigarettes. Compare *id.*, with *Surgeon General’s Warning Cigarettes*, WIKIMEDIA COMMONS (Jan. 28, 2017, 2:01 PM), https://commons.wikimedia.org/wiki/File:Surgeon_General%27s_warning_cigarettes.jpg [<https://perma.cc/MW9X-2Z8K>].

198. Durning, *supra* note 195, at 234.

199. QUINONES, *supra* note 10, at 6.

200. Hughes et al., *supra* note 35 (stating that 62.6% of people who abused prescription opioids in 2015 did so to relieve pain).

School has adopted a “bio-psycho-social” approach to pain relief, using occupational therapists, physical therapists, social workers, and others to treat pain, and teaching patients medical and life strategies to control pain through exercise and maintaining a healthy diet.²⁰¹ These types of programs have been shown to improve psychological and physical function in patients,²⁰² even more so than conventional medical treatments.²⁰³ For instance, patients who undertake multidisciplinary pain treatment are almost twice as likely to return to work as patients treated with only one medical discipline.²⁰⁴ The CDC is supportive of these treatments as well, stating that opioids are “not the first-line therapy for [non-cancer, palliative, or end-of-life] chronic pain,” and recommending a number of non-opioid treatments that “can provide relief to those suffering from chronic pain, and are safer.”²⁰⁵ The National Institutes of Health has also endorsed a multi-disciplinary approach, stating that the “best practice models for chronic pain management require a multidisciplinary approach similar to that recommended for other chronic complex illnesses such as depression, dementia, eating disorders, or diabetes.”²⁰⁶ The National Institutes of Health has also noted that “[r]esearch demonstrates that [pain] can be managed successfully using an interdisciplinary team-based approach to care (e.g. medicine, psychology, nursing, pharmacy, social work).”²⁰⁷ However, there are several reasons why this method is not used more often.

201. QUINONES, *supra* note 10, at 86.

202. Jaime Guzmán et al., *Multidisciplinary Rehabilitation for Chronic Low Back Pain: Systematic Review*, 322 *BMJ* 1511, 1511 (2001) (finding evidence that “intensive multidisciplinary biopsychosocial rehabilitation with functional restoration reduces pain and improves function in patients with chronic low back pain”); Mark P. Jensen et al., *Correlates of Improvement in Multidisciplinary Treatment of Chronic Pain*, 62 *J. CONSULTING & CLINICAL PSYCHOL.* 172, 172 (1994).

203. Herta Flor et al., *Efficacy of Multidisciplinary Pain Treatment Centers: A Meta-Analytic Review*, 49 *PAIN* 221, 225 (1992); Luca Scascighini et al., *Multidisciplinary Treatment for Chronic Pain: A Systematic Review of Interventions and Outcomes*, 47 *RHEUMATOLOGY* 670, 676 (2008) (finding multidisciplinary programs are more effective “than standard medical treatment”).

204. See Flor et al., *supra* note 203, at 226; see also Anders Norlund et al., *Multidisciplinary Interventions: Review of Studies of Return to Work After Rehabilitation for Low Back Pain*, 41 *J. REHABILITATIVE MED.* 115, 120 (2009) (finding that multidisciplinary treatment has a “significant effect” on return to work for “people with low back pain who are on sick leave for longer than 4 weeks”).

205. *CTRS. FOR DISEASE CONTROL & PREVENTION*, *supra* note 191, at 1.

206. *NAT’L INSTS. OF HEALTH, PATHWAYS TO PREVENTION WORKSHOP: THE ROLE OF OPIOIDS IN THE TREATMENT OF CHRONIC PAIN* 16 (2014), https://prevention.nih.gov/sites/default/files/documents/programs/p2p/ODPPainPanelStatementFinal_10-02-14.pdf [<https://perma.cc/W5KB-4SYX>].

207. *Id.*

1. *Despite the Impediments to Multi-Disciplinary Approaches to Pain Treatment, It Still Represents an Effective Alternative to Opioids*

There are three main impediments to multi-disciplinary approaches to pain treatment. The first is a “quick fix” mentality among patients that is adverse to the lengthy therapy of multi-disciplinary treatment.²⁰⁸ The second impediment is that not all areas of the country have access to multi-disciplinary treatment programs.²⁰⁹ Finally, the third is the fact that many traditional medical insurers do not cover these types of programs. As a result of the managed care movement, health insurers began cutting costs and reducing the types and amounts of reimbursable services.²¹⁰ Included among the “cuts” were aspects of multidisciplinary treatment that were not strictly “medical” (components which made up a substantial portion of multidisciplinary treatment),²¹¹ because pills were more convenient and less costly.²¹²

Although there is no “quick fix” to the problem of a “quick fix” mentality among patients, the rationale of insurance companies is misguided. Studies have shown multi-disciplinary treatments to result in a 43% savings in disability payments (estimated by some investigations to result in billions of dollars to third parties)²¹³ and an estimated \$184 million savings in medical and surgical expenses.²¹⁴ A study done by Daisha J. Cipher, et al. demonstrated that patients who were treated only with pharmacological treatments imposed the highest costs to the healthcare system as compared to patients who received both pharmacological and cognitive behavioral treatment because their condition deteriorated after treatment.²¹⁵ In response to this kind of data, insurance companies should be incentivized to subsidize multi-disciplinary treatment as a proven strategy to cut or contain costs associated with chronic pain.

208. QUINONES, *supra* note 10, at 87.

209. *Last Week Tonight with John Oliver: Opioids*, *supra* note 104 (showing footage of an interview with a doctor stating that many rural areas, which have been the hardest hit by the opioid crisis, do not have access to alternative treatments).

210. QUINONES, *supra* note 10, at 97.

211. *See id.* at 87.

212. *See id.* at 253.

213. *See* Flor et al., *supra* note 203, at 227.

214. Daisha J. Cipher et al., *Cost-Effectiveness and Health Care Utilization in a Multidisciplinary Pain Center: Comparison of Three Treatment Groups*, 8 J. CLINICAL PSYCHOL. MED. SETTINGS 237, 238 (2001).

215. *Id.* at 243–44.

Drug manufacturers could also help ameliorate the lack of multi-disciplinary treatments in certain areas. Currently, a multi-district litigation (MDL) against opioid drug manufacturers is brewing in the Northern District of Ohio.²¹⁶ Judge Polster, who is overseeing the MDL, has expressed his desire to take concrete action to stop the opioid crisis rather than merely engage in traditional litigation.²¹⁷ To that end, one such solution could be a *cy pres* remedy in which drug manufacturers agree, as part of a settlement, to spend money funding and setting up multi-disciplinary pain clinics. Typically, *cy pres* remedies are reserved for when “a settlement cannot feasibly compensate class members directly,” and instead these efforts would provide funding to organizations or interests that share similar goals with the class.²¹⁸ Through patient records, it is possible that the affected plaintiffs could be identified and compensated by a global settlement.²¹⁹ However, if funds are left over, a *cy pres* settlement funding multi-disciplinary pain clinics would serve the same interests as plaintiffs (i.e., deterring future opioid abuse by transferring money from drug manufacturers and generating alternative treatment options to pain), thereby satisfying the court’s goals. In fact, Purdue did something similar to this by helping fund an opioid addiction and pain treatment center at Oklahoma State University as part of a settlement agreement with the state of Oklahoma.²²⁰

If it is not feasible to provide multi-disciplinary clinics in areas that need them, other options exist to alleviate the opioid crisis. If opioids must continue to be distributed to treat chronic pain, the CDC’s guidelines for opioid treatment²²¹ should be followed. The guidelines suggest, among other things: starting treatment with immediate-

216. *In re National Prescription Opiate Litigation*, No. 17-md-02804 (N.D. Ohio 2017), <http://www.ohnd.uscourts.gov/mdl-2804> [<https://perma.cc/EY73-4T2D>].

217. Transcript of Proceedings at 4–6, *In re National Prescription Opiate Litigation*, Doc. No. 58.

218. See Howard M. Erichson, *Aggregation as Disempowerment: Red Flags in Class Action Settlements*, 92 NOTRE DAME L. REV. 859, 882 (2016).

219. See *What Information Does an Electronic Health Record (EHR) Contain?*, *supra* note 158.

220. German Lopez, *OxyContin Maker Purdue Pharma Is Being Held Accountable for the Opioid Epidemic*, VOX (Mar. 26, 2019, 11:40 AM), <https://www.vox.com/science-and-health/2019/3/26/18282262/opioid-epidemic-purdue-pharma-oxycontin-oklahoma-lawsuit-settlement> [<https://perma.cc/HQ9B-ABV5>].

221. DEBORAH DOWELL ET AL., CTRS. FOR DISEASE CONTROL & PREVENTION, CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN – UNITED STATES, 2016 (2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> [<https://perma.cc/KJ3H-3BYH>] [hereinafter CDC GUIDELINE].

release opioids,²²² prescribing opioids for acute pain for a short duration,²²³ continual evaluation by physicians regarding the costs and benefits of the treatment,²²⁴ reviewing a patient's drug prescription history for concomitant medications and assessing if these medications, in combination with opioids, put the patient at a high risk for overdose,²²⁵ and using urine tests, both to ensure that the patient is not using any other illicit drugs²²⁶ and to test for the lack of drugs to verify that the patient is actually taking the medication and not selling it.²²⁷ The guidelines also recommend alternative treatments, even ones that are readily available, such as exercise.²²⁸

B. The Problem of Cancer Patients and Other Similarly Situated Patients

The second consequence of exposing drug manufacturers to increased liability, thereby restricting the flow of opioids, is that such a policy will restrict access to opioids by those most reliant on these agents: cancer patients and those in palliative or end-of-life care.²²⁹ Opioids are an important component of treatment for these patients,²³⁰ and there is no easy solution to ensuring these patients

222. *Id.* at 21.

223. *Id.* at 24 (recommending prescribing no more than three to seven days-worth of opioids).

224. *Id.* at 25.

225. *Id.* at 29. The current monitoring system — known as the prescription drug monitoring program (PDMP) — needs improvement, however. Although every state but Missouri has such a system, patients can opt out of the system for privacy reasons, and insurers (who supply the data) can refuse to opt in. Jan Hoffman, *Patients in Pain, and a Doctor Who Must Limit Drugs*, N.Y. TIMES (Mar. 16, 2016), <https://www.nytimes.com/2016/03/17/health/er-pain-pills-opioids-addiction-doctors.html> [<https://perma.cc/3M6X-G9T9>]. Further, most states' systems are not compatible with one another, meaning a patient can move from one state to another and appear to have a clean slate. *Id.* A solution to these problems might include mandatory reporting for opioid use, but also a national reporting system, or at least standardization of state systems so that they work with one another. The latter policy — a national reporting system or standardized state reporting systems — is supported by the American College of Physicians. See generally Neil Kirschner et al., *Prescription Drug Abuse: Executive Summary of a Policy Position Paper from the American College of Physicians*, 160 ANNALS INTERNAL MED. 198, 199 (Feb. 4, 2014), <https://annals.org/aim/fullarticle/1788221/prescription-drug-abuse-executive-summary-policy-position-paper-from-american> [<https://perma.cc/QDK7-PBST>].

226. CDC GUIDELINE, *supra* note 221, at 30.

227. Hoffman, *supra* note 225.

228. CDC GUIDELINE, *supra* note 221, at 17.

229. *Cf. id.* at 1 (noting the guidelines do not apply to such patients).

230. QUINONES, *supra* note 10, at 80 (noting the importance of “pain relief and a dignified death” and the irrelevance of addiction “[i]f people were soon to die” as

would still have the same degree of access to opioids. Stringent regulations could be imposed to limit the distribution of opioids to only these types of patients. Drug manufacturers and insurance companies could also work together to reduce the costs of these medications for these patients. Or, perhaps most effectively, more research could be conducted to ascertain which opioids are most effective for cancer patients.²³¹ Surprisingly, there are few, if any, nationwide studies on opioid prescriptions for cancer patients,²³² and not all oncologists have adequate knowledge of pain management.²³³ Further, not every opioid is suitable for treating cancer patients,²³⁴ and there are conflicting results as to which opioids work for cancer patients. For instance, weaker opioids are a major part of treatment for cancer patients in Taiwan, but the European Society of Medical Oncology and European Association of Palliative Care have put out guidelines emphasizing the use of strong opioids in treating cancer patients.²³⁵ Accordingly, further research should be conducted concerning the types of opioids that benefit cancer patients and other similarly situated patients. This strategy might allow drug manufacturers to focus their efforts on creating drugs that benefit this class of patients and allowing these select opioids to pass regulatory hurdles, making them easier to access.

CONCLUSION

For decades, the learned intermediary doctrine has served as a formidable protection against tort liability for drug manufacturers, absolving them of the harms caused by their products so long as they adequately warned prescribing physicians. However, drug manufactures have abused this exception and defeated its meaning by interfering with the doctor-patient relationship through excessive

underlying the movement in the 1970s to treat cancer patients and terminally ill patients with opioids); Chih-Peng Lin et al., *Key Opioid Prescription Concerns in Cancer Patients: A Nationwide Study*, 54 ACTA ANAESTHESIOLOGICA TAIWANICA 51, 51 (2016) (noting opioids are crucial to pain management in cancer patients).

231. See NAT'L INSTS. OF HEALTH, *supra* note 206, at 34 (“At the root of the problem [of pain treatment] is the inadequate knowledge about the best approaches to treat various types of pain, balancing the effectiveness with the potential for harm, as well as a dysfunctional health care delivery system that encourages clinicians to prescribe the easiest rather than the best approach for addressing pain.”).

232. See Lin et al., *supra* note 230, at 54 (noting this study was the first to “specifically focus on the nationwide opioid prescription to patients with cancer”).

233. *Id.* at 52.

234. *Id.* at 51.

235. *Id.* at 55.

marketing and misleading statements. In response, the principles underlying the learned intermediary doctrine have been questioned by legal scholars. The benefits of some drugs do not necessarily outweigh their risks, and excessive marketing campaigns affect the expectations of patients and encourage doctors to prescribe drugs against their best judgment. The opioid crisis represents a confluence of these actions, and it undermines the very pillars upon which the learned intermediary doctrine rests. To remedy this crisis, an opioid exception to the learned intermediary doctrine must be crafted so that opioid manufacturers may be held liable in tort for the harm caused by their drugs.