NOTES

A NEW PRESCRIPTION: THE CASE FOR ENTERPRISE LIABILITY REFORM IN LIGHT OF THE OPIOID EPIDEMIC

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ABSTRACT

This paper argues that the current scheme of enterprise liability needs reform. Enterprise liability has already experienced a significant shift in the early twentieth century from a purely contract-based liability to a more modern tort liability framework in response to changing socioeconomic conditions. Much like the shift championed by Kessler in the early twentieth century, another reformation in current enterprise liability is long overdue. The opioid epidemic has rocked every corner of American society. This epidemic is unique in both the breadth and intentionality used by drug manufacturers to put a knowingly addictive and harmful product into the streams of commerce. The current scheme of enterprise liability does not capture or begin to address a situation like what we see today, and thus needs reform to help provide a solution to one of the most pressing problems of our time.

INTRODUCTION

"[M]ore than 200,000 people have died in the United States from overdoses involving prescription opioids" in the past two decades.[1] As alarming as this statistic is, the rate at which this epidemic has grown is even more concerning. There were 17,029 deaths involving prescription opioid overdoses in 2017, up from 3,442 in 1999. "Drug overdose deaths involving prescription opioids rose from 3,442 in 1999 to 17,029 in 2017."[2] The legal response to this growing epidemic has been swift. Major opiate manufacturers such as Purdue Pharma have been buried in a mountain of lawsuits by Attorney Generals and municipalities.[3] Even distributors have faced steep litigation for the role that they have played.[4]

1. Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew its Opioids Were Widely Abused*, N.Y. TIMES (May 29, 2018), ".

2. *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (last visited Feb. 20, 2020).

3. In Re: Nat'l Prescription Opiate Litig., No. 1:17-md-2804 (N.D. Ohio Sep. 3, 2019) (order denying summary judgment motions on causation).

4. *Id.* at 2.

Despite the recent avalanche of litigation against opioid manufacturers and distributors, there is a noticeable lack of litigation coming from the perceived "victims" in these situations—the users of the opioids and their families. Lawsuits against a manufacturer for a product that causes harm to consumers would fall under the general umbrella of enterprise liability. The lack of litigation in this area in response to this crisis begs the question, "does the current enterprise liability scheme provide an adequate remedy for the widespread intentional damage inflicted by large pharmaceutical companies?"

This Note answers this question through a four-part analysis of enterprise liability. Part I discusses the historical origins and transformation of enterprise liability, drawing heavily from a historical account of enterprise liability written by George L. Priest. Part II analyzes the modern opioid epidemic in context of the current tort scheme. Part III examines why the current scheme is not adequate to redress grievances brought as a result of the current crisis, and Part IV proposes alternative solutions that can better address these concerns.

I. A HISTORICAL DISCUSSION OF ENTERPRISE LIABILITY

A. The Origins of Enterprise Liability

Enterprise liability is an evolving field. In the last century, it has experienced a "conceptual revolution that is among the most dramatic ever witnessed in the Anglo-American legal system."[5] In the 1920s, contract law chiefly determined any recovery for an injury. This contract system is exemplified in the landmark case *Winterbottom v. Wright*.[6] The court summarizes the rationale of the day, stating that "it is a general rule, that wherever a wrong arises merely out of the breach of a contract, which is the case on the face of this declaration . . . the party who made the contract *alone* can sue . . . if privity of contract were not requisite, there would be no limit to such actions."[7] In this system, only a specific purchaser of a product in privity of contract was allowed to recover only what was expressly enumerated in the products warranty or implied warranty of merchantability.[8] During this time, there was not a widespread recognition of negligence claims to parties that did not have privity of contract.[9][Priest at 461] Thus, under the contract era of liability, the privity of contract requirement created a substantial standing barrier that would need to be overcome even to bring a case against a product manufacturer. If one could establish standing, their recovery would still be limited to what was in the express terms of product warranty or what would be allowed within an implied warranty of merchantability.[10]

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5. George L. Priest, *The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law*, 14 J. LEGAL STUD. 461, 465 (1985).

6. Winterbottom v. Wright, 152 Eng. Rep. 402 (Ex. 1842).

7. *Id.* at 403 (emphasis added).

8. Priest, *supra* note 5, at 461.

9. *Id.*

10. *Id.*

B. The Intellectual Revolution of Products Liability

The contract scheme that dominated enterprise liability underwent a shift in the 1950s and 1960s, which created the foundation for the modern enterprise liability scheme we see today. This transition started with a change in the academic focus on manufacturer liability in the 1950s. By 1957, manufacturer liability had become one of the prominent issues in tort law instead of "a backwater in the flood of attention to automobile accidents."[11] This new theory of enterprise liability was championed by scholars such as Kessler, Hale, James, and others.[12] The two main points of these new advances were that (1) "modern consumers were powerless in contrast to manufacturers[;]" and (2) "if courts were to protect consumers, contract law provided inadequate grounds because of the nonconsensual character of the modern transaction."[13] The new socioeconomic realities demonstrated that the corporate enterprise had a superior position to control the risk of injury and to ensure for uncontrollable losses.[14]

The new academic focus on product liability combined with changing socioeconomic realities resulted in a synthesis of the old contracts regime with new academic discussion into the modern product liability scheme that is seen today. It had become clear through contract scholarship of the time that warranty law was insufficient to protect powerless consumers from the efforts of powerful manufacturers to avoid liability for product-related injuries.[15] "Tort scholarship also established that society would benefit from internalizing injury costs to manufacturing enterprises, to encourage such enterprises either to prevent injuries or to insure for them."[16] "The convergence of these streams of thought constitutes the mature theory of enterprise liability that dominates modern tort law today."[17] This socioeconomic imbalance between contracting parties also gave the new product liability scheme a "moral mission."[18] The new scheme continued to recognize the importance of contract law in society while balancing the importance with the fact that standardized contracts now allowed more bargaining power for parties that drafted the contracts used.

Kessler discusses nineteenth century contract transactions as one where both parties were able to look out for their own interests, and oppressive bargains could be avoided by shopping around.[19] During this era, courts refused to contract for parties, and merely interpreted contracts strictly.[20] Courts looked to maintain the "the utmost liberty of contracting" as the principle freedom of

11. *Id.* at 504.
12. *See id.* at 495–96.
13. *Id.* at 496.
14. *Id.* at 492.
15. *Id.* at 505.
16. *Id.*
17. *Id.* at 505.
18. *Id*. at 483.
19. *Id.* at 493.
20. *Id.*

negotiation.[21] Kessler, however, points out that both academics and courts recognized that this era of "equal skill and bargaining power" between parties had come to an end, and courts had begun to make "efforts to protect the weaker parties [in] standardized transactions by selective interpretation . . . even where ambiguity was totally absent."[22] This acknowledgment of inequity allowed for courts to continue to protect weaker parties in transactions while appearing to maintain and uphold the basic principles in contract law.[23] This synthesis began a shift away from traditional strict contract liability, but these judicial efforts also "introduce[ed] confusion and uncertainty into the law."[24]

C. "The Assault Upon the Citadel" and Judicial Adoption of the Modern Liability Scheme

The final step in the academic and judicial evolution in products liability is epitomized in Prosser's article *The Assault upon the Citadel*. He begins by highlighting the expansion of negligence into product defects cases.[25] He then turns to a poignant criticism of the contract liability scheme, pointing out the socioeconomic imbalances present in using standard form contracts to settle product liability. He states that sellers possess a "dangerous power" to insert any term in a product warranty or to disclaim any affirmative legal obligation and that the ability to exercise this power to their unilateral benefit creates "a booby-trap for the unwary."[26] Prosser's article concisely enumerates the arguments and discussions surrounding the trend towards total abolition of the privity of contract requirement and the adoption of the strict liability standard as the standard of tort liability in product defect actions.[27] His ability to merge the traditional contractual scheme with the new tort structure has been viewed by legal scholars as highly influential. Prosser's article, along with others such as Harper and James, received frequent recognition in the years following 1960 as jurisdictions began to adopt the strict liability tort standard.[28] In 1960, almost concurrently with Prosser's publication, the New Jersey Supreme Court ruled that a disclaimer of the implied warranties and an exclusion of consequential (personal injury) damages in a product warranty was void as against public policy in *Henningsen v. Bloomfield Motors, Inc*.[29] Similarly, in 1963, the California Supreme Court declared a standard of strict tort liability in personal injuries caused by a product in *Greenman v. Yuba Powers Products, Inc*.[30]

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21. *Id.* (footnote omitted).

22. *Id.* at 494.

23. *Id.*

24. *Id.*

25. William L. Prosser, *The Assault upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1100–11 (1960).

26. *Id.* at 1130–32.

27. Priest, *supra* note 5, at 506.

28. *Id.*

29. 161 A.2d 69 (N.J. 1960).

30. 377 P.2d 897 (Cal. 1963).

Henningsen and *Greenman* were the first judicial adoptions of the theory. Still, in 1964 the American Law Institute in the Restatement (Second) of Torts adopted Section 402A, which adopted a theory of manufacturer liability in certain faulty product situations.[31]

Prosser's ability to simultaneously predict and confirm this transformative shift has been widely recognized as both a unique and remarkable feat. Prosser's writings which ultimately correctly predicted the direction of products liability (as it was developing before him) has been likened to "Einstein's relativity paper [which] had been delivered to its readers exactly during the 1919 eclipse of the sun."[32] Prosser's work helps capture the "accumulated effect of thirty years of scholarship that had created a consensus about the relatively inferior bargaining power of consumers, the importance of internalizing costs to manufacturers," and the growing trend in embracing a products liability scheme that mirrors what we see today.[33]

The dramatic shift from a contract to tort liability was a result of multiple catalysts worth highlighting. First, the change in bargaining inequality that undermined the assumptions the previous system was based on. The advent of standard form contracts allowed unscrupulous companies that drafted contracts to insert exculpatory clauses that freed them from liability for defective products. These actions ran opposite to the intentions of the original contract system. The contract system was originally intentioned to allow two independent parties to freely bargain for and reach an optimal deal and hold the parties in privity to the contract accountable in situations when disagreements arose. Over time, this system was subverted by companies who drafted contracts to use the legal system to shirk responsibility. By abandoning the anticipated negotiating that helped justify the contract system originally, drafting companies in part led to the demise of the contract system.

Second, the socioeconomic realities of the 1950s and 1960s reflected a different world than the one that existed when the contract scheme was introduced. The lack of actual negotiating between contracting parties shifted the bargaining power between parties. This was exacerbated by the changing nature of the consumer. The American economy in the 1950s and 1960s was a larger, more inclusive, and more robust marketplace than America in 1914, and that welcomed the Uniform Sales Act. The average consumer looked different—since the turn of the century, women and minorities had seen increasing incorporation and enfranchisement in the marketplace and in society. Furthermore, the roles and expectations of the average consumer had changed. The American marketplace had become an integrated, fast-paced forum of commerce.[34] In this market, consumers did not expect to haggle over every minute detail during every transaction; rather, they began to rely on brand

31. Priest, *supra* note 5, at 505.

32. *Id.* at 507.

33. *Id.* at 517.

34. Jordan Gamble, et al., *The Marketing Concept in the 21st Century: A Review of How Marketing Has Been Defined Since the 1960s*, 11 MKTG. REV. 227, 228 (2011).

names, product familiarity, and expectations to guide their decision making.[35] This transformation could be partially attributed to the advent of standard form contracts; though criticized for their potential for abuse, these contracts did help bring a level of efficiency to market transactions.

Third, a shift in public policy also helped spurn change in the products liability field. As it became evident that contracts were not sufficient in protecting claimants, courts looked to other ways to remedy these situations. Public policy was used in cases during this time to void disclaimers of implied warranties and exclusion of consequential (personal injury) damages.[36]

Finally, there was a shift in academic attention that spurned thought and innovation in the field. Product liability leaping to the forefront of tort law scholarship led to a revolution in academic, and eventually, judicial and legislative thought. It seems almost intuitive that the more that people discuss a problem, the more likely they are to come up with solutions—and that instinct held in the 1950s and 1960s as tort scholars began to reexamine the product liability scheme. Historically, these factors had catalyzed major legislative reform. In the context of modern tort reform, these factors give precedential guidance as to what could be considered an adequate basis for considering new changes.

D. Product Defects in the Modern Liability Scheme

In the modern products liability scheme, product defects are divided into three main categories: (1) manufacturing defects; (2) design defects; and (3) warning defects.

Manufacturing defects are those that may be properly designed but can become "unreasonably dangerous" due to a defect that arose during the manufacturing process.[37] Manufacturing defect cases are unique in contrast to other defect types because courts have referred to and seen these cases as a "fairly straightforward concept," where defining a standard has been relatively easy.[38] This stems from the fact that a manufacturing defect tends to result from "a physical departure from a product's intended design[,]"[39] such circumstances are usually random and affect only a small percentage of the products designed.[40] Defects result during either one of two points of the manufacturing process, during the testing or the inspection of the product before it is distributed.[41] The failure to test arises in two situations: "[F]irst, where adequate tests for defects were not conducted . . . during or after the production

35. *Id.*

36. Henningsen v. Bloomfield Motors, Inc., 161 A.2d 69 (N.J. 1960).

37. Priest, *supra* note 5, at 505 (referencing RESTATEMENT (SECOND) OF TORTS, §402A).

38. Jones v. Amazing Prods., Inc., 231 F. Supp. 2d 1228, 1236 (N.D. Ga. 2002)

39. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 cmt. a (AM. L. INST. 1998).

40. Wood v. Old Trapper Taxi, 952 P.2d 1375, 1380 (Mont. 1997).

41. BRUCE L. OTTLEY ET AL., UNDERSTANDING PRODUCTS LIABILITY LAW, 162 (2d ed. 2013).

process and a product containing a defect was placed on the market[.]"[42] "[S]econd, where the particular product was not defective but the properties of the product in general were not tested adequately before it was placed on the market."[43] In these cases, the plaintiff must establish not only what tests or inspections should have been performed, but also that those tests or inspections would have caught the defect.[44] These tests are measured against the standard of care based on industry-wide customs, the past practices of the manufacturer, or expert testimony.[45] In these cases, strict liability is applied where the manufacturing defect departed from the product's "intended design[.]"[46]

The second kind of product liability defect is a design defect. "A design defect exists when the product is built in accordance with its intended specifications but the design itself is inherently defective."[47] The design of a product in this context includes the manufacturer's specifications, choice of materials, as well as design of the product.[48] "The largest number of products liability cases that reach [the] trial level involve . . . allegation[s] that the plaintiff's injuries were caused by a design defect in the product in question."[49] This is, in part, because "there are no objective standards by which to judge a design defect."[50] The most frequently used standards "to determine whether a defect in a product makes it unreasonably dangerous are the 'consumer expectations test' and the 'risk-utility analysis.'"[51] Plaintiffs frequently include separate counts of negligence and strict liability in design defect complaints.[52] According to one court, a negligent design case requires three basic requirements: "(1) a duty to anticipate and design against reasonably foreseeable hazards; (2) breach of that duty; and (3) injury proximately caused by the breach."[53] The focus in a negligence case lies in the manufacturer's conduct. Specifically, whether the "manufacture acted reasonably in choosing the specifications, materials, or structure for the product, in light of the risks it

42. *Id.*

43. *Id.*

44. Messer v. Amway Corp., 106 F. App'x 678 (10th Cir. 2004) (applying Kansas law); Weiss v. Chrysler Motors Corp., 515 F.2d 449 (5th Cir. 1975).

45. Nicklaus v. Hughes Tool Co., 417 F.2d 983 (8th Cir. 1969); Lindquist v. Ayerst Laboratories, Inc., 607 P.2d 1339 (Kan. 1980).

46. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(a) (AM. L. INST. 1998).

47. Chavez v. Glock, Inc., 144 Cal. Rptr. 3d 326, 342 (Cal. Ct. App. 2012); Leichtamer v. Am. Motors Co., 424 N.E. 2d 568 (Ohio 1981).

48. Boudreau v. Baughman, 368 S.E. 2d 849, 860 (N.C. 1988) (citing Husky Indus. v. Black, 434 So. 2d 988 (Fla. Dist. Ct. App. 1983)); *see also Husky Indus.*, 434 So. 2d at 991; Jones v. White Motor Corp., 401 N.E.2d 223 (Ohio Ct. App. 1978).

49. OTTLEY ET AL., *supra* note 41, at 124.

50. *Id. See also* Prentis v. Yale Mfg. Co., 365 N.W.2d 176 (Mich. 1984); O'Brien v. Muskin Corp., 463 A.2d 298 (N.J. 1983).

51. OTTLEY ET AL., *supra* note 41, at 124.

52. *See* Mullaney v. Hilton Hotels Corp., 634 F. Supp. 2d 1130 (D. Haw. 2009); Malen v. MTD Prod., Inc., 628 F.3d 296 (7th Cir. 2010) (applying Illinois law).

53. Jablonski v. Ford Motor Co., 955 N.E. 2d 1138 (Ill. 2011); Kirk v. Hanes Corp. of N.C., 771 F. Supp. 856 (E.D. Mich. 1991) (applying Michigan law).

knew about or should have known about."[54] In contrast to negligence, the emphasis in strict liability cases on a Section 402A action is based on "the design of the product itself and whether the design made it unreasonably dangerous at the time it left the control of the manufacturer."[55] There is no specific mention of design defect in Section 402A, so in order for plaintiffs to establish a prima facie case in a design defect case, they must prove the general elements for liability under the section.[56] These general elements would require proof that:

> (1) the design of [the] product resulted in a "defective condition unreasonably dangerous" to the ultimate user or consumer of the product; (2) the product was expected to and did reach the user or consumer "without substantial change in the condition in which it was sold;" (3) the defective design must have been the cause of the plaintiff's injuries; (4) the defendant that sold the product was engaged in the business of selling such products; and (5) the plaintiff suffered injury as a result.[57]

The final kind of product liability defect is warning defects. Warning defects arise in situations where a manufacturer fails to warn or provide adequate warnings about a product's dangers or fails to provide adequate instructions about how to use a product safely.[58] Product warnings and use for instructions serve the same purpose—to prevent a product from being unreasonably dangerous by giving consumers information about the product of which they are not aware.[59] By making consumers aware of risks, an effective warning permits them to decide whether the potential benefits outweigh the risks.[60] In warning defect cases, a duty to warn is imposed on the manufacturer of a product as well as on the manufacturer of a specific component part incorporated in the final product.[61] "[T]hose in the chain of distribution of a product may also have a duty to warn."[62] The Restatement (Third) states that "sellers down the chain of distribution must warn when doing so is feasible and reasonabl[e] . . . ."[63] These actors' duty to warn arises in situations where a manufacturer (1) knows or should have known that at product posed a sufficiently serious risk of harm when used for its intended or reasonably foreseeable purposes, and (2) had no reason to believe that the users or

54. OTTLEY ET AL., *supra* note 41, at 126.

55. *Id.* at 127 (citing Wagatsuma v. Patch, 879 P.2d 572, 584 (Haw. 1994)).

56. RESTATEMENT (SECOND) OF TORTS § 402A

57. *Id.* (internal citations omitted).

58. Thompson v. Sunbeam Prods., No. 2:10-cv-98, 2011 U.S. Dist. LEXIS 110677 (S.D. Ohio Sept. 28, 2011) (applying Ohio law); Moore v. Ford Motor Co., 332 S.W. 3d 749 (Mo. 2011).

59. RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (AM. L. INST. 1965).

60. Ontai v. Straub Clinic and Hosp., Inc., 659 P.2d 734 (Haw. 1983).

61. OTTLEY ET AL., *supra* note 41, at 177–78.

62. *Id.* at 178.

63. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. i (AM. L. INST. 1998).

consumers of the product would be aware of and understand the risk of harm.[64] Foreseeability in this context refers to a serious risk of harm that is objectively reasonable to expect, not just what might conceivably occur.[65] In cases for items such as alcohol, cigarettes, and medicine, government regulations dictate when a duty arises.[66] This duty is often judged against a standard of negligence.[67] The comments to Section 402A and Section 2 of the Restatement of Torts show that there is no difference between negligence and strict liability in failure to warn cases, and the analysis is practically identical.[68]

E. Judicial and Academic Adoption of the Modern Scheme

Two cases in particular help to capture the growth of the modern enterprise liability scheme. The first is *MacPherson v. Buick Motor Co*.[69] This landmark New York Court of Appeals case removed the privity of contract requirement in the negligence action.[70] This case added to the principle laid out in *Thomas v. Winchester* by expanding liability to any item which in "their normal operation are implements of destruction."[71] Following this case, any item that was deemed destructive, irrespective of contract privity, would result in liability for the manufacturer of the product. The second case is *Escola v. Coca-Cola Bottling Co*.[72] The holding of this case was important because it affirmed that, even when the product was not under the exclusive control of the defendant at the time of the injury, under *res ipsa loquitor* the defendant can still be held liable if they had control of the product at the time the alleged negligent act took place.[73] There it was the packaging of a defective soda bottle.[74] As integral as the holding is to the evolution of enterprise liability, the real impact that this case had on the field is Justice Traynor's concurrence, which is widely heralded as one of the premier discussions on strict product liability. He proposed the idea that "a manufacturer incurs an absolute liability when an article that he has placed on the market . . . to be used without inspection, proves to have a defect that causes injury to human beings."[75] He further states that "even if there is no

64. Stringer v. NFL, 749 F. Supp. 2d 680 (S.D. Ohio 2009) (applying Ohio law); Glittenberg v. Doughboy Recreational Indus., 491 N.W. 2d 208 (Mich. 1992).

65. RESTATEMENT (SECOND) OF TORTS § 402A cmt. h (AM. L. INST. 1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. p (AM. L. INST. 1998).

66. OTTLEY ET AL., *supra* note 41, at 182.

67. For example, Restatement (Second) of Torts § 402A cmt. K discusses medicine liability and this is also reflected throughout various regulations promulgated by the Federal Drug Administration.

68. RESTATEMENT (SECOND) OF TORTS § 402A cmt. h (AM. L. INST. 1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. p (AM. L. INST. 1998).

69. MacPherson v. Buick Motor Co., 111 N.E. 1050 (N.Y. 1916).

70. *Id.*

71. *Id.* at 1053.

72. 150 P.2d 436 (Cal. 1944).

73. *Id.* at 459–61.

74. *See id.*

75. *Id.* at 461–62.

negligence . . . [in manufacturing or inspection of components], public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market.[76] Justice Traynor writes:

> It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot. Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business. It is to the public interest to discourage the marketing of products having defects that are a menace to the public.[77]

Traynor's concurrence has played an important historical role in the development of enterprise liability into the current scheme we see today.

The judicial and academic transformation of enterprise liability is captured in the restatements. Sections 402A and 402B of the Second Restatement of Torts in many ways mirror Traynor's concurrence in *Escola* by applying strict liability in such cases without the requirement of privity of contract.[78] Section 402A lays out the fact that "*any* product in a defective condition" that can cause harm to a consumer can give rise to a suit, regardless of whether the seller has exercised "*all* possible care in the preparation or sale" or if "the user or consumer has not bought the product from or entered into any contractual relation with the seller."[79] This theory laid out in the restatements was formally adopted as law in landmark cases such as *Henningsen v. Bloomfield Motors Inc.*,[80] *Greenman v. Yuba Powers Product*,[81] and *Goldberg v. Kollsman Instrument Co*.[82] Section 402B in many ways mirrors the current thought on warning defect liability by extending liability to companies that make misrepresentations on "a material fact concerning the character or quality of a chattel sold[,]" regardless of whether such statements were made "fraudulently or negligently," and applies without consideration to whether there was privity of contract.[83] Similarly, the Third Restatement of Torts on Product Liability also discusses these issues, while also dedicating specific discussion to

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76. *Id.*

77. *Id.* at 440–41.

78. *Accord* Henningsen v. Bloomfield Motors, Inc., 161 A.2d 69 (N.J. 1960); Greenman v. Yuba Powers Prod., 377 P.2d 897 (Cal. 1963); Goldberg v. Kollsman Instrument Co., 191 N.E.2d 81 (N.Y. 1963).

79. RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965) (emphasis added).

80. 161 A.2d 69 (N.J. 1960).

81. 377 P.2d 897 (Cal. 1963).

82. 191 N.E.2d 81 (N.Y. 1963)

83. RESTATEMENT (SECOND) OF TORTS § 402B (AM. L. INST. 1965).

prescription drug liability.[84] Section 2 of the Third Restatement, in many ways, mirrors Section 402A in its analysis of product defect liability.[85] Likewise, Section 9 of the Third Restatement Mirrors Section 402B's discussion of factual misrepresentation by manufacturers.[86] Section 6 of the Third Restatement, however, is unique to the previous academic discussions highlighted because of its discussion specifically related to prescription drugs and medical prices. This Section asserts that the law holds manufacturers liable for prescription drugs that have defective manufacturing, design, or warning.[87] The manufacturing and design analysis seen in this Section is similar to what has been previously discussed. This Section on warning requirements, however, differs from previous requirements as the warning requirement is not only to protect the consumer in their use but also an intermediary (the doctor) in their distribution. Section 6 extends warning liability in situations where the warning fails to warn "health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings" or "the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings."[88]

It is also important to note that there are still manufacturer defenses available in enterprise liability cases. Some courts still recognize that contributory negligence can play a role in damages caused to consumers of a product, even though the view is quickly diminishing.[89] For example, states such as California, Iowa, and Pennsylvania have stated that consumer misuse was no longer a defense in a products liability case.[90] Courts that refuse to embrace contributory negligence reflects the thinking that consumers remain generally powerless in situations compared to manufacturers. Some state supreme courts have gone as far as establishing the legal proposition that a consumer can assume that a product is safe for consumption, making an affirmative defense of contributory negligence nearly impossible.[91] Furthermore, the assumption of the risk defense remains an uncertain defense in cases of this nature.[92]

Overall, any advancement that has been made in this field occurred while still accepting three main underlying assumptions which function as pillars of modern enterprise liability law. These assumptions—"the relative powerlessness of consumers, the advantages of cost internalization, and the

84. *See generally* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (AM. L. INST. 1998).

85. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (AM. L. INST. 1998).

86. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 9 (AM. L. INST. 1998).

87. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(b) (AM. L. INST. 1998).

88. *Id.*

89. Priest, *supra* note 5, at 526–27.

90. *See id.* at 526.

91. *Id.*

92. *Id.*

benefits of manufacturer insurance [are] accepted virtually unanimously."[93] The first pillar is that "[m]anufacturers possess vastly greater power than consumers . . . in all relevant aspects of the product defect problem" because "[c]onsumers have little influence over" a product's quality or creation outside of buying behavior.[94] "It follows [this assumption] that manufacturers, if allowed to do so, would exploit the inferior bargaining power of consumers."[95] The second pillar is the benefit of manufacture implied insurance. This benefit arises "because manufacturers can easily collect a small insurance premium in the price charged for [each] product[,]" allowing them to spread risk more conveniently than consumers in private insurance markets.[96] The third pillar is the internalization of injury costs to manufactures. "Manufacturers, if forced to internalize costs, may make greater research investments into the sources of product-related injuries.[97] At the very least, this results in manufacturers "introduce[ing] an appropriate control on the level of manufacturing activities . . . ."[98]

II. PURDUE PHARMACEUTICAL AND THE ROLE OF DRUG MANUFACTURERS IN THE OPIOID EPIDEMIC

A. Purdue Pharmaceutical Aggressively Marketed OxyContin

The meteoric rise of Oxycontin since its introduction to American society has been unprecedented and unparalleled. Oxycontin is a prescription pain medicine manufactured by Purdue Pharma "that contains an opioid . . . that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not" work for patients.[99] Oxycontin is a high-risk drug, which can lead to addiction and death when misused,.[100] Though this fact is apparent today, this was not always necessarily the case.[101]

Upon its introduction in 1996, Oxycontin was aggressively marketed by Purdue Pharma, and such efforts were clearly effective.[102] Between 1996 and 2000, sales went from $48 million in the drug's first year, to over $1.1 billion only four years later.[103] In those four years, Purdue hosted "more than 40

93. *Id.* at 511–12.

94. *Id.* at 520.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. U.S. Food and Drug Admin., MEDICATION GUIDE: OXYCONTIN® (2015).

100. *See id.*

101. Meier, *supra* note 1.

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

103. *Id.*

national pain-management and speaker-training conferences at resorts in Florida, Arizona, and California . . . . [and] [m]ore than 5000 physicians, pharmacists, and nurses attended these all-expense-paid symposia . . . ."[104] This was just a small part of Purdue Pharma's concerted effort to influence doctors' prescription of the drug. Purdue also used sophisticated marketing data to influence physicians.[105] Purdue used its database of physicians to "target the physicians who were the highest prescribers for opioids across the country."[106] This database had prescriber profiles that allowed the company to see prescribing patterns of physicians nationwide, including the "highest and lowest prescribers of particular drugs in a single state, county, or zip code."[107] In addition, Purdue used this database to identify which physicians served large client bases with chronic pain issues.[108]

Armed with this information, Purdue sent an army of sales reps into hospitals to make sure that their product was being prescribed at an increasing rate. The company increased its internal sales force over 100% from 1996 to 2000, going from 318 representatives to 671.[109] Purdue also increased the company's physician call list from "approximately 33,400 to 94,000 physicians" in this same time span.[110] Further, "[a] lucrative bonus structure also encouraged sales representatives to increase sales of OxyContin in their territories . . . ."[111] The average sales representative salary was $55,000, but "annual bonuses averaged $71,500, with a range of $15,000 to nearly $240,000."[112] In just one year, "Purdue paid over $40 million in sales incentive bonuses to its sales representatives."[113] Purdue Pharma's aggressive marketing was simply one piece in a mounting pile of evidence that demonstrated an aggressive corporate culture that prioritized sales over everything else.

Purdue's marketing paid dividends for the company. It was demonstrated that "Purdue promoted among primary care physicians a more liberal use of opioids . . . ."[114] As a result, "by 2003, nearly half of all physicians prescribing OxyContin were primary care physicians," and the company's "promotion of OxyContin for the treatment of non-cancer-related pain contributed to a nearly tenfold increase in OxyContin prescriptions for this type of pain."[115] Purdue Pharma saw its sales skyrocket from $44 million in 1996 (coming from about

104. *Id.*

105. *Id*.

106. *Id.* at 222.

107. *Id.*; Sheryl G. Stolberg & Jeff Gerth, *High-Tech Stealth Being Used to Sway Doctor Prescriptions*, N.Y. TIMES (Nov. 16, 2000), https://www.nytimes.com/2000/11/16/us/high-tech-stealth-being-used-to-sway-doctor-prescriptions.html.

108. Van Zee, *supra* note 102, at 222.

109. *Id*.

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.* at 222–23.

316,000 prescriptions), to "a 2001 and 2002 combined sales of nearly $3 billion" (coming from over 14 million prescriptions).[116]

B. OxyContin Achieved Popularity Through Chronic Misrepresentation

It is demonstratable that Purdue Pharma did not achieve market success for OxyContin based on the merit of the drug. The benefits of OxyContin were in no way exceptional compared to alternative methods available at the release of the drug. "The FDA's medical review officer, in evaluating the efficacy of OxyContin in Purdue's 1995 new drug application, concluded that OxyContin had not been shown to have a significant advantage over conventional, immediate-release oxycodone taken 4 times daily other than a reduction in the frequency of dosing."[117] Further, "[t]he *Medical Letter on Drugs and Therapeutics* concluded in 2001 that oxycodone offered no advantage over appropriate doses of other potent opioids."[118] In fact, "double-blind studies comparing OxyContin given every 12 hours with immediate-release oxycodone given 4 times daily showed comparable efficacy and safety for use with chronic back pain and cancer-related pain." also found comparable efficacy and safety.[119]

Though Purdue Pharma might have overstated the benefits of OxyContin, the true misrepresentation came in diminishing the negative effects of the drug.

> A consistent feature in the promotion and marketing of OxyContin was a [concerted campaign] to minimize the [perception of] risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain. . . .
>
> In much of its promotional campaign—in literature and audiotapes for physicians, brochures and videotapes for patients, and its "Partners Against Pain" Web site—Purdue claimed that the risk of addiction from OxyContin was extremely small.[120]

Purdue sales representatives consistently claimed that "the risk of addiction was 'less than one percent.'"[121] The company cited studies by Jane Porter and Hershel Jick, who found iatrogenic addiction in only 4 of 11,882 patients using opioids,[122] and by Perry and Heidrich, who found no addiction among 10,000 burn patients treated with opioids.[123] These claims made by sales representatives have proven to be patently false when looking at data resulting from addiction as a result of treatment. "The lifetime prevalence of addictive

116. *Id.* at 223.

117. *Id.* at 221.

118. *Id.*

119. *Id.*

120. *Id.* at 223.

121. *Id.* (quoting BARRY MEIER, PAIN KILLER 99 (2003)).

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

123. Samuel Perry & George Heidrich, *Management of Pain During Debridement: A Survey of U.S. Burn Units*, 13 PAIN 267, 276–77 (1982).

disorders has been estimated at 3% to 16% of the general population."[124] This number could be higher, as "we lack any large, methodically rigorous prospective study addressing the issue of iatrogenic addiction during long-term opioid use for chronic nonmalignant pain."[125]

> Misrepresenting the risk of addiction proved costly for Purdue. On May 10, 2007, Purdue Frederick Company Inc., an affiliate of Purdue Pharma, along with 3 company executives, pled guilty to criminal charges of misbranding OxyContin by claiming that it was less addictive and less subject to abuse and diversion than other opioids, and will [have to] pay $634 million in fines.[126]

Purdue's misrepresentations of the risk of addiction to Oxycotin coincided with their ongoing expansion of the drug's potential uses. "Purdue 'aggressively' promoted the use of opioids for use in the 'non-malignant pain market.'"[127] By 1999, non-cancer-related pain made up over 86% of the total opioid market.[128] Purdue Pharma capitalized on this growth, and OxyContin use for non-cancer-related pain increased by a factor of ten—with about 670,000 prescriptions in 1997, to about 6.2 million prescriptions in 2002.[129] During this time, cancer-related pain prescriptions only increased fourfold.[130] The use of opioids for non-cancer-related pain has been controversial and questionable because of the lack of clarity in what the risks and benefits are. "[R]andomized, controlled trials lasting at least 4 weeks that evaluated the use of opioids for chronic, non-cancer-related pain showed statistically significant but small to modest improvement in pain relief, with no consistent improvement in physical functioning."[131] A recent review of the use of opioids in chronic back pain concluded that opioids may be efficacious for short-term pain relief, but longer-term efficacy . . . is unclear."[132] This misrepresentation, combined with underselling the drug's risk, created a perfect storm for addiction. Purdue Pharma was pressuring physicians they had misled to overprescribe a drug they knew was highly addictive to people who did not need it.

The growth of the United States' OxyContin problem is considered reflective of "the escalating national prescription opioid abuse problem.[133] The increased use of opioids for non-cancer-related pain opened the door for a nationwide abuse epidemic. For example, between 1997 to 2002, there was an increase in fentanyl prescriptions by 226%, of morphine prescriptions by73%,

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124. Van Zee, *supra* note 102, at 223.
125. *Id.*
126. *Id.*
127. *Id.* at 222–23.
128. *Id.* at 223.
129. *Id.*
130. *Id.*
131. *Id.*
132. *Id.*
133. *Id.* at 224.

and of oxycodone prescriptions by 402%.).[134] During this same period emergency hospital visits increased "for fentanyl, morphine, and oxycodone . . . [by] 641%, 113%, and 346%, respectively."[135] The use of opioids became so rampant that its use surpassed that of marijuana, the quintessential "gateway drug," as the first drug tried by first-time drug users.[136] Statistics show that among first-time drug users in 2005, "2.1 million [people] reported prescription opioids as the first drug they had tried, [a much higher figure than those using] marijuana and almost equal to the number of new cigarette smokers (2.3 million)."[137] "Most abusers . . . g[o]t their diverted drugs directly from a doctor's prescription or from the prescriptions of friends and family.[138] By 2008, prescription opioids had surpassed cocaine and heroin in terms of illicit drug abuse, just barely trailing marijuana.[139] As a result, mortality rates from opioid overdoses have also exponentially increased: "Drug overdose deaths involving prescription opioids rose from 3,442 in 1999, to 17,029 in 2017,"[140] surpassing the mortality rates of both heroin and cocaine nationwide.[141]

Recent litigation has brought to light how intentional Purdue Pharma and other companies were in pushing opioid prescriptions despite evidence demonstrating its potential to be extremely addictive. Large pharmaceuticals, including Purdue Pharma, had gone as far as hiring elite consulting firms, such as McKinsey & Co., to help boost their sales. "[T]he State of Massachusetts released new documents from 2013 that detailed McKinsey's recommendations on how Purdue Pharma could 'turbocharge' sales of its widely abused opioid OxyContin" by "sharply increas[ing] sales visits to targeted doctors and to consider mail orders as a way to bypass pharmacies that had been tightening oversight of opioid prescriptions."[142] Even beyond targeted marketing and sales tactics, Purdue Pharma engaged in a systematic coverup of the drug's addictiveness which ultimately resulted in over $600 million in company fines and the prosecution of the company's President, Chief Legal Officer, and former Chief Medical Officer, all whom plead guilty to criminal charges of misbranding.[143]

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134. *Id.* (these statistics were measured by the source author in grams per 1000,000 population).

135. *Id.*

136. *See infra* notes 136–37 and accompanying text.

137. Van Zee, *supra* note 102, at 224.

138. *Id.*

139. *Id.*

140. *Overdose Death Rates*, *supra* note 2.

141. Van Zee, *supra* note 102, at 224.

142. Walt Bogdanich, *McKinsey Advised Johnson & Johnson on Increasing Opioid Sales*, N.Y. TIMES (July 25, 2019), https://www.nytimes.com/2019/07/25/business/mckinsey-johnson-and-johnson-opioids.html.

143. Press Release, John L. Brownlee & Heidi Coy, The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin; Will Pay Over $600 Million (May 10,

C. OxyContin and Other Opioids Devastated Communities

Purdue Pharma and other major pharmaceutical companies introduced opioids to lower income communities with almost surgical precision, devastating these communities. *Twelve states have more opioid prescriptions than people*, according to a 2014 study by the CDC.[144] Of this overwhelming number of prescriptions, 21 to 29% of all patients prescribed opioids for chronic pain will misuse them, and between 8 and 12% develop an opioid use disorder.[145] This crippling addiction has translated into chilling death rates for users. In 2019, there were over 49,000 overdose deaths involving opioids.[146] In fact, "[m]ore than 130 people died every day from opioid-related drug overdoses in 2016 and 2017."[147] To put this death rate in more relevant terms: By the time you finish reading this Note, about four people would have died from an opioid-related overdose.[148]

The catastrophic public injury has led to tremendous social and political pressure for a response to the epidemic. There has been an onslaught of litigation against Purdue Pharma and other major pharmaceuticals for the role they played. Purdue Pharma is one of many opioid companies that is facing suits brought by city governments. Currently, Purdue Pharma has been "sued by more than 2,000 cities and counties for 'grossly' misrepresenting 'the risks of long-term use of [opioid] drugs for persons with chronic pain.'"[149] President Trump spoke heavily on the campaign trail about opioid addiction, and once in office, instituted a Commission on Combating Drug Addiction and the Opioid Crisis.[150]

There have been tremendous steps taken in combatting companies that have pushed prescription opioids. In April 2019, the U.S. Department of Justice (DOJ) indicted "Rochester Drug Cooperative, Inc. (Rochester Drug) and two of its executives under the Controlled Substances Act (CSA) based on the company's sale of oxycodone and fentanyl to pharmacies that illegally

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2007), https://www.health.mil/Reference-Center/Publications/2007/05/10/The-Purdue-Frederick-Company-Inc-and-Top-Executives-Plead-Guilty.

144. CNN Editorial Research, *Opioid Crisis Fast Facts*, CNN (Feb. 27, 2020), https://www.cnn.com/2017/09/18/health/opioid-crisis-fast-facts/index.html.

145. *Overdose Death Rates*, *supra* note 2 (calculated using the prescription data in this source and population data found in the 2010 National Census).

146. CNN Editorial Research, *supra* note 144.

147. *Id.*

148. Marc Brysbaert, *How Many Words Do We Read Per Minute? A Review and Meta-Analysis of Reading Rate*, 109 J. MEMORY & LANGUAGE 1, 14 (2019). Calculated based on the reading rate of 238 words per minute, and the approximate length of this paper at 10,400 words, and an approximate death every 11 minutes.

149. Laura Strickler, *Purdue Pharma Offers $10–12 Billion to Settle Opioid Claims*, NBC NEWS (Aug. 27, 2019), https://www.nbcnews.com/news/us-news/purdue-pharma-offers-10-12-billion-settle-opioid-claims-n1046526#:~:text=The%20maker%20of%20OxyContin%2C%20Purdue,%2410%20billion%20to%20%2412%20billion.

150. Exec. Order No. 13784, 84 Fed. Reg. 16,283 (2017), https://www.govinfo.gov/app/details/DCPD-201700207.

distributed the drugs."[151] "[T]he Rochester Drug indictments mark the first time DOJ has brought felony charges against a pharmaceutical company under the general drug trafficking provisions of the CSA."[152] Despite this, there has still been an increase in calls for civil and criminal legislation.[153] Some scholars are arguing that corporate executives should face criminal penalties for the actions of the companies they run.[154]

There is also an increase in civil litigation against non-opioid corporations that could create critical practice precedent for potential opioid litigation that may occur in the future. In cases against the parent company of popular herbicide "Roundup," the science behind the tort is getting its separate trial. Rather than a traditional case where jurors would "simultaneously hear allegations" about a company's product being dangerous and how "the company hid dangers about its product from the public," rather,"[the jury will] take part in an unusual [bifurcated] trial."[155] First, the jurors will have a trial focused on the science, and "then, only if they find the plaintiff's claims valid," will they have a trial "on the question of negligence."[156] This bifurcated trial was approved by a federal judge at the request of Roundup attorneys to allow the trial to proceed without "significant distraction of attacks on the company's behavior."[157] This approach is a novel one taken by courts looking to resolve the question of "how to ensure the fairest decisions in cases concerning complicated science."[158] How this case plays out could have a significant effect on not only future Roundup cases but any product liability cases involving an underlying scientific claim. This litigation could be exacerbated by a little-known niche group that has been bankrolling cases against companies such as Bayer AG, Roundup's manufacturer. These groups help recruit potential plaintiffs as well as financers to pay law firms. Furthermore, they enlist expert witnesses such as doctors and scientists when cases go to court.[159] These firms look to turn lawsuits into "commodities that [can be] bought and

151. JOANNA R. LAMPE, CONG. RSCH. SERV., LSB10307, CORPORATE DRUG TRAFFICKING LIABILITY—A NEW LEGAL FRONT IN THE OPIOID CRISIS 1 (2019).

152. *Id.*

153. *See* Letitia James, *New York AG: Purdue Pharma Settlement Doesn't Undo the Losses we've Felt*, LOHUD (Sept. 9, 2021, 3:20 AM), https://www.lohud.com/story/opinion/2021/09/09/ny-ag-letitia-james-purdue-pharma-settlement-doesnt-undo-our-losses/5777567001/.

154. *See generally* BRANDON L. GARRETT, TOO BIG TO JAIL: HOW PROSECUTORS COMPROMISE WITH CORPORATIONS (2014).

155. Sara Randazzo, *In Roundup Case, the Science Will Go on Trial First*, WALL ST. J. (Feb. 15, 2019, 10:58 AM), https://www.wsj.com/articles/in-roundup-case-the-science-will-go-on-trial-first-11550246311?mod=article_inline.

156. *Id.*

157. *Id.*

158. *Id.*

159. Sara Randazzo & Jacob Bunge, *Inside the Mass-Tort Machine That Powers Thousands of Roundup Lawsuits*, WALL ST. J. (Nov. 25, 2019), https://www.wsj.com/articles/inside-the-mass-tort-machine-that-powers-thousands-of-roundup-lawsuits-11574700480?mod=hp_lead_pos5.

sold" by these firms looking for a return on their suits.[160] The bottom line: "The more lawsuits that get filed [by these firms], the more pressure companies face to settle."[161] These companies have perfected the art of mass tort civil litigation. If there was an expansion of civil liability law that allowed victims of the opioid crisis to bring claims directly against drug manufacturers, we could see a dramatic overflow of tort litigation backed by companies in this industry.

THE NEED FOR ENTERPRISE LIABILITY REFORM

The opioid epidemic demonstrates that the law does not fully accommodate present conditions and help redress the unique circumstances facing society today. This is because the crisis has created a situation that undercuts typical presumptions that underly our current scheme. In the current situation, consumers are the ones that are injured, but also bear the loss of those injuries in a way that does not allow for equitable distribution.

In the early twentieth century, prominent scholars such as Kessler were able to advocate and bring about substantial change in enterprise liability by establishing those modern consumers were powerless in contrast to manufacturers and that if courts were to protect consumers, contract law provided inadequate grounds because of the nonconsensual character of the modern transaction.[162] Much like the shifts in business that brought about change in the early twentieth century, the socioeconomic reality of modern society gives reason to reexamine whether the current scheme is still adequate in providing just outcomes for potential plaintiffs.

The first point made by Kessler and other prominent scholars is that there is a relative level of powerlessness compared to the manufacturers.[163] That presumption is as valid, if not more so, today as it was in the early twentieth century. Major drug manufacturers are some of the wealthiest companies in the country. Purdue Pharma, the manufacturer of OxyContin, is no exception. The company is privately held, so the valuation of the company can only be estimated, but the Sackler family who owns the company has been valued at over $13 billion.[164] The drug has also reportedly made the company over $35 billion in revenue since its debut over 20 years ago.[165]

In contrast to the Sacklers, the communities most afflicted by opioid use are some of the poorest in the country. Alabama, a state which had more opioid

160. *Id.*

161. *Id.*

162. George L. Priest, The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law, 14 J. LEGAL STUD. 461, 496 (1985).

163. Priest, supra note 5, at 465 (citing William L. Prosser, The Assault upon the Citadel (Strict Liability to the Consumer), 69 Yale L. J. 1099, 1131 (1960)).

164. Patrick Radden Keefe, *The Family That Built an Empire of Pain*, NEW YORKER (Oct. 23, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

165. *Id.*

prescriptions than people at a point, is one of the poorest in the country.[166] As of 2019, over 800,000 Alabama citizens lived under the federal poverty threshold. At a county level, 11 of Alabama's 67 counties have over 25% of residents living in poverty.[167] Overall, Alabama has a 16.9% poverty rate, which surpasses the national average of 13.4%.[168] Though Alabama is used as an example of income inequality, it is hardly an anomaly.

We currently have one of the most significant gaps in wealth distribution in our country's history, with income inequality at its highest level in fifty years.[169] One way of measuring income inequality is through the use of the Gini Index. This index measures inequality "on a scale of 0 to 1, where a score of "0" indicates perfect equality, while a score of "1" indicates perfect inequality, where one household has all the income."[170] The U.S. Gini Index "grew from 0.482 in 2017, to 0.485 to 2018."[171] This puts the United States at least a tenth of a point behind other leading western democracies such as Canada, Germany, and the United Kingdom.[172] The United States, however, did not find itself alone in income inequality. Countries that also scored in the same range as the United States include Russia, Zimbabwe, Iran, and Saudi Arabia.[173] Needless to say, there is still a clear lack of equality in bargaining power between the impoverished who are affected by these drugs and the major companies that sell them. If the turn of the last century provided enough basis for rethinking the contractual scheme, the same basis is present today. A country that fosters economic inequality akin to dictatorships, kingdoms, and oligarchies is a country ripe for legal reform. Much like Kessler argued in the twentieth century, consumers today are powerless compared to large manufacturers.

The second point made by Kessler in favor of reform is that if courts were to protect consumers, contract law provided inadequate grounds because of the nonconsensual character of the modern transaction.[174] Much like the standard form contract that Kessler argued against, drug prescription is not a procedure that is based on consensual negotiation. When someone goes to their doctor looking for medicine, it is a situation where the consumer states a problem then

166. *2019 Poverty Data Sheet: 800,000 Alabamians Live Below Poverty Threshold*, ALABAMA POSSIBLE (July 25, 2019), http://alabamapossible.org/2019/07/25/2019-poverty-data-sheet-800000-alabamians-live-below-poverty-threshold/#:~:text=Alabama%20is%20the%20sixth%20poorest,for%20a%20family%20of%20four.

167. *Id.*

168. *Id.*

169. Associated Press, *U.S. Income Inequality at Highest Level in 50 Years, Economic Gap Growing in Heartland*, NBC NEWS (Sept. 26, 2019), https://www.nbcnews.com/news/us-news/u-s-income-inequality-highest-level-50-years-economic-gap-n1058956.

170. *Id.*

171. *Id.*

172. CIA, COUNTRY COMPARISON: DISTRIBUTION OF FAMILY INCOME — GINI INDEX, https://www.cia.gov/library/publications/the-world-factbook/rankorder/2172rank.html.

173. *Id.*

174. *See supra* Part I.B.

implicitly puts trust in a healthcare specialist (their doctor) and bureaucratic agencies (the FDA) to make an informed decision for them as to what their next step should be. The average consumer does not know the chemistry or advanced science that goes into their medicine. Rather, that responsibility has been entrusted to government agencies first in regulating what drugs are even allowed into the marketplace, then to doctors to make the informed decision as to what drug is right for a patient based on the information that is relayed to them by their patients. The modern medical transaction, in many ways, shares the characteristics seen in the nonconsensual transactions Kessler looked to reform. According to Kessler, the standard form contract created a nonconsensual transaction because consumers did not truly bargain for the product that they received. Rather, they simply were forced to accept a product under terms and conditions that may contain exculpatory provisions that are unknown to the buyer. The same is seen in today where modern medical consumers accept the decisions of medical professionals unilaterally, most lacking the expertise to truly 'bargain' for a better prescription.

Patients that enter a doctor's office may only know the name of a drug, what ailment it is supposed to cure, and any potential side effects. Patients do not control the manufacturing of the drug; they do not control its testing, the distribution of the drug, or the prescription of the drug. Even when the drug is prescribed, it is the doctor's responsibility to write when and how much of a drug is taken. The doctor's decision on what drug is prescribed and how much is taken in many ways depends on what the FDA approves and how clinical studies of the trial go. Any break along this supply chain would keep the drug out of consumer's hands. Similarly, any misrepresentation about the drug, its use, or its side effects could have downstream impacts as well.

"[R]egulations require that all promotional materials for prescription drugs be submitted to the FDA for review when the materials are initially disseminated or used, it is generally not required that these materials be approved by the FDA prior to their use."[175] Purdue Pharma did not even do that much. "In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review. . . ."[176] Even after acknowledging this oversight, a second video was not even reviewed until late 2002, "after the General Accounting Office inquired about its content."[177] After review, "the FDA concluded that the video minimized the risks from OxyContin and made unsubstantiated claims regarding its benefits to patients."[178] A medical prescription is a transaction where there is minimal bargaining between a patient and a doctor. Patients put their trust in the FDA and doctors to regulate the product that is prescribed to them, and there is an expectation that the patient will use the medicine given to them as told. In this transaction, there is minimal space for the patient to push back outside of refusing to take the drug altogether. The "check" on drug manufacturers happens through the work of the doctors

175. Van Zee, *supra* note 102, at 224.

176. *Id.*

177. *Id.*

178. *Id.*

and the FDA, who ensure not only that the medicine clears safety testing but also that its messaging is accurate. Purdue Pharma actively avoided correction by sending factually incorrect material to doctors without even alerting the FDA to the fact. It is evident that the current system does not offer a means for courts to protect consumers from this uneven bargaining power. Much like Kessler argued in the twentieth century, this Note asserts that the consumer today is in need of a new kind of protection from the legal system.

A reexamination of judicial decisions surrounding the previous shift in enterprise liability could also give credence to the need for current reform. The current scheme of enterprise liability law is based on three pillar assumptions: the relative powerlessness of consumers, the advantages of cost internalization, and the benefits of manufacturer insurance."[179] These concepts have been used to justify the modern tort law scheme. Judicial opinions, such as Traynor's concurrence in *Escola*, accepted these premises but have also distinguished that in certain situations, the current scheme was nonetheless inadequate in stopping what was happening.[180]

When revisited today, Traynor's concurrence in *Escola* reinforces the need for liability reform. Traynor argued for absolute liability for a manufactured item that causes harm, irrespective of contract.[181] This idea revolutionized the scheme by modifying the standing requirement by removing the need for privity of contract. Restructuring the standing requirement is one of the largest barriers keeping families looking to sue opioid manufacturers from doing so directly. In the context of the opioid crisis, standing still creates a substantial barrier for bringing claims against manufacturers. Reformation of the standing requirement would fundamentally transform the way opioid litigation is looked at today. Traynor also discusses the need for reform due to the source of the negligence. In products liability cases, "the source of the manufacturer's liability was [the manufacturer's] negligence in the manufacturing process or the inspection of component parts supplied by others."[182] Much like the products liability cases Traynor referred to, the creation and distribution of opioids take part in a supply chain that excludes the customer in every step. As discussed previously, the only autonomy a patient has over their opioid prescription is in the description of symptoms that lead a doctor to prescribe a drug, and their decision to take the drugs or refuse altogether.

The creation, distribution, and supply of the drugs is something controlled almost exclusively by drug manufacturers. Drug manufacturers are in a better position to anticipate hazards than the public as they are in exclusive control of the product that they put on the market. Furthermore, as Traynor rightly notes,

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179. Priest, *supra* note 5, at 512.

180. Escola v. Coca-Cola Bottling Co., 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring) ("I concur in the judgment, but I believe the manufacturer's negligence should no longer be singled out as the basis of a plaintiff's right to recover in cases like the present one.").

181. *Id.*

182. *Id.*

an injured person is not positioned "to refute evidence or identify the cause of the defect" as they are generally unfamiliar with the manufacturing process or the manufacturer themselves.[183] The average consumer of the prescription opioid medication does not have the knowledge necessary to refute the creation or approval of a drug scientifically. The drug creation process is highly technical and complicated, and as such, is left to the expertise of specialized bureaucratic agencies for approval and only distributed at the behest of a prescribing doctor. If a company misrepresents its drug, relies on faulty studies, or shirks oversight, the consumer cannot be relied on to check the company for its deviations from the process. Thus, in the context of the opioid epidemic, the onus must be put on manufacturers to regulate their product to maintain public safety reasonably and effectively.

Justice Traynor's opinion also discusses the altered relationship between manufacturers and consumers. The Justice points out the problem in the modern consumer interaction by stating that consumers cannot investigate "the soundness of a product" and rather are sold on "the steady efforts of manufacturers to build up confidence by advertising and marketing devices such as trademarks."[184] Likewise, in today's market, the patient nor the doctor has a chance to inspect a product. Patients rely heavily on the advice of medical professionals, and in turn, the doctors rely heavily on the results of trials and the approval of government agencies of the drug. The current tort system, as previously discussed, has already been demonstrated as flawed. Because the consumer has no way to inspect the product themselves, and the system has failed to adequately correct missteps by drug manufacturers, it is clear that an alternative method is necessary.

Traynor also discusses the public policy need to keep dangerous items out of the market. This is because of those who suffer injury from products who are unprepared to meet the consequences.[185] The prescription opioid epidemic has disproportionately affected those with low incomes. Victims who have been afflicted by addiction have been put in a precarious situation where they do not have the financial ability or the technical knowledge to fight back against these companies. Thus, it follows, as Justice Traynor stated, that manufacturers of inherently dangerous items should bear the responsibility for whatever injury these items bring once on the market.[186]

Expanded manufacturer liability has also seen a growing popularity in the context of gun manufacturing. In a recent case concerning families involved in the Sandy Hook school shooting and Remington gun manufacturers, a judge ruled that "Remington can be sued over its marketing practices under a Connecticut state law, despite protections offered to gun manufacturers by

183. *Id.* at 441.

184. *Id.* at 443.

185. *Id.* at 441.

186. *Id.* at 440.

federal law."[187] The narrow majority opinion acknowledged the federal protection for gun manufacturers while still recognizing that "Congress did not intend to immunize firearms suppliers who engage in truly unethical and irresponsible marketing practices promoting criminal conduct."[188] The court recognized that federal protection does not extend to companies in a way that shields them from liability when "tragedy can be laid at their feet."[189] Politicians have also recently aimed at the federal protections afforded to gun manufactures as well, for example some of the leading 2020 presidential candidates spoke of stripping manufacturers of the federal immunity they currently possess during their campaigns.[190] This could set a precedent for an alternative way of approaching pharmaceutical litigation. In opening the door for litigation against companies that engaged in "truly unethical and irresponsible marketing practices,"[191] a standard could be set that still allows drug companies immunity from practically all claims, but would still create a narrow avenue where one currently doesn't exist for the law to provide a remedy to egregious offenses.

Finally, Justice Traynor discusses a need for reform because of an implied warranty of safety on products that enter the market.[192] This is especially important in the context of medicine. People take medicine to improve their health, not make it worse. The dishonest marketing of opioids ran completely contrary to this implied warranty, directly undercutting this warranty which is guaranteed in every purchase. Thus, the law must find a way to redress grievances in this context.

Dishonest marketing also creates a warning defect problem. Defective warnings undercut this warranty of safety and strip consumers of the ability to make informed decisions. This is especially critical in the context of prescription medicine. It is well understood that any medicine one takes may come with unintended side effects. Furthermore, some medicines can't even be used in conjunction with other medicines or with substances such as alcohol. When a patient goes to see a doctor, this presumption is understood, and they are willing to accept the side effects and follow the warnings because of their desire to cure their alignment. Economically, it could be said that patients are consumers willing to engage in this sort of trade because of a perceived net benefit. For example, someone with chronic heart problems would be willing to take a medicine that cures their ailment even if it causes nosebleeds; but they

187. Ryan Lindsay, *Lawsuit by Sandy Hook Victims Against Gun Manufacturer Allowed to Move Forward*, NPR (Mar. 14, 2019), https://www.npr.org/2019/03/14/703439924/lawsuit-by-sandy-hook-victims-against-gun-manufacturer-allowed-to-move-forward.

188. Soto v. Bushmaster Firearms Int'l, LLC, 202 A.3d 262, 324 (Conn. 2019).

189. *Id.*

190. Morgan Phillips, *Biden Slams Sanders Over Brady Bill Vote in Speech to Gun-Control Activists*, FOX NEWS (Feb. 20, 2020), https://www.foxnews.com/politics/biden-slams-sanders-brady-bill-vote-speech-gun-control-activists.

191. Lindsay, *supra* note 187.

192. Escola v. Coca-Cola Bottling Co., 150 P.2d 436, 444 (Cal. 1944) (Traynor, J., concurring).

would not take medicine for nose bleeds that resulted in chronic heart failure. Unfortunately, in the opioid context, the latter situation has manifested itself. People had come in seeking medicine for non-cancer-related pain, and left addicts. Purdue Pharma and other opioid pharmaceuticals engaged in an active disinformation campaign that downplayed the adverse side effects of the drug, leading doctors and patients to believe the drug they were taking was not nearly as dangerous or addictive as it was. This resulted in a situation where most people were coming in seeking pain medication for non-threating conditions and left addicted to prescription medication. This happened despite viable alternatives already on the market, but because of the aggressive marketing campaign launched by Purdue Pharma, OxyContin became the drug of choice. Warning defect liability is another potential avenue that can be used to reform the current system of enterprise liability.

IV. ALTERNATIVE LIABILITY PROPOSALS

The nation is in the midst of an unprecedented epidemic. In response to this problem, there have been a variety of political responses looking to curb the problem. The U.S. Senate passed the Opioid Crisis Response Act of 2018 with a 99-1 vote after the input of over 70 senators and five committees.[193] The Act represented an overwhelming bipartisan response that attempted to combat the crisis through enhanced access to treatment and recovery services, protection of youth and their families, and development of opioid alternatives. Still, some experts have said that the only way to overcome the epidemic is through a "massive infusion of funding and a fundamental restructuring of how we treat addiction in this country."[194] This continued need for a further response has made combatting the crisis one of the most prominent issues today.

The Trump Administration created a commission to combat addiction and the opioid crisis. The Commission outlined proposals that would use a combination of financial leveraging, regulation, and criminal enforcement to combat opioid distribution and curb addition.[195] The Commission looked to stop federal reimbursement policies that incentivized opioid prescriptions, instead seeking to emphasize access to non-addictive treatments for pain.[196] The Commission also proposed medical regulation that would mandate that individuals with acute or chronic pain must have access to non-opioid pain

193. James Hodge, Chelsea Gulinson & Drew Hensley, *The Opioid Crisis Response Act: Looking Ahead, Ignoring the Present*, JURIST (Sept. 22, 2018, 3:15 PM), https://www.jurist.org/commentary/2018/09/james-hodge-opioid-responseact/.

194. German Lopez, *Congress Is on the Verge of a Bipartisan Opioid Package. But Experts Have Big Concerns*, VOX (Sep. 12, 2018), https://www.vox.com/policy-and-politics/2018/9/12/17847358/senate-opioid-crisis-response-act.

195. THE PRESIDENT'S COMM'N ON COMBATING DRUG ADDICTION & THE OPIOID CRISIS, RECOMMENDATIONS (2017),
https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.

196. *Id.* at 8.

management options and that discharged patients would be monitored more.[197] The Commission also took a drastic step in requesting an end to the expectation of eliminating a patient's pain as an indication of successful treatment. Some medical professionals have stated that this is a mandate unique to the United States and is "cited as a core cause of the culture of overprescribing in this country that led to the current health crisis."[198] Next, the Commission looks to give the Department of Labor more authority to regulate the health insurance industry. The Commission claims that insurers have not followed "federal law requiring parity in the reimbursement for mental health and addiction," which has further enabled the rapid increase in prescriptions.[199] Finally, the Commission looks to expand the role of the judiciary by establishing a drug court in every one of the 93 federal district courts.[200] The Commission points out that "Drug Courts are known to be significantly more effective than incarceration, but 44% of U.S. Counties do not have an adult drug court."[201] The Commission's plan proposes a comprehensive set of reforms, but it is worth noting that the proposal does *not* increase tort or criminal liability for drug manufacturers and only seeks extra enforcement of current laws in respect to insurance companies and drug users.

Democratic proposals to combat the opioid crisis create a stark contrast to those proposed by the Commission appointed by President Trump. For example, President Joe Biden, the winner of the 2020 Presidential Election, seeks to combat the epidemic through increased treatment and public health proposals.[202] Vice President Biden's proposal also takes the increased step of holding pharmaceutical companies, executives, and others both criminally and civilly responsible for their role in the opioid crisis.[203] Specifically, he seeks to "[d]irect the U.S. Justice Department to make actions that spurred this crisis a top investigative and, where appropriate, civil and criminal enforcement priority," where appropriate.[204] Furthermore, he proposes "ban[ning] drug manufacturers from providing payments or incentives to physicians and other prescribers" and "terminating pharmaceutical corporations' tax break for advertisement spending."[205] Finally, Vice President Biden seeks to make treatment available to those who need it by strengthening existing public health government programs such as Medicare, Medicaid, and "Obamacare."[206]

197. *Id.* at 8–9.

198. *Id.* at 9.

199. *Id.*

200. *Id.* at 10.

201. *Id.*

202. *The Biden Plan to End the Opioid Crisis*, JOE BIDEN FOR PRESIDENT, https://joebiden.com/opioidcrisis/ (last visited Apr. 25, 2020).

203. *Id.*

204. *Id.*

205. *Id.*

206. *Id.*

The divergence in the two political proposals creates an opportunity for an alternative approach which would exist in the ideological middle of these two very different proposals. One policy problem that enterprise liability must balance is the ability to hold manufacturers liable while not making judgments so punitive that it disincentivizes continued growth and creation. Scientific and medical innovation is a process that takes place through trial and error, and to create liability for *all* failure would certainly disincentivize one from even trying. On the other hand, absolute immunity from liability for manufacturers creates a situation where the impact of all failures is burned only by those with no ability to recover losses they may incur.

The Remington gun manufacturer case serves as an example of how pharmaceutical liability could be reformed in a way that strikes a balance between protecting manufacturers without providing absolute immunity in practice. Enterprise liability should be expanded to situations where parties "engage in truly unethical and irresponsible marketing practices promoting criminal conduct."[207] This standard could reach manufacturers such as Purdue Pharma, who saw their drug OxyContin prescribed at unconscionable rates, while still protecting the ordinary business conduct of all drug manufacturers.

This new standard would not necessarily fit neatly into the previous categories of enterprise liability discussed, but rather would exist as a hybrid of both design and warning liability. A design defect exists when a product is built in accordance with its intended specifications but the design itself is inherently defective. Opioids, much like guns, are not true design defects because the product works exactly as it is intended. If anything, the problem at hand is that the product design is *too* efficient. The new standard would seek to redefine design defects to bring stricter scrutiny to the design of inherently dangerous products. From there, Congress can continue to grant immunity as necessary as it has already done in the case of gun manufacturers. The increased enforcement of existing warning defect duties, such as the duty of those in a supply chain to warn of a product's danger, could also help bolster compliance of the newly proposed enterprise liability.[208] Overall, the proposal seeks to recognize the creation of inherently dangerous products as a basis of enterprise liability and expand enforcement for a company's failure to warn of this danger.

CONCLUSION

The current scheme of enterprise liability needs reform. Enterprise liability has already experienced a large shift in the early twentieth century from a purely contract-based liability to a more modern tort liability framework in response to changing socioeconomic conditions. Much like the shift championed by Kessler in the early twentieth century, current enterprise liability is long overdue another reformation. The opioid epidemic has rocked every corner of American society. This epidemic is unique in both the breadth and intentionality used by drug manufacturers to put a knowingly addictive and

207. Soto v. Bushmaster Firearms Int'l, LLC, 202 A.3d 262, 324 (Conn. 2019).

208. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 2 cmt. *i* (AM. L. INST.1998).

harmful product into the streams of commerce. The socioeconomic reality has demonstrated that the current scheme is inadequate in providing just outcomes for potential plaintiffs. Consumers are powerless compared to drug manufacturers. If courts are to protect consumers, the current scheme of current enterprise liability does not provide an adequate remedy. It does not allow patients to go directly after manufacturers who have shirked oversight and engaged in targeted and dishonest marketing campaigns to take advantage of the trust that a patient puts into their doctor. Thus, the current scheme of tort liability must be reconsidered.