BIG TOBACCO'S BIG SETTLEMENT: WHAT PHARMACEUTICAL COMPANIES CAN LEARN TO PROTECT THEMSELVES IN OPIOID LITIGATION

*Mason A. Leichhardt**

I. INTRODUCTION

In 2018, the Centers for Disease Control and Prevention (CDC) reported that an average of forty-one adults died each day from prescription related opioid overdoses.[1] That amounts to nearly fifteen thousand people dying from an opioid prescription overdose in the United States alone, which does not include illegal narcotics like fentanyl or heroin.[2] With such a staggering amount of deaths from prescription opioids alone, it leads one to wonder where liability sits in relation to these deaths. The answer is complicated and currently being litigated.

Purdue Pharma, the manufacturer of OxyContin, recently reached a settlement of $8.34 billion in connection with ongoing investigations regarding their liability in the opioid crisis.[3] Subsequently, Purdue Pharma filed for bankruptcy protection in September 2019 in an effort to halt litigation after every state and nearly 2,600 cities filed lawsuits against the company.[4] However, Purdue Pharma is not the only defendant in the opioid crisis.[5] Recently, a judicial panel placed more than two thousand pending claims before a single federal judge who will be responsible for guiding the litigation process.[6] The consolidated lawsuit is titled the "National

* The author would like to thank Mick McGraw for his time and contributions to this Note. He would also like to thank Beth and his family for their immense support.

[1] Ctrs. for Disease Control and Prevention, *Overdose Death Maps*, CDC, https://www.cdc.gov/drugoverdose/deaths/prescription/maps.html [https://perma.cc/A5U9-ZLHF] (last visited Nov. 1, 2020).

[2] *Id.*

[3] Sara Randazzo, *Purdue Pharma Reaches $8.34 Billion Settlement Over Opioid Probes*, WALL STREET JOURNAL (Oct. 21, 2020, 5:10 PM), https://www.wsj.com/articles/purdue-pharma-reaches-8-34-billion-settlement-over-opioid-probes-11603292613 [https://perma.cc/B75Z-XP9M].

[4] Sara Randazzo & Jared S. Hopkins, *OxyContin Maker Purdue Pharma Files for Bankruptcy Protection*, WALL STREET JOURNAL (Sept. 16, 2019, 12:06 AM), https://www.wsj.com/articles/oxycontin-maker-purdue-pharma-files-for-bankruptcy-protection-11568604141 [https://perma.cc/GXQ8-WVBS].

[5] Colin Dwyer, *Your Guide to the Massive (and Massively Complex) Opioid Litigation*, NPR (Oct. 15, 2019, 9:05 AM), https://www.npr.org/sections/health-shots/2019/10/15/761537367/your-guide-to-the-massive-and-massively-complex-opioid-litigation [https://perma.cc/KF5J-MWV3].

[6] *Id.*

Prescription Opiate Litigation."[7] Therefore, it is evident that litigation is only getting more complicated with even higher stakes.[8]

Purdue Pharma is the first major pharmaceutical company facing opioid litigation,[9] but it will not be the last. Purdue Pharma's willingness to settle for such a staggering amount shows that there are high stakes if opioid claims go to trial.[10] Even though the size of the mass tort litigation and looming threat of massive settlements is new to the opioid crisis,[11] they are very similar to that of Big Tobacco's[12] litigation history.[13] Big Tobacco settled with forty-six states for $206 billion for harm caused by smoking.[14] The outcome of Big Tobacco's battle in the courts gives the pharmaceutical industry a foreshadowing of how opioid litigation will likely look post-Purdue Pharma.

This Note will help pharmaceutical companies strategize legal defenses to prevent litigation and minimize damage awards by identifying similarities and differences between tobacco and opioid litigation. In Part II, this Note will give background information as well as a brief history of the opioid crisis and Big Tobacco's litigation. In Part III, this Note will explain five lessons learned from Big Tobacco's litigation history: (1) Class actions and *parens patriae* claims are powerful litigation techniques; (2) offensive use of issue preclusion can bar defenses in later claims; (3) FDA control over an industry can preempt state tort law; (4) presenting all known risks can prevent failure to warn claims; and (5) plaintiffs' conduct can be used as a bar to recovery. By analyzing the similarities and differences between tobacco litigation and opioid litigation, pharmaceutical companies can better understand how to apply the lessons learned by Big Tobacco. Subsequently, Part IV will offer strategies that pharmaceutical companies and their attorneys can employ to prevent major damage awards, which could cost billions of dollars, by applying the five lessons from Big Tobacco's litigation: (1) Prevent the formation of a class action and argue that *parens patriae* does not apply; (2) prevent offensive use of issue preclusion early in the lawsuit; (3) use FDA

---

[7] *Id.*

[8] *Id.*

[9] Randazzo, *supra* note 3.

[10] *Id.*

[11] For the purposes of this Note, the term "opioid crisis" will be used but it equates to the "opioid epidemic."

[12] *See infra* note 13 (for the purposes of this Note, "Big Tobacco" refers to the four largest tobacco companies during the litigation history: (1) Philip Morris, Inc.; (2) R.J. Reynolds Tobacco Co.; (3) Brown & Williamson Tobacco Co.; and (4) Lorillard Tobacco Co.).

[13] Robin Miller, Annotation, *Validity, Construction, Application, and Effect of Master Settlement Agreement (MSA) Between Tobacco Companies and Various States, and State Statutes Implementing Agreement; Use and Distribution of MSA Proceeds*, 25 A.L.R.6th 435, at § 2 (2007).

[14] *See* Master Settlement Agreement 55–58 (Nov. 23, 1998), https://1li23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/09/MSA.pdf [https://perma.cc/4BR8-4MZK].

control of pharmaceuticals to preempt state tort law claims; (4) present all known risks; and (5) use plaintiffs' conduct as a bar to recovery. Ultimately, by following the lessons derived from Big Tobacco's litigation pharmaceutical companies can attempt to limit their liability and minimize settlement awards.

II. BACKGROUND

A. Background on Opioid Crisis

With opioid overdoses mounting, the United States government officially declared the opioid crisis a public health emergency in October 2017.[15] New programs, legislation, and control strategies have helped decrease the severity of the crisis over time; however, it is still an ongoing crisis that affects millions of people in the United States alone.[16] In recent years, because more national attention has been directed on the opioid crisis, calls for reform and action continue to come from healthcare workers, legislators, families of addicts, and others.[17] This crisis reaches from New York to California, affecting all fifty states.[18]

1. What Are Opioids and How Are They Controlled?

Opioids "are a class of drugs naturally found in the opium poppy plant that work in the brain to produce a variety of effects, including the relief of pain."[19] Opioids are mainly used to treat pain, but street drugs, such as heroin, are classified as an opioid as well.[20] While opioids are commonly "referred to as narcotics[,] and although they do relieve pain, they do not fall into the same category as over-the-counter painkillers such as aspirin and Tylenol."[21]

---

[15] Mark R. Jones et. al, *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, NCBI (June 7, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5993682/pdf/40122_2018_Article_97.pdf [https://perma.cc/DV86-6KZ4].

[16] *Id*. at 16–17.

[17] *See generally* Editorial Board, *The Opioid Crisis Didn't Disappear Amid the Pandemic. It Still Calls for Urgent Action*, THE WASHINGTON POST (OCT. 16, 2020, 7:15 PM), https://www.washingtonpost.com/opinions/the-opioid-crisis-didnt-disappear-amid-the-pandemic-it-still-calls-for-urgent-action/2020/10/16/7df74fd0-0d7f-11eb-b1e8-16b59b92b36d_story.html [https://perma.cc/7DWD-9TED].

[18] *See generally id*.

[19] *What Are Opioids?*, JOHNS HOPKINS MEDICINE, https://www.hopkinsmedicine.org/opioids/what-are-opioids.html [https://perma.cc/F8V2-FUPD (last visited Nov. 1, 2020)].

[20] *Id*.

[21] *Id*.

Common prescription opioids are OxyContin, Vicodin, and legal fentanyl—a synthetic opioid fifty to one-hundred times more potent than morphine.[22]

Regular use of prescription opioids can increase one's tolerance to the medication, ultimately requiring higher and more frequent doses.[23] Moreover, in some instances long-term use can lead to "opioid use disorder," which equates to opioid addiction.[24] Today, hydrocodone or oxycodone combination products are some of the United States' most commonly abused prescription medications.[25] Thus, because opioids can be addictive and dangerous if misused, legislatures and other agencies enacted laws and procedures in order to prevent prescription opioid misuse.[26]

a. Statutes and Law Controlling Opioids

As of February 2021, at least thirty-one states have laws and regulations controlling opioid prescriptions.[27] The federal government has enacted legislation to combat the opioid crisis.[28] The Food and Drug Administration (FDA) oversees narcotics and prescription drugs as an administrative agency of the federal government.[29] The agency classifies drugs according to "schedules."[30] The FDA categorized controlled substances in a series of five schedules,[31] and prescription opioids are a Schedule II narcotic.[32] Schedule II means that the "drug or other substance has a high potential for abuse" and it has an "accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," as well as "abuse of the drug or other substances may lead to severe psychological or physical dependence."[33]

Part of the federal government's attempt to reduce the severity of the crisis has been to criminalize controlled substances without a prescription.[34] Thus, the federal government criminalized unlawful opioid possession in 21 U.S.C. § 844(a); the statute says that it is "unlawful for any person knowingly

---

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] Brandi C. Fink et al., *An Effective Intervention: Limiting Opioid Prescribing as a Means of Reducing Opioid Analgesic Misuse, and Overdose Deaths*, 48 J. L. MED. & ETHICS 249, 250 (2020).

[26] *Id.* at 251–52.

[27] *Id.* at 252.

[28] 21 U.S.C. 812 (2011).

[29] *See generally* Fink, *supra* note 25, at 251–52.

[30] 21 U.S.C. § 812(a) (2011).

[31] *Id.*

[32] 21 U.S.C. § 812(b)(2) (2011).

[33] *Id.*

[34] 21 U.S.C. § 844(a) (2011).

or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice."[35] Moreover, 21 U.S.C. § 823 of the Code requires pharmaceutical companies and healthcare providers to register with the government in order to manufacture and distribute controlled substances.[36]

While the federal government oversees a lot of controlled substance regulation, the states also enact their own laws and regulations.[37] For example, in 2010 and 2011 the Florida legislature enacted new laws, known as pill-mill laws, in response to an alarming increase in prescription opioid overdose deaths; these laws placed multiple restrictions on pain management clinics in order to prevent individuals from gaining access to opioids when it was not medically necessary.[38] By 2017, eleven other states passed similar legislation to help alleviate the opioid crisis.[39]

In 2016, Massachusetts became the first state to pass legislation limiting opioid prescriptions.[40] Now, at least thirty states have enacted legislation that limits opioid prescriptions.[41] Generally, "[m]ost of this legislation limits first-time opioid prescriptions to a certain number of days' supply—seven days is most common, though some laws set limits at three, five or fourteen days."[42] Furthermore, states sometimes set dosage limits in conjunction with supply limits.[43]

While prescription limits are a key part of states' strategies to curb the opioid misuse rates, they are not the only strategies.[44] Various states enacted new laws creating prescription drug monitoring programs, access to naloxone, prescription regulation, provider education and training, and other new programs in order to help reduce opioid overdoses and misuse.[45] For example, the Kentucky Cabinet for Health and Human Services uses a program called Kentucky All Schedule Prescription Electronic Reporting (KASPER) to "assist practitioners and pharmacists with providing medical and pharmaceutical patient care using controlled substance medications."[46]

---

[35] *Id*.

[36] 21 U.S.C. § 823(a) (2011).

[37] Fink, *supra* note 25, at 252.

[38] *Id.*

[39] *Id.*

[40] National Conference of State Legislatures, *Prescribing Policies: States Confront Opioid Overdose Epidemic*, NCSL (Oct. 30, 2019) https://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx [https://perma.cc/8FUA-KFD3].

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] Drug Enforcement and Professional Practices Branch, *KASPER—Kentucky All Schedule*

In addition, "KASPER also provides an investigative tool for law enforcement and regulatory agencies to assist with authorized reviews and investigations."[47]

Both states and the federal government recognize the importance of alleviating the opioid crisis.[48] Thus, states and the federal government are trying to combat this crisis through legislation and government sponsored programs.[49] However, healthcare organizations have created their own policies and procedures for prescribing opioids in order to do their part.[50]

b. Procedures and Policies Regarding Opioid Prescriptions

Because of the ongoing threat that the opioid crisis has presented to the United States, the CDC recognized a need for opioid education in the healthcare market.[51] Primary care providers have worried about patient addiction to controlled substances, and have felt insufficiently trained on best practices in prescribing opioids.[52] Thus, the CDC released a comprehensive guideline of best practices in prescribing opioids for pain.[53] The guideline focuses on three main areas: "[D]etermining when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use."[54] Most states and healthcare organizations, such as the Mayo Clinic, see the CDC guidelines as best practice and use it when creating their own policies.[55]

In addition, many healthcare organizations have created internal workgroups and panels to create policies and procedures for prescribing opioids.[56] For example, the Mayo Clinic has created subgroups to set policies,

---

Prescription Electronic Reporting, KENTUCKY CABINET FOR HEALTH AND FAMILY SERV., https://chfs.ky.gov/agencies/os/oig/dai/deppb/Pages/kasper.aspx (last visited Nov. 1, 2020).

[47] *Id.*

[48] Fink, *supra* note 25; National Conference of State Legislatures, *supra* note 40.

[49] *Id.*

[50] *See generally* Arizona Dep't. of Health Serv., *Arizona Opioid Prescribing Guidelines*, AZDHS, https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf **[**https://perma.cc/5TE9-34WS**]** (last updated Dec. 2019**)** (proving guidelines to promote safety in patients being prescribed opioids).

[51] Ctrs. for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, CDC, https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm [https://perma.cc/Y5YP-EFX3] (last visited Nov. 1, 2020).

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] Arizona Dep't. of Health Serv., *supra* note 50.

[56] Halena M. Gazelka et. al, *An Institutional Approach to Managing the Opioid Crisis*, MAYO CLINIC (Nov. 19, 2019)**,** https://www.mayoclinicproceedings.org/article/S0025-6196(19)31017-1/pdf [https://perma.cc/AFC3-986E].

discuss funding, understand best practices, and strategize to decrease opioid misuse.[57] Now, even biotechnology companies are trying to add safeguards to aid healthcare providers to alleviate the opioid crisis.[58] Epic Systems Corporation, a large company specializing in electronic medical record systems, has created questionnaires for providers to complete when prescribing controlled substances.[59] With the addition of an opioid-risk questionnaire created by Epic, "clinicians [can] see when a patient might be at a higher risk for opioid addiction based on documentation already in the patient's chart. Based on the risk score, the strength of the medication being prescribed, and a patient's mental health status, clinicians see suggestions for alternative therapies."[60]

Moreover, pharmacies, the front lines of the opioid crisis, have tried to implement ideas and practices to help curb the crisis.[61] Walgreens—one of the nation's largest pharmacy chains—has implemented drug disposal kiosks in all of its pharmacies, provided Narcan (a drug used to reverse overdoses) in all pharmacies, and shared information with public health and law enforcement agencies.[62]

While all of these steps have slightly helped in controlling the opioid crisis, they certainly have not solved the problem entirely.[63] The opioid crisis stems from poor pain management and lack of knowledge in best practices,[64] and it has created a problem that cannot be solved overnight.[65] The question remains: Who is responsible for the crisis, and who should be held liable? The root of the crisis helps explain possible answers to this complex question.

2. The Opioid Crisis

Much like Big Tobacco's history, the CDC breaks down the opioid crisis into three waves.[66] The first wave started in the 1990s as opioid prescriptions

---

[57] *Id.*

[58] Epic Systems Corp., *Better Prescribing for Opioids with Epic*, EPIC (Aug. 5, 2019), https://www.epic.com/epic/post/better-prescribing-opioids-epic **[**https://perma.cc/TJM7-E4LF**]**.

[59] *Id.*

[60] *Id.*

[61] *Combatting Drug Abuse*, WALGREENS, https://news.walgreens.com/newspackages/combating-drug-abuse.htm [https://perma.cc/B48Y-KF5W] (last visited Nov. 1, 2020).

[62] Richard Ashworth et al., *Dealing with Addiction Before it Starts*, WASHINGTON EXAMINER (Apr. 28, 2018, 12:00 AM), https://www.washingtonexaminer.com/opinion/op-eds/dealing-with-addiction-before-it-starts [https://perma.cc/FST6-TUNC].

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *Opioid Data Analysis and Resources*, CDC, https://www.cdc.gov/opioids/data/analysis-resources.html [https://perma.cc/2VS8-9XSJ] (last visited Jan. 19, 2021) [hereinafter *Opioid Data Analysis and*

rose in popularity.[67] The second wave began in 2010 as more people started overdosing on opioids.[68] The third wave began in 2013 as more people overdosed on legal and illegal opioids such as synthetically manufactured fentanyl.[69] By understanding how the opioid crisis progressed, the effects it has had on society, and the litigation history thus far, one can compare and contrast opioid litigation patterns with tobacco litigation.

a. How Did It Progress Into A Crisis?

Opioids are not a new phenomenon; humans have used opioids for centuries to relieve pain.[70] Following the Civil War, many soldiers became addicted to opioids to treat pain from injuries.[71] However, following World War II doctors became increasingly reluctant to prescribe opioids because of their addictive nature.[72] By the 1970s, when Percocet and Vicodin entered the market, many physicians refused to prescribe the medications because for many years medical schools trained doctors to avoid prescribing opioids.[73] It was not until 1980 when the New England Journal of Medicine published an article[74] rebutting the presumption that opioids were dangerously addictive that opioids gained popularity.[75]

By 1990 doctors and patients started viewing pain as the "fifth vital sign," and there was a "real push to do a better job of treating pain."[76] In 1996, Purdue Pharma released OxyContin as a long-term painkiller which led to painkiller prescriptions increasing by two million to three million each year.[77] In 1998, Purdue Pharma released a marketing video[78] featuring patients struggling with chronic pain talking about how OxyContin helped them "get

---

Resources].

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] Paul L. Keenan, Note, *Death by 1000 Lawsuits: The Public Litigation in Response to the Opioid Crisis Will Mirror the Global Tobacco Settlement of the 1990s*, 52 NEW ENG. L. REV. 69, 69 (2017).

[71] *Id.*

[72] *Id.*

[73] Sonia Moghe, *Opioid History: From 'Wonder Drug' to Abuse Epidemic*, CNN (Oct. 14, 2016, 6:41 AM), https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html [https://perma.cc/52GJ-4CS3].

[74] Jane Porter & Herschel Jick, *Addiction Rare in Patients Treated with Narcotics*, NEW ENG. J. MED. (1980), https://www.nejm.org/doi/suppl/10.1056/NEJMc1700150/suppl_file/nejmc1700150_appendix.pdf [https://perma.cc/86BH-PXNP].

[75] Keenan, *supra* note 70.

[76] Moghe, *supra* note 73.

[77] *Id.*

[78] STAT, *1998 Purdue Pharma Marketing Video*, YOUTUBE (Feb. 28, 2019), https://www.youtube.com/watch?v=LaxlJXpwkzs [https://perma.cc/S2M5-85RE].

their life back."[79] A year after Purdue Pharma released that video, opioid prescriptions jumped to eleven million prescriptions filled each year.[80] Suddenly, more and more people became addicted to opioids, and OxyContin could not satisfy the high they craved.[81] Therefore, some patients turned to illegal drugs such as heroin.[82]

b. What Effects Has It Had On Society?

i. Nationally

Even though the long-term effects are not fully known at this time, it is clear that the opioid crisis has had a devastating impact on the United States—both medically and financially.[83] The National Institute on Drug Abuse reported in 2018 that each day 128 people in the United States die from opioid overdoses.[84]

Not only has the crisis caused numerous deaths, but it has also impacted the economy.[85] The opioid crisis cost the U.S. economy at least $631 billion from 2015 to 2018.[86] More reports from economists and healthcare officials estimate that the opioid crisis will continue to cost the United States economy around $181 billion dollars each year.[87] Studies show that this impact comes from healthcare initiatives to prevent deaths from opioids, criminal justice activities, lost productivity, premature mortality, as well as child and family assistance programs.[88] It is no secret that the crisis stretches from California to New York, but the opioid crisis has hit some states, such as Kentucky and West Virginia, especially hard.[89]

---

[79] Moghe, *supra* note 73.

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] Douglas L. Leslie et al., *The Economic Burden of the Opioid Epidemic on States: The Case of Medicaid*, AM. J. MANAGED CARE (July 30, 2019), https://www.ajmc.com/view/the-economic-burden-opioid-epidemic-on-states-case-of-medicaid [https://perma.cc/V7WP-RYZA].

[84] Nat'l Inst. on Drug Abuse, *Opioid Overdose Crisis*, NIH (Feb. 25, 2018) https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis [https://perma.cc/7EPV-ERR8].

[85] Managed Healthcare Exec. Staff, *The Financial Burden of the Opioid Epidemic*, MANAGED HEALTHCARE EXECUTIVE (Oct. 22, 2019), https://www.managedhealthcareexecutive.com/view/financial-burden-opioid-epidemic [https://perma.cc/BQM7-HUXG].

[86] *Id.*

[87] *Id.*

[88] *Id.*

[89] *See generally* Jennifer L. Brinkley, *Opioid Crisis and the Law: An Examination of Efforts Made in Kentucky*, 70 S.C. L. REV. 741, 741 (2019).

ii. Kentucky Specifically

In 2018, Kentucky physicians prescribed opioids at a rate of 79.5 prescriptions per every one hundred people; the national average is 51.4.[90] The University of Kentucky reported that "rates of HIV, Hepatitis C, overdose deaths, and other afflictions have risen significantly due to the scourge of opioid drug abuse and addiction."[91] In 2017, 1,565 people died from an opioid overdose in Kentucky alone.[92] Furthermore, over eighty percent of heroin users in Kentucky started using prescription opioids first and then advanced to heroin; this has created trends of poverty and disease throughout the state.[93]

Because of the deadly consequences of this crisis in Kentucky, state law makers and administration officials created new programs and policies aimed at curbing the growth of the crisis.[94] For example, officials created task forces, implemented drug courts across the state, passed legislation, and even brought eight lawsuits against pharmaceutical companies on behalf of the State.[95] While new programs and legislation certainly help,[96] litigation is one of the most effective weapons individuals and states can use in combatting problems.

B. Background of Tobacco Litigation

1. Three Eras of Litigation

There are multiple parallels between Big Tobacco's mass tort litigation and opioid litigation today,[97] from which pharmaceutical companies can learn valuable lessons. By 1950, reports emerged surrounding the risk of smoking cigarettes to one's health.[98] In 1964, the first Surgeon General's

---

[90] Nat'l Inst. on Drug Abuse, *Kentucky: Opioid-Involved Deaths and Related Harms*, NIH (Apr. 3, 2020), https://www.drugabuse.gov/download/21961/kentucky-opioid-involved-deaths-related-harms.pdf?v=48f39c8f5b2bbc4a6b165fcc055481f5 [https://perma.cc/3KAC-8PHG].

[91] *Confronting the Opioid Epidemic*, UNIVERSITY OF KENTUCKY: OFFICE OF THE PRESIDENT, https://www.uky.edu/president/opioid [https://perma.cc/VW55-FEYW] (last visited Jan. 23, 2021).

[92] Brinkley, *supra* note 89, at 741.

[93] *Id.* at 744.

[94] *Id.*

[95] *Id.* at 748–55.

[96] *See generally id.*

[97] Margaret S. Thomas, *Parens Patriae and The States' Historic Police Power*, 69 SMU L. REV. 759, 762 (2016).

[98] Vernellia R. Randall, *History of Tobacco*, U. OF DAYTON SCH. OF L. (Aug. 31, 1999), https://academic.udayton.edu/health/syllabi/tobacco/history.htm [https://perma.cc/G8FW-NKBW].

report on smoking and health was released,[99] but litigation had already begun ten years prior to the release of the report.[100] Over the next five decades individual plaintiffs and state attorneys general filed thousands of lawsuits against Big Tobacco[101] which led to one of the biggest and most well-known settlements in American history: The 1998 Tobacco Master Settlement Agreement.[102]

The history of tobacco litigation can be better understood in terms of eras.[103] The first era spans from the mid-1950s into the late-1970s.[104] The second era stretches from 1980 into the mid-1990s.[105] Finally, the third era spans from the mid-1990s to the present.[106] Professor Rabin of Stanford Law School categorized the three eras by looking at the different types of claims filed against Big Tobacco through the span of five decades.[107] Each era showcased different successes and failures of Big Tobacco based on the type of claims it faced in the courts.[108] These eras showcase some of Big Tobacco's greatest legal defenses, as well as some of its biggest mistakes, helping pharmaceutical companies learn.

a. First Era: 1950-1979

The first era of tobacco litigation was ultimately unsuccessful because of new theories of tort law and the evolution of doctrinal elements within the law.[109] Thus, because the first era of tobacco litigation coincided with other product liability claims around the United States, it was difficult to succeed in a claim with such a fluid evolution of tort law.[110] *Bouvier Law Dictionary*

---

[99] Luther Terry, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service*, U.S. DEP'T OF HEALTH, EDUC., AND WELFARE (Jan. 11, 1964), https://www.scribd.com/document/199073624/Smoking-and-Health#fullscreen&from_embed [https://perma.cc/M8QG-DGY7].

[100] *History of Tobacco Product Litigation*, HHS, https://www.hhs.gov/sites/default/files/consequences-smoking-appendix14-2-history-tobacco-litigation.pdf [https://perma.cc/6CRB-3H95] (last visited Nov. 1, 2020).

[101] James A. Henderson, Jr. & Aaron D. Twerski, *Reaching Equilibrium in Tobacco Litigation*, 62 S.C. L. REV. 67, 70 (2010).

[102] Master Settlement Agreement, *supra* note 14.

[103] Henderson, *supra* note 101, at 70 (describing tobacco litigation in a series of three eras: (1) First Era: 1950–1979; (2) Second Era: 1983–1993; and (3) Third Era: 1994–Present).

[104] *Id.*

[105] *Id.* at 72.

[106] *Id.* at 73.

[107] *Id.* at 70.

[108] *Id.* at 76.

[109] Stephen D. Sugarman, *Mixed Results from Recent United States Tobacco Litigation*, 10 TORT L. REV. 1, 2 (2002).

[110] RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965).

defines product liability as "the civil liability of a designer, manufacturer, seller, or other person or entity engaged in the creation and supply of a product to the ultimate user of that product, for injuries or harm caused by a defect in its design or manufacture."[111] In 1963, the landmark case *Greenman v. Yuba Power Products, Inc.* solidified the rule of strict products liability.[112] The Supreme Court of California held that manufacturers are held strictly liable for placing products on the market if they know that (1) the products will likely not be inspected for defects, and (2) the product causes harm to the user.[113] Moreover, under the theory of strict liability, "the focus is on the product's condition, not the manufacturer's conduct. Consequently, if a product is defective, an injured party can recover without showing that a manufacturer failed to exercise due care in the manufacture or design of the product."[114] In strict liability, a manufacturer has a duty to not allow any hazardous defect or failure in an already inherently dangerous product when it reaches the consumer.[115]

Coinciding with the notion of strict liability, cigarette smokers started bringing their own suits against the tobacco industry.[116] In *Ross v. Philip Morris & Co.* the Eighth Circuit held that Philip Morris & Co. was not strictly liable because the plaintiff "made no contention that defendant's cigarettes do not conform to the standard of the cigarette industry," but rather the plaintiff presented evidence "in an attempt to prove not only that smoking defendant's cigarettes caused his cancer, which is required, but also to show the general causative relationship between smoking cigarettes."[117] Additionally, in *Green v. American Tobacco Co.* the court used the same rationale that cigarette manufacturers could not be held liable for "the harmful effects of which no developed human skill or foresight can afford knowledge."[118] Furthermore, in *Lartigue v. R.J. Reynolds Tobacco Co.* the court held that the cigarette manufacturer could not be held strictly liable because the "manufacturer was in no better position than the consumer" to know about a defect.[119] Thus, many of the early claims failed because courts could not find a breach of duty to smokers.[120]

---

[111] *Product Liability*, BOUVIER LAW DICTIONARY, Westlaw (2012).

[112] Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 901 (Cal. 1963).

[113] *Id.*

[114] Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L. J. 705, 710 (1990).

[115] Robert J. Guite et al., *Product Liability Claims, Defenses, and Remedies*, LexisNexis Practice Note, (last updated May 11, 2021).

[116] Henderson, *supra* note 101, at 70.

[117] Ross v. Philip Morris & Co., 328 F.2d 3, 9 (8th Cir. 1964).

[118] Green v. Am. Tobacco Co., 304 F.2d 70, 77 (5th Cir. 1962).

[119] Lartigue v. R. J. Reynolds Tobacco Co., 317 F.2d 19, 39 (5th Cir. 1963).

[120] Alex J. Grant, *New Theories of Cigarette Liability: The Restatement (Third) of Torts and the Viability of a*

Many of the early claims "were based on allegations that cigarettes were inherently and unreasonably dangerous, breaching the implied warranty of merchantability."[121] However, plaintiffs in these early claims "faced formidable obstacles" as the issue fell on causation.[122] It was extremely difficult to prove that the tobacco companies were the cause of the plaintiffs' injuries.[123] However, Congress, prompted by the Surgeon General's report on the health effects of smoking, enacted the Federal Cigarette Labeling and Advertising Act in 1965.[124] The new legislation required the tobacco industry to print the following warning on all cigarette packages: "Caution: Cigarette Smoking May Be Hazardous to Your Health."[125] Consequently, even though the legislation seemed to be detrimental to the tobacco industry, it actually ended up helping it.[126] Subsequently, the tobacco industry was able to use the required-warning legislation as a defense against claims that plaintiffs did not know that smoking cigarettes was harmful.[127] Therefore, because plaintiffs' claims were wildly unsuccessful against Big Tobacco, twenty years would pass before the second era of tobacco litigation started in the late 1980s.[128]

b. Second Era: 1983-1993

By 1980, little had changed in terms of claims against tobacco companies. The second era of litigation is characterized once again by individual tort claims against the tobacco industry, in which plaintiffs would add failure to warn claims and strict liability claims as proof of the tobacco industry's fault in the harm caused.[129] However, towards the end of the second era, plaintiffs had their first victory against Big Tobacco in *Cipollone v. Liggett Group, Inc*.[130] In *Cipollone*, a jury awarded the plaintiff $400,000 after finding that the tobacco company failed to warn about the health effects of smoking.[131] However, the Third Circuit reversed holding that

Design Defect Cause of Action, 3 CORNELL J. L. & PUB. POL'Y 344, 349 (1994).

[121] Henderson, *supra* note 101.

[122] *Id.*

[123] *Id.*

[124] Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282.

[125] Andrei Sirabionian, Comment, *Why Tobacco Litigation Has Not Been Successful in the United Kingdom: A Comparative Analysis of Tobacco Litigation in the United States and the United Kingdom*, 25 NW. J. INT'L L. & BUS. 485, 487 (2005).

[126] *Id.*

[127] *Id.* at 488.

[128] Henderson, *supra* note 101.

[129] Jeffrey S. Quinn, *Does Mass Product Tort Litigation Facilitate Or Hinder Social Legislative Reform? A Comparative Study of Tobacco Regulation*, 9 RUTGERS J. L. & PUB. POL'Y 106, 115 (2012).

[130] Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 530 (1992).

[131] Cipollone v. Liggett Grp., Inc., 693 F. Supp. 208, 210 (D. N.J. 1988).

congressional legislation preempted state tort claims.[132] The United States Supreme Court granted certiorari, and held that federal legislation only preempted those claims based on failure to warn, but the legislation did not preempt claims based on "express warranty, fraud, misrepresentation, or conspiracy."[133] However, "neither the family nor the law firm could afford to continue the litigation after the Supreme Court's ruling."[134] Thus, litigation ceased.[135]

Over seven hundred lawsuits were filed against the tobacco industry by 1995.[136] Yet, *Cipollone* was the only case that plaintiffs ever won among those suits.[137] Amazingly, "from 1954 to 1995, the tobacco companies did not pay one penny to a single plaintiff."[138] However, tobacco litigation changed drastically starting in 1994.[139]

c. Third Era: 1994-Present

The most well-known era of tobacco litigation is the third era, which began in 1994.[140] "The third [era] of litigation saw three main types of litigation: Private class actions, state *parens patriae* actions, and litigation over the authority of the FDA."[141] It is actually so well-known that Hollywood created a major motion picture[142] documenting Brown & Williamson's[143] part in tobacco litigation.[144] The popularity of the third era of Big Tobacco's litigation stems from former Mississippi Attorney General Mike Moore's leadership of the *parens patriae* claims against Big Tobacco.[145] He, along with other state attorneys general threatened the tobacco industry with *parens patriae* claims for cigarette-related harms to

---

[132] Cipollone v. Liggett Grp., Inc., 893 F.2d 541 (3d Cir. 1990).

[133] *Id.*

[134] Quinn, *supra* note 129, at 116.

[135] *Id.*

[136] *Id.*

[137] *Id.*

[138] *Id.*

[139] *Id.* at 117.

[140] *Id.*

[141] *Id.*

[142] Bilge Ebiri, *20 Years Later,* The Insider *is Michael Mann's Greatest Prophecy,* VULTURE (Oct. 30, 2019), https://www.vulture.com/2019/10/the-story-behind-the-insider-michael-manns-prophetic-film.html [https://perma.cc/3EZR-ERWS] (*The Insider,* starring Al Pacino and Russell Crowe, is Hollywood's take on the events that captured the nation's attention in the 1990s).

[143] Marie Brenner, *The Man Who Knew Too Much*, VANITY FAIR (Apr. 1, 2004, 12:00 AM), https://www.vanityfair.com/magazine/1996/05/wigand199605 [https://perma.cc/V64H-A8WT] (Brown & Williamson Tobacco Corp. was one of the four major tobacco companies in the United States at the time).

[144] Ebiri, *supra* note 142.

[145] Lowell Bergman, *Inside the Tobacco Deal*, PBS (1998), https://www.pbs.org/wgbh/pages/frontline/shows/settlement/interviews/moore.html [https://perma.cc/9UVF-HBVM].

their citizens brought on by Big Tobacco.[146] This culminated in a massive $206 billion settlement between Big Tobacco and forty-six states.[147] The settlement and threat of *parens patriae* claims defined a new generation of mass tort litigation strategies.[148]

i. Class Actions

The first downfall of tobacco companies came from class action lawsuits starting in the mid-1990s.[149] Previously, the tobacco industry fought suits from individual plaintiffs, and it was easy to win because the issue fell on causation.[150] However, class actions proved to be more difficult to overcome.[151] Specifically, in *Broin v. Philip Morris Co.* a group of non-smoking flight attendants brought a class action suit against the large tobacco company Phillip Morris.[152] With a class of 60,000 flight attendants, they brought a claim for "damages under theories of strict tort liability, breach of implied warranty, negligence, fraud, misrepresentation, and conspiracy to commit fraud."[153] In response, Philip Morris filed motions to dismiss.[154] Subsequently, the "court granted the motions, finding that the class was very large, the complaint presented issues of first impression, and the class representatives raised issues which might not be shared by the entire class."[155]

On appeal, the Florida Court of Appeals analyzed the class action under rules of civil procedure to determine the legality of the class and claim.[156] The court found that the class action was appropriate and reversed the dismissal order and remanded the cause, directing the lower court to reinstate the class action in the revised complaint.[157] This decision came in 1994 and it was a loss for Big Tobacco after a decades of wins.[158] *Broin* settled for $300 million, and the money was placed in a fund to establish a tobacco-related diseases research center.[159]

---

146 *Id.*
147 Master Settlement Agreement, *supra* note 14.
148 Bergman, *supra* note 145.
149 Quinn, *supra* note 129, at 117.
150 Sirabionian, *supra* note 125, at 487–88.
151 Broin v. Philip Morris Co., 641 So.2d 888 (Fla. Dist. Ct. App. 1994).
152 *Id.* at 889.
153 *Id.*
154 *Id.*
155 *Id.*
156 *Id.*
157 *Id.* at 892.
158 Quinn, *supra* note 129, at 117.
159 *Id.*

However, even after a victory in *Broin*, plaintiffs faced another loss in *Castano v. American Tobacco Co*.[160] In *Castano*, the plaintiffs tried to create a massive class that contained anyone who smoked a cigarette from 1943 onward, any of the administrators of their estates, and any of their spouses or children.[161] The Fifth Circuit reversed the district court's order allowing the class.[162] The Fifth Circuit directed the lower court to dismiss the case because it did not meet the necessary requirements to establish a class action.[163] Subsequently, the loss of *Castano* forced the plaintiffs' lawyers to amend their strategy, moving from national class actions to multi-state lawsuits.[164]

For example, in *R.J. Reynolds Tobacco Co. v. Engle* the Florida Court of Appeals reviewed a case in which the plaintiffs narrowed the class from a nationwide class to only Florida smokers.[165] The court held that it was proper to reduce the size of the class.[166] Thus, the case did not need to be dismissed.[167] Consequently, plaintiffs began relying on state tort law and state courts to bring their class action cases; the lawsuits became known as "son of Castano class actions."[168] However, even with a change in venue and strategy, most state courts dismissed the class action lawsuits because they failed the elements similar to the ones referenced in the Fifth Circuit's opinion.[169] Even though class actions proved to be more successful than the individual claims from the first two eras,[170] plaintiffs' major successes came from *parens patriae* claims.[171]

ii. Parens Patriae Claims

While class actions proved more successful than individual product liability claims, *parens patriae* claims ultimately pushed Big Tobacco into a massive settlement agreement.[172] *Parens patriae* claims are "civil suits brought by state attorneys general against mass tortfeasors for injuries to the

---

[160] Castano v. Am. Tobacco Co., 84 F.3d 734, 752 (5th Cir. 1996).
[161] *Id*. at 737.
[162] *Id*.
[163] *Id*. at 752.
[164] Quinn, *supra* note 129, at 118.
[165] R.J. Reynolds Tobacco Co. v. Engle, 672 So.2d 39, 40 (Fla. Dist. Ct. App. 1996).
[166] *Id*.
[167] *Id*. at 42.
[168] Susan E. Kearns, Note, *Decertification of Statewide Tobacco Class Actions*, 74 N.Y.U. L. REV. 1336, 1354 (1999).
[169] *Id*.
[170] *Id*. at 1354.
[171] Bergman, *supra* note 145.
[172] Master Settlement Agreement, *supra* note 14.

states' citizenry."[173] *Parens patriae* was seldomly used before tobacco litigation, though antitrust and environmental suits sometimes utilized this policy power.[174] However, in the mid-1990s, former Mississippi Attorney General Mike Moore led efforts to sue Big Tobacco on behalf of the states.[175]

Parens patriae is Latin for "parent of his or her own country."[176] Modern use of *parens patriae* is rooted in sovereignty of one's own nation or territory—referring to the English monarchy's control.[177] However, the American judicial system molded the legal theory to "a state's quasi-sovereign power to sue to protect its environment on behalf of its citizens, and it was upheld in other contexts, including diverting stream water, cross-border air pollution from an industrial plant, natural gas, and drainage of waterways."[178] Moore led the way in demonstrating the effectiveness of *parens patriae* claims, and consequently the past few decades have shown "an explosion of litigation brought by state attorneys general on behalf of consumers, dramatically affecting the nature of product regulation," resulting in massive money damages awarded to consumers.[179]

In order for Moore and other state attorneys general to succeed with their *parens patriae* claims against the tobacco industry, they needed more than just the Surgeon General's report regarding the dangers of smoking.[180] Two whistleblowers from Louisville, Kentucky came forward with privileged information about the tobacco industry—giving Moore exactly what he needed to move forward with the *parens patriae* claim.[181]

2. The Tobacco Master Settlement's Evolution

In order for the *parens patriae* claim to pressure the tobacco industry far more than any class action or individual product liability claim ever could, Moore and the other attorneys general needed more than the Surgeon General's report about cigarettes.[182] In the mid-1990s, two whistleblowers, Jeffrey Wigand and Merrell Williams, came forward with inside, privileged

---

[173] Thomas, *supra* note 97, at 761.

[174] *Id*.

[175] Marie Brenner, *Jeffrey Wigand: The Man Who Knew Too Much*, VANITY FAIR (May 1996), https://www.vanityfair.com/magazine/1996/05/wigand199605 [https://perma.cc/3HG7-7NJM].

[176] Legal Info**.** Inst**.**, *Parens Patriae*, CORNELL **L.** SCH**.**, https://www.law.cornell.edu/wex/parens_patriae **[**https://perma.cc/ZKK5-SJXZ**]** (last visited Feb. 28, 2021).

[177] Thomas, *supra* note 97, at 770.

[178] *Id*. at 790.

[179] *Id*. at 794–95.

[180] Brenner, *supra* note 175.

[181] *Id*.

[182] *Id.*

information about the tobacco industry.[183] Wigand was previously the head of research and development at Brown & Williamson[184] in Louisville, Kentucky.[185] Because of his role at Brown & Williamson, Wigand had access to top-secret scientific documents that could have been dangerous in the wrong hands.[186] Wigand stole trade secrets and other privileged information from Brown & Williamson culminating in an infamous interview with Lowell Bergman of CBS' *60 Minutes*.[187] The documents included scientific studies by the company about the need for a safer cigarette and the dangers of smoking.[188] Not only did Wigand's disclosure of protected trade secrets help Moore's case, it also hurt the tobacco industry's image even further in the eyes of public opinion.[189]

In contrast, Merrell Williams worked as a paralegal at the law firm Wyatt, Tarrant & Combs, which provided legal services for Brown & Williamson.[190] Before the firm terminated Williams' job because of budget cuts, he copied thousands of Brown & Williamson's documents and gave them to Moore to help his case against Big Tobacco.[191] The documents included trade secrets and corporate correspondence that discussed the contents and science behind cigarettes.[192]

These revelations by Wigand and Williams helped Moore and other attorneys general support their *parens patriae* claims, pushing the tobacco industry into a corner and forcing a settlement.[193] With pressure mounting from forty-six state attorneys general, the tobacco industry saw a settlement as a safer option compared to risking damage award amounts with a jury in litigation.[194] On November 23, 1998, the four major tobacco companies

---

[183] Lindsay Graham, *Big Tobacco: The New Frontier*, AMERICAN SCANDAL, (Aug. 4, 2020), https://open.spotify.com/episode/7Ahg1X9S02DIpngznnrhzT.

[184] *See generally* Brenner, *supra* note 175 (explaining that at the time, Brown & Williamson was the third largest tobacco company in the United States).

[185] *Id.*

[186] *Id.*

[187] *Id.*

[188] Lindsay Graham, *Big Tobacco: Smoking Guns*, AMERICAN SCANDAL, (July 7, 2020), https://open.spotify.com/episode/1gW1eSZv1H9rG10pxUE5AV.

[189] Brenner, *supra* note 175.

[190] Douglas Martin, *Merrell Williams Jr., Paralegal Who Bared Big Tobacco, Dies at 72*, N.Y. TIMES (Nov. 26, 2013), https://www.nytimes.com/2013/11/27/business/merrell-williams-jr-paralegal-who-bared-big-tobacco-dies-at-72.html [https://perma.cc/MJ53-EX8T].

[191] *Id.*

[192] Graham, *supra* note 183.

[193] *See generally* Interview with Mick McGraw, Former Chief Gen. Couns., Brown & Williamson Tobacco Co., in Louisville, Ky. (Dec. 18, 2020) (explaining that Brown & Williamson filed a suit against Wigand for breaking his non-disclosure agreement and for lying to federal investigators about witness intimidation, yet the suit was dropped as part of the settlement agreement).

[194] Dennis C. Vacco, *As an Attorney General, I Sued the Tobacco Companies. Exxonmobil is Nothing Like Them*, WASH. POST (July 14, 2016), https://www.washingtonpost.com/opinions/as-an-attorney-general-i-sued-the-tobacco-companies-exxonmobil-is-nothing-like-them/2016/07/14/b5e04f82-492f-11e6-acbc-4d4870a079da_

settled with fifty states and several territories of the United States.[195] The settlement agreement drastically changed the tobacco industry's marketing techniques, as well as imposed limitations on the industry.[196] Moreover, the settlement is well known for the $206 billion to be paid over twenty-five years to the states for damages caused from cigarettes.[197]

In return for Big Tobacco settling with the states, the states forfeited their right to current and future legal claims against the cigarette manufacturers for smoking-related costs.[198] In addition, the settlement agreement focused heavily on regulating the tobacco industry's marketing techniques.[199] For example, the settlement agreement specifically prohibited the "targeting of underage persons in tobacco advertising, banned the use of cartoons in cigarette advertising, and sharply restricted brand name sponsorship and outdoor advertising."[200] However, even with the massive settlement award and multiple marketing restrictions, the tobacco industry continued to generate billions of dollars in revenue.[201] For example, the Federal Trade Commission reported that in 2017 that the tobacco industry sold over 216 billion cigarettes and spent over $8 billion in marketing.[202]

C. Opioid Litigation History Thus Far

Opioid litigation began in the early 2000s but civil actions have steadily increased over the years.[203] The earliest actions in opioid litigation point to Purdue Pharma, the maker of OxyContin (oxycodone), for its fault in personal injury claims brought on behalf of those who overdosed on opioids.[204]

While litigation started with individual plaintiffs suing pharmaceutical companies for liability in people's opioid addictions,[205] litigation has since

---

story.html [https://perma.cc/UQZ6-S72U].

[195] Miller, *supra* note 13.

[196] *Id.*

[197] *Id.*

[198] Micah L. Berman, *Using Opioid Settlement Proceeds for Public Health: Lessons from the Tobacco Experience*, 67 U. KAN. L. REV. 1029, 1036 (2019).

[199] *Id.*

[200] *Id.*

[201] *Id.*

[202] *FTC Releases Reports on Cigarette and Smokeless Tobacco Sales and Marketing Expenditures for 2018*, FTC (Dec. 30, 2019), https://www.ftc.gov/news-events/press-releases/2019/12/ftc-releases-reports-cigarette-smokeless-tobacco-sales-marketing [https://perma.cc/U2PC-6U23].

[203] Rebecca Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301 (2020).

[204] *Id.*

[205] Michelle L. Richards, *Pills, Public Nuisance, and* Parens Patriae*: Questioning the Propriety of the Posture of the Opioid Litigation*, 54 U. RICH. L. REV. 405, 405 (2020).

grown into class actions and *parens patriae* claims.[206] Civil opioid litigation has targeted "drug manufacturers and physicians by individual plaintiffs, and suits brought by state and local governments that targeted not only the manufacturers and physicians, but also opioid distributors and pharmacy retailers."[207]

Much like tobacco litigation, the early stages of opioid litigation have proven mostly unsuccessful.[208] The majority of early opioid litigation claims were either individual suits or class actions.[209] Plaintiffs alleged that opioid manufacturers presented fraudulent and negligent marketing of the opioids as a less addictive alternative to pain management.[210] Plaintiffs sought damages in those cases to cover the costs associated with the prescriptions and for expenses related to addiction.[211] Most of these claims were dismissed when defendants filed motions for summary judgment because they lacked duty or causation elements.[212]

However, once states and government entities started filing *parens patriae* claims, litigation proved more successful.[213] For example, in 2001 West Virginia's Attorney General sued Purdue Pharma "for maintaining a public nuisance, as well as violating the West Virginia Consumer Credit Protection Act, negligence, and antitrust violations, among others."[214] West Virginia sought over $30 million in damages, however, the State eventually settled with Purdue Pharma for $10 million in 2004.[215] West Virginia's suit helped push twenty-six other states to sue Purdue Pharma for its role in the opioid crisis.[216]

In 2007, Purdue Pharma and three of its executives:

> [A]greed to pay $600 million in civil and criminal fines to the federal government and almost $20 million to twenty-six states and the District of Columbia following a plea agreement in which the company pleaded guilty to a felony charge of misbranding OxyContin with the intent to defraud or mislead, and the executives pleaded guilty to a misdemeanor charge of misbranding.[217]

---

206 *Id.*
207 *Id.* at 438.
208 Haffajee & Mello, *supra* note 203.
209 *Id.*
210 Richards, *supra* note 205, at 438.
211 *Id.*
212 *Id.* at 439.
213 *Id.* at 440.
214 *Id.*
215 *Id.*
216 *Id.* at 441.
217 *Id.*

Furthermore, Purdue Pharma spent an additional $130 million to settle private civil claims related to OxyContin.[218] Pike County, Kentucky and the Commonwealth of Kentucky settled with Purdue Pharma in 2013 for $4 million and $23 million, respectively.[219]

Since December 2017, individuals, states, and private entities filed more than two thousand lawsuits against drug manufacturers, distributors, and pharmacies.[220] In order to administer judicial oversight, the cases "have been consolidated and transferred for pre-trial coordination to the Northern District of Ohio by the Judicial Panel on Multidistrict Litigation under the MDL process set forth in 28 U.S.C. § 1407 (National Prescription Opiate MDL)."[221]

While Purdue Pharma was one of the first pharmaceutical companies to find itself in legal trouble from the opioid crisis, it certainly will not be the last. More and more pharmaceutical companies will soon find themselves in very similar situations as Purdue Pharma for their role in creating addictive pain medications. By analyzing the tobacco industry's litigation and settlement history alongside of the current opioid litigation data, pharmaceutical companies can learn five key lessons in order to prevent massive settlements.

III. ANALYSIS

A. Lessons Learned from Big Tobacco's Litigation

Pharmaceutical companies can learn a great deal of information about effective and ineffective litigation strategies by comparing and contrasting the tobacco industry's litigation with current opioid litigation, ultimately learning five key lessons from Big Tobacco's litigation history: (1) Class actions and *parens patriae* claims are powerful litigation techniques; (2) offensive use of issue preclusion can bar defenses in later claims; (3) FDA control over an industry can preempt state tort law; (4) presenting all known risks can prevent failure to warn claims; and (5) plaintiffs' conduct can be used as a bar to recovery. By looking closely at the similarities and differences between opioid and tobacco litigation, pharmaceutical companies can understand how the tobacco industry succeeded and failed, and apply the lessons to opioid litigation.

---

[218] *Id.*
[219] *Id.* at 443.
[220] *Id.*
[221] *Id.*

1. Lesson One: Class Actions and *Parens Patriae* Claims Are Powerful Litigation Techniques

a. Class Actions

As noted, the tobacco industry successfully defended countless individual claims prior to the early 1990s.[222] Peter Pringle described Big Tobacco's victories up until 1992 in his book as, "eight-hundred and thirteen claims filed against the industry, twenty-three tried in court, [and] two lost—both overturned on appeal. Not a penny paid in damages."[223] However, use of class actions still presented challenges and pharmaceutical companies can learn from the tobacco industry's relationship with strategies pertaining to class action claims.

Rule 23 of the Federal Rules of Civil Procedure (FRCP) governs court rules regarding class action certifications.[224] The rule says that "one or more members of a class may sue or be sued as representative parties on behalf of all members" only if four prerequisites are satisfied.[225] First, the class must be "so numerous that joinder of all members is impracticable."[226] Second, there must be "questions of law or fact common to the class."[227] Third, the claims or defenses of the representative parties must be "typical of the claims or defenses of the class."[228] Fourth, the potential representative parties must "fairly and adequately protect the interests of the class."[229] Rule 23 is in place to prevent inconsistent judgments regarding the same or similar issues as well as to protect the interests of all parties.[230]

In *Castano v. American Tobacco Corp.*, the Fifth Circuit made a surprising decision by decertifying the entire class action.[231] The district court certified a class of all "nicotine-dependent persons" based on FRCP 23, however, the Fifth Circuit reversed on appeal.[232] The Fifth Circuit reasoned that the "district court erred in its analysis in two distinct ways.[233] First, it failed to consider how variations in state law affect predominance and

---

[222] PETER PRINGLE, CORNERED: BIG TOBACCO AT THE BAR OF JUSTICE 25–26 (1st ed. 1998).
[223] *Id.* at 7.
[224] Fed. R. Civ. P. 23.
[225] Fed. R. Civ. P. 23(a).
[226] Fed. R. Civ. P. 23(a)(1).
[227] Fed. R. Civ. P. 23(a)(2).
[228] Fed. R. Civ. P. 23(a)(3).
[229] Fed. R. Civ. P. 23(a)(4).
[230] Fed. R. Civ. P. 23(b).
[231] Castano v. Am. Tobacco Co., 84 F.3d 734, 737 (5th Cir. 1996).
[232] *Id.*
[233] *Id.* at 740.

superiority.[234] Second, its predominance inquiry did not include consideration of how a trial on the merits would be conducted."[235] Thus, on interlocutory appeal the Fifth Circuit reversed, decertifying the entire class action.[236]

Consequently, in response to *Castano*, "tobacco litigation splintered into single-state class actions filed in federal and state courts across the country" because federal courts expressed apprehension toward nationwide mass tort class actions.[237] The splintered class-action suits became known as "son of *Castano* class actions."[238] These actions once again proved unsuccessful as all federal courts and most state courts would not certify the class actions because of the inconsistency with Rule 23 or its state counterparts.[239] Big Tobacco realized the danger that class actions presented compared to individual claims.[240] Not only were class actions against Big Tobacco more complex, but they also carried a risk of massive damage awards.[241]

b. Parens Patriae

Class actions are not the only litigation tool pharmaceutical companies need be cautious of; the legal doctrine of *parens patriae* has become increasingly popular over the past two decades in mass tort litigation.[242] *Parens patriae*'s popularity grew out of tobacco litigation when multiple state attorneys general sued the tobacco industry, forcing a massive settlement agreement.[243] As seen in the tobacco industry's litigation history, *parens patriae* claims carried the biggest sting as opposed to individual claims and class actions.[244] *Parens patriae* suits usually rely on claims such as public nuisances, which is an interference with a public right.[245] The Restatement (Second) of Torts explains that a "public right is one common to all members of the general public. It is collective in nature and not like the individual right that everyone has not to be assaulted or defamed or defrauded

---

[234] *Id.*
[235] *Id.*
[236] *Id.* at 737.
[237] Kearns, *supra* note 168.
[238] *Id.* at 1354.
[239] *Id.* at 1354–55.
[240] *See* Castano v. Am. Tobacco Co., 84 F.3d 734, 737 (5th Cir. 1996).
[241] *Id.*
[242] Thomas, *supra* note 97, at 762.
[243] *Id.*
[244] *Id.*
[245] Michael L. Rustad & Thomas Koenig, *Reforming Public Interest Tort Law to Redress Public Health Epidemics*, 14 J. Health Care L. & Pol'y 331, 343 (2011) (quoting Restatement (Second) of Torts § 851B, cmt. G (Am. Law Inst. 1965)).

or negligently injured."[246] The state's ability to employ *parens patriae* to protect public rights is commonly referred to as the state's police powers.[247]

When a state asserts a *parens patriae* claim it must: (1) "[A]llege injury to a sufficiently substantial segment of its population;" (2) "articulate an interest apart from the interests of particular private parties, i.e., the State must be more than a nominal party;" and (3) "express a quasi-sovereign interest."[248] Moreover, states are not likely to succeed in *parens patriae* claims against public health threats if they cannot demonstrate an injury that extends beyond the individual.[249] For example, the South Carolina Supreme Court held in *Baltzeger v. Carolina Midland Ry. Co.* that there was no public nuisance because the public health threat did not extend beyond the plaintiff and his family.[250]

Parens patriae claims are powerful, in part because of the difficulty to "victim-blame" the plaintiffs.[251] For example, in litigation Big Tobacco tried to defend *parens patriae* suits by arguing that smokers chose to buy and smoke cigarettes.[252] However, the states were not affected by these arguments because the states, as the plaintiffs in the case, never smoked a cigarette.[253] Attorney General Mike Moore, who led the tobacco litigation on behalf of the states, famously said, "[y]ou caused the health crisis, you pay for it. The free ride is over. It's time these billionaire tobacco companies start paying what they rightfully owe to Mississippi taxpayers."[254]

The United States Supreme Court analyzed a *parens patriae* claim in *Alfred L. Snapp & Son v. P.R.*[255] The Court concluded that in order to maintain a *parens patriae* claim, "the State must articulate an interest apart from the interests of particular private parties, i. e., the State must be more than a nominal party," and the State "must express a quasi-sovereign interest."[256] The Court continued by saying that these "characteristics fall into two general categories. First, a State has a quasi-sovereign interest in the health and well-being—both physical and economic—of its residents in general. Second, a State has a quasi-sovereign interest in not being

---

[246] RESTATEMENT (SECOND) OF TORTS § 851B, cmt. g (Am. Law Inst. 1965).

[247] Rustad & Koenig, *supra* note 245, at 344.

[248] *Id.* at 367.

[249] *Id.* at 345.

[250] Baltzeger v. Carolina Midland Ry. Co., 32 S.E. 358, 360 (S.C. 1899).

[251] Rustad & Koenig, *supra* note 245, at 358.

[252] Barnes v. Am. Tobacco Co., 161 F.3d 127, 147 (3d Cir. 1998).

[253] Rustad & Koenig, *supra* note 245, at 358.

[254] Carrick Mollenkamp et. al., *The People vs. Big Tobacco: How the States Took On the Cigarette Giants*, BLOOMBERG PRESS (1998), [https://perma.cc/3JMC-HHBC].

[255] Alfred L. Snapp & Son v. P.R., 458 U.S. 592, 607 (1982).

[256] *Id.*

discriminatorily denied its rightful status within the federal system."[257] Because *parens patriae* claims were relatively new to mass tort litigation, Big Tobacco did not know how to defend the claims and ended up settling.[258]

2. Lesson Two: Offensive Use of Issue Preclusion Can Bar Defenses in Later Claims

Big Tobacco understood the importance of defending all claims scrupulously because plaintiffs are sometimes able to offensively use issue preclusion to bar future defenses.[259] Issue preclusion, sometimes called collateral estoppel, is a civil procedure tool that focuses on whether the same issue is in the court in different cases.[260] Issue preclusion is important because it can "control the outcome of an entire claim."[261] Issue preclusion relies on four basic elements: (1) The same issue is present; (2) the issue was actually litigated in case one; (3) the court must decide the question, and the question must be material; and (4) the ruling must have been necessary to the judgment rendered.[262] Therefore, litigation between two people can directly affect third parties.[263]

However, plaintiffs cannot be bound by an earlier case if the plaintiffs were not parties to the earlier suit, given notice and an opportunity to be heard, or adequately represented by the existing parties.[264] In *Richards v. Jefferson County*, the United States Supreme Court held that a judgment binds a non-party who is in privity with one of the named parties in the case.[265] Therefore, if a non-party is in privity with the named parties, both issue and claim preclusion apply.[266] This idea survives any Due Process challenge as long as the non-party's interests were adequately represented by one of the parties in the case.[267] In determining privity, many courts favor the functional view which asks if the rights of the non-party were "fully and fairly" represented.[268]

---

[257] *Id.*

[258] *See generally* Master Settlement Agreement, *supra* note 14.

[259] *See, e.g.*, Brown v. R.J. Reynolds Tobacco Co., 611 F.3d 1324, 1333 (11th Cir. 2010).

[260] JOHN T. CROSS ET AL., CIVIL PROCEDURE: CASES, PROBLEMS, AND EXERCISES 671 (4th ed. West Academic, 2016).

[261] *Id.*

[262] *Id.* at 672

[263] *Id.*

[264] JOHN T. CROSS ET AL., CIVIL PROCEDURE: CASES, PROBLEMS, AND EXERCISES ch. 13 § E, at 3 (4th ed. West Academic 2016) (ebook).

[265] Richards v. Jefferson Cty., 517 U.S. 793, 801 (1996).

[266] *Id.*

[267] *Id.*

[268] CROSS, *supra* note 264, at 9.

Over time, courts have allowed offensive use of issue preclusion.[269] Offensive use allows a plaintiff to preclude a third-party from raising a defense or issue previously litigated if the third party's rights were fairly represented in the previous case.[270] For example, if a homeowner secured a judgment against a pesticide company for harmful products, a third-party homeowner who sustained injuries would likely be able to take advantage of the judgment, precluding the pesticide company from raising the same issue again because it already had the fair opportunity to argue its case previously. However, courts usually use the *Parklane* test to determine if offensive use of issue preclusion is fair and appropriate.[271]

In *Parklane*, the Court held that two considerations should be weighed before allowing offensive use of issue preclusion.[272] First, the court should ask whether the non-party could have easily joined the first action.[273] If yes, then offensive use of issue preclusion is inappropriate.[274] Second, the court should determine whether it would be unfair to the other side (e.g., inconsistent prior judgments, procedural advantages not present in case one, or little incentive to litigate case one).[275] If it would be unfair, then offensive use of issue preclusion is inappropriate.[276] It is important to note that if privity exists, not only can the non-party use issue preclusion without the *Parklane* limits, but the non-party is bound by the judgment if the previous litigant (party with whom the non-party is in privity) lost in the case.[277] Moreover, the plaintiff has the burden to "prove that all of the elements to establish offensive nonmutual issue preclusion have been satisfied."[278]

Thus, Big Tobacco understood that offensive use of issue preclusion could be detrimental to future litigation.[279] For example, in *Brown v. R.J. Reynolds Tobacco Co.*, the Eleventh Circuit analyzed a preclusive effect of a previous judgment.[280] The previous judgment came from the Florida Supreme Court in *Engle v. Liggett Group., Inc*.[281] In *Engle*, the Florida Supreme Court decertified a class action but held that the findings of the jury in Phase One of the litigation would have preclusive effect on future litigation

---

[269] *Id*. at 11.
[270] *Id.*
[271] Parklane Hosiery Co., Inc. v. Shore, 439 U.S. 322, 331 (1979).
[272] *Id.*
[273] *Id.*
[274] *Id.*
[275] *Id.*
[276] *Id.*
[277] CROSS, *supra* note 264, at 15.
[278] Shaffer v. R.J. Reynolds Tobacco Co., 860 F. Supp. 2d 991, 995 (D. Ariz. 2012).
[279] *See* Brown v. R.J. Reynolds Tobacco Co., 611 F.3d 1324, 1333 (11th Cir. 2010).
[280] *Id.*
[281] Engle v. Liggett Grp., Inc., 945 So.2d 1246, 1276 (Fla. 2006).

for former class members.[282] In *Brown v. R.J. Reynolds Tobacco Co.*, the United States District Court for the Middle District of Florida held that allowing the jury's findings from *Engle*, precluding further litigation of the facts in other cases, violated R.J. Reynold's due process rights.[283]

On appeal, the Eleventh Circuit reversed the judgment holding that the findings should be given preclusive effect.[284] The Eleventh Circuit reasoned that the district court reached that conclusion,

> [W]ithout first giving preclusive effect to the Phase I approved findings. The Phase I approved findings have to be given preclusive effect; they do establish some facts that are relevant to this litigation. Otherwise, the Florida Supreme Court's statement in Engle III that the Phase I approved findings were to have res judicata effect in trials involving former class members would be meaningless.[285]

Thus, the Eleventh Circuit remanded the case back to the district court to determine "precisely what facts are established when preclusive effect is given to the approved findings."[286] Therefore, the tobacco industry quickly realized how detrimental preclusive effects can be on future litigation and defended all claims scrupulously.[287]

3. Lesson Three: FDA Control Over An Industry Can Preempt State Tort Law

In 2000, the United States Supreme Court held that the Food and Drug Administration (FDA) does not have the authority to regulate tobacco products.[288] The FDA argued that when Congress passed the Food, Drug, and Cosmetic Act it granted the FDA authority to regulate tobacco.[289] Justice O'Connor wrote for the majority and relied on *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*[290] In *Chevron*, the Court said that when analyzing an administrative agency's construction of a statute, it must determine whether Congress specifically addressed the subject matter in the statute.[291] If Congress did address the subject, the Court must give deference

---

[282] *Id.*
[283] Brown v. R.J. Reynolds Tobacco Co., 576 F. Supp. 2d 1328, 1344-45 (M.D. Fla. 2008).
[284] *Brown*, 611 F.3d at 1335-36.
[285] *Id.*
[286] *Id.* at 1336.
[287] *See generally supra* notes 265–273.
[288] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000).
[289] *Id.* at 130.
[290] *Id.* at 126.
[291] Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).

to the intent of Congress.[292] If Congress has not addressed the matter, the Court should follow the administrative agency's construction of the statute as long as it is permissible.[293] Applying *Chevron*, the Court held that because Congress enacted six separate pieces of legislation since 1965 that prevent FDA control over tobacco it was evident that Congress did not intend for an administrative agency to have control over Big Tobacco.[294]

Even though Big Tobacco was not controlled by FDA regulations, Big Tobacco understood that FDA regulation brought new complexities to litigation.[295] Thus, Big Tobacco knew that FDA control over tobacco would likely bring more harms than benefits.[296] However, federal administrative regulation over an industry is not always bad because it can preempt other law in the field.[297] Federal preemption of state tort law is a highly debated subject within courts and public opinion.[298] The debate might be contentious because a "successful preemption defense can dispose of cases in their entirety and often quite rapidly."[299] Therefore, even though FDA regulation would likely not be in the best interest of Big Tobacco, pharmaceutical companies can use FDA preemption as a defense to state tort claims.[300]

The Supremacy Clause of the United States Constitution says that, "this Constitution, and the laws of the United States shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding."[301] Thus, much debate surrounds the issue of whether the FDA's regulations preempt state tort law.[302]

The FDA regulates new drug approval in 21 U.S.C. § 355.[303] The statute requires FDA approval before a new drug is able to be sold and marketed within the United States. Therefore, the drug manufacturer must submit a new drug application following all specified guidelines outlined by the

---

[292] *Id*.

[293] *Id*.

[294] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125 (2000).

[295] *See generally id*. at 126.

[296] *Id*.

[297] Arameh O'Boyle & Clancy Galgay, *"Newly Acquired Information" and Federal Preemption Defenses in Pharmaceutical Products Liability Cases*, AM. BAR ASS'N (June 28, 2018), https://www.americanbar.org/groups/litigation/committees/mass-torts/practice/2018/newly-acquired-information-federal-preemption-defenses-pharmaceutical-products-liability-cases/ [https://perma.cc/MLA9-SXNG].

[298] Kathryn B. Armstrong, *Is Impossibility Preemption Impossible? Federal Drug Law and Preemption of State Tort Claims*, CONG. RESEARCH SERV. (Jan. 19, 2018), https://fas.org/sgp/crs/misc/LSB10064.pdf [https://perma.cc/B279-EJSL].

[299] O'Boyle, *supra* note 297.

[300] *Id*.

[301] U.S. Const. art. VI, cl. 2.

[302] Armstrong, *supra* note 298.

[303] 21 U.S.C. § 355 (2020).

FDA.[304] When submitting the application, 21 U.S.C. § 352 requires the manufacturer to provide a drug label that is neither false nor misleading.[305] Therefore, even though the FDA is charged with approving drug labels, the drug manufacturers are responsible for maintaining that the label is accurate as long as the drug is on the market.[306] If a drug manufacturer decided to amend a drug label, the manufacturer would need permission from the FDA.[307] Consequently, the FDA almost exclusively controls drug manufacturing and distribution.[308]

FDA preemption issues have risen all the way to the United States Supreme Court on multiple occasions.[309] In *Wyeth v. Levine*, the Supreme Court held that FDA drug labeling requirements preempt state tort failure-to-warn claims if "clear evidence" shows that the FDA would have rejected a drug label change required by state law.[310] The Court reasoned that state tort law will only be preempted when it is impossible to comply with both federal and state law.[311] Ten years later, in *Merck v. Albrecht* the Court once again held that the drug manufacturer must show that it is impossible to comply with both federal and state law for preemption to be applicable.[312] However, the Court added that a judge, not a jury, must decide the preemption question.[313] Thus, while FDA regulations cannot preempt all state tort law, it does preempt state law that directly conflicts with FDA regulations.[314]

4. Lesson Four: Presenting All Known Risks Can Prevent Failure to Warn Claims

The tobacco industry's problems started when the Surgeon General released his report about the dangers of smoking in 1964.[315] Big Tobacco faced decades of mass tort claims based on the premise that tobacco companies failed to warn consumers of dangerous risks.[316] However, after decades of litigation and massive settlements, the tobacco industry seems to understand the importance of disclosing risks associated with its products.

---

304 *Id.*
305 21 U.S.C. § 352 (2020).
306 Armstrong, *supra* note 298.
307 *Id.*
308 *Id.*
309 *Id.*
310 Wyeth v. Levine, 555 U.S. 555, 571-72 (2009).
311 *Id.*
312 Merck Sharpe & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1676 (2019).
313 *Id.* at 1680.
314 *E.g.*, *Merck Sharpe & Dohme Corp.*, 139 S. Ct. at 1676; *Wyeth*, 555 U.S. at 571–72.
315 Terry, *supra* note 99.
316 Quinn, *supra* note 129, at 115.

Recently, Philip Morris International ran a full-page advertisement in the Wall Street Journal—titled "Transparency Is the Gateway to A Better Future."[317] In the advertisement, Philip Morris' vice president for strategic and scientific communications, Dr. Moira Gilchrist, explained that the company is committed to transparency and seeks to create a "smoke-free future" with new products and innovation.[318]

In the mid-1990s, Brown & Williamson Tobacco Corporation also sought to create transparency within the tobacco industry.[319] The former Chief General Counsel for the company said that it created a website in the mid-1990s to "tell the whole story about the dangers of smoking."[320] With the internet being fairly new for consumer use, this was a very innovative approach.[321] In addition, Brown & Williamson employed a smoking-health scientist who routinely testified that smoking could cause cancer.[322] Furthermore, in 1984 Congress passed legislation that required tobacco companies to print warnings on every tobacco product's packaging.[323]

However, the warnings did not come quickly enough, and Big Tobacco faced liability for years of hiding risks.[324] Yet, even with massive settlements and presenting the dangerous risk associated with smoking, the tobacco industry continued to bring in billions of dollars in revenue.[325] Thus, the same is true for the pharmaceutical industry: People can handle risks, and it is better to disclose them. Even though the pharmaceutical industry is heavily regulated by the FDA and required to produce accurate warnings on labels, they should go the extra mile to disclose all known risks.[326]

---

[317] Dr. Moira Gilchrist, *Transparency is the Gateway to a Better Future*, THE WASHINGTON POST (Dec. 2, 2020), https://www.washingtonpost.com/brand-studio/wp/2020/12/02/transparency-is-the-gateway-to-a-better-future/ [https://perma.cc/2PPZ-KYAA].

[318] *Id*.

[319] Interview with Mick McGraw, *supra* note 193.

[320] *Id*.

[321] *Id*.

[322] *Id*.

[323] John D. Blum, *A Fifty-Year Retrospective on Major Laws of the 91st Congress: Tobacco Product Warnings in the Mist of Vaping: A Retrospective on the Public Health Cigarette Smoking Act*, 23 CHAP. L. REV. 53, 73 (2020).

[324] Interview with Mick McGraw, *supra* note 193.

[325] *FTC Releases Reports on Cigarette and Smokeless Tobacco Sales and Marketing Expenditures for 2019*, *supra* note 202.

[326] Armstrong, *supra* note 298.

5. Lesson Five: Plaintiffs' Conduct Can Be Used As A Bar To Recovery

Comparative and contributory negligence theories in tort law can provide a solid defense to, or minimize damage awards in, product liability claims.[327] Addressing these potential strategies, one legal scholar stated:

> While the precise question whether contributory negligence or assumption of risk is a defense to a strict products liability in tort action is of recent origin, the basic problem of applying negligence defenses in an action not founded on negligence is not a new one, and the reasoning of earlier cases which have debated the basic question in other contexts may have relevance to the resolution of the present problem.[328]

Contributory negligence jurisdictions, which are very few, allow the defendant to show that the plaintiff was partially at fault for the injury; if the defendant can successfully provide a prima facie case for contributory negligence, it completely bars the plaintifff from bringing a claim.[329] If a defendant can establish a *prima facie* case for comparative negligence, the court will apportion damages based on the percentage of fault it finds the plaintiff in the injuries.[330] Thus, if a defendant can prove that the plaintiff was seventy-five percent responsible for the injury, then the defendant would only be responsible for twenty-five percent of the damage award.[331] Big Tobacco often used comparative and contributory negligence defenses in their litigation.[332]

For example, in early litigation the Third Circuit held that assumption of risk "involves voluntary exposure to an obvious or known danger which negates liability. Under this concept recovery is barred because the plaintiff is assumed to have relieved the defendant of any duty to protect him."[333] Additionally, in *Barnes v. American Tobacco Co.* the Third Circuit held that American Tobacco Co. was able to use contributory negligence as a defense

---

[327] Gary D. Spivey, Annotation, *Products Liability: Contributory Negligence or Assumption of Risk as Defense Under Doctrine of Strict Liability in Tort*, 46 A.L.R.3d 240, § 2[a] (1972).

[328] *Id*.

[329] Legal Info. Inst., *Contributory Negligence*, CORNELL L. SCH., https://www.law.cornell.edu/wex/contributory_negligence [https://perma.cc/ZX8N-JK69] (last visited Feb. 28, 2021).

[330] Legal Info. Inst., *Comparative Negligence*, CORNELL L. SCH., https://www.law.cornell.edu/wex/comparative_negligence [https://perma.cc/B54A-MERZ] (last visited Feb. 28, 2021).

[331] *Id*.

[332] *E.g.*, Pritchard v. Liggett & Myers Tobacco Co., 350 F.2d 479, 484 (3d Cir. 1965); Barnes v. Am. Tobacco Co., 161 F.3d 127, 147 (3d Cir. 1998); Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, 171 F.3d 912, 918 (3d Cir. 1999).

[333] *Pritchard*, 350 F.2d at 484.

in the class action suit.[334] In a footnote, the court noted the distinction between contributory and comparative negligence defenses using a Pennsylvania statute as guidance:

> In all actions brought to recover damages for negligence resulting in death or injury to person or property, the fact that the plaintiff may have been guilty of contributory negligence shall not bar a recovery by the plaintiff or his legal representative where such negligence was not greater than the causal negligence of the defendant or defendants against whom recovery is sought, but any damages sustained by the plaintiff shall be diminished in proportion to the amount of negligence attributed to the plaintiff.[335]

Moreover, in *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris* the Third Circuit dismissed the plaintiffs' claim for lack of standing.[336] However, in a footnote, the court said comparative and contributory negligence defenses "presumably would be available in the present case, in the sense that smokers' own wrongdoing (or ignoring of known risks) would be a factor in establishing and measuring the link between the tobacco companies' actions and the Funds' damages."[337]

Therefore, Big Tobacco understood the benefit of contributory negligence or comparative negligence defenses to prevent or reduce damage awards.[338] Many jurisdictions favor comparative negligence defenses, as opposed to contributory negligence defenses, because it prevents the all-or-nothing approach.[339] By implementing comparative or contributory negligence defenses, Big Tobacco was able to drastically reduce damage awards or completely bar recovery.[340]

B. Similarities in Opioid and Tobacco Litigation

Similarities between the two litigation patterns can help the pharmaceutical industry learn from the successes and failures of the tobacco industry's litigation. The first main similarity is that both litigation patterns are thought of in a series of eras or waves.[341] As discussed, the tobacco

---

[334] *Barnes*, 161 F.3d at 147.

[335] *Id.* at 147 n.23.

[336] *Steamfitters*, 171 F.3d at 918.

[337] *Id.* at 933 n.16.

[338] Terry, *supra* note 99.

[339] Thomas R. Trenkner, Annotation, *Modern Development of Comparative Negligence Doctrine Having Applicability to Negligence Actions Generally*, 78 A.L.R.3d 339, § 1[a] (1977).

[340] Terry, *supra* note 99.

[341] *Opioid Data Analysis and Resources*, *supra* note 66; Henderson, *supra* note 101.

industry's litigation spans a period of six decades starting in the 1950s.[342] The three eras of the tobacco industry's litigation correspond with different types of claims: The first era corresponds with individual claims, the second era corresponds with class actions, and the third era corresponds with *parens patriae* claims.[343] Similarly, opioid litigation is beginning to follow the same three-era litigation pattern.[344] Opioid litigation's story began in the 1990s as opioids quickly rose in popularity for pain management.[345] By 2010, opioid-related overdoses and deaths quickly rose within the United States.[346] Three years later, overdoses and deaths spiked to a new high in 2013.[347] Even though opioid litigation's story is progressing quicker than Big Tobacco's, pharmaceutical companies should expect a long, grueling fight in the courts. Pharmaceutical companies should also expect waves of different claims similar to Big Tobacco's history.[348] As the pharmaceutical industry has started to see, lawsuits started with individual claims and now they are progressing into class actions and *parens patriae* claims.[349]

Another simple but important similarity is that both litigation patterns involve products liability claims.[350] Both opioid and tobacco litigation center on failure-to-warn claims and defective products.[351] Moreover, addictive tendencies of the products play an important part in litigation.[352] Many people who smoked were angry because they claimed that they did not know that cigarettes were addictive.[353] Similarly, those who took opioid prescription medications claimed that they did not know about the addictive nature of the medication.[354]

C. Contrasts Between Opioid and Tobacco Litigation

While opioid litigation reflects many similarities compared to the tobacco industry's mass tort litigation,[355] this analysis would be incomplete without outlining key differences as well. The major differences between

---

342 Henderson, *supra* note 101, at 70.
343 *Id.*
344 *Opioid Data Analysis and Resources*, *supra* note 66.
345 *Id.*
346 *Id.*
347 *Id.*
348 *Id.*; Henderson, *supra* note 101.
349 Haffajee, *supra* note 203.
350 *Id.*; *e.g.*, Lartigue v. R. J. Reynolds Tobacco Co., 317 F.2d 19, 39 (5th Cir. 1963).
351 Haffajee, *supra* note 203.
352 *Id.*
353 *Id.*
354 *Id.*
355 *Supra* notes 326–339.

tobacco and opioid litigation can be summarized in three categories: FDA regulation, settlement funding, and the class of defendants.

First, the tobacco and opioid industries are regulated very differently, since the FDA regulates the pharmaceutical industry.[356] Under FDA regulation, before any prescription drug is able to hit the market the FDA must approve it, and the FDA has approved prescription opioids to treat pain.[357] On the other hand, tobacco products are not regulated by any agency, the only regulation for tobacco products being outlined in legislation.[358] Therefore:

> Preventing drug manufacturers from creating and distributing opioids is not an option as around fifty million Americans suffer from chronic pain, and many rely on prescribed opioids to relieve the burden on their lives. The health benefit consideration of opioids is a factor that was simply not present in the tobacco litigation.[359]

Thus, in opioid litigation, pharmaceutical companies will have to handle the added complexity of federal regulatory bodies, whereas tobacco companies did not have to deal with federal regulatory issues.[360] However, as seen later in the resolution of this note, pharmaceutical companies can try to leverage FDA regulation as a defense to certain claims.

Second, settlement and litigation funding differ greatly in comparison between the opioid and tobacco industries.[361] While some may hope for a large settlement agreement similar to the Tobacco Master Settlement, it is very unlikely to be nearly as large.[362] A large settlement agreement is unlikely because, "[e]ven if distributors could be held solely responsible, the financial differences between big tobacco and opioid distributors is so stark that it would be impossible for states to rely on continued funding by opioid distributors in the same way they might be able to with" the tobacco industry.[363] The tobacco industry brought in $93.4 billion from cigarette sales in 2016, even after years of damaging litigation.[364] Moreover, tobacco

---

[356] 21 U.S.C. § 355 (2011).

[357] *Id*.

[358] Elizabeth Orrick, *Mistakes Were Made: Applying Lessons Learned from the Tobacco Master Settlement Agreement to the Opioid Settlement Agreement*, 42 MITCHELL HAMLINE L.J. PUB. POL'Y & PRAC. 1, 31 (2021).

[359] *Id*. at 31–32.

[360] *Id*. at 33.

[361] *Id*. at 31.

[362] Brian Eckert, *This is How Opioid Lawsuits Differ from Big Tobacco's*, MORGAN & MORGAN (Jan. 26, 2018), https://www.classaction.com/news/opioid-lawsuits-big-tobacco [https://perma.cc/897Y-F24J].

[363] Orrick, *supra* note 358.

[364] Jennifer Maloney & Saabira Chaudhuri, *Against All Odds, the U.S. Tobacco Industry is Rolling in Money*, THE WALL STREET JOURNAL (Apr. 23, 2017, 1:31 PM), https://www.wsj.com/articles/u-s-tobacco-industry-rebounds-from-its-near-death-experience-1492968698 [https://perma.cc/A7WV-9Q7W].

companies spent $8.64 billion on advertising alone in 2018.[365] In comparison, prescription opioid sales generated $8.5 billion.[366] Therefore, the tobacco industry generates a lot more money than opioid producers, and it will be tougher to convince pharmaceutical companies to agree to as large of a settlement as tobacco litigation produced.

Lastly, tobacco and opioid litigation differ in the number of defendants. In tobacco litigation, most claims and class actions focused on the four major United States tobacco companies: Philip Morris, Inc., R.J. Reynolds Tobacco Co., Brown & Williamson Tobacco Corp., and Lorillard Tobacco Co.[367] In contrast, plaintiffs in the opioid litigation named both manufacturers and distributors as defendants.[368] Thus, not only are the major opioid manufacturers, such as Purdue Pharma, facing lawsuits, but distributors and other parties, such as McKesson and CVS Pharmacy, are named in the suits.[369] Moreover, litigation also differs because the tobacco litigation's *parens patriae* claims arose from forty-six state attorneys general,[370] whereas in the opioid litigation, more than two thousand cities, counties, and state attorneys general have filed claims against opioid manufacturers and distributors.[371] By adding this many plaintiffs and defendants, it makes litigation that much more complicated and time-consuming.[372]

Therefore, even though tobacco and opioid litigation have important similarities, their differences are just as important. By understanding those similarities and differences, pharmaceutical companies can better prepare themselves for the complex and challenging litigation arising from opioids.

IV. RESOLUTION

The goal of this Note is to provide pharmaceutical companies, and their attorneys, strategies to prevent lawsuits and minimize damage awards once they begin. The Resolution is broken into two parts: Subsection A provides legal strategies for pharmaceutical companies' attorneys, while Subsection B

---

[365] Mitchell J. Katz, *FTC Releases Reports on Cigarette and Smokeless Tobacco Sales and Marketing Expenditures for 2017*, FEDERAL TRADE COMMISSION (Feb. 27, 2019), https://www.ftc.gov/news-events/press-releases/2019/02/ftc-releases-reports-cigarette-smokeless-tobacco-sales-marketing [https://perma.cc/RES3-SQF4].

[366] Orrick, *supra* note 358.

[367] Master Settlement Agreement, *supra* note 14.

[368] Haffajee, *supra* note 203.

[369] Wen S. Shen, *Overview of the Opioid Litigation and Related Settlements and Settlement Proposals*, CONG. RES. SERV. (Nov. 25, 2019), https://crsreports.congress.gov/product/pdf/LSB/LSB10365 [https://perma.cc/45Q8-V6JH].

[370] Master Settlement Agreement, *supra* note 14.

[371] Dwyer, *supra* note 5.

[372] *Id.*

provides practical tips for pharmaceutical executives and compliance specialists. By applying these proposed strategies, pharmaceutical companies can attempt to limit liability and minimize damage awards.

A. Applying the Five Lessons from Big Tobacco's Litigation

1. Lesson One: Prevent the Formation of Class Actions and Argue that *Parens Patriae* Does Not Apply

a. Class Actions

The first important lesson that pharmaceutical companies can apply in response to opioid litigation is that preventing the certification of class actions can deenergize the momentum of the claim and lessen the sting of litigation. In trying to prevent the certification of a class action, pharmaceutical companies should complete three important steps. First, they should look for any and all defects in the plaintiff's claim that the class action is certifiable according to Rule 23.[373] Common defects to look for are: (1) The class definition is vague, overbroad, imprecise, or subjective; (2) the class is not so numerous that joinder is impractical; (3) common issues to the class are missing; (4) the class representative's claim differs from the class in a substantially meaningful way; or (5) the class representative has a substantially meaningful conflict of interest with the class as a whole.[374]

Second, pharmaceutical companies should "analyze which elements of the proposed Rule 23(b) class cannot be satisfied."[375] While Rule 23(a) offers the prerequisites for certifying a class action, Rule 23(b) sets out certain restrictions.[376] Rule 23(b)(1)(A) requires no substantial risk of other actions by the class members and the class must be seeking substantial damages.[377] Moreover, Rule 23(b)(1)(B) requires that there is no limited fund from which each class member seeks relief.[378] It also requires that relief for one class member does not affect relief for all class members.[379]

Third, and finally, because the class action representative bears the burden of proof, pharmaceutical companies should try to understand all

---

[373] 1 *Federal Class Action Deskbook* § 3.103 (2020).
[374] *Id.*
[375] *Id.*
[376] Fed. R. Civ. P. 23(b).
[377] *Federal Class Action Deskbook, supra* note 373.
[378] *Id.*
[379] *Id.*

avenues of evidence likely to be presented.[380] By understanding evidence likely to be presented, pharmaceutical companies will be better poised to object to certain aspects.

Class actions have a dangerous potential to impose heavy damage awards or force defendants into massive settlements.[381] As seen in historical mass tort litigation, class actions are a popular and dangerous tool that plaintiffs usually weaponize.[382] Thus, it is vital that pharmaceutical companies fight vigorously to prevent certification of class actions.

b. Parens Patriae

The best way for pharmaceutical companies to defend a *parens patriae* claim is to argue that the state does not have standing to bring the claim. Pharmaceutical companies should assert that injuries from opioids did not violate a public right. Public rights are "collective in nature and not like the individual right that everyone has not to be assaulted or defamed or defrauded or negligently injured."[383] Furthermore, "the rights protected by public nuisance law are not simply aggregations of private rights."[384] Thus, the question becomes "whether governmental entities, such as state attorneys general and local governments, are attempting to obscure the individual nature of injuries allegedly suffered by individuals in their jurisdictions and attributed to opioid manufacturers by focusing on the widespread use of the product or its potential to cause harm."[385] If the answer to that question is yes, then courts should explain "why the remedy sought by the governmental entities is compensable when the claims brought by private citizens have nearly all been dismissed for lack of causation due to misuse of the product; intervening, superseding conduct of the plaintiff or the physician who prescribed it; or illegal conduct."[386] Moreover, in many of the states' prayers for relief in opioid litigation, the state asks for damages to compensate individual citizens' injuries.[387] Therefore, pharmaceutical companies should point out that states do not have standing to bring *parens patriae* claims

---

[380] 1 *Federal Class Action Deskbook* § 3.04[4] (2020).

[381] Legal Info. Inst., *Class Action: An Overview*, CORNELL L. SCH., https://www.law.cornell.edu/wex/class_action [https://perma.cc/W8ND-JK6B] (last visited Mar. 1, 2020).

[382] *Id.*

[383] Richards, *supra* note 205, at 455.

[384] *Id.*

[385] *Id.*

[386] *Id.*

[387] *E.g*, Complaint, State v. Purdue Pharma L.P., No. 217-2017-CV-00402, 2018 WL 4566129 (N.H. Super. Ct. Sept. 18, 2018); Complaint, State v. Purdue Pharma, L.P., No. CV-17 CI000261 (Ohio Ct. Com. Pl. Ross Cty. May 31, 2017); Complaint, State v. Purdue Pharma, L.P., No 2017-L-013180 (Cook Cty. Ct. Dec. 27, 2017).

unless a public right is violated.[388] Thus, unless a public right is violated, states have no quasi-sovereign interest required by *Snapp*.[389]

2. Lesson Two: Fight Defensively in Early Suits to Prevent Offensive Use of Issue Preclusion

Consequently, pharmaceutical companies should take every claim seriously and fight defensively in order to prevent offensive use of issue preclusion in later litigation. Moreover, if a party tries to gain preclusive effect against the pharmaceutical company, the company should try to argue that applying issue preclusion violates the *Parklane* test. However, issue preclusion is hard to overcome, especially if privity exists.[390] Therefore, pharmaceutical companies should take every opioid related claim seriously as to protect from offensive use of issue preclusion—defending claims zealously.

3. Lesson Three: Use FDA Control of Pharmaceuticals to Preempt State Tort Law

Thus, while FDA regulations cannot preempt all state tort law, it does preempt state law that directly conflicts with FDA regulations.[391] Pharmaceutical companies should be prepared to argue that FDA regulations preempt state tort law, as many state suits will likely involve failure-to-warn claims. The tobacco industry viewed FDA regulation as more of a burden than a help; Brown & Williamson argued that the FDA had no jurisdictional control of tobacco products, and the United States Supreme Court agreed.[392] While FDA regulation probably would not help the tobacco industry, it certainly can be used as a strong defense for pharmaceutical companies in state tort claims. Therefore, pharmaceutical companies should find places where FDA regulation and state law conflict in product label requirements, using FDA preemption as a defense to failure-to-warn claims.

---

[388] *See id.*

[389] *See generally* Alfred L. Snapp & Son v. P.R., 458 U.S. 592, 607 (1982).

[390] *See* Parklane Hosiery Co., Inc. v. Shore, 439 U.S. 322, 331 (1979).

[391] *E.g.*, Merck Sharpe & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1676 (2019); Wyeth v. Levine, 555 U.S. 555, 571–72 (2009).

[392] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000).

4. Lesson Four: Present All Known Risks

Even though the pharmaceutical industry is heavily regulated by the FDA[393] and required to produce accurate warnings on labels, they should go the extra mile to disclose all known risks.[394] Some pharmaceutical companies already understand the importance of disclosing risks.[395] For example, Mallinckrodt Pharmaceuticals, which is one of the largest opioid producers, gives a comprehensive list of risks and side effects.[396] At the top of the list is the risk of addiction and how healthcare providers should try to mitigate the risk of addiction.[397] To the contrary, Purdue Pharma "trained its sales representatives to relay to prescribers that OxyContin presented a less than 1% risk of addiction, despite a lack of scientific studies addressing addiction from long-term opioid use, to substantiate its bold and deceptive claims."[398] Therefore, Purdue Pharma's "aggressive marketing scheme of soft-pedaling the addictive nature of opioids catapulted the pharmaceutical company's commercial success, as the promise of a low addiction risk motivated prescribers to treat long-term chronic-pain sufferers with OxyContin."[399]

Thus, pharmaceutical companies can learn from both the tobacco industry and Purdue Pharma's failure to disclose all known risks and side effects from using the product. By disclosing all known risks, pharmaceutical companies can also prevent fraudulent misrepresentation claims.[400] Moreover, Big Tobacco's history proves that, even after damaging litigation and disclosure of all dangerous risks, people will continue to buy products they want or need.[401] More importantly, opioids provide a greater public health benefit than tobacco and public policy favors products that give more of a benefit than a risk. Thus, people will likely continue to buy opioids even if they know about dangerous side effects or addictive nature of the medication.

---

393 Orrick, *supra* note 358.

394 Armstrong, *supra* note 298.

395 *Id.*

396 *Roxicodone™ (oxycodone hydrochloride) Tablets USP, CII 15 mg: Indications and Usage*, MALLINCKRODT PHARM., https://www.mallinckrodt.com/products/generics/non-promoted-brands/opioid-products/roxicodone-oxycodone-hydrochloride-tablets-usp-cii-15-mg/ [https://perma.cc/72AD-4URU] (last visited March 1, 2021).

397 *Id.*

398 Katherine Spiser, Comment, *Combatting the Opioid Epidemic in Texas by Holding Big Pharma Manufacturers Liable*, 50 ST. MARY'S L. J. 1353, 1367 (2019).

399 *Id.*

400 *Id.*

401 *FTC Releases Reports on Cigarette and Smokeless Tobacco Sales and Marketing Expenditures for 2018*, *supra* note 202.

Consequently pharmaceutical companies can take three important steps when presenting all known risks: (1) Create training and marketing materials for healthcare professionals relating to best practices in prescribing opioids; (2) continually research possible adverse effects and disclose them to the public; (3) reduce opioid marketing on television and in other non-healthcare setting advertisements. By enacting these steps, pharmaceutical companies can prevent failure-to-warn and fraudulent misrepresentation claims, limiting liability.

5. Lesson Five: Use Plaintiff's Conduct as a Bar to Recovery

Pharmaceutical companies should use comparative or contributory negligence defenses—depending on the jurisdiction—to reduce damages liability or completely prevent a claim. Because very few states use contributory negligence, pharmaceutical companies should focus on using comparative negligence defenses to reduce damage liability.[402] Prescription opioids are the fastest growing form of drug abuse and cause of overdose deaths.[403] Opioid drug abuse rose from four thousand users to over sixteen thousand in 2010.[404] Moreover, half of these opioid overdose deaths involve individuals using another drug in combination with opioids, most commonly benzodiazepines.[405]

Moreover, pharmaceutical companies should investigate pharmacists and doctors who abuse their role as prescription distributors and prescribers. For example, the U.S. Attorney's Office for the Eastern District of Missouri recently charged a pharmacist for illegally distributing controlled substances out of her pharmacy.[406] Additionally, the U.S. Attorney's Office for the Western District of Pennsylvania dedicated a large portion of resources to prosecute pharmacists and doctors who illegally distribute opioids.[407] U.S. Attorney Brady said: "One of the key sources of opioid addiction was prescription opioids by medical professionals and pharmacists."[408] His office

---

[402] Spivey, *supra* note 327; Legal Info. Inst., *supra* notes 329–330.

[403] Mark J. Edlund et al., *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-Cancer Pain: The Role of Opioid Prescription*, NCBI (July 1, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4032801/pdf/nihms541772.pdf [https://perma.cc/78FW-MYDZ].

[404] *Id.*

[405] *Id.*

[406] U.S. Att'y's Off. for the E. Dist. of Mo., *Justice Department Files Lawsuit Against Creve Coeur Pharmacist for Controlled Substances Act Violations*, DEP'T OF JUSTICE (Feb. 24, 2021), https://www.justice.gov/usao-edmo/pr/justice-department-files-lawsuit-against-creve-coeur-pharmacist-controlled-substances-0 [https://perma.cc/6LTN-BQ9V].

[407] U.S. Att'y's Off. for the W. Dist. of Pa., *U.S. Attorney Scott Brady Announces Resignation*, DEP'T OF JUSTICE (Feb. 26, 2021), https://www.justice.gov/usao-wdpa/pr/us-attorney-scott-brady-announces-resignation [https://perma.cc/KCM5-BGP9].

[408] *Id.*

prosecuted more doctors and pharmacists than any other U.S. Attorney's Office.[409] Therefore, pharmaceutical companies can use facts of medical professionals' impropriety in prescribing and distributing opioids to reduce apportionment of liability. Moreover, because pharmaceutical companies are required by the FDA to print all waring and side effects of using prescription opioids,[410] they can try to argue that opioid users assumed the risk of the medication when they chose to purchase and use the product.

B. Proposed Response to the Opioid Crisis for Pharmaceutical Executives and Compliance Specialists

Even though attorneys hold a prominent role in opioid litigation, pharmaceutical executives and compliance specialists play an important part too. Legal tools and strategies can help pharmaceutical companies prevent or minimize litigation costs, but pharmaceutical executives and compliance specialists can take four other steps to help bolster the company's reputation in the eyes of society, and prevent future litigation: (1) Create more training and educational resources for drug prescribers and pharmacists; (2) set up charitable foundations to help combat opioid addiction in the United States; (3) reduce traditional opioid marketing; and (4) research less addictive alternatives to opioid medications. By adjusting and implementing new protocols and strategies within pharmaceutical organizations, executives and compliance specialists can attempt to minimize the risk of future litigation and show good faith in present litigation.

V. CONCLUSION

In conclusion, pharmaceutical companies can prevent lawsuits and minimize damage awards by applying the five key lessons learned from Big Tobacco's mass tort litigation: (1) Prevent the formation of a class action and argue that *parens patriae* does not apply, (2) prevent offensive use of issue preclusion early in lawsuits, (3) use FDA control of pharmaceuticals to preempt state tort law claims, (4) present all known risks, and (5) use plaintiff's conduct as a bar to recovery. By employing these strategies, pharmaceutical companies can attempt to avoid a mass influx of litigation and limit damage awards against them. Mass tort litigation surrounding the opioid crisis is just getting started, and pharmaceutical companies should start preparing a strong defense to counter plaintiffs' claims.

---

[409] *Id.*

[410] Orrick, *supra* note 358.