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Fighting America's Best-Selling Product: An Analysis of and Solution to the Opioid Crisis

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Fighting America's Best-Selling Product: An Analysis of and Solution to the Opioid Crisis

Ashley Duckworth*

Abstract

Deaths from drug overdoses have doubled over the last ten years and are now the leading cause of accidental death in the United States. Although some overdoses may have involved more than one drug, prescription and/or illicit opioids were involved in many of these drug overdose fatalities. The Food and Drug Administration (FDA), Center for Disease Control and Prevention (CDC), and Congress have enacted a string of regulations, statutes, and programs since the early 1990s, but nothing has seriously improved the opioid epidemic as it stands. If anything, the use of opioids has persisted. Many people want pharmaceutical companies to be held responsible, and although the companies can be portrayed as the most at fault, they are not the only ones to blame. Medical doctors have also contributed significantly to the opioid crisis by prescribing large amounts of opioid painkillers to patients when a smaller amount or lower dosage is adequate. The relationship between pharmaceutical companies and doctors is the root of the problem. The two have worked in tandem, perpetuating the crisis. Although the opioid crisis itself is a matter of enormous magnitude, this Note proposes that more intensive, yet reasonable, federal action through the construction of a civil model law is needed. A federal model law would include concepts like more actively monitoring the distributorship of pharmaceutical companies, regulating doctors' prescribing habits, implementing a tax or licensing fee against pharmaceutical companies, and making

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a more concerted effort to end prescription opioid addiction while at the same time recognizing that there are individuals who need opioids to manage their pain.

Part II of this Note provides a history of opioid use in the United States, including background on the three periods of increased opioid use, and provides examples of states that are most affected. Part III analyzes regulations and statutes put in place since the beginning of the current crisis and their overall failure to remedy the crisis. Part III also evaluates the effectiveness of regulations and statutes currently in place and acknowledges proposed regulations and statutes. Part IV looks at the relationship between pharmaceutical companies and doctors and explains how these two groups create and control the availability of opioid painkillers. Part V suggests remedying the opioid crisis with a more constructive, yet intensive, federal model law encouraging doctors to stop the extreme prescription of opioid painkillers while simultaneously holding pharmaceutical companies accountable for their actions.

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I. Introduction

Driving through a small town in East Tennessee looks much different than it did just twenty years ago.¹ The landscape was once a rural area, dotted with small farms and neighborhoods.² Now, the hillsides are littered with abandoned or ragged-out trailers and crack houses.³ The living conditions are stomach-churning.⁴ What was once a population composed of farmers,

1. *Compare Farming Heritage*, TENN. DEPT OF AGRIC., <https://www.tn.gov/agriculture/farms/heritage.html> (last visited Dec. 2, 2019) (describing Tennessee’s farming heritage and decline in farmland) [<https://perma.cc/7F5L-9FME>], with Chris Salvemini, *Transportation Structure of East Tenn. Makes Region Drug Trafficking Hub*, UT DAILY BEACON (Jan. 23, 2015), http://www.utdailybeacon.com/news/transportation-structure-of-east-tenn-makes-region-drug-trafficking-hub/article_b7b87651-328a-540e-b4c4-c965e8cdc034.html (last visited Nov. 25, 2019) (describing drug houses in Tennessee) [<https://perma.cc/G5X8-PLJH>].

2. *See Tennessee—Rural Definitions: State-Level Maps*, U.S. DEPT OF AGRIC., https://www.ers.usda.gov/webdocs/DataFiles/53180/25597_TN.pdf?v=0 (last visited Nov. 25, 2019) (showing maps that label parts of East Tennessee as rural) [<https://perma.cc/H4NN-V739>].

3. *See Salvemini, supra* note 1 (explaining how East Tennessee has recently seen an influx of drugs).

4. *See* Tim Craig, *Homeless Deaths Surge*, WASH. POST (Apr. 13, 2018), <https://www.washingtonpost.com/news/national/wp/2018/04/13/feature/surge-in-homeless-deaths-linked-to-opioids-extreme-weather-soaring-housing-cost/> (last visited Nov. 25, 2019) (describing the deplorable living conditions that those who have fallen victim to opioid abuse endure) [<https://perma.cc/QNS4-56C3>].

factory workers, and professionals is now a population subject to lost hope and drug addiction.⁵

More than 72,000 Americans died from drug overdoses in 2017.⁶ Deaths from drug overdoses have doubled over the last ten years, and are now the leading cause of accidental death in the United States.⁷ Although some overdoses may have involved more than one drug, “prescription and/or illicit opioids were involved in 66.4% (42,249) of these drug overdose fatalities.”⁸ Pharmaceutical companies are often blamed for exacerbating the crisis because they have encouraged the use of prescription opioids and advertised the “non-addictive” nature of the drugs since the 1990s.⁹ The Food and Drug Administration (FDA), Center for Disease Control and Prevention (CDC), and Congress have enacted a string of regulations, statutes, and programs since the early 1990s, but nothing has seriously improved the opioid epidemic as it stands.¹⁰ If anything, the use of opioids has persisted.¹¹ “In 2017, 17.4% of the U.S. population received one or more opioid prescriptions,” averaging 3.4 prescriptions per person.¹²

5. See Clay Duda, *On the Front Lines of Knoxville’s Battle Against Opiate Addiction*, KNOXVILLE MERCURY (June 1, 2016), <http://www.knoxmercury.com/2016/06/01/front-lines-knoxvilles-battle-opiate-addiction/> (last visited Nov. 25, 2019) (describing many individuals in East Tennessee being addicted to opiates) [<https://perma.cc/7M8W-5N8A>].

6. See Nat’l Inst. on Drug Abuse, *Overdose Death Rates*, DRUGABUSE.GOV, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (last updated Jan. 2019) (last visited Nov. 25, 2019) (describing the disturbing statistics behind the opioid crisis) [<https://perma.cc/4HR4-W4SB>].

7. See *id.* (noting the stark increase in opioid related deaths).

8. CDC NAT’L CTR. FOR INJURY PREVENTION AND CONTROL, 2018 ANNUAL SURVEILLANCE REPORT OF DRUG-RELATED RISKS AND OUTCOMES 7 (2018).

9. See Lindsey Liu, Diana N. Pei & Pela Soto, *History of the Opioid Epidemic: How Did We Get Here?*, NAT’L CAP. POISON CTR., <https://www.poison.org/articles/opioid-epidemic-history-and-prescribing-patterns-182> (last visited Nov. 25, 2019) (describing the beginning stages of the opioid crisis) [<https://perma.cc/S3CC-YUYY>].

10. See RICHARD J. BONNIE ET AL., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 276–94 (2017) (noting that nothing the government has done thus far has significantly helped the state of America’s opioid addiction).

11. See CDC NAT’L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 6 (describing the fact that opioid use and addiction continues to increase).

12. CDC NAT’L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 6.

Many people want pharmaceutical companies to be held responsible, and although the companies can be portrayed as the most at fault, they are not the only ones to blame.¹³ Medical doctors have also contributed significantly to the opioid crisis by prescribing large amounts of opioid painkillers to patients when a smaller amount or lower dosage is adequate.¹⁴ In addition to the legal instances, the number of doctors who illegally prescribe pain medication for profit have also contributed to the epidemic.¹⁵

The relationship between pharmaceutical companies and doctors is the root of the problem.¹⁶ The two have worked in tandem, perpetuating the crisis through pharmaceutical companies offering benefits to doctors for prescribing certain amounts of opioid painkillers, and doctors reaping the rewards.¹⁷ Although the opioid crisis itself is a matter of enormous magnitude, this Note proposes that more intensive, yet reasonable, federal action through the construction of a civil model law is needed.¹⁸ The criminal aspects, although significant to the crisis, are not discussed because the illicit behavior contributing to the crisis is difficult to regulate.¹⁹ A federal model law would include

13. See *City of Chicago v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1062–64 (N.D. Ill. 2016) (providing a prime example of courts holding pharmaceutical companies responsible).

14. See Nat'l Inst. on Drug Abuse, *supra* note 6 (describing the contribution of doctors to the opioid crisis).

15. See Press Release, Dep't of Justice, Moody Pill Mill Doctor Charged with Illegal Prescribing (Oct. 30, 2017), <https://www.justice.gov/usao-ndal/pr/moody-pill-mill-doctor-charged-illegal-prescribing> (last visited Nov. 25, 2019) [hereinafter Moody Pill Mill Doctor] (referencing one of many instances that the DOJ is currently fighting where doctors illegally prescribe opioids for financial benefit) [<https://perma.cc/2PW2-W67J>].

16. See Sheryl Calabro, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 CARDOZO L. REV. 2241, 2256–57 (2004) (noting that doctors and pharmaceutical companies are both to blame for the state of the crisis as opposed to one over the other).

17. See *id.* (describing the relationship between doctors and pharmaceutical companies along with the incentives attached to maximizing the sale of opioids).

18. See *infra* Part V (describing the creation of a civil model law and potential roadblocks).

19. See *Trends in Opioid Use, Harms, and Treatment*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., <https://www.ncbi.nlm.nih.gov/books/NBK458661/> (last visited Nov. 25, 2019) (explaining the impact of those involved in the criminal justice system on the opioid crisis and suggesting solutions that do not involve regulation) [<https://perma.cc/Z8CW-L24P>].

concepts like more actively monitoring the distributorship of pharmaceutical companies, regulating doctors' prescribing habits, implementing a tax or licensing fee against pharmaceutical companies, and making a more concerted effort to end prescription opioid addiction while at the same time recognizing that there are individuals who need opioids to manage their pain.²⁰

Part II provides a history of opioid use in the United States, including background on the three periods of increased opioid use, and provides examples of states that are most affected.²¹

Part III analyzes regulations and statutes put in place since the beginning of the current crisis and their overall failure to remedy the crisis.²² Part III also evaluates the effectiveness of regulations and statutes currently in place and acknowledges proposed regulations and statutes.²³

Part IV looks at the relationship between pharmaceutical companies and doctors and explains how these two groups create and control the availability of opioid painkillers.²⁴

Part V suggests remedying the opioid crisis with a more constructive, yet intensive, federal model law encouraging doctors to stop the extreme prescription of opioid painkillers while simultaneously holding pharmaceutical companies accountable for their actions.²⁵

II. Background

A. History of Opioid Use in the United States

The final quarter of the twentieth century brought about the acceptance of opioids in mainstream medical practice and

20. See *infra* Part V (proposing a new federal model law).

21. See *infra* Part II (documenting the history of opioid use in the United States).

22. See *infra* Part III (examining regulations, statutes, and their failure to remedy the opioid crisis).

23. See *infra* Part III (evaluating proposed statutes and regulations aimed at curbing the opioid crisis).

24. See *infra* Part IV (explaining the interplay between doctors and pharmaceutical companies as it relates to the prescription of opioids).

25. See *infra* Part V (describing a possible remedy to the opioid crisis).

treatment.²⁶ Prior to the 1980s, opioid use was minimal.²⁷ In fact, physicians and nurses were trained to give minimal opioids for pain, unless death seemed imminent.²⁸ This mindset changed as researchers and specialists determined chronic pain was vastly undertreated.²⁹ Highly influential articles and studies were published in the 1980s reporting on the low incidence of addictive behavior.³⁰ These articles claimed there was “no published long-term data that gave evidence of high addiction rates among pain patients.”³¹ A large number of doctors, patients, and opioid manufacturers supported these results, and within a decade, pain management had changed.³² By 1996, the American Society of Anesthesiology adopted a new set of guidelines for treating chronic pain including recommendations about evaluating patients for drug therapies involving opioids.³³ At that point, opioids became a staple form of pain reliever.³⁴

26. See Hilary Homenko, *Rehabilitating Opioid Regulation: A Prescription for the FDA's Next Proposal of an Opioid Risk Evaluation and Mitigation Strategy (REMS)*, 22 HEALTH MATRIX 273, 277–78 (2012) (describing the earlier history of opioids in America).

27. See Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 106 AM. J. PUB. HEALTH 1365, 1365 (2016) (providing that opioid use prior to the introduction of persuasive research articles on their non-addictive nature was minimal).

28. See *id.* (emphasizing that opioid use was minimal prior to the 1980s and that opioids were only used in emergencies).

29. See *id.* (noting that the introduction of opioid use as a more normal treatment for pain was in response to the need to treat pain better).

30. See *id.* (referencing the research articles written in the 1980s telling individuals that opioids were safe to use and non-addictive).

31. *Id.*

32. See *id.* (describing how, after the results supporting opioid use for pain treatment were released, the rest of the industry quickly caught up and supported opioid use).

33. See Homenko, *supra* note 26, at 277–78 (referring to the guidelines established by the late 1990s for assisting patients and doctors with the use of opioids and how to do so properly).

34. See Homenko, *supra* note 26, at 277–78 (“Opioid pain relievers commonly used today include morphine, hydrocodone, and oxycodone.”).

B. The Start of the Crisis

One way to map the escalation of the opioid crisis is by the number of overdose deaths from opioid use.³⁵ As the number of deaths increased, the crisis arguably intensified.³⁶ The timeline illustrating this can be broken down into three waves.³⁷ “The first wave began with the increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids (natural and semi-synthetic opioids and methadone) increasing since 1999.”³⁸ This was the foundation of the crisis.³⁹ Prescription painkillers were prescribed at alarming rates, causing mass dependency issues that are still prevalent and increasing today.⁴⁰ Reassurances given to prescribers by pharmaceutical companies and medical societies claiming that the risk of addiction to prescription opioids was very low contributed to increased prescription rates.⁴¹ Pharmaceutical companies also began promoting the use of opioids in patients with non-cancer related pain, and by 1999, eighty-six percent of patients using opioids were using them for non-cancer pain.⁴² With the increase in opioid usage, communities where opioids were made available and

35. See *Opioid Overdose*, CDC, <https://www.cdc.gov/drugoverdose/data/analysis.html> (last visited Nov. 25, 2019) (describing the general mapping of the opioid crisis from its start in the 1980s to the 2010s) [<https://perma.cc/LDQ9-HSLH>].

36. *Id.*

37. See *id.* (“This rise in opioid overdose deaths can be outlined in three distinct waves.”).

38. *Id.*

39. See Kate Vidinsky, *Opioid Crisis: This Doctor’s Street-Level Views Could Change the Course of the Epidemic*, UNIV. CAL. S.F. (June 12, 2018), <https://www.ucsf.edu/news/2018/06/410636/opioid-crisis-doctors-street-level-views-could-change-course-epidemic> (last visited Nov. 25, 2019) (“The foundational base of the crisis . . . was the prescription painkiller epidemic.”) [<https://perma.cc/P3M4-8M2H>].

40. See *id.* (“Powerful opiates were prescribed at alarming rates, causing mass dependency issues that continue today.”).

41. See Liu, Pei & Soto, *supra* note 9 (“The increase in opioid prescriptions was influenced by reassurances given to prescribers by pharmaceutical companies and medical societies claiming that the risk of addiction to prescription opioids was very low.”).

42. See Liu, Pei & Soto, *supra* note 9 (“By 1999, 86% of patients using opioids were using them for non-cancer pain.”).

prescribed generously were the first places to experience increased opioid abuse.⁴³

“The second wave began in 2010, with rapid increases in overdose deaths involving heroin.”⁴⁴ As early efforts to decrease opioid prescribing by making them harder to obtain came into force, addicts turned to heroin.⁴⁵ Heroin was a cheaper and more widely available illegal opioid that increased in use as prescription drug patients and other new users combined into a larger force of addicts.⁴⁶ The increase in heroin usage is evident in statistics as overdose deaths due to heroin increased by 286% from 2002 to 2013.⁴⁷ Approximately eighty percent of heroin users admitted to misusing prescription opioids before turning to heroin, illustrating the connection in use.⁴⁸

“The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids, particularly those involving illicitly manufactured fentanyl (IMF).”⁴⁹ The nation is currently grappling with this problematic IMF market involving heroin, counterfeit pills, opioids, and cocaine, which continues to evolve and worsen.⁵⁰ However, most often, addiction begins with a legal prescription for an opioid painkiller.⁵¹

43. See Liu, Pei & Soto, *supra* note 9 (“Communities where opioids were readily available and prescribed liberally were the first places to experience increased opioid abuse and diversion.”).

44. *Opioid Overdose*, *supra* note 35.

45. See Liu, Pei & Soto, *supra* note 9 (“As early efforts to decrease opioid prescribing began to take effect, making prescription opioids harder to obtain, the focus turned to heroin, a cheap, widely available, and potent illegal opioid.”).

46. See Liu, Pei & Soto, *supra* note 9 (referencing the increase in usage of heroin because they were cheaper and more available than prescription opioids); see also Vidinsky, *supra* note 39 (noting that prescription opioids served as a sort of gateway drug to illegal use of illicit drugs that were obtained more cheaply).

47. See Liu, Pei & Soto, *supra* note 9 (“Deaths due to heroin-related overdose increased by 286% from 2002 to 2013 . . .”).

48. See Liu, Pei & Soto, *supra* note 9 (“[A]pproximately 80% of heroin users admitted to misusing prescription opioids before turning to heroin.”).

49. *Opioid Overdose*, *supra* note 35.

50. See *Opioid Overdose*, *supra* note 35 (describing the IMF market).

51. See *Opioid Overdose*, *supra* note 35 (describing how the mixing of other drugs with prescription opioids is a significant proportion of drug overdose deaths).

C. Examples of Where the Crisis Is Most Serious

The opioid crisis is generally more serious in rural and impoverished areas.⁵² The Appalachian region, in particular, has higher overdose death rates than the rest of the country.⁵³ There is also a correlation between overdose death rates, high rates of poverty, and individuals with low rates of educational attainment.⁵⁴ Such characteristics are prevalent in Appalachia.⁵⁵ Predictably, compared to the country as a whole, “Appalachian residents are 55 percent more likely to die from drug overdoses.”⁵⁶ West Virginia and Tennessee offer two instructive examples for analysis.⁵⁷

West Virginia has the highest drug overdose death rate in the nation at fifty-two overdose deaths per 100,000.⁵⁸ These numbers are comprised of both intentional and unintentional drug overdoses that reflect a statewide problem.⁵⁹ The state is “ground zero” of the opioid crisis and has been experiencing a public health epidemic of drug overdose deaths for more than a decade.⁶⁰ The

52. See Leonard J. Paulozzi et al., *Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008*, 60 MORBIDITY & MORTALITY WKLY REP. 1487, 1487–92 (2011) (“More rural and more impoverished counties tend to have higher prescription drug overdose death rates.”).

53. See Aaron Payne, *CDC Outlines Plan to Address Ohio Valley’s Opioid Crisis*, W. VA. PUB. BROAD. (Mar. 22, 2018), <http://www.wvpublic.org/post/cdc-outlines-plan-address-ohio-valleys-opioid-crisis-0> (last visited Nov. 25, 2019) (“The Appalachian Region has been taking a disproportionate hit in overdose deaths in relation to the rest of the country.”) [<https://perma.cc/Y8Q3-6CCU>].

54. See *id.* (describing the strong correlation between overdose deaths and areas with high rates of poverty, people on disability, and low rates of educational attainment).

55. See *id.* (illustrating the characteristics that correlate between opioid overdoses and the Appalachian region overlap).

56. *Id.*

57. See *infra* notes 58–65 and accompanying text (describing the opioid crisis in West Virginia); see also *infra* notes 66–71 and accompanying text (describing the opioid crisis in Tennessee).

58. CDC NAT’L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 26.

59. See W. VA. DEPT. OF HEALTH & HUMAN RES. BUREAU FOR PUB. HEALTH, WEST VIRGINIA DRUG OVERDOSE DEATHS HISTORICAL OVERVIEW 2001–2015 4 (2017) (noting that all areas of the state are affected by opioid abuse).

60. See *United States v. Walker*, No. 2:17-cr-00010, 2017 U.S. Dist. LEXIS 98233, at *7 (S.D. W. Va. June 26, 2017) (explaining the cultural context of the opioid crisis and the havoc wreaked on West Virginia).

details embedded in the data can be chilling.⁶¹ Just one night in 2016, twenty-six individuals overdosed in Cabell County, West Virginia.⁶² The sheer number of the calls overwhelmed police and EMS responders, and although this was an extraordinary case in terms of the number of individuals that overdosed, unfortunate overdoses happen all too often in West Virginia.⁶³ The opioid crisis is even reflected in West Virginia's case law.⁶⁴ The epidemic must be explained in depth in order for others to grasp the cultural context of the area and the fact that the "opioid crisis is a cancer that has grown and metastasized in the body politic of the United States."⁶⁵

Tennessee provides an alternative example of how the crisis has progressed through the Appalachian region.⁶⁶ In Tennessee, the opioid prescribing rate was 94.4 per 100 persons in 2017, the third highest in the nation behind Alabama and Arkansas.⁶⁷ Moreover, "[i]n 2016, there were 1,186 opioid-related overdose deaths in Tennessee—a rate of 18.1 deaths per 100,000 persons—higher than the national rate of 13.3 deaths per 100,000 persons."⁶⁸ To put this number into perspective, these are more lives than the

61. *See id.* (discussing the dire effects the opioid crisis has had on West Virginia).

62. *See* Taylor Stuck, *26 Overdoses Reported Monday Evening*, HERALD DISPATCH (Aug. 16, 2016), http://www.herald-dispatch.com/news/overdoses-reported-monday-evening/article_81990238-4a74-5431-9420-76e0f35c5cbf.html (last visited Nov. 25, 2019) (providing a newspaper report on twenty-six individuals overdosing in Huntington, West Virginia) [<https://perma.cc/Q2JU-Y3TM>].

63. *See id.* ("By 9 p.m., 26 overdoses had been reported, more than Cabell County EMS responds to in a week.")

64. *See Walker*, 2017 U.S. Dist. LEXIS 98233, at *7 ("The plea agreement proffered by the parties in this case was made in the context of a clear, present, and deadly heroin and opioid crisis in this community.")

65. *Id.*

66. *See* Mandy Pellegrin & Courtnee Melton, *The Opioid Epidemic in Tennessee: 2018 Update on Indicators of Progress*, SYCAMORE INST. (Aug. 9, 2018), <https://www.sycamoreinstitute.org/2018/08/09/opioid-epidemic-tn-indicators/> (last visited Nov. 25, 2019) (clarifying that the situation in Tennessee concerning the opioid crisis is still worsening) [<https://perma.cc/VBN4-5LPS>].

67. *See* CDC NAT'L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 11 (noting that these numbers may seem distorted but that several individuals have multiple prescriptions for opioids, inflating the numbers).

68. Nat'l Inst. on Drug Abuse, *supra* note 6.

state lost in combat during the entire Vietnam War.⁶⁹ To provide an alternative example, in July of 2009, members of a Tennessee drug task force seized several one-hundred-tablet bottles of oxycodone made by the pharmaceutical company Mallinckrodt.⁷⁰ Task-force agents alerted Mallinckrodt because the company's lot numbers were printed on the labels, allowing for easy tracking of the pills, but rather than taking action to halt the extreme amount of opioids being sent to the state, Mallinckrodt continued shipping pills knowing that they would more than likely be misused.⁷¹ Although Tennessee as a whole is not the worst case, an afternoon observing an East Tennessee criminal courtroom illustrates countless cases almost all dealing with drugs, repeat offenders, and an obvious problem with opioids.⁷²

III. Regulations and Their Failure

A. Current Regulations and Guidelines

A significant number of statutes and regulations have been implemented to combat the crisis.⁷³ However, attempts at regulating and lawmaking have proven largely ineffective thus

69. See Phil Roe, *Working Together to Tackle the Opioid Epidemic*, GREENEVILLE SUN (June 15, 2018), https://www.greenevillesun.com/opinion/local_columns/working-together-to-tackle-the-opioid-epidemic/article_a3809b78-7740-5fcf-9d4c-cfa114951da8.html (last visited Nov. 25, 2019) (comparing the death toll from opiates in Tennessee with the death toll of soldiers from the state during the Vietnam War) [<https://perma.cc/4W5B-RLW7>].

70. Lenny Bernstein & Scott Higham, *Major DEA Opioid Case Falters on Uncertain Legal Ground*, HERALD NET (Apr. 2, 2017, 5:54 PM), <https://www.heraldnet.com/news/major-dea-opioid-case-falters-on-uncertain-legal-ground/> (last visited Nov. 25, 2019) [<https://perma.cc/F52U-DRBE>].

71. See *id.* (noting that Mallinckrodt was held accountable for its transgressions in a \$35 million settlement yet still found itself blameless).

72. See *Court Responses to the Opioid Epidemic: Happening Now*, CTR. FOR CT. INNOVATION, https://www.courtinnovation.org/sites/default/files/media/documents/2019-07/handout_happeningnow_pageview_07112019.pdf (last visited Nov. 25, 2019) (describing a new docket created in Tennessee courts which implements new strategies for helping those involved in opioid-related cases) [<https://perma.cc/2ZFG-CVVN>].

73. See *infra* notes 75–107 (describing several attempts at regulating and law-making in an attempt to combat the opioid epidemic).

far.⁷⁴ President Trump issued an executive order in November of 2017 authorizing the executive branch “to combat the scourge of drug abuse, addiction, and overdose (drug addiction), including opioid abuse, addiction, and overdose (opioid crisis).”⁷⁵ This order established the President’s Commission on Combating Drug Addiction and the Opioid Crisis, which is composed of members designated or appointed by the President.⁷⁶ The mission of the Commission is “to study the scope and effectiveness of the [f]ederal response to drug addiction and the opioid crisis described . . . and to make recommendations to the President for improving that response.”⁷⁷ The results from the Committee’s recommendations are still developing, and mainly call for better strategized federal funding, better agency action, better opioid addiction treatment programs, and better education on opioid addiction and the crisis itself.⁷⁸

In terms of governing statutes and guidelines, the CDC recently issued a set of comprehensive guidelines for prescribing opioids for chronic pain outside of cancer treatment, palliative care, and end-of-life care.⁷⁹ These guidelines were promulgated in an effort to reduce the risk and maximize the benefits of available pain treatment options.⁸⁰ Congress has also made multiple findings and declarations regarding controlled substances, with 21 U.S.C. § 801 serving as a prime example.⁸¹ This statute, also

74. See *Provisional Drug Overdose Death Counts*, CDC, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> (last visited Nov. 25, 2019) (showing the number of deaths from opioid abuse to be largely flat or slightly decreasing since late 2017) [<https://perma.cc/4D6N-89E3>].

75. Exec. Order No. 13784, 82 Fed. Reg. 16283 (Mar. 29, 2017).

76. See *id.* (providing that the Commission reports to the President on its findings in helping to solve the opioid crisis).

77. *Id.*

78. See THE PRESIDENT’S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS (2017) (explaining that previous methods have been ineffective and that, in the future, the government needs to focus on better funding and strategizing).

79. See Liu, Pei & Soto, *supra* note 9 (providing that non-opioid treatments are the preferred first step for treatment of chronic pain, and opioid medications should only be added after careful assessment of pain control and followed by regular evaluations of their continued need).

80. See Liu, Pei & Soto, *supra* note 9 (providing the reasoning for the CDC issuing these guidelines).

81. See 21 U.S.C. § 801 (2018) (providing an example of one of the many

known as the Controlled Substances Act, establishes that although many drugs have a

useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people . . . the illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.⁸²

However, the statute acts as a set of guidelines as opposed to laws that put actual limits and repercussions into place.⁸³

In contrast to the Controlled Substances Act, 21 U.S.C. § 355-1, part of the Federal Food, Drug, and Cosmetic Act, prescribes steps to determine whether a drug is safe and how to administer it properly to the public, including risk evaluation and mitigation strategies.⁸⁴ The statute “gave the FDA more authority to regulate prescription drugs, including prescription pain relievers known as opioids.”⁸⁵

Another example of a stricter statute is 21 U.S.C. § 333, which is also a part of the Federal Food, Drug, and Cosmetic Act.⁸⁶ This statute puts into place specific penalties regarding drug market violations and is fairly detailed.⁸⁷ On its face, 21 U.S.C. § 333 appears to have the potential to be effective in combating the crisis because of its penalties for violators.⁸⁸ However, the latest amendments to the statute were made in 2017, and unfortunately, not much improvement has been seen since then.⁸⁹

findings released by Congress regarding opioids and controlled substances).

82. *Id.*

83. *See id.* (illustrating that the statute itself is mainly a list of looser suggestions and guidelines).

84. *Id.* § 355-1.

85. Homenko, *supra* note 26, at 290.

86. *See* 21 U.S.C. § 333 (2018) (describing specific penalties for failing to comply with the Act).

87. *See id.* (explaining that failing to comply results in a fine or imprisonment).

88. *See id.* (analyzing the statute as providing effective assistance in ending crisis because of the penalties in place).

89. *See id.* (providing that the 2017 amendment only added that “knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug shall be imprisoned for not more than 10 years or fined in accordance with title

There are relatively few administrative regulations that govern the conduct of practitioners who prescribe opioids.⁹⁰ For example, 21 C.F.R. 1306.07 states that “a practitioner may administer or dispense directly . . . a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment.”⁹¹ However, the practitioner must be “separately registered with DEA as a narcotic treatment program” and remain “in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.”⁹² 21 C.F.R. 1306.07 essentially qualifies practitioners to administer opioids for the purpose of treating individuals going through withdraw.⁹³ More treatment and accreditation programs similar to those prescribed by 21 C.F.R. 1306.07 are also reinforced by 42 C.F.R. 8.2.⁹⁴

21 C.F.R. 1301.28 establishes that “[n]othing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms.”⁹⁵ However, the regulation only allows administering drugs to individuals in this manner “when necessary while arrangements are being made for referral for treatment.”⁹⁶ “This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction”⁹⁷ Overall, 21

18, United States Code, or both.”).

90. *See infra* notes 91–98 (describing the administrative regulations that govern the conduct of practitioners who prescribe opioids).

91. 21 C.F.R. § 1306.07 (2005).

92. *Id.*

93. *See id.* (providing that the main thrust of the regulation deals with individuals going through opioid withdrawal as opposed to regulating opioids themselves).

94. *See* 42 C.F.R. § 8.2 (2016) (providing a set of definitions regarding accreditation and opioid treatment programs).

95. 21 C.F.R. § 1301.28 (2018).

96. *Id.*

97. *Id.*

C.F.R. 1301.28 once again authorizes practitioners to administer narcotics in order to maintain or detoxify a person.⁹⁸ With the regulations 21 C.F.R. 1306.07 and 21 C.F.R. 1301.28 in mind, there are not many federal regulations explicitly describing how to regulate opioids beyond when to administer opioids to individuals who have overdosed or are going through withdraw.⁹⁹ The regulating itself seems to have been left mostly with the legislature and governing statutes.¹⁰⁰

Federal and state enforcement authorities have also devoted a considerable amount of resources to prohibiting kickbacks, bribes, rebates, and gifts from pharmaceutical companies to doctors.¹⁰¹ Congress has added onto an anti-kickback statute over the past several years, and most recently amended it in 2018, which provides:

Whoever knowingly and willfully solicits or receives any remuneration (including kickback, bribe or rebate) directly or indirectly, overtly or covertly, in case or in kind in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a [f]ederal health care program, or in return for purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a [f]ederal health care program shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than ten years or both.¹⁰²

However, the statute only applies to services covered by federal or state-funded healthcare programs, not to all prescription drugs.¹⁰³

98. *See id.* (illustrating another statute that focuses on regulating the administration of drugs in response to an opioid overdose).

99. *See id.* (explaining the exemption from separate registration for practitioners dispensing or prescribing drugs specifically for use in maintenance or detoxification treatment); *see also* 21 C.F.R. § 1306.07 (2005) (providing guidelines to practitioners for administering narcotics).

100. *See supra* notes 75–88, *infra* notes 101–104 (describing governing statutes and actions by legislatures to regulate opioids).

101. *See* Calabro, *supra* note 16, at 2260 (describing the kickbacks and bribes the pharmaceutical companies were providing to doctors that authorities sought to eliminate).

102. 42 U.S.C. § 1320a–7b (2012).

103. *See* Calabro, *supra* note 16, at 2260 (describing to whom and what the statute applies and its general shortcomings).

Hence, many pharmaceutical companies' practices that would otherwise violate the statute have been permitted without legal implication.¹⁰⁴

Congress also recently passed the Eliminating Kickbacks in Recovery Act of 2018, which makes it a criminal offense to "solicit or receive any remuneration . . . directly or indirectly, in return for referring a patient or patronage to a recovery home, clinical treatment facility or clinical laboratory."¹⁰⁵ The Act criminalizes any offers or payments of kickbacks to "induce a referral of an individual to a recovery home, clinical treatment facility or clinical laboratory, or in exchange for an individual using the services of a recovery home, clinical treatment facility or clinical laboratory."¹⁰⁶ Being fairly recently enacted, it remains to be seen whether the law will be effective, but it mainly affects the clinical laboratory industry and illustrates Congress's continued efforts to help the opioid crisis and root out corruption in the industry.¹⁰⁷

B. Newly Instated and Proposed Regulations and Guidelines

Bills are constantly being presented to Congress to hold pharmaceutical companies directly accountable for their role in the opioid crisis.¹⁰⁸ Although a bill that was intended "to hold pharmaceutical companies accountable for illegal marketing and distribution of opioid products and for their role in creating and

104. See Calabro, *supra* note 16, at 2260 (illustrating the essential loophole in the statute allowing for questionable modes of operation to be used by pharmaceutical companies).

105. 18 U.S.C. § 220 (2018).

106. *Id.*

107. See Edward J. Cyran, *New Anti-Kickback Law Targets Opioid Crisis*, FOX ROTHSCHILD LLP (Nov. 20, 2018), <https://physicianlaw.foxrothschild.com/2018/11/articles/fraud-and-abuse/new-anti-kickback-law-targets-opioid-crisis/> (last visited Nov. 25, 2019) (discussing the impacts of the Eliminating Kickbacks in Recovery Act of 2018 and the fact that it mostly affects clinical laboratories) [<https://perma.cc/MSY5-YM4G>].

108. See Margot Sanger-Katz & Thomas Kaplan, *Congress Is Writing Lots of Opioid Bills. But Which Ones Will Actually Help?*, N.Y. TIMES (June 20, 2018), <https://www.nytimes.com/2018/06/20/upshot/congress-is-writing-lots-of-opioid-bills-but-which-ones-will-actually-help.html> (last visited Nov. 25, 2019) ("If the opioid crisis could be solved by the sheer weight of proposed legislation, Congress would be able to pat itself on the back.") [<https://perma.cc/T2GP-YXCX>].

exacerbating the opioid epidemic in the United States” recently failed, others are frequently introduced because this is an issue of grave national concern.¹⁰⁹ House Bill 5782 was intended to amend 21 U.S.C. § 333 by prohibiting illegal marketing and distribution practices with respect to opioids and putting in place a system in which violators are penalized for non-compliance.¹¹⁰ The implementation of this statute would have meant a harsher stance against pharmaceutical companies, and even though it failed, others like it will surely follow.¹¹¹

With the failure of this bill, another recently took its place.¹¹² In 2018, the U.S. Senate voted on the Opioid Crisis Package, including \$50 million “to help state education agencies, school districts, and tribal governments increase evidence-based trauma support services and mental health care.”¹¹³ The bill also allocates \$20 million in annual funding for state and local governments and nonprofits to develop and run residential treatment programs along with plans for regulatory fixes.¹¹⁴ These fixes include expanding access to treatment for those in Medicaid and blocking shipments of opioids.¹¹⁵ Although bills like the Opioid Crisis Package are typically applauded as a bipartisan effort, some worry that this bill does not go nearly as far as Congress has gone in the past to support research and grant funding for epidemics.¹¹⁶ This

109. H.R. 5782, 115th Cong. (2018).

110. *See id.* (referring to the changes asked for in the Opioid Crisis and Accountability Act); *see also* 21 U.S.C. § 333 (2018) (setting forth penalties for prescription marketing and distribution violations).

111. *See* H.R. 5782 (arguing for a harsher penalty against pharmaceutical companies and doctors).

112. *See* Liz Farmer, *The Week in Public Finance: States Intent on Taxing Big Pharma over the Opioid Crisis*, GOVERNING: THE STATES & LOCALITIES (Oct. 5, 2018, 3:00 AM), <http://www.governing.com/week-in-finance/gov-taxing-pharmaceutical-industry-opioid-crisis.html> (last visited Nov. 25, 2019) (reporting on the Opioid Crisis Package passed by Congress in the fall of 2018) [<https://perma.cc/4EKF-TPSZ>].

113. *Id.*

114. *See id.* (explaining the different elements supported and provided by the new act which could prove beneficial in the coming year to helping end the opioid crisis).

115. *See id.* (explaining different regulatory fixes aimed at ending the opioid crisis).

116. *See id.* (providing the Ryan White Care Act, passed in 1990—which to this day allows for billions in treatment and support for people with HIV and

brings concern about how serious Congress is about fixing the opioid crisis.¹¹⁷

States are also considering taxation as a way to handle the opioid crisis.¹¹⁸ Lawmakers have sought to raise taxes on pharmaceutical companies in order to help pay for the cost of the opioid crisis while at the same time imposing a vice-like tax on the industry.¹¹⁹ A tax like this is comparable to the large amount of licensing fees liquor stores have to pay in order to sell alcohol.¹²⁰ In theory, the tax would raise millions “in new annual funding for abuse prevention and treatment efforts by charging pharmaceutical companies a fee for every opioid painkiller they sell.”¹²¹ However, the possibility of these taxes passing in the immediate future looks bleak.¹²² California, Delaware, Iowa, Kentucky, Maine, Massachusetts, Minnesota, Montana, New Jersey, Tennessee, and Vermont all tried and failed to pass opioid taxes in 2018, and although lawmakers in those states said they would try again in 2019, the only state where a tax like this had passed at the time of the writing of this Note was New York.¹²³

Even in New York, however, the legislation was placed on hold due to a lawsuit filed by the pharmaceutical industry in the summer of 2018 and was subsequently struck down by a U.S. district court in December of 2018.¹²⁴ U.S. District Judge

AIDS—as an example).

117. *Id.*

118. *See id.* (reporting on state attempts to hold pharmaceutical companies responsible for the opioid crisis by imposing a tax).

119. *See id.* (noting a plan to help the opioid crisis that is steadily growing in popularity amongst lawmakers and government officials).

120. *See id.* (“Liquor stores and bars pay thousands of dollars each year for the privilege of selling alcohol . . . but drug companies only pay a few hundred dollars in licensing fees.”).

121. *Id.*

122. *See id.* (describing how heavy lobbying by pharmaceutical companies has prevented bills setting a tax for the sale of opioid painkillers).

123. *See id.* (explaining how the tax in New York raises \$100 million a year for addiction treatment, prevention, and education through a tax on pharmaceutical manufacturers and distributors).

124. *See* Sara Randazzo, *Federal Judge Strikes Down New York Tax on Opioid Industry*, WALL ST. J. (Dec. 19, 2018, 4:00 PM), <https://www.wsj.com/articles/federal-judge-strikes-down-new-york-tax-on-opioid-industry-11545253207> (last visited Nov. 25, 2019) (“A federal judge struck down Wednesday a New York law that aimed to collect \$600 million from the

Katherine Polk Failla called the law “an unconstitutional regulatory penalty on the makers and distributors of opioid painkillers.”¹²⁵ Even though she acknowledged the validity of trying to legislate a solution to the epidemic, she ruled the law unconstitutional based on the Dormant Commerce Clause, which prohibits state regulation of interstate commerce.¹²⁶ Pharmaceutical companies also continue to assert that prescription medications are important and needed by some patients, and the proposed laws would make access to the drugs by those individuals much more difficult.¹²⁷ Arguments on behalf of pharmaceutical companies along with constitutional arguments presented in court make it unlikely that a successful tax initiative against pharmaceutical companies will pass anytime soon, but they should be kept in mind as more individuals begin to take a stand against pharmaceutical companies and more courts take on these cases.¹²⁸

pharmaceutical industry to help combat the opioid crisis.”) [<https://perma.cc/F9AU-5ZGS>]; see also *Healthcare Distrib. All. v. Zucker*, Nos. 18 Civ. 6168 (KPF); 18 Civ. 8180 (KPF); 18 Civ. 9830 (KPF), 2018 U.S. Dist. LEXIS 213661, at *4 (S.D.N.Y. Dec. 19, 2018) (“The OSA is not a tax, but is rather a regulatory penalty on opioid manufacturers and distributors.”).

125. Randazzo, *supra* note 124.

126. See Randazzo, *supra* note 124 (“A federal judge struck down Wednesday a New York law that aimed to collect \$600 million from the pharmaceutical industry to help combat the opioid crisis.”); see also *Healthcare Distrib. All.*, 2018 U.S. Dist. LEXIS 213661, at *4 (“[T]he method by which the Act extracts payments from opioid manufacturers and distributors to redress those concerns violates the Dormant Commerce Clause of the United States Constitution.”); U.S. CONST. art. I, § 8, cl. 3 (setting forth the Commerce Clause, from which the Dormant Commerce Clause is inferred).

127. See Farmer, *supra* note 112 (referring to the PhRMA deputy vice president’s statement on making sure the people who needed prescription opioids were able to access them).

128. See *Purdue Pharma Tentatively Settles Thousands of Opioid Cases*, N.Y. TIMES (Sept. 11, 2019), <https://www.nytimes.com/2019/09/11/health/purdue-pharma-opioids-settlement.html> (last visited Nov. 25, 2019) (citing the deal in which Purdue settled to pay \$3 billion along with various other settlement terms in light of their role in the opioid crisis) [<https://perma.cc/M3R6-R7RZ>]; see also Randazzo, *supra* note 124 (referencing the U.S. district court in Ohio that cleared the way for a large group of consolidated opioid tax-related lawsuits to move forward over the objections of the defendants).

*IV. The Pharmaceutical Companies' Relationship with Doctors**A. The Pharmaceutical Companies' Role in the Crisis**1. Early Contribution*

In the early years of the crisis, “[t]he increase in opioid prescriptions was influenced by reassurances given to prescribers by pharmaceutical companies and medical societies claiming that the risk of addiction to prescription opioids was very low.”¹²⁹ Pharmaceutical companies were promoting the use of opioids with non-cancer-related pain regardless of the lack of data regarding the risks and benefits to these patients.¹³⁰ By 1999, eighty-six percent of patients using opioids were using them for non-cancer-related pain.¹³¹ The introduction of OxyContin by Purdue Pharma in 1996 was a landmark event in the early years of the crisis.¹³² Shortly after its introduction, the sale of OxyContin skyrocketed.¹³³ However, the large increase in sales was not without great effort on behalf of Purdue Pharma.¹³⁴ The pharmaceutical company relied heavily on an unprecedented and rigorously financed promotional and marketing campaign for the new drug.¹³⁵

Thousands of doctors were treated to all-expenses-paid pain management conferences in resort communities. An additional twenty thousand other pain-related educational programs sponsored Purdue Pharma between 1996 and 2002 were available to doctors free of charge. The company sent out mass mailings of promotional materials to physicians and paid

129. Liu, Pei & Soto, *supra* note 9.

130. *See* Liu, Pei & Soto, *supra* note 9 (describing the pharmaceutical companies' promotion of opioids in the early 1990s based on the relatively little research articles released at the time and with little to no actual data).

131. *See* Liu, Pei & Soto, *supra* note 9 (providing a timeline on the progression of the opioid crisis and possible reason why the opioid crisis progressed).

132. *See* STEPHEN L. FISHER & BARBARA E. SMITH, *TRANSFORMING PLACES: LESSONS FROM APPALACHIA 199* (2012) (describing the introduction of OxyContin to the market and its detrimental effects).

133. *See id.* at 200 (“OxyContin sales accelerated from \$48 million in 1996 to a blockbuster \$1.1 billion in 2000.”).

134. *See id.* at 199–200 (describing the great lengths Purdue Pharma would go to in order to advertise and market OxyContin).

135. *See id.* at 200 (describing Purdue Pharma's marketing techniques for OxyContin in great detail).

lucrative incentives to its sales representatives. Free starter vouchers and coupons for OxyContin were made available for doctors to give to their patients. The company provided doctors logo-branded OxyContin fishing hats, tote bags, clocks, plush stuffed toys, and music compact discs.¹³⁶

Early incentives for doctors to prescribe opioids were intense and heavily directed at getting physicians to prescribe as many opioid painkillers as possible.¹³⁷ These marketing techniques and incentives laid the foundation for the current state of the opioid crisis.

2. Current Contribution

Currently, pharmaceutical companies do the bare minimum to fulfill their legal duty to warn consumers about the dangers of prescription drugs by merely providing a warning to the prescribing physician.¹³⁸ By warning physicians, pharmaceutical companies decrease their liability and place the duty to actually warn the consumer in the hands of the doctor.¹³⁹ The lack of responsibility on behalf of pharmaceutical companies for the large amounts of opioids shipped to towns and cities is shocking, particularly in today's world of increased corporate social responsibility.¹⁴⁰ For example, nine million opioids were shipped to a town of only 400 people in West Virginia by a wholesale drug company.¹⁴¹ Further, an investigation performed by the House

136. *Id.*

137. *See id.* (illustrating that the techniques were used to increase revenue and profit margin more than anything).

138. *See* Calabro, *supra* note 16, at 2242–43 (describing the fact that all pharmaceutical companies have to do now by law is warn consumers).

139. *See* Calabro, *supra* note 16, at 2243 (explaining that most of the duty to enforce limits on opioids ends up falling on the doctors themselves).

140. *See* Klaus M. Leisinger, *The Corporate Social Responsibility of the Pharmaceutical Industry: Idealism without Illusion and Realism without Resignation*, 15 BUS. ETHICS Q. 577, 577–78 (2005) (referring to the increased responsibility that pharmaceutical companies should be taking on in the corporate social responsibility realm).

141. *See* *9 Million Painkillers Shipped to Tiny West Virginia Town*, MSNBC (Mar. 10, 2017), <https://www.msnbc.com/all-in/watch/9-million-painkillers-shipped-to-tiny-west-virginia-town-895420995808> (last visited Nov. 25, 2019) (describing the large quantity of opioids that flooded into Kermit, W.Va.)

Energy and Commerce Committee in West Virginia “revealed that 20.8 million hydrocodone and oxycodone pills have been delivered to Williamson, West Virginia, a town with a community college, a rail yard—and fewer than 3200 residents, according to the most recent Census figures,” totaling to more than 6500 pills per person.¹⁴² These two separate instances exemplify an outrageous ratio that is not being handled or helped by current legislation or regulation, regardless of efforts to remedy the situation.

Indirect intervention by the pharmaceutical industry through lobbying and advocacy groups have pushed back on changes to opioid prescribing patterns through “attempts to halt measures to restrict opioid overprescribing, efforts to undermine the CDC guidelines, and thwarting attempts to hold prescribers and pharmaceutical companies accountable.”¹⁴³ However, legal action has been taken against pharmaceutical companies in an attempt to hold them accountable for their marketing techniques and distribution.¹⁴⁴

A prime example of an attempt to hold pharmaceutical companies responsible is the string of cases and settlements with Purdue Pharma.¹⁴⁵ Although Purdue Pharma was not the only pharmaceutical manufacturer distributing opioid products containing oxycodone, Purdue Pharma’s OxyContin was a focal point in the conversation of opioid addiction.¹⁴⁶ The rapid spread of opioid abuse captured the attention of local, state, and federal government officials in the early years of the epidemic, and by

[<https://perma.cc/Z6FP-F48Q>].

142. Lindsey Bever, *A Town of 3,200 Was Flooded with Nearly 21 Million Pain Pills as Addiction Crisis Worsened, Lawmakers Say*, WASH. POST (Jan. 31, 2018, 3:24 PM), https://www.washingtonpost.com/news/to-your-health/wp/2018/01/31/a-town-of-3200-was-flooded-with-21-million-pain-pills-as-addiction-crisis-worsened-lawmakers-say/?utm_term=.0741f5fc5540 (last visited Nov. 25, 2019) [<https://perma.cc/UCZ9-EZM7>].

143. Liu, Pei & Soto, *supra* note 9.

144. See Abby Cunningham, *Purpose, Prudence, and Path: Reevaluating the Primary Jurisdiction Doctrine in the Context of Opioid Litigation*, 9 N. ILL. U. L. REV. ONLINE J. 1, 31 (2017) (referring to the legal proceedings against Purdue Pharma to hold them accountable for essentially fraud and relaying misleading information).

145. See *id.* (referring to the multiple allegations and class actions against the pharmaceutical company in the 2000s).

146. See *id.* at 29–30 (describing the centrality of Purdue Pharma in the opioid addiction conversation).

2001, the FDA recognized the problems presented by OxyContin, leading it to contact Purdue Pharma about the agency's concerns.¹⁴⁷ "The FDA changed OxyContin's label to include a 'black box' warning of the dangers of the product, the strongest warning label available for an FDA regulated product."¹⁴⁸ Nevertheless, the sale of OxyContin continued to increase due to Purdue Pharma's aggressive marketing strategies.¹⁴⁹ "[T]he product had earned the company over \$2.8 billion in revenue" by 2001 even with the "negative press and increased governmental and regulatory scrutiny."¹⁵⁰ In fact, "OxyContin is estimated to have generated revenues in excess of \$30 billion since its entry onto the market and has been hailed as 'America's bestselling painkiller.'"¹⁵¹ Individuals were able to start bringing product liability lawsuits and domestic class actions against Purdue Pharma and other opioid makers beginning in the early 2000s as the rate of death from opioids increased.¹⁵² Although these lawsuits in the early 2000s had little success, with many ending in the pleading stage, several settlements in 2019 achieved tangible results that are leaving their mark on the pharmaceutical industry.¹⁵³

The Purdue Pharma settlement of 2007 provided one of the first specific examples of holding a pharmaceutical company

147. *See id.* at 30 (referring to the early attempt of the FDA to enforce some regulations against pharmaceutical companies).

148. *Id.*

149. *See id.* (noting that the presence of warning labels accomplished virtually nothing in terms of deterring the use of OxyContin).

150. *Id.*

151. *Id.* at 30–31.

152. *See id.* at 31 (noting the starting point of lawsuits geared at holding pharmaceutical companies accountable).

153. *See id.* (stating that these early opioid "lawsuits met with little success, ending primarily in the pleading stage"); *see also* Jackie Fortier & Brian Mann, *Johnson & Johnson Ordered to Pay Oklahoma \$572 Million in Opioid Trial*, NPR (Aug. 26, 2019, 4:19 PM), <https://www.npr.org/sections/health-shots/2019/08/26/754481268/judge-in-opioid-trial-rules-johnson-johnson-must-pay-oklahoma-572-million> (last visited Nov. 25, 2019) (detailing "the first ruling to hold a pharmaceutical company responsible for one of the worst drug epidemics in American history") [<https://perma.cc/J8XT-TQ5H>]; *see also* Jan Hoffman, *Purdue Pharma Tentatively Settles Thousands of Opioid Cases*, N.Y. TIMES, <https://www.nytimes.com/2019/09/11/health/purdue-pharma-opioids-settlement.html> (last updated Sept. 13, 2019) (last visited Nov. 25, 2019) (detailing the 2019 Purdue settlement) [<https://perma.cc/8F3V-LY4L>].

accountable.¹⁵⁴ The company and three current and former executives pled guilty to criminal charges that they misled regulators, doctors, and patients about the drug's risk of addiction and its potential for abuse.¹⁵⁵ As a result, the company agreed to pay \$600 million in fines and other payments to resolve all civil and criminal charges, the largest amount ever paid by a drug company in such a case at the time.¹⁵⁶ Allegations against Purdue continued following this settlement, arguing that "defendant pharmaceutical companies, through a deceptive and unfair marketing campaign, reversed the medical understanding of opioids so that prescribing opioids to treat chronic pain long-term would be commonplace."¹⁵⁷

Following this settlement and several proceedings, pharmaceutical companies in 2019 were held more directly accountable than ever before.¹⁵⁸ The first of these cases is illustrated in the *Oklahoma v. Johnson & Johnson*.¹⁵⁹ The Oklahoma judge in the case ruled that "drugmaker Johnson & Johnson helped ignite the state's opioid crisis by deceptively marketing painkillers."¹⁶⁰ Consequently, the company was ordered

154. See Cunningham, *supra* note 144, at 30 (providing a solid and more renowned case example of plaintiffs attacking pharmaceutical companies for their misguidance on opioid usage); see also Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <https://www.nytimes.com/2007/05/10/business/11drug-web.html> (last visited Nov. 25, 2019) (detailing the 2007 Purdue settlement) [<https://perma.cc/FRA4-HS7L>].

155. See Meier, *supra* note 154 ("The company that makes the narcotic painkiller OxyContin and three current and former executives pleaded guilty today in federal court here to criminal charges . . .").

156. See Meier, *supra* note 154 ("To resolve criminal and civil charges related to the drug's 'misbranding,' the parent of Purdue Pharma, the company that markets OxyContin, agreed to pay some \$600 million in fines and other payments, one of the largest amounts ever paid by a drug company in such a case.").

157. *City of Chicago v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1062 (N.D. Ill. 2016); see also Cunningham, *supra* note 144, at 30 (explaining the Purdue Pharma litigation that followed the initial 2007 settlement).

158. See, e.g., Fortier & Mann, *supra* note 153 (describing a 2019 judgment as "the first ruling to hold a pharmaceutical company responsible for one of the worst drug epidemics in American history").

159. See *Oklahoma v. Johnson & Johnson*, No. CJ-2017-816, 2019 WL 4409690, at *30 (Okla. Aug. 26, 2019) (finding Johnson & Johnson liable).

160. Fortier & Mann, *supra* note 153.

to pay \$465 million to the state.¹⁶¹ Although Johnson & Johnson will appeal the judgment, the ruling was a win for those making efforts to hold pharmaceutical companies accountable for their role in the opioid crisis.¹⁶²

The most recent Purdue Pharma settlement concerning thousands of opioid cases is another illustration of holding these pharmaceutical companies accountable.¹⁶³ The broad scope of the settlement includes: Purdue filing for Chapter 11 bankruptcy; the creation of a new company to continue selling OxyContin and other medicines, the profits of which will be used to pay the plaintiffs after the dissolution of the previous company; the donation of drugs for addiction treatment and overdose reversal; and the payment of \$3 billion over the course of seven years.¹⁶⁴ All of this being said, the settlement notably does not include any admission of wrongdoing.¹⁶⁵ It is uncertain at this early stage where courts are seen ruling against pharmaceutical companies whether or not these rulings and recent settlements will have a lasting or permanent impact on discouraging the ever increasing sale of opioids.¹⁶⁶ The fact that the pharmaceutical companies as a whole seem to avoid blame is discouraging, and based on the past, it is still unknown whether the companies will be held totally

161. See Colin Dwyer & Jackie Fortier, *Oklahoma Judge Shaves \$107 Million Off Opioid Decision against Johnson & Johnson*, NPR (Nov. 15, 2019, 3:31 PM), <https://www.npr.org/2019/11/15/779439374/oklahoma-judge-shaves-107-million-off-opioid-decision-against-johnson-johnson> (last visited Nov. 25, 2019) (describing how the Oklahoma judge initially ordered a \$572 million fine but changed the number due to a calculation error) [<https://perma.cc/BG2N-L85L>].

162. See Fortier & Mann, *supra* note 153 (explaining that Judge Balkman's ruling affirmed the key legal argument of the state's case, that the drugmaker had created a "public nuisance").

163. See Hoffman, *supra* note 153 ("Thousands of municipal governments nationwide and nearly two dozen states that sued the pharmaceutical industry for the destructive opioid crisis have tentatively reached a settlement with Purdue Pharma. . . ."); see also *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, at *83–85, *88 (Ohio Aug. 19, 2019) (providing background and detailing involvement in the massive opioid litigation Purdue settled).

164. See Hoffman, *supra* note 153 (detailing the tentative settlement agreement which remains to be approved by a bankruptcy judge).

165. See Hoffman, *supra* note 153 (noting that neither the company nor the owning family admit any wrong doing in terms of marketing techniques or otherwise).

166. See Hoffman, *supra* note 153 (discussing the ambiguities of the Johnson & Johnson settlement).

accountable by the courts, but the recent settlements do provide hope.¹⁶⁷

Regardless of the lawsuits and regulations put in place to keep pharmaceutical companies in check, the pharmaceutical industry continues to exercise tremendous economic influence over physicians and the health care industry.¹⁶⁸ Americans spend trillions on health care, and this amount seems to constantly be on the rise.¹⁶⁹ Along with excessive expenses on health care, “[p]harmaceutical companies are exerting increasing pressure on physicians’ prescription patterns through various means, including providing gifts and other benefits for brand loyalty.”¹⁷⁰ The pharmaceutical industry annually spends roughly \$12 billion promoting and marketing their products to physicians through gifting, travel reimbursements, and meal expenses.¹⁷¹ Spending at this level could lead to questions regarding the quality of patient care if the physician’s financial motives exceed patient needs.¹⁷² Although the kickback programs of the 1990s and early 2000s have recently been checked by regulations, the advertisement and intense marketing on behalf of the pharmaceutical companies continues.¹⁷³ In fact, doctors who prescribe large amounts of opioids still receive large payments from drug makers, according to an analysis by CNN and researchers at Harvard University.¹⁷⁴

167. See Fortier & Mann, *supra* note 153 (citing the fact that Johnson & Johnson is appealing and this could be reversed in the future particularly given the unusual grounds on which they were found culpable); see also Hoffman, *supra* note 153 (noting that Purdue still avoids admitting responsibility and that casts some doubt over whether the settlement will be approved by the bankruptcy judge).

168. See Calabro, *supra* note 16, at 2256–57 (referring to the fact that pharmaceutical companies still have a strong hold on doctors economically regardless of the regulations currently in place).

169. See Calabro, *supra* note 16, at 2257 (noting that the healthcare industry is a huge money-making industry).

170. Calabro, *supra* note 16, at 2257.

171. See Calabro, *supra* note 16, at 2257 (describing the extravagant spending of pharmaceutical companies).

172. See Calabro, *supra* note 16, at 2258 (noting that a conflict of interest can easily be created with the physician stuck in a conflict between their duties to patients and financial needs).

173. See 42 U.S.C. § 1320a–7b (2012) (providing the kickback statute put in place to keep financial incentives out of patient care).

174. See *The More Opioids Doctors Prescribe, the More They Get Paid*, HARV. T.H. CHAN: SCH. OF PUB. HEALTH, <https://www.hsph.harvard.edu/news/hsph-in->

B. Doctors' Role in the Crisis

1. Bad Habits

Over the years, doctors have also contributed significantly to the crisis.¹⁷⁵ Unfortunately, they have done so through both illegal and legal methods.¹⁷⁶ Doctors have been caught illegally prescribing opioid painkillers outside the scope of their professional practice for non-medical purposes.¹⁷⁷ Illegal prescribing methods are not the focus of legislation because illegal actions are impossible to regulate at the civil level, and are left to the realm of criminal authority.¹⁷⁸ Nonetheless, the actions of crooked doctors need to be mentioned because of their contribution to the opioid crisis.¹⁷⁹

Some doctors have also been found to prescribe very dangerous combinations of opioids or large quantities of drugs legally, contributing to the crisis.¹⁸⁰ For example, individuals are

the-news/opioids-doctors-prescriptions-payments/ (last visited Nov. 25, 2019) (discussing the cycle of doctors prescribing large quantities of opioids and in turn making more money) [<https://perma.cc/HUJ7-FWBB>]; see also Partnership News Service Staff, *Drug Makers Pay Doctors Who Prescribe Large Amounts of Opioids, Analysis Finds*, DRUGFREE.ORG (Mar. 15, 2018), <https://drugfree.org/learn/drug-and-alcohol-news/drug-makers-pay-doctors-prescribe-large-amounts-opioids-analysis-finds/> (last visited Nov. 25, 2019) (“The more opioids doctors prescribe, the more money they receive.”) [<https://perma.cc/WX2W-98M8>].

175. See Calabro, *supra* note 16, at 2256–60 (noting that, in addition to pharmaceutical companies, doctors are to blame for drug safety problems).

176. See Moody Pill Mill Doctor, *supra* note 15 (“Federal prosecutors . . . charged a Vestavia Hills physician with illegally prescribing controlled substances, including opioid painkillers. . . .”); see also Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J. LAW MED. 7, 8 (2016) (describing instances in which physicians may be acting negligently in prescribing opioids and not suffer legal consequences because they are merely not acting with the appropriate duty of care).

177. See Moody Pill Mill Doctor, *supra* note 15 (noting that agencies like the DOJ are coming for physicians and medical providers who abuse their positions and prescribing authority).

178. See Moody Pill Mill Doctor, *supra* note 15 (“Doctors prescribing opioids within the bounds of legitimate medicine are not the focus of the Department of Justice.” (quoting Assistant U.S. Attorney Mohammad Khatib)).

179. See Moody Pill Mill Doctor, *supra* note 15 (noting the connection between illegal prescription methods and the opioid crisis).

180. See CDC NAT'L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 8 (describing the high prescribing rate which has been on the decline since

sometimes prescribed both benzodiazepines and opioid drugs simultaneously—a common denominator with individuals that end up addicted to prescription opioids.¹⁸¹ “In a study of over 300,000 continuously insured patients receiving opioid prescriptions between 2001 and 2013, the percentage of persons also prescribed benzodiazepines rose to 17 percent in 2013 from nine percent in 2001.”¹⁸² The study illustrated that people concurrently using both drugs are at a higher risk of visiting the emergency department or being admitted to a hospital for a drug-related emergency.¹⁸³ And interestingly, physicians are the ones allowing these prescribing rates even with the statistics and knowledge that the opioid combination can cause an increased risk of drug-related issues.¹⁸⁴

Not only are physicians prescribing dangerous combinations, they are also prescribing large quantities of opioids which are equally dangerous to the creation of addicts.¹⁸⁵ Studies performed on emergency room statistics illustrate the problem.¹⁸⁶ According to the findings of a study from Harvard T.H. Chan School of Public Health and Harvard Medical School, “[e]mergency room patients treated by physicians who prescribe opioids more often are at greater risk for long-term opioid use even after a single prescription than those who see less-frequent prescribers.”¹⁸⁷

2012 but is still three times higher than it was in 1999).

181. See *Benzodiazepines and Opioids*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (last updated Jan. 2019) (last visited Nov. 25, 2019) (describing the common drug cocktail prescribed by physicians for pain) [<https://perma.cc/D4XV-3JVB>].

182. *Id.*

183. See *id.* (noting the increase in risk as a result of the doctors' drug concoction).

184. See *id.* (describing the interesting fact that physicians continue to prescribe these dangerous opioid combinations even with the warnings and knowledge).

185. See CDC NAT'L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 8 (describing the high prescribing rates of physicians in the United States which is still dangerously high).

186. See *Physicians' Opioid Prescribing Patterns Linked to Patients' Risk for Long-term Drug Use*, HARV. T.H. CHAN: SCH. OF PUB. HEALTH (Feb. 15, 2017), <https://www.hsph.harvard.edu/news/press-releases/opioids-addiction-physicians/> (last visited Nov. 25, 2019) (basing the findings on accounts from Boston, Mass. emergency rooms) [<https://perma.cc/59QP-LDXM>].

187. *Id.*

However, it is not merely a problem of the emergency room, the specific physician a patient sees is equally important.¹⁸⁸ For example, in the same study conducted by the Harvard T.H. Chan School of Public Health and Harvard Medical School,

[a]lthough the physicians saw patients with similar complaints, they treated them differently. On the low end of the spectrum, one quarter of providers gave opioid prescriptions to just 7 percent of the patients they saw. At the other extreme, the top quarter of prescribers gave opioids to 24 percent of their patients.¹⁸⁹

However, case law on physician liability for overprescribing medication that leads to the development of patient addiction is conflicting.¹⁹⁰ On one hand, courts have found physicians liable in cases where the physician prescribed too much medication.¹⁹¹ Findings like this may be because the physician did not have proper cause to prescribe the amount of opioids that they did, or because the physicians failed to conduct a proper investigation.¹⁹² These cases frequently show that the number of pills issued greatly exceeded the recommended dosage, or that the prescriptions continued to be refilled without a physical examination, leading courts to find physicians at fault even though what they were doing was in fact legal within the provided statutes and regulations.¹⁹³ Cases like these contrast with other courts who found physicians not liable because the physicians did not fail to warn the patient and therefore did not breach his or her duty to warn.¹⁹⁴

188. See *id.* (providing other examples of average physicians who also arguably over prescribe opioids).

189. *Id.*

190. See Jack Hubbard et al., *Opioid Abuse: The Fall of a Prince*, 21 QUINNIPIAC HEALTH L.J. 159, 190 (2018) (providing that the case law on physician opioid prescribing has gone both ways).

191. See *United States v. McIver*, 470 F.3d 550, 564 (4th Cir. 2006) (holding doctors liable for prescribing too many opioids in a criminal proceeding).

192. See Hubbard et al., *supra* note 190 (“Some courts have found physicians liable in cases where the physician prescribed too much medication without proper cause or failed to conduct a proper investigation.”).

193. See *Duarte v. Zachariah*, 22 Cal. App. 4th 1652, 1665 (1994) (holding a physician liable for negligent over-prescription).

194. See *Posner v. Walker*, 930 So. 2d 659, 667 (Fla. Dist. Ct. App. 2006) (holding that doctor was not liable, even though he failed to warn the patient of the dangers of opioid use).

2. Recent Improvements

There have been recent improvements in the healthcare industry in terms of clearer guidelines for physicians and fewer opioid prescriptions, a change from the previously constant increase in prescriptions from year to year.¹⁹⁵ For example,

[h]ealthcare providers wrote 72.4 opioid prescriptions per 100 persons in 2006. This rate increased annually by 3.0% from 2006 to 2010, decreased 1.6% annually from 2010 to 2014, and continued to decrease annually by 8.2% until 2017, reaching a rate of 58.5 prescriptions per 100 persons. This represents an overall relative reduction of 19.2% from 2006 to 2017.¹⁹⁶

The reduction in prescriptions per person illustrates improvement, but the crisis is still not greatly improving.¹⁹⁷ For instance, “[i]n 2017, 17.4% of the U.S. population received one or more opioid prescriptions, with the average person receiving 3.4 prescriptions.”¹⁹⁸ In short, experts still find that the overprescribing of opioid painkillers in the late 1990s contributed to widespread misuse of the drugs, and regardless of recent improvements, “[o]verdose deaths from prescription and nonprescription opioids were five times higher in 2016 than in 1999.”¹⁹⁹

195. See Julie Appleby & Elizabeth Lucas, *Doctors Can Change Opioid Prescribing Habits, But Progress Comes in Small Doses*, KAISER HEALTH NEWS (Aug. 14, 2019), <https://khn.org/news/doctors-opioid-prescribing-habits-change-comes-in-small-doses/> (last visited on Nov. 25, 2019) (discussing the implementation of guidelines which have decreased the amount of opioids prescribed) [<https://perma.cc/PA6G-MXUB>].

196. CDC NAT'L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 6.

197. See CDC NAT'L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 6 (discussing the reduction in opioid prescriptions per person as being beneficial to solving the crisis).

198. CDC NAT'L CTR. FOR INJURY PREVENTION AND CONTROL, *supra* note 8, at 6.

199. Nat'l Inst. on Drug Abuse, *Misuse of Prescription Drugs*, DRUGABUSE.GOV, <https://www.drugabuse.gov/publications/misuse-prescription-drugs/overview> (last updated Dec. 2018) (last visited Nov. 25, 2019) [<https://perma.cc/B5FN-RPJT>].

V. Moving Forward

A. The Creation of a Federal Model Law

Moving forward, a lobby for reasonable legislation in the form of a federal model law is a possible solution to fix the current state of the crisis at the civil level.²⁰⁰ Model laws are beneficial tools that set national standards and guidelines.²⁰¹ Each state would need to pass the law in order for it to be entirely effective, and in the process, states may alter pieces of the act, but regardless, the implementation of a federal model law could be the best avenue, considering previous legislation and regulations have not been completely successful.²⁰² A model law governing the prescription opioid industry could involve monitoring the pharmaceutical companies, further regulation of physician prescribing methods, and perhaps the implementation of a sort of vice tax or at least increased licensing requirements for pharmaceutical companies while at the same time not greatly affecting the profit margins of pharmaceutical companies.

1. Monitoring the Pharmaceutical Companies

For starters, it would prove beneficial to do away with financial incentives for prescribing opioids.²⁰³ A conflict of interest

200. See BONNIE ET AL., *supra* note 10, at 301 (noting studies that “suggest that, despite the existence of various guidelines, pain assessment, and reassessment and some other provisions of the guidelines are not always adhered to, and . . . pain control can be improved when guidelines are followed”) (citations omitted).

201. See Legal Info. Inst., *Uniform Laws*, CORNELL L. SCH., <https://www.law.cornell.edu/uniform> (last visited Nov. 25, 2019) (establishing the difference between uniform laws and model acts and acknowledging that the goal of model acts is reform as opposed to uniformity) [<https://perma.cc/WJ5Q-NAEB>].

202. See *id.* (“Those creating model acts contemplate that state legislatures may make alterations or even take bits and pieces.”).

203. See Charles Orenstein et al., *Drug-Company Payments Mirror Doctors’ Brand-Name Prescribing*, NPR (Mar. 17, 2016, 5:00 AM), <https://www.npr.org/sections/health-shots/2016/03/17/470679452/drug-company-payments-mirror-doctors-brand-name-prescribing> (last visited Nov. 25, 2019) (discussing the conversations between doctors on how there is not much difference between name brand and generic drugs but that doctors receive payments for prescribing the name brand ones) [<https://perma.cc/N459-Y7RF>].

can be created when the professional judgment of a physician is influenced by a secondary interest such as financial incentives.²⁰⁴ “A physician has a professional duty to provide for his patients’ welfare, yet this duty can be compromised when pressure is exerted by pharmaceutical companies,” and although not all doctors are influenced by the pharmaceutical companies, this is the state of the market.²⁰⁵ More than 83,000 pharmaceutical representatives regularly visit physicians, hospitals, and pharmacies with intense marketing techniques and reasons why the medical professional should use the next big opioid.²⁰⁶ A model law keeping these marketing techniques in check could prove beneficial in helping the state of the opioid crisis just like other model laws, such as the NAIC Model Laws, which focus on consumer protection and ensuring at least some uniformity in insurance across state lines.²⁰⁷

Closer regulation of pharmaceutical distributorship is another aspect that could be implemented by a model law.²⁰⁸ There is an obvious issue with the number of opioids that are shipped to small rural towns, as evident by the cases in West Virginia.²⁰⁹ “Primary pharmaceutical distributors are solely responsible for the safe and efficient distribution of all medications, including controlled substances, from drug manufacturers to licensed pharmacies and other healthcare providers.”²¹⁰ Although distributors claim to

204. See Calabro, *supra* note 16, at 2258 (describing conflicts of interest created by financial kickbacks provided by the pharmaceutical companies).

205. Calabro, *supra* note 16, at 2258.

206. See Calabro, *supra* note 16, at 2258 (noting that pharmaceutical companies are constantly marketing their product with high intensity).

207. See *NAIC Model Laws*, NAIC, https://www.naic.org/cipr_topics/topic_naic_model_laws.htm (last updated Sept. 26, 2019) (last visited Nov. 25, 2019) (citing the NAIC Model Laws as an example that assists in balancing the needs of the insurance companies and the consumer with a strong emphasis on consumer protection) [<https://perma.cc/MB37-GBBS>].

208. See *The Opioid Epidemic: Are Drug Manufacturers Liable?*, NAT'L PARALEGAL C., <https://nationalparalegal.edu/ViewNews.aspx?intTakeOnNewsID=108> (last visited Nov. 25, 2019) (noting that regulations “play[] a role in trying to stem the opioid crisis”) [<https://perma.cc/MG7X-Y8AE>].

209. See *9 Million Painkillers Shipped to Tiny West Virginia Town*, *supra* note 141 (providing an example of significant amounts of opioids shipped to small towns where the ratio of opioids to people is shocking).

210. *The Rest of the Story: Facts about Pharmaceutical Distributors and the*

merely fulfill orders from entities licensed by the U.S. Drug Enforcement Administration (DEA) and state regulatory authorities, the gross proportions of opioids to people, as illustrated by the cases in West Virginia, should arguably cause the average distributor to pause.²¹¹ Regulations keeping distributors in check would be beneficial for this reason.²¹² Through regulation, the distributors would be held responsible for their actions and would not merely be able to hide behind an excuse that they were just following orders.²¹³

Encouraging the pharmaceutical industry to pursue research and development of new treatment and medications as opposed to the highly addictive opioids is another option for helping the industry.²¹⁴ As recently as November 2018, the pharmaceutical company AcelRx introduced a potent new opioid painkiller, Dsuvia, a 3-millimeter-wide tablet of sufentanil.²¹⁵ The drug was introduced to the FDA and then approved despite warnings from physicians who say the drug will contribute to the opioid epidemic.²¹⁶ Although the FDA's approval speaks to its role in the

Opioid Crisis, HEALTHCARE DISTRIBUTION ALLIANCE (May 18, 2017), <https://www.hda.org/news/facts-about-rx-distributors-and-the-opioid-crisis> (last visited Nov. 25, 2019) [hereinafter *The Rest of the Story*] [<https://perma.cc/BA2Q-99Q7>].

211. See *id.* (“Wholesale distributors are not ‘pill mills.’ Distributors fulfill orders only from entities licensed by the U.S. Drug Enforcement Administration (DEA) and state regulatory authorities.”).

212. See *The Opioid Epidemic: Are Drug Manufacturers Liable?*, *supra* note 208 (referencing the laws and regulations relating to marketing and other practices relating to the distribution of opioids, which are regulated but contain lot of holes).

213. See *The Rest of the Story*, *supra* note 210 (noting that some distributors argue that they are only fulfilling the orders given to them by licensed physicians and that they are not in charge of making medical determinations).

214. See *Non-Opioid Treatment*, AM. SOC'Y OF ANESTHESIOLOGISTS, <https://www.asahq.org/whensecondscount/pain-management/non-opioid-treatment/> (last visited Nov. 25, 2019) (describing several alternatives to opioids for pain relief that are just as successful) [<https://perma.cc/63LF-TRPV>].

215. See Jake Harper, *Despite Warnings, FDA Approves Potent New Opioid Painkiller*, NPR (Nov. 2, 2018, 3:05 PM), <https://www.npr.org/sections/health-shots/2018/11/02/663395669/despite-warnings-fda-approves-potent-new-opioid-painkiller> (last visited Nov. 25, 2019) (providing that sufentanil is potent and Dsuvia was opposed by many physicians and individuals working against the opioid crisis) [<https://perma.cc/B9FS-9F8U>].

216. See *id.* (“The Food and Drug Administration has approved a potent new opioid painkiller, despite warnings from physician critics. . .”).

crisis as well, many critics believe Dsuvia contributes nothing new or unique to the market and is frankly unnecessary.²¹⁷ In light of the introduction of Dsuvia and multiple other prescription pain medications flooding the market, discouraging pharmaceutical companies from continuing the creation of new opioid painkillers in lieu of other options as scientists and researchers discover other ways to deal with pain could be another solution to helping end the epidemic.²¹⁸ Nonopioid alternatives to pain relief could be encouraged with the FDA's assistance and the guidance of a model law discouraging the further manufacture of highly addictive opioid pain medication.²¹⁹

2. *Regulating Prescribing Methods of Doctors*

Regulating doctors more clearly concerning dosage and duration amounts as opposed to arbitrary guidelines would also add a beneficial aspect to the proposed model law.²²⁰ Many consider doctors' habits of overprescribing medications to blame.²²¹ By placing a portion of the blame on physicians, the burden is not completely on the pharmaceutical companies, giving doctors the responsibility to know their patients' needs and treat them

217. See *id.* (quoting Dr. Sidney Wolfe, senior adviser to Public Citizen's Health Research Group, as saying that Dsuvia is "not unique at all," that it was not "adequately tested in emergency settings," and that pain relief from the drug was "slow") (omitting internal quotations).

218. See Phil Skolnick & Nora D. Volkow, *Re-Energizing the Development of Pain Therapeutics in Light of the Opioid Epidemic*, 92 NEURON 294, 294–96 (2016) (discussing scientific background on the subject and the opportunities that exist to explore alternative pain reliefs).

219. See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, NEW ENG. J. MED. 1480, 1483 (2016) ("The FDA has approved nonopioid medications for treatment of various chronic-pain syndromes, including gabapentin (Neurontin), pregabalin (Lyrica), milnacipran (Savella), duloxetine (Cymbalta), and others . . .").

220. See BONNIE ET AL., *supra* note 10, at 301–04 (suggesting better guidelines for physicians).

221. See Bethany Bump, *Are Doctors to Blame for Opioid Crisis? New Yorkers Think So*, TIMES UNION, <https://www.timesunion.com/local/article/Are-doctors-to-blame-for-opioid-crisis-New-12851255.php> (last visited Nov. 25, 2019) (noting that when New Yorkers were "asked to pick a single contributor they believe is most responsible for the opioid crisis most . . . picked doctors who overprescribed") [<https://perma.cc/9TFN-WWQK>].

adequately.²²² “The subject of guidelines for acute pain management currently revolves primarily around use rather than dosage or duration.”²²³ Although dosage guidelines are widely available and accepted, opioids prescribed for acute pain syndromes are often provided at dosing intervals and durations unlikely to yield optimal effects.²²⁴ If these guidelines were more directed at dosage amounts and duration, while at the same time more focused on a unified basis at the federal level through a model law, there could be better results.²²⁵ Patients’ reliance on opioids to manage pain could then be helped as other forms of pain management are introduced as opposed to large amounts of opioids.²²⁶

A Virginia regulation passed in the fall of 2018 provides another framework for the model law to follow regarding the regulation of doctors.²²⁷ The regulation tightens even further how and when a practitioner may prescribe opioids, but does not apply to patients receiving pain treatment for cancer, sickle cell, hospice, or palliative care.²²⁸ By regulating in this manner, the individuals who need opioids can access them without a lot regulatory red tape while the opioids themselves remain under strict regulation.²²⁹ The regulation makes it very clear to the medical profession that if physicians do not abide by the regulation, then they will not be

222. *See id.* (providing survey results indicating that New Yorkers believe that there are several factors, in addition to doctors’ over-prescription, that have led to the opioid epidemic).

223. BONNIE ET AL., *supra* note 10, at 299.

224. *But see* BONNIE ET AL., *supra* note 10, at 300 (providing an example of guidelines which “call for opioids. . . to be issued in carefully limited amounts . . . after education of the patient concerning appropriate use and storage”).

225. *See* BONNIE ET AL., *supra* note 10, at 301 (noting that better guidelines that are more unified regarding opioids could be more beneficial).

226. *See* BONNIE ET AL., *supra* note 10, at 295 (stating that physicians often receive inadequate pain management training and noting that “[a] consequence of this failure in education is that . . . some patients receive the wrong treatment and/or medications”).

227. *See* Rodney K. Adams, *Virginia Regulations Governing Prescribing of Opioids*, VA. LAW. MAG. FOR ST. BAR, Feb. 2019, at 18 (describing the new regulation and that physicians should ensure they remain in compliance).

228. *See id.* (noting that the regulation is strict but does not apply to groups that sincerely need opioids because of the amount of pain they have to endure).

229. *See id.* (“Of note is that these regulations are focused on out-patient care.”).

able to continue to prescribe opioids because their license will be revoked.²³⁰ Virginia's regulation could be a useful tool in formulating a model law by allowing doctors to treat the patients who need opioids while at the same time ensuring doctors are not negligently prescribing opioids to those who do not.²³¹

3. Implementing a Financial Burden to Pharmaceutical Companies

One of the more interesting yet also difficult pieces to implement into a model law aimed at curbing the opioid crisis is a sort of tax on pharmaceutical companies.²³² New York is the only state to pass a system like this thus far, but it did not last long.²³³ Opioid makers and distributors fought the law because it aimed to collect hundreds of millions of dollars from the industry in order to help defray costs of the opioid crisis.²³⁴ Pharmaceutical companies argued in three legal challenges filed in recent months that the law, which sought \$600 million over six years, was unconstitutional.²³⁵ The concept behind imposing a tax could prove beneficial as billions of dollars in government revenue could be generated from the tax to fight addiction and overdose.²³⁶ Even

230. See *id.* at 20 (“A physician should immediately review their practices to assure compliance with these detailed regulations for the safety of their patients and their license.”).

231. See *id.* at 18–20 (outlining the regulations’ requirements).

232. See Farmer, *supra* note 112 (looking into the idea of the tax on pharmaceutical companies as implemented through states in the past several years).

233. See *A Unique New York Law Allows State to Collect Taxes from Opioid Makers to Defray Cost of Crisis. Companies Are Not Happy About It.*, KAISER HEALTH NEWS (Nov. 20, 2018), <https://khn.org/morning-breakout/a-unique-new-york-law-allows-state-to-collect-taxes-from-opioid-makers-to-defray-cost-of-crisis-companies-are-not-happy-about-it/> (last visited Nov. 25, 2019) (illustrating the trials being faced by the lawmakers of New York being the lone state to pass a system like this taxing pharmaceutical companies) [<https://perma.cc/22WZ-NET4>].

234. See *id.* (describing the scene in New York as pharmaceutical companies fought and ultimately won in court that the tax law was constitutional and unenforceable).

235. *Id.*

236. See Farmer, *supra* note 112 (noting the potential benefits of implementing a tax against pharmaceutical companies which could directly be

though several states have already tried and failed to pass opioid taxes, lawmakers in those states say they will try again in 2019, and with dozens continuing to sue opioid makers and distributors, it is possible pharmaceutical companies could begin to buckle as lawmakers crack down.²³⁷ More guidance and support could be implemented through a federal model law suggesting how to tax or increase licensing fees on the industry.²³⁸

4. Possible Roadblocks

Unfortunately, there are potential obstacles facing the passage of a model law of this magnitude.²³⁹ For starters, getting past the pharmaceutical lobby and influence in general will be difficult.²⁴⁰ Their lobby is very strong and influential when it comes to lawmaking as evident by the previous laws and regulations Congress has attempted to pass in an effort to handle the opioid crisis.²⁴¹ Difficulty in passing laws regarding the opioid crisis has been illustrated in the past as the pharmaceutical company lobby is able to funnel millions of dollars into stopping bills that would

funneled back into assisting those fighting opioid addiction and the crisis in general).

237. See Randazzo, *supra* note 124 (referencing the U.S. district court in Ohio allowing a large group of opioid tax-related lawsuits to move forward); see also Bob Salsberg, *Baker Tax Plan Would Hit Firms that Make Opioid Drugs*, WBUR 90.9 (Jan. 26, 2019), <https://www.wbur.org/commonhealth/2019/01/26/baker-opioid-excise-tax> (last visited Nov. 25, 2019) (discussing the high-profile attempt by Governor Baker of Massachusetts to tax manufacturers of opioids) [<https://perma.cc/ZM49-LA9R>].

238. See Farmer, *supra* note 112 and accompanying text.

239. See Liu, Pei & Soto, *supra* note 9 (discussing the barriers created by pharmaceutical lobbyists); see also Jeff Bendix, *Opioid Policy Fallout*, MEDICALECONOMICS.COM (May 30, 2018), <https://www.medicaleconomics.com/article/opioid-policy-fallout> (last visited Nov. 25, 2019) (discussing the concern that regulating the prescription of painkillers will hinder doctors' ability to properly treat patients) [<https://perma.cc/Q78F-ZWH6>].

240. See Liu, Pei & Soto, *supra* note 9 (“Attempts to change opioid prescribing patterns have been opposed primarily by indirect intervention by the pharmaceutical industry through lobbying and advocacy groups.”).

241. See Liu, Pei & Soto, *supra* note 9 (stating that pharmaceutical companies “attempt[] to halt measures to restrict opioid overprescribing . . . undermine the CDC guidelines, and thwart[] attempts to hold prescribers and pharmaceutical companies accountable”).

crack down on regulating the sale and distribution of opioids.²⁴² “Hundreds of millions of dollars flow to lobbyists and politicians on Capitol Hill each year to shape laws and policies that keep drug company profits growing.”²⁴³ The pharmaceutical industry has approximately two lobbyists for every member of Congress and spent \$152 million on influencing legislation in 2016, according to the Center for Responsive Politics, while contributing more than \$20 million directly to political campaigns in 2015.²⁴⁴ These contributions to campaigns are hard to ignore, and are evidence of how closely tied the pharmaceutical industry is to Congress through their lobby and funding which presents a possible issue in passing a model law of the magnitude proposed to keep the pharmaceutical industry in check.²⁴⁵ That being said, Senate committees and investigative journalists have scrutinized the financial associations of opioid manufacturers and patient advocacy and professional organizations.²⁴⁶ They recognize the major concern that “opposition to regulatory, payment, or clinical policies to reduce opioid use may originate from groups that stand to lose financially if sales of opioids decline.”²⁴⁷ As a result, most find that greater transparency is required concerning the financial

242. See Chris McGreal, *How Big Pharma's Money—and Its Politicians—Feed the U.S. Opioid Crisis*, THE GUARDIAN (Oct. 19, 2017, 6:00 AM), <https://www.theguardian.com/us-news/2017/oct/19/big-pharma-money-lobbying-us-opioid-crisis> (last visited Nov. 25, 2019) (referencing the substantial contribution from pharmaceutical companies to politicians and campaigning against bills further regulating the pharmaceutical industry) [<https://perma.cc/USQ4-QNXZ>].

243. *Id.*

244. See *id.* (“Drugmakers have poured close to \$2.5 billion into lobbying and funding members of Congress over the past decade.”); see also Ctr. for Responsive Politics, *Industry Profile: Pharmaceutical Manufacturing*, OPENSECRETS.ORG, <https://www.opensecrets.org/lobby/induscode.php?id=H4300&year=2016> (last visited Nov. 25, 2019) (comparing campaign contributions from the pharmaceutical industry for the year 2016 totaling \$152,852,025) [<https://perma.cc/5HPL-F6WW>].

245. See McGreal, *supra* note 242 (“Pharmaceutical companies spend far more than any other industry to influence politicians.”).

246. See Dora H. Lin et al., *Financial Conflicts of Interest and the Centers for Disease Control and Prevention's 2016 Guideline for Prescribing Opioids for Chronic Pain*, 177 JAMA INTERN. MED. 427, 427–28 (2017) (referencing a study performed by researchers on 158 organizations that submitted information to the CDC on their reformed guidelines regarding opioids).

247. *Id.* at 428.

relationships between opioid manufacturers and patient and professional groups in order to improve the opioid crisis, but the reality is that it is hard to compete with financial backing.²⁴⁸

There also has to be an understanding and acknowledgment that some patients need opioids and balancing that with the law.²⁴⁹

The concern among physicians and public health and pain management experts is that laws and regulations designed to limit use of prescription narcotics, however well-intentioned, are yet another constraint on doctors' ability to treat patients as they think best. Worse, they say, some of the limitations on prescribing could result in patients turning to heroin or buying the medications on the street. And because heroin in particular now is often laced with fentanyl and other synthetic painkillers, doing so astronomically increases the risk of death.²⁵⁰

Concerns regarding pain management are not unfounded.²⁵¹ Some patients need opioid pain killers and the further regulation of opioids and pharmaceutical companies could complicate matters in getting opioids to those who truly need them.²⁵² PhRMA Deputy Vice President Priscilla VanderVeer has expressed her concerns that prescription medications such as Vicodin or Oxycodone are important treatment for some patients, and that the proposed laws would punitively affect those drugs across the board.²⁵³ Concerns

248. See *id.* at 427–28 (describing the results from the study performed and the need for greater transparency in the relationship between pharmaceutical companies and the rest of the population).

249. See Bendix, *supra* note 239 (acknowledging that the opioid crisis needs to be addressed in a manner that will not deprive chronic pain patients of necessary medication).

250. Bendix, *supra* note 239.

251. See Marilyn Serafini, *The Physicians' Quandary with Opioids: Pain Versus Addiction*, NEJM CATALYST (Apr. 26, 2018), <https://catalyst.nejm.org/quandary-opioids-chronic-pain-addiction/> (last visited Nov. 25, 2019) (describing the case of physicians who are frustrated with the difficulties when it comes to prescribing opioids to patients who need pain relief) [<https://perma.cc/D9T6-XLKC>].

252. See *id.* (referencing patients who suffer from chronic pain and need the medications in question); see also Lauren Vogel, *More Regulation Not the Answer for Opioids*, CMAJ, Sept. 22, 2015, at 957 (“[P]atients who legitimately need the drugs face greater barriers to access, and those using opioids to get high simply move on to a more readily available agent.”).

253. See Farmer, *supra* note 112 (“There are people who need access to those medicines . . . We want to make sure we’re not making these people who need it feel like criminals.”).

about affecting individuals who need pain medication is the main argument on behalf of pharmaceutical companies, and it has its merits, but better regulations and guidelines overall are arguably better than no regulation at all.²⁵⁴ The issue is not that opioids themselves are bad.²⁵⁵ The issue is that pharmaceutical companies and distributors are placing millions of highly addictive opioids in the hands of individuals who are being prescribed painkillers at high rates with little regulation.²⁵⁶

VI. Conclusion

The grip that pharmaceutical companies maintain on society is a problem.²⁵⁷ It is arguably the root of the opioid crisis that was jumpstarted by the transmission of bad information that opioids were non-addictive in the early 1990s.²⁵⁸ The crisis then continued to worsen as pharmaceutical companies realized the profit margins they stood to gain off of the sale of opioid pain killers and continued to ship opioids out by the millions even after the death tolls started to rise.²⁵⁹ The pharmaceutical industry continues to stand virtually untouchable in terms of statutes and regulations that are seeking to protect the American people.²⁶⁰ With their constant involvement

254. See, e.g., *The Opioid Epidemic: What Can We Learn from Europe?*, CLEVELAND CLINIC (Aug. 14, 2018), <https://consultqd.clevelandclinic.org/the-opioid-epidemic-what-can-we-learn-from-europe/> (last visited Nov. 25, 2019) (providing interviews with pain management experts who describe the situation in Europe where the regulations are much tighter and they have significantly fewer opioid overdoses) [<https://perma.cc/4W2S-33RF>].

255. See Teresa A. Rummans et al., *How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis*, 93 MAYO CLINIC PROC. 344, 348 (2018) (describing the fact that opioids came with good intentions to treat pain and help individuals).

256. See *id.* (noting that the current state of the opioid crisis is not the fault of any one group or organization but the product of multiple factors that need to be addressed).

257. See *supra* notes 239–245 and accompanying text (discussing the influence that pharmaceutical companies have on lawmakers).

258. See Liu, Pei & Soto, *supra* note 9 (explaining how pharmaceutical companies contributed to a spike in opioid prescriptions).

259. See Nat'l Inst. on Drug Abuse, *supra* note 6 (providing statistics demonstrating that the “main driver of drug overdose deaths were opioids . . . with a 12.9-fold increase from 2007 to 2017”).

260. See Liu, Pei & Soto, *supra* note 9 (discussing the pervasive effort by pharmaceutical lobbyists to stymie legal reform).

in Congress, and money distributed to physicians and campaigns, the pharmaceutical companies have made themselves even harder to touch in terms of holding them accountable.²⁶¹ Although recent settlements and decisions provide room for optimism, it is still uncertain whether these decisions will make an impact on the industry as a whole.²⁶² However, hope remains.²⁶³ It is possible through the implementation of a reasonable, yet stricter, set of federal guidelines imposed through the form of a model law regulating both pharmaceutical companies and doctors, there could be significant improvement in the efforts to end the opioid crisis plaguing America.²⁶⁴

261. See Liu, Pei & Soto, *supra* note 9 (noting research that “found that the opposition to the CDC guidelines was significantly more common among organizations that received funding from opioid manufacturers”); see also Calabro, *supra* note 16, at 2258 (“More than 83,000 pharmaceutical representatives regularly visit physicians, hospitals, and pharmacies laden with expensive gifts.”).

262. See *supra* notes 165–166 and accompanying text (acknowledging that, although these cases are tentative and not entirely satisfying, they seem to be a step in the direction of pharmaceutical companies taking accountability).

263. See *supra* notes 200–238 and accompanying text (discussing a path that could help to alleviate the opioid crisis).

264. See *supra* notes 200–238 and accompanying text (recommending the introduction of a model law and discussing the positive impact that a model law could have on the opioid crisis).