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# The Opioid Crisis: The States' And Local Governments' Response To Bigpharma's Deception And Why The Supremacy Clause May Provide A Cloak For Opioid Manufacturers To Hide Behind

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**THE OPIOID CRISIS: THE STATES' AND LOCAL GOVERNMENTS'  
RESPONSE TO BIGPHARMA'S DECEPTION AND WHY THE  
SUPREMACY CLAUSE MAY PROVIDE A CLOAK FOR OPIOID  
MANUFACTURERS TO HIDE BEHIND**

*Tracie Childers\**

*Drug addiction has long been recognized in the medical community as a disability.<sup>1</sup> Two of our nation's largest benefit providers for individuals with disabilities, Social Security Disability (SSDI) and Supplemental Security Income (SSI), treated addiction as a disability and provided income, treatment, and medical care to individuals with an addiction disorder from the mid-1970s until the 1990s.<sup>2</sup> Then, as part of the 1996 welfare reform package, individuals whose only disorder was addiction were disqualified from receiving benefits.<sup>3</sup>*

*On the heels of this change the opioid crisis took form. The Food and Drug Administration's (FDA) acting commissioner, Dr. Stephen M. Ostroff, addressed the current crisis during the Food and Drug Law Institute (FDLI) Annual Conference in Washington, D.C. on May 4, 2017. Dr. Ostroff began by recognizing the opioid epidemic as a monumental health crisis and one of the greatest modern tragedies of our time.<sup>4</sup> Dr. Ostroff then pledged that the FDA would not be part of the opioid problem, but instead would ensure an "ironclad" commitment to finding a solution to the opioid epidemic.<sup>5</sup> These words are difficult to digest when the FDA regulates and approves the opioids for use and distribution in the United States, especially when benefits for addiction disability treatment are nearly non-existent.<sup>6</sup>*

This article will begin by providing an introduction into the depths of opioid addiction disability in America today: statistical information as to what constitutes

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<sup>1</sup> Max Slever, *Disability Benefits and Addiction; Resolving an Uncertain Burden*, 91 N.Y.U. L. Rev. 954, 954 (2016).

2. *Id.* at 955–56.

3. *Id.* at 957. See also *THE PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT OF 1996*, U.S. DEP'T OF HEALTH & HUM. SERV. (Sept. 1, 1996), <https://aspe.hhs.gov/report/personal-responsibility-and-work-opportunity-reconciliation-act-1996> (describing the 1996 welfare plan as a bipartisan reform plan, signed into law by then-President Bill Clinton on August 10, 1996, that mandates work requirements in exchange for time limited assistance and provides state bonuses for moving welfare recipients off of assistance and into the workforce); H.R. 3136, 104th Cong. (1996) (Section 105 of Public Law 104–121, enacted as part of the "Right to Work Act" of 1996, which states in part, "An individual shall not be considered to be disabled for purposes of this title if alcoholism or drug addiction would 'but for this subparagraph' be a contributing factor material to the Commissioner's determination that the individual is disabled").

4. Stephen M. Ostroff, Article, *Remarks by Acting FDA Commissioner Stephen M. Ostroff, MD FDLI Annual Conference May 4, 2017 Washington D.C.: FDA: Looking Back, Looking Forward*, 72 FOOD AND DRUG L.J. 378, 382 (2017).

5. *Id.*

6. See Academies of Sciences, Engineering, and Medicine, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* 359 (2017); *supra* note 3 and accompanying text.

an addiction disability crisis; the organizations being blamed for the widespread epidemic; and the government's response (i.e., the ensuing litigations) to the issue.

Next, a background will be laid out that will timestamp the evolution of opioid distribution and use, the backlash of proliferation of opioids, and the initiation of the legal disputes against BigPharma to recover losses incurred by government entities battling the ongoing opioid epidemic.

Third, this article will provide an overview of the federal government's role in approving and regulating opioids, a Schedule II narcotic, for use in the United States. It is imperative to understand the FDA's actions and inactions in promoting and deterring opioid use when determining accountability for the epidemic. Is the FDA's approval and regulation of opioids enough to trump state and local legal claims?

Fourth, an analysis of the legal claims will be discussed as well as a comparative examination of the current lawsuits against opioid manufacturers and the lawsuits against tobacco manufacturers during the 1990s. One distinct difference between the two legal battles involves the FDA's role in regulating the two products. Tobacco was not FDA regulated until 2009, and as such, tobacco was not federally regulated during the onset of the lawsuits against tobacco manufacturers.<sup>7</sup>

Last, this article will set forth remedial measures to consider, for example, legislative and policy changes on the treatment of addiction disability and funding incentives that may assist in alleviating future epidemics. Regulatory changes should be considered to prevent potentially harmful drugs from further making their way into mainstream society. Additionally, this article will set forth an overview of where potential legal funds would be most effective in the treatment of addiction disability.

## I. INTRODUCTION

More than 115 individuals are dying each day in the United States alone as a result of an opioid overdose.<sup>8</sup> What is now known is that 21%–29% of patients prescribed opioids will misuse them; the misuse yields another 8%–12% that will develop an addiction; and another 4%–6% that will transition to heroin.<sup>9</sup> Approximately 80% of all heroin users are linked to first abusing opioids.<sup>10</sup> Statistics also show a nationwide increase of 30%, from July 2016 through September 2017 for overdose treatment by emergency departments.<sup>11</sup> In 2016 a reported 11.5 million Americans, ages 12 and older, abused opioids and roughly 950,000 individuals used heroin.<sup>12</sup> According to the President of the United States Donald J. Trump, “drug

7. *The Facts on the FDA's New Tobacco Rule*, U.S. FOOD & DRUG ADMIN., [www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm) (last updated Nov. 9, 2017); see also German Lopez, *The Growing Number of Lawsuits Against Opioid Companies Explained*, Vox, (last updated May 15, 2018), <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-epidemic-lawsuits-purdue-oxycotin>.

8. *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last visited Mar. 2018).

9. *Id.*

10. *Id.*

11. *Opioid Overdoses Treated in Emergency Departments*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/vitalsigns/opioid-overdoses/> (last updated Mar. 16, 2018).

12. See Press Release, THE WHITE HOUSE, FACT SHEET: PRESIDENT DONALD J. TRUMP IS TAKING ACTION ON DRUG ADDICTION AND THE OPIOID CRISIS (Oct. 26, 2017), <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis>.

overdoses are now the leading cause of injury death in the United States, outnumbering both traffic crashes and gun related deaths”.<sup>13</sup> All of this computes to an estimated expense of “\$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.”<sup>14</sup> A nationwide public health emergency has been declared by President Donald J. Trump to address what is now coined the “opioid crisis.”<sup>15</sup>

Who is to blame for the increase of individuals with addiction to opioids? According to hundreds of government entities throughout the United States, the blame falls on the manufacturers of opioids, their key opinion leaders (KOLs), distributors of the product, and the physicians prescribing the drugs;<sup>16</sup> a claim that the BigPharma<sup>17</sup> industry adamantly denies.<sup>18</sup> While the answer to this question remains uncertain, some facts are conclusive: addiction disability is growing among Americans; state and local agencies are footing an astronomical amount of money combating addiction-related issues; and government officials are preparing to fight to recover losses incurred.<sup>19</sup> Over 300 entities including states, counties, and cities have filed lawsuits against opioid manufacturers, and the number is continuing to grow.<sup>20</sup> Many outlets are comparing the current opioid lawsuits to the tobacco lawsuits of the 1990s, which awarded government entities billions of dollars in damages.<sup>21</sup> Much like the preceding tobacco lawsuits, the recent legal allegations against BigPharma include deceptive trade practices and product misrepresentation.<sup>22</sup> The question is

13. *Id.*

14. Nat’l Inst. on Drug Abuse, *supra* note 8.

15. Press Release, White House, *supra* note 12.

16. See KAISER HEALTH NEWS, *More than 320 Counties, Cities and States are Suing Drug Makers for Role in Opioid Epidemic*, KHN MORNING BRIEFING (Feb. 14, 2018), <https://khn.org/morning-breakout/more-than-320-counties-cities-and-states-are-suing-drugmakers-for-role-in-opioid-epidemic/>. See also *City of Chicago v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1074 (N.D. Ill. 2016); Complaint at 3–4, *Florida v. Purdue Pharma L.P., et. al.*, No. 2018-CA-001438 (Fla. Cir. Ct. filed May 15, 2018); Nadia Kounang, *41 State Attorneys General Subpoena Opioid Manufacturers*, CNN (Sept. 20, 2017), <https://www.cnn.com/2017/09/19/health/state-ag-investigation-opioids-subpoenas/index.html>; Katie Benner & Jan Hoffman, *Justice Dept. Backs High-Stakes Lawsuit Against Opioid Makers*, N.Y. TIMES, (Feb. 27, 2018), <https://www.nytimes.com/2018/02/27/us/politics/justice-department-opioid-lawsuit.html>; Csaba Sukosd, *City of Columbus Sues 25 Drug Companies, Claiming Damages for Opioid Epidemic*, ABC 6 NEWS, (Dec. 15, 2017), <https://abc6onyourside.com/news/local/city-of-columbus-sues-25-drug-companies-claiming-damages-for-opioid-epidemic>; John C. Moritz, *6 States Sue Maker of OxyContin as they Battle Expenses, Human Costs of Opioid Crisis*, USA TODAY, (May 15, 2018 | Updated 8:37 AM ET May 16, 2018), <https://www.usatoday.com/story/news/nation-now/2018/05/15/six-attorney-generals-opioid-lawsuits/612721002/>, archived at <http://perma.cc/78RS-9MQJ>.

17. “Big Pharma,” Cambridge Dictionary Online, 2018, <https://dictionary.cambridge.org/us/dictionary/english/big-pharma> (Dec. 29, 2018), archived at <https://perma.cc/LVT3-UYPA>.

18. See Sukosd, *City of Columbus Sues 25 Drug Companies, Claiming Damages for Opioid Epidemic*, *supra* note 16, see also Lopez, *supra* note 7.

19. See, e.g., Katie Zezima, *Scope of Opioid Battle Headed to Ohio Court Compared to ‘90s Tobacco Industry Settlements*, Chi. Trib., Apr. 7, 2018, <http://www.chicagotribune.com/news/nationworld/ct-opioid-battle-ohio-20180407-story.html>; see Moritz, *supra* note 16.

20. See KAISER HEALTH NEWS, *supra* note 16.

21. See, e.g., Lopez, *supra* note 7; Katie Zezima, *supra* note 19; Bill Meagher, *America’s Opioid Crisis Looks a Lot Like Big Tobacco Spats of Yesteryear*, THE STREET (last visited, Jan. 7, 2018, 7:18 AM), <https://www.thestreet.com/story/14397159/1/how-opioid-crisis-of-today-resembles-big-tobacco-lawsuits-battles>; James E. Tierney, *It’s Time to Take on Big Opioid Like We Did with Big Tobacco*, AM. CONST. SOC’Y FOR L. & POL’Y (Mar. 5, 2018), <https://www.acslaw.org/acsblog/its-time-to-take-on-big-opioid-like-we-did-with-big-tobacco>.

22. See, e.g., *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1105–06 (D.C. Cir. 2009). The United States alleged that Defendants fraudulently misrepresented their products and used deceptive trade practices by covering up the negative health effects of smoking, underplaying the addictiveness of nicotine, and marketing to specific individuals and classes of people, e.g., children, that would be most likely to use tobacco.

whether key players involved in the manufacturing, distributing, and prescribing of opioids used deceptive tactics to promote the product when opioids are FDA regulated, unlike the tobacco industry during the 1990s.<sup>23</sup>

## II. BACKGROUND

### A. The Introduction of OxyContin in the United States

In 1996, OxyContin, an opioid pain medication with a high addiction and dependency risk, was introduced into the United States by Purdue Pharma and aggressively campaigned and marketed as a non-addictive medication to treat acute pain.<sup>24</sup> Purdue's aggressive marketing of OxyContin reached figures of approximately \$200 million a year.<sup>25</sup> Within a four-year span, the sales of OxyContin increased from \$48 million to nearly \$1.1 billion.<sup>26</sup> In 2001, OxyContin was the most prescribed opioid medication for moderate to severe pain.<sup>27</sup> By 2004, OxyContin was documented as the most abused drug in the United States.<sup>28</sup> The marketing tactics employed by Purdue Pharma were, among other things, carefully calculated.<sup>29</sup> Unfortunately, the billions of dollars that Purdue Pharma profited from the sale of OxyContin left behind a trail of millions of individuals with addiction disorders.<sup>30</sup>

Proliferation of OxyContin in the United States led to the pills getting into the hands of not only the individuals prescribed the drug but also others.<sup>31</sup> To put this into perspective, pharmacists filled 245 million opioid prescriptions in 2010 alone, with OxyContin accounting for the vast majority.<sup>32</sup> This led to millions of these

23. See National Academies of Sciences, Engineering, and Medicine, *supra* note 64, at 359; Lopez, *supra* note 7. See also *THE FACTS ON THE FDA'S NEW TOBACCO RULE*, *SUPRA* NOTE 7.).

24. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) AM. J. OF PUB. HEALTH 221, 221 (2009).

25. *Id.*

26. *Id.*

27. U.S. Gen. Accounting. Off., GAO-04-110, OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM 2 (2003).

28. Van Zee, *supra* note 24, at 224.

29. *Id.* at 222. ("From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker-training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau. It is well documented that this type of pharmaceutical company symposium influences physicians' prescribing, even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns. One of the cornerstones of Purdue's marketing plan was the use of sophisticated marketing data to influence physicians' prescribing. . . . A lucrative bonus system encouraged sales representatives to increase sales of OxyContin in their territories, resulting in a large number of visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign aimed at them. In 2001, in addition to the average sales representative's annual salary of \$55,000, annual bonuses averaged \$71,500, with a range of \$15,000 to nearly \$240,000. Purdue paid \$40 million in sales incentive bonuses to its sales representatives that year. . . . Purdue promoted among primary care physicians a more liberal use of opioids, particularly sustained-release opioids. . . . Primary care physicians began to use more of the increasingly popular OxyContin; by 2003, nearly half of all physicians prescribing OxyContin were primary care physicians. Some experts were concerned that primary care physicians were not sufficiently trained in pain management or addiction issues." *Id.* at 124)

30. See generally Patrick Radden Keefe, *Empire of Pain*, THE NEW YORKER (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

31. Lopez, *supra* note 7.

32. Katherin Eban, *OxyContin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>.

highly addictive pills flooding mainstream society. As the dependency rate continued to grow, the demand for the drug sent opioid-dependent individuals to the black market to feed their addictions.<sup>33</sup> The cost for OxyContin in 2011 was estimated to be \$50–\$80 a pill on the black market.<sup>34</sup> In addition to overprescribing by medical prescribers, another major contributing factor to the black market supply was “pill mills” operating as pain clinics. The term “pill mill” refers to a medical facility where medical providers prescribe Schedule II narcotic medications, often times for cash, to individuals without any medical need for the drugs.<sup>35</sup> These facilities habitually do not keep medical records, frequently require no medical exams, and treat alleged symptoms with only drugs.<sup>36</sup> Additionally, patients are in and out of their appointments in a matter of minutes, are able to choose what drugs they want prescribed, and are provided a return date at check out.<sup>37</sup> Patients of these facilities can often be seen using the drugs they obtain from the clinic in plain sight of the facility, and there is frequently a line of patients waiting to enter.<sup>38</sup> Southern states became a hub for “pill mills” and pain medication distribution.<sup>39</sup>

For instance, Florida is the state known as the epicenter of the prescription pain medication epidemic.<sup>40</sup> Florida lacked a system for monitoring the disbursement of pain medications, and as such, could not prevent the inevitable “doctor shopping” that was occurring.<sup>41</sup> “Doctor shopping” is when individuals travel around from doctor to doctor to avoid detection from being overprescribed powerful pain medications.<sup>42</sup> “Doctor shopping” allowed individuals to purchase Schedule II narcotics as often as they wanted without the detection of being overprescribed the drug. Interstate 75 in Florida became known as the “Oxy Express” because of the abundance of “pill mills” located throughout the state in close proximity to the interstate exits.<sup>43</sup> The reality is that corrupt medical doctors have been acting as street-level drug dealers for financial gain and have been doing so at the expense of the lives of the individuals with addiction disorders, as well as states, cities, and communities.<sup>44</sup>

### B. The Withdrawal – The Physical Cost of Opioid Use

The physical withdrawal process off of opioids is extremely daunting and painful. Signs of withdrawal will begin six to twelve hours after the last dose was taken and will include tearing up, muscle aches, agitation, insomnia, excessive yawning,

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33. *Id.*

34. *Sky High Prices for Prescription Opioids Sold on Street*, PARTNERSHIP FOR DRUG-FREE KIDS (June 1, 2011), <https://drugfree.org/learn/drug-and-alcohol-news/sky-high-prices-for-prescription-opioids-sold-on-street/>.

35. *See The Ugly Truth About Pill Mills in the United States*, NORTHPOINT RECOVERY (Dec. 21, 2017), <https://www.northpointrecovery.com/blog/ugly-truth-pill-mills-united-states/>.

36. *Id.*

37. *Id.*

38. *Id.*

39. Greg Allen, *The Oxy Express: Florida’s Drug Abuse Epidemic*, NPR, (Mar. 2, 2011), <https://www.npr.org/2011/03/02/134143813/the-oxy-express-floridas-drug-abuse-epidemic>.

40. *Id.*

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

anxiety, runny nose, cold sweats, racing heart, hypertension, and fever.<sup>45</sup> Long-term symptoms will be felt at approximately day three and can last up to two weeks thereafter.<sup>46</sup> The long-term symptoms will include nausea and vomiting, diarrhea, goose bumps, stomach cramps, depression, and immense drug cravings.<sup>47</sup> Any one of these symptoms would be difficult for someone to go through; so the idea of experiencing many of them, or all of them at once, for an extended period of time, would be seemingly impossible to handle. The fear of the pain of withdrawal associated with opioid use contributes immensely to the repetitive nature of addiction.<sup>48</sup>

The longer an individual takes an opioid the more tolerant their system will become to the drug.<sup>49</sup> This will lead to an opioid user needing higher and more frequent doses to prevent withdrawal and the inevitable ensuing pain.<sup>50</sup> It is foreseeable that, in time, the physical need for the drug becomes an expense that many users can no longer afford.

### C. The Repercussions of Addiction Disability

Individuals with an active addiction disorder will begin to turn to alternative methods to obtain the funds to maintain their comfort zone and avoid withdrawal.<sup>51</sup> Many of them will first commonly turn to their families and friends for financial support to obtain the drug.<sup>52</sup> This typically manifests by an individual with an addiction disorder repeatedly asking to borrow money, and then will eventually lead to lying and stealing from family and friends in determination of securing enough money to keep purchasing more of the drug.<sup>53</sup> Very often family and friends will discontinue financial assistance to a loved one battling an addiction disorder in an effort to prevent enabling the disorder further.<sup>54</sup> The backlash to families and friends of isolating an individual with addiction disorder is that the individual often times cannot find alternative, accessible, and appropriate help or are not in the right state of mind to want and accept help if it is available. This places the burden on the community at large. A correlation between widespread crime sprees and opiate use is

45. See *Opiate Withdrawal Timelines, Symptoms and Treatment*, AM. ADDICTION CTR., <https://americanaddictioncenters.org/withdrawal-timelines-treatments/opiate/> (last visited July 2018); *Withdrawing from Opiates and Opioids*, HEALTH LINE, <https://www.healthline.com/health/opiate-withdrawal> (last visited July 2018).

46. *Id.*

47. *Id.*

48. *Opiate Withdrawal Timelines, Symptoms and Treatment*, *supra* note 45.

49. See *OxyContin Dependence—Signs of OxyContin Use Vs. Abuse, Tolerance*, <https://web.archive.org/web/20171010233418/https://www.dependency.net/learn/oxycontin/> (last visited July 2018).

50. *Id.*

51. Lisa Frederiksen, *Why Addicts / Alcoholics Lie, Cheat, Steal*, BREAKING THE CYCLES BLOG (June 10, 2013), <http://www.breakingthecycles.com/blog/2013/06/10/why-alcoholics-lie-cheat-steal/>; see also *The Ugly Truth About Pill Mills in the United States*, *supra* note 35.

52. See Marisa Crane, *When a Friend or Family Member Is Stealing From You for Drugs*, REHABS.COM, <http://luxury.rehabs.com/drug-addiction/when-someone-is-stealing/> (last visited July 2018).

53. *Id.*

54. See *9 Tips for Family Members to Stop Enabling an Addict*, THE RECOVERY VILLAGE, <https://www.the-recoveryvillage.com/family-friend-portal/stop-enabling-an-addict/#gref> (last visited July 2018).

evident.<sup>55</sup> The criminal justice system is encountering increased cases of theft, burglary, and other crimes related to opioid drug use.<sup>56</sup> It is not solely family, friends, and the criminal justice systems that are affected by fallout of opioid addiction; the medical community is seeing an increase of babies born addicted to opiates, opioid overdoses, hepatitis C infections, HIV, and other opioid-use-related issues.<sup>57</sup> The commonality amongst the repercussions of opioid drug addiction is the burden and expense it places on the individuals with the disability, their family and friends as well as counties, cities, and states.

#### D. Recovering the Losses of Addiction Disability

In 2014, the City of Chicago, Illinois, made a bold move by filing a lawsuit in Illinois state court against Purdue Pharma, the manufacturer of OxyContin, along with four other large manufacturers of other powerful and popular pain medications.<sup>58</sup> On June 3, 2014, City of Chicago Mayor Rahm Emanuel announced that:

For years, big pharma has deceived the public about the true risks and benefits of highly potent and highly addictive painkillers in order to expand their customer base and increase their bottom line. This has led to a dramatic rise in drug addiction, overdose and diversion in communities across the nation, and Chicago is not immune to this epidemic. . . Today, we're saying enough is enough – it's time for these companies to end these irresponsible practices and be held accountable for their deceptive actions.<sup>59</sup>

The lawsuit alleged misrepresentation of opioids by Purdue Pharma as well as the other named manufacturers.<sup>60</sup> The City of Chicago's goal is not to ban the drug completely, but instead, to end the deceptive marketing of the drug so that doctors and patients alike are able to make informed and educated decisions when it comes to prescribing and taking the powerful pain medications.<sup>61</sup> Chicago's complaint was initiated seven years after Purdue Pharma and three of its executives pled guilty to

55. See generally Matthias Pierce et al., *Insights into the Link Between Drug Use and Criminality: Lifetime Offending of Criminally-Active Opiate users*, 179 DRUG & ALCOHOL DEPENDENCE 309 (2017).

56. *Drug and Crime Facts*, BUREAU OF JUST. STAT., <https://www.bjs.gov/content/dcf/duc.cfm> (last visited June 8, 2018) (“In 2002 about a quarter of convicted property and drug offenders in local jails had committed their crimes to get money for drugs. . . . Among state prisoners in 2004 the pattern was similar, with property (30%) and drug offenders (26%) more likely to commit their crimes for drug money than violent (10%) and public-order offenders (7%). In federal prisons property offenders (11%) were less than half as likely as drug offenders (25%) to report drug money as a motive in their offenses.”).

57. See Press Release, Centers for Disease Control and Prevention, Increase in Hepatitis C Infections Linked to Worsening Opioid Crisis (Dec. 21, 2017), <https://www.cdc.gov/nchstp/newsroom/2017/hepatitis-c-and-opioid-injection-press-release.html>; Elizabeth E. Krans et al., *Caring for Opioid Dependent Pregnant Women: Prenatal and Postpartum Care Considerations*, 58(2) CLINICAL OBSTETRICS & GYNECOLOGY 370 (2015).

58. Press Release, Off. of the Mayor, City of Chicago Sues BigPharma for Deceptively Marketing Highly Addictive Prescription Painkillers (June 2014), <https://www.cityofchicago.org/content/dam/city/depts./mayor/Press%20Room/Press%20Releases/2014/June/06.03.14BigPharma.pdf>.

59. *Id.*

60. *Id.*

61. *Id.*



misleading the public and were ordered to pay \$634.5 million in fines, serve probation, and complete community service.<sup>62</sup> The news of Chicago's lawsuit came at a time when the United States, as a nation, was fighting a seemingly losing war against the opioid crisis. It was a likely outcome that others would follow Chicago's lead and initiate further lawsuits against Purdue Pharma and other manufacturers. From the time of the earlier lawsuits emerging in 2014 through present day, hundreds of government entities, inclusive of Attorneys General, have filed lawsuits against opioid manufacturers, with Purdue Pharma a named staple among them.<sup>63</sup>

### III. THE FDA'S INVOLVEMENT

#### A. The Application Process

The FDA is the federal organization responsible for investigating, approving, regulating, and classifying new drugs for use in the United States as well as the subsequent promoting of the drugs.<sup>64</sup> As such, the FDA has a critical role in the manufacturing and prescribing of OxyContin and other highly addictive opioids that are at the root of the current epidemic. The FDA's involvement begins as early as the identification of cellular targets and possible candidate compounds, the stage in which new drugs are being tested on animals.<sup>65</sup> Once compounds are found to be satisfactory in their preclinical trials, and warrant human testing, an Investigational New Drug Application is then filed with the FDA.<sup>66</sup> The application goes into effect 30 days after it has been reviewed by the FDA.<sup>67</sup> It is at this point that the FDA oversight becomes more essential and human clinical studies begin; human clinical studies are broken down into three phases.<sup>68</sup> Phase one typically uses just a few healthy human volunteers for clinical trials; phase two explores the results of the experimental drug on targets that have a specific condition of interest; and finally, phase three studies, which should take years to complete after enrolling hundreds to thousands of human subjects for testing the effects of the drugs on subjects with specific conditions over long periods of time.<sup>69</sup> However, according to a review of the phase three studies by the Committee on Pain Management and Regulatory Strategies—to address prescription opioid abuse—two-thirds of phase three studies actually last less than six months.<sup>70</sup> During the clinical phases the manufacturer is the entity that remains responsible for organizing and controlling the clinical trials, but

62. Sue Lindsey, *Judge Fines OxyContin Maker and 3 Executives*, THE WASH. POST (July 21, 2007), <http://www.washingtonpost.com/wpdyn/content/article/2007/07/20/AR2007072001714.html?noredirect=on>.

63. See *Opioid Overdose Crisis*, *supra* note 8.

64. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID Use 361–65 (2017); see also 7 U.S.C. § 2131 (2012) (for the application for an Investigational New Drug); *WHAT DOES FDA REGULATE?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last updated Mar. 28, 2018).

65. See NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *supra* note 6, at 361.

66. *Id.*

67. *Id.* at 362.

68. See 7 U.S.C. § 2131.

69. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *supra* note 6, at 362.

70. *Id.*

it will, and very often does, consult with a team of FDA experts in the field of pharmaceutical studies.<sup>71</sup>

At the completion of the clinical trials, the manufacturer will then file a New Drug Application with the FDA.<sup>72</sup> It is at this stage that a team of FDA experts in the field of pharmaceutical studies reviews the data to determine if the product is safe for consumer use in the United States.<sup>73</sup> There is a 60 day New Drug Application filing period during which time the FDA ensures that all of the data required by the FDA has been furnished.<sup>74</sup> The FDA, thereafter, will begin to review the data provided. The standard review period is ten months; however, if the drug appears to have therapeutic advances the ten month review period can be granted a six month priority review status.<sup>75</sup>

The standard of review that the FDA conforms to when analyzing the data is a risk-benefit assessment.<sup>76</sup> Leaving behind the traditional standard of review—a two prong test that incorporated safety and substantial evidence—the FDA now relies on whether the benefit of the approval for the particular interest sought will outweigh the risks associated with the drug’s use; this is referred to as evidence of efficacy.<sup>77</sup> During the review process the FDA can use review committees which are comprised of outside experts; ironically these committees are inclusive of one consumer representative and one non-voting industry representative.<sup>78</sup> This unquestionably creates a bias review of the drugs. A review of these advisory committees over a four-year span showed that the committees recommended approval of the new drugs 74% of the time, with the FDA granting the subsequent approval 79% of the time.<sup>79</sup>

Despite counter measures the FDA enacts to ensure the public’s safety, there are many obvious holes in the laws and provisions in place. For example, if a medication is proven effective, does that make the medication “more effective” than one already in circulation, or less harmful during long term use? Another fallacy in pain medication testing is that it is inclusive of only one type of pain (e.g. back pain) and not encompassing the entire population of end users that will be prescribed the medication for various degrees of pain due to significantly different reasons.<sup>80</sup> Furthermore, nearly all opioid medications are a derivative (i.e. reformulation) of an already tested and approved formula, and as such, the application process relies on published data and prior FDA findings in lieu of clinical trials.<sup>81</sup> This is a less rigorous way to get opioids into the marketplace without the expense and time of further clinical testing and the critical oversight of the FDA.

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71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *supra* note 6, at 362.

76. *Id.* at 363.

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.* at 364.

81. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *supra* note 6, at 363.

## B. Off-label Use

In accordance with 21 United States Code § 352, the FDA has the authority to regulate and prohibit any advertising that misleads the public and further to prohibit any false or misleading contents of a drug's label.<sup>82</sup> The Code of Federal Regulations prescribes the appropriate manner in which companies shall advertise and promote their products and sets forth the restrictions imposed on them in doing so.<sup>83</sup> These guidelines are to encourage a fair and accurate representation of a drug including its side effects and potential risks.<sup>84</sup>

However, after the FDA approves a new drug for use in the United States, a medical provider is essentially free to prescribe that medication for anything judged medically appropriate for the patient.<sup>85</sup> The use of medications for purposes other than what they were approved by the FDA for is typically referred to as "off-label" use.<sup>86</sup> This is especially true in the use of opioids.<sup>87</sup> In fact, any medical provider is justified in prescribing any medications he or she feels are appropriate to treat an ailment or injury, even if there has been no clinical trial and the FDA has not approved it for that specific use.<sup>88</sup> This creates another loop-hole in the system to get opioids into the hands of consumers without any intervention by the FDA. This outcome seems to be counterproductive to labeling guidelines and restrictions. It almost certainly contradicts the intent of the FDA to force manufacturers to represent their medications in a fair and accurate manner if manufacturers are unaware of the possible side-effects and repercussions of consuming the medications for uses other than those that the drugs were tested for.

## C. Ineffective Post-Approval Regulatory Decisions

Despite the FDA's attempt to use data recovered about opioid abuse in its post-approval regulatory decisions, opioids have continued to flood the streets of the United States.<sup>89</sup> As early as 2001, Purdue Pharma and the FDA teamed up to develop

82. See 21 U.S.C. § 352 (2012).

83. See 21 C.F.R. § 202.1 (2018).

84. *Id.*

85. *Understanding Unapproved Use of Approved Drugs "Off Label"*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForPatients/Other/OffLabel/default.htm> (last visited Nov. 5, 2018).

86. *Id.*

87. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *supra* note 6, at 369.

88. U.S. Food & Drug Admin., *supra* note 85. For example, the FDA states, "If your healthcare provider is thinking about using an approved drug for an unapproved use, you may want to ask your healthcare provider questions like these: What is the drug approved for? Are there other drugs or therapies that are approved to treat my disease or medical condition? What scientific studies are available to support the use of this drug to treat my disease or medical condition? Is it likely that this drug will work better to treat my disease or medical condition than using an approved treatment? What are the potential benefits and risks of treating my disease or medical condition with this drug? Will my health insurance cover treatment of my disease or medical condition with this drug? Are there any clinical trials studying the use of this drug for my disease or medical condition that I could enroll in?"

89. *Compare NEW SAFETY MEASURES ANNOUNCED FOR EXTENDED-RELEASE AND LONG-ACTING OPIOIDS*, U.S. FOOD & DRUG ADMIN, <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm> (last visited Nov. 5, 2018), with Eli Rosenberg and Nate Schweber, *Three Brooklyn Clinics, 6.3 Million Oxycodone Pills and 13 Indictments*, N.Y. TIMES (Apr. 7, 2017), <https://www.nytimes.com/2017/04/07/nyregion/brooklyn-clinics-oxycodone-indictments.html>.

a risk management plan which aimed to improve surveillance of the drugs and educate prescribers of the potential abuse risks.<sup>90</sup> Then, in 2013, the FDA announced “significant” remedial measures to enhance the safe and appropriate use of opioids.<sup>91</sup> The FDA has been implementing post-approval remedial measures nearly every year since.<sup>92</sup> Changes include, but are not limited to: labeling modifications, notifications of opioid misuse and abuse, and refinements to clinical studies.<sup>93</sup> More recently, the FDA began taking a more aggressive approach to countering the opioid crisis by approving the use of Lucemyra, a drug that is supposed to mitigate withdrawal symptoms.<sup>94</sup>

In the face of the efforts by the FDA to control the rampant use of opioids, the FDA has continued to approve new opioids for use.<sup>95</sup> Additionally, doctors have unremittently filled prescriptions for opioids, in some areas six times more prescriptions per person than other countries, and opioid use remains at an all-time high.<sup>96</sup> State and local governments are no longer sitting idly by amidst the wake of destruction.

#### IV. THE LEGAL ANALYSIS

##### A. Unfair and Deceptive Acts and Practices

The underlying claim amid the resulting law-suits against BigPharma is deception on part of the manufacturers, and their front groups, for downplaying the addictive nature of the drugs and misleading prescribers of the medications.<sup>97</sup> State and local governments are alleging violations of Unfair and Deceptive Acts and Practices

90. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *supra* note 6, at 371.

91. U.S. Food & Drug Admin., *supra* note 85, at 371.

92. *Id.*

93. *Id.*

94. Scott Gottlieb, Comm’r, U.S. Food & Drug Admin., Remarks at the Public Workshop on Strategies for Promoting the Safe Use and Appropriate Prescribing of Prescription Opioids (Feb. 15, 2018), <https://www.fda.gov/NewsEvents/Speeches/ucm596893.htm> (“[A]t [the] FDA, we still have a very important role to play. This is especially true when it comes to helping make sure that fewer new people become addicted through the medical use of these drugs. We have an important role to play in supporting the development of improved medication-assisted treatments for opioid dependence, which will expand treatment options for those currently addicted to opioids.”). We also have a role in helping support the development of new, safe and effective treatments for pain that don’t carry all the same risks of addiction as opioid medicines. And we have a role to play in interdicting illicit drugs that are pouring into our country, often through the mail.”); *see also* News Release, U.S. FOOD & DRUG ADMIN., FDA APPROVES THE FIRST NON-OPIOID TREATMENT FOR MANAGEMENT OF OPIOID WITHDRAWAL SYMPTOMS IN ADULTS (MAY16, 2018), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm607884.htm> (last visited Nov. 5, 2018).

95. *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm>, (last visited Nov. 5, 2018).

96. Susan Blumenthal & Emily Kaplan, *The Opioid Epidemic Is A National Public Health Emergency*, HUFFINGTON POST (Aug. 9, 2017), [https://www.huffingtonpost.com/entry/the-opioid-epidemic-a-national-public-health-emergency\\_us\\_598b0179e4b0f25bdfb320c9](https://www.huffingtonpost.com/entry/the-opioid-epidemic-a-national-public-health-emergency_us_598b0179e4b0f25bdfb320c9).

97. Tina Bellon, *U.S. State Lawsuits Against Purdue Pharma Over Opioid Epidemic Mount*, REUTERS, May 15, 2018, <https://www.reuters.com/article/us-usa-opioids-litigation/us-state-lawsuits-against-purdue-pharma-over-opioid-epidemic-mount-idUSKCN1IG2WU>.

(UDAP) statutes.<sup>98</sup> All 50 states have UDAP statutes in place to protect consumers from predatory and unscrupulous business practices.<sup>99</sup>

State UDAP statutes operate like § 5 of the Federal Trade Commission Act, which declares it a federal crime to engage in unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.<sup>100</sup> The difference among the various state UDAP statutes is the interpretation of the statute and the remedies available in each individual state. UDAP statutes vary immensely. Some state UDAP statutes may be interpreted very broadly and others are very narrow; for example, requiring knowledge and intent of the wrongdoing as a required element of the claim.<sup>101</sup> Many states have made it nearly impossible to succeed on a UDAP claim by granting exemptions to entire industries, capping the maximum recovery amounts to as low as \$1,000 in civil suits, and placing hindrances in the way of officials that have the authority to enforce UDAP laws.<sup>102</sup> As difficult as it can be to recover under violations of UDAP statutes, state and local governments, nonetheless, are bringing forth these very allegations against opioid manufacturers and are getting the green light to proceed.<sup>103</sup> It is reminiscent of the tobacco lawsuits of the early 1990s.

## B. The Tobacco Lawsuits vs. The Opioid Lawsuits

The tobacco lawsuits were initiated on the argument that the industry withheld pertinent information regarding the significant health risks of their products, and as a result, was responsible for a sweeping health crisis due to smoking-related illnesses and should be held accountable.<sup>104</sup> States began to band together, much like the current trend of cases against the opioid manufacturers, to bring claims against the tobacco industry to recover state funds lost treating illnesses related to tobacco products and to shift the burden of these expenses onto the tobacco companies that were reaping astronomical profits on their products.<sup>105</sup>

The counts in the complaints against the tobacco companies alleged consumer fraud—a violation of UDAP statutes—for decades of findings that the industry downplayed the risks associated with smoking, deceptively marketed their product,

98. See, e.g., Complaint at 42, *Florida v. Purdue Pharma L.P.*, No. 2018-CA-001438 (Fla. Cir. Ct. filed May 15, 2018); see also Third Amended Complaint at 293–94, 312–25, *City of Chicago v. Purdue Pharma L.P.*, No. 14-CV-04361 (N.D. Ill. filed Oct. 25, 2016).

99. Carolyn L. Carter, *Consumer Protection In the States, A 50-State Report on Unfair and Deceptive Acts and Practices Statutes*, NAT'L CONSUMER L. CTR., INC. 5 (Feb. 2009), [http://www.nclc.org/images/pdf/udap/report\\_50\\_states.pdf](http://www.nclc.org/images/pdf/udap/report_50_states.pdf).

100. 15 U.S.C. § 45(a) (2012); see also *Consumer Protection In the States, Appendix B, State-by-State Summaries of State UDAP Statutes*, NAT'L CONSUMER L. CTR. (January 10, 2009), <https://www.nclc.org/images/pdf/udap/analysis-state-summaries.pdf> (for examples of state by state summaries of UDAP statutes).

101. See, e.g., Carter, *supra* note 99.

102. *Id.*

103. Brendan Pierson, *Chicago Lawsuit Over Opioid Marketing Gets Green Light*, REUTERS, September 30, 2016, <https://www.reuters.com/article/health-opioids-idUSL2N1C6228> (“A lawsuit filed by the city of Chicago in federal court accusing five drug makers of promoting painkiller addiction through deceptive marketing can go forward.”).

104. Karen E. Meade, *Breaking through the Tobacco Industry's Smoke Screen State Lawsuits for Reimbursement of Medical Expenses*, 17 J. LEGAL MED. 113, 121–24 (1996).

105. *Id.* at 124–25.

and even covered up research that showed causation between cigarette smoking and cancer.<sup>106</sup>

Tobacco companies were widely successful battling individual consumers and states during the second wave of lawsuits in the late 1980s.<sup>107</sup> The defendants' success was attributed to the tobacco industry's defenses such as assumed risk and proclamations that tobacco was not harmful and that other environmental exposures and genetics caused the cancer and the ailments tied to the allegations.<sup>108</sup> Additionally, the defendants' asserted that federal laws regarding the advertising of their product preempted local state laws.<sup>109</sup> These defenses appeared bullet-proof until evidence began to surface that revealed that the tobacco industry was downplaying and, in fact, suppressing relevant risk factors about its products.<sup>110</sup> This became the turning point for state and local governments to succeed.

The third wave of suits in the late-1990s started to show signs of success for the plaintiffs.<sup>111</sup> The newly discovered evidence refuted the tobacco industry's defense that tobacco was not harmful to smokers, and as such, states had found their golden ticket.<sup>112</sup> By late-1998, 46 state attorneys along with 4 of the tobacco industry's largest corporations settled in what became known as the "Master Settlement Agreement."<sup>113</sup> This agreement placed restrictions on the marketing and advertising of tobacco products, set forth requirements that the tobacco companies pay annual sums of money to the states to compensate them for health care costs related to smoking, funded educational programs, and dissolved three of the biggest industry organizers.<sup>114</sup>

The opioid suit allegations are strikingly similar. State and local governments are claiming that opioid manufacturers, their dispensers, and distributors of the opioids were aware of the significant risks for abuse and misuse of the product as well as the high probability of addiction to the product; but they downplayed the information, withheld the truth, and did nothing to warn of the danger.<sup>115</sup> Another key similarity is that evidence has surfaced that Purdue Pharma knew of the significant abuse of OxyContin in the first few years after it debuted in 1996 and suppressed the information from the public.<sup>116</sup> Furthermore, in 2007 top officials of Purdue Pharma pleaded guilty to allegations that they misstated facts about the risks associated with

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106. *Id.* at 125–26.  
 107. Kathleen Michon, *Tobacco Litigation: History and Recent Developments*, NOLO, <https://www.nolo.com/legal-encyclopedia/tobacco-litigation-history-and-development-32202.html> (last visited July 2018).

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. Michon, *supra* note 107.

114. *Id.*

115. Benner & Hoffman, *supra* note 16.

116. Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES (May 29, 2018), <https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html>. (“a copy of a confidential Justice Department report shows that federal prosecutors investigating the company found that Purdue Pharma knew about ‘significant’ abuse of OxyContin in the first years after the drug’s introduction in 1996 and concealed that information.”).

OxyContin.<sup>117</sup> A settlement occurred only after a four-year investigation of the officials that led to a recommendation of felony charges against the company and those officials for conspiracy to defraud the United States.<sup>118</sup>

As foolproof as the opioid cases appear at first glance, there is a distinct difference between the tobacco law-suits and the current wave of opioid suits. The difference is the preemptive nature of the Supremacy Clause. The FDA's involvement in approving the opioids for use may have the potential to trump any state and local claims against the opioid industry.

### C. The Supremacy Clause and the FDA

The Supremacy Clause establishes that federal laws made pursuant to the Constitution of the United States of America constitute the supreme law of the land.<sup>119</sup> Recent efforts by organizations to use federal regulatory preemption in their favor against state legislative intent have the potential to greatly impact the outcome of opioid suits.<sup>120</sup> For instance, pharmaceutical companies are using a federal preemption defense, or what is otherwise referred to as the "FDA Compliance Defense," to counter products liability "failure to warn" allegations being brought against them.<sup>121</sup> The basis of the preemption defense is that since the FDA is a federal agency with authority to approve new drugs, keep continued surveillance on new and existing drugs, and force the removal of a drug from the market, organizations in compliance with FDA regulations should be afforded protection from state claims.<sup>122</sup>

The FDA also has the authority to bring criminal charges or civil penalties against manufacturers found to be in violation of the FDA mandates.<sup>123</sup> Pharmaceutical companies are attempting to shift the burden of responsibility onto the FDA for its role in approving and regulating the use of drugs in the United States marketplace.<sup>124</sup> Essentially, anything that conflicts with a federal regulation is unlawful and preempted by federal law; thus, in theory, compliance with federal regulations shields pharmaceutical companies from liability. Historically, federal preemption under these circumstances rarely proved successful in court because state laws that provide more rights to citizens than the Constitution are not a violation. However, *Dusek v. Pfizer, Inc.*, set the precedent for such claims to succeed.<sup>125</sup>

In February 2004, the *Dusek* court found that a state requiring suicide warnings to be placed on Zolofit medication, contrary to the FDA's determination that no warning was necessary, would be considered misbranding or mislabeling of a drug in

117. 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>.

118. Meier, *supra* note 116.

119. See *Supremacy Clause*, LEGAL INFO. INST., [https://www.law.cornell.edu/wex/supremacy\\_clause](https://www.law.cornell.edu/wex/supremacy_clause) (last visited Nov. 5, 2018).

120. Christopher R. J. Pace, *Supremacy Clause Limitations on Federal Regulatory Preemption*, 11 TEX. REV. L. & POL. 157, 158 (2006).

121. Jason T. Ams, *Reviving Lazarus: Status of the FDA Compliance Defense after Bates v. Dow Agrosciences and the New FDA Regulations*, 95 KY. L.J. 765, 765 (2006).

122. *Id.* at 768.

123. *Id.*

124. *Id.*

125. *Id.* at 771. See also *Dusek v. Pfizer, Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804, at \*9–10 (S.D. Tex. Feb. 20, 2004).

direct conflict with FDA mandates and, therefore, would be preempted.<sup>126</sup> This is not to say that FDA compliance is a fail-proof defense. Indeed, subsequent opinions citing the *Dusek* case disagreed with the *Dusek* holding.<sup>127</sup> Two later cases examining similar facts found that FDA regulation does not generally preempt state laws that provide stricter consumer protections.<sup>128</sup> The courts in these cases reasoned that the plaintiff was not seeking a product label change that warned of an actual “causal” effect between suicide and Zoloft, instead, the plaintiff was seeking a label change that provided for a mere “association” between the two; noting that by doing so, no tangible conflict existed<sup>129</sup> This proved to be a way for the court to bypass federal preemption by establishing differences between an actual scientifically proven side-effect of the drug and the direct and proven association of a specific side-effect with the drug.

A subsequent Texas court, hearing an allegation of misbranding against the Environmental Protection Agency (EPA) in violation of the Texas State Deceptive Trade Practices Act, did not address the issue of federal regulatory preemption specifically; however, instructions to the lower court did allude to a bar of a preemptive defense.<sup>130</sup> In that case, however, there were key differences that would prove more successful in barring a preemptive defense. For example, the EPA’s product-labeling guidelines under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) are much less stringent than those of the FDA’s regulations for prescription drug labeling, and FIFRA contained an express preemption provision protecting the EPA from tort claims.<sup>131</sup>

Another court, undermining the federal preemption defense, held that tort suits could be used as a facilitator in the progression of warning labels on products since there are not fixed and absolute warnings on most pharmaceutical products.<sup>132</sup> That court reasoned that drug warnings will need to change as reporting comes back regarding the drugs’ long-term effects on broad ranges of society.<sup>133</sup> A manufacturer’s accountability lies in the fact that it is in a superior position to have this first-hand knowledge and is better outfitted to modify its product warnings.<sup>134</sup>

With such disparity amongst the courts, it is still unsettled as to whether or not the FDA’s involvement with the approval and regulation of opioids will provide a cloak for manufacturers to hide behind. It is, however, still very likely that when factoring in reformulations and off-label uses of opioids, coupled with the rampant widespread health crisis, courts may find that manufacturers curtailed the FDA’s mandates, especially when the manufacturers get the first-hand reporting and feedback once a drug is disbursed for consumption. Courts more often than not look to legislative intent,<sup>135</sup> and although opioid manufacturers gained approval through

126. Ams, *supra* note 121, at 771.

127. *Id.* at 773.

128. *Id.* at 774. *See also* Cartwright v. Pfizer, Inc., 369 F. Supp. 2d 876 (E.D. Tex. 2005); Zikis v. Pfizer, Inc., No. 04 C 8104, 2005 WL 1126909, (N.D. Ill. May 9, 2005).

129. Ams, *supra* note 121, at 774.

130. *Id.* at 777. *See also* Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 431 (2005).

131. Ams, *supra* note 121, at 777.

132. *Id.* at 778.

133. *Id.*

134. *Id.*

135. Slever, *supra* note 1, at 968.



FDA compliance, the intent of those mandates is to ensure efficacy and safety of products entering mainstream society in the United States.<sup>136</sup> Allowing holes in the approval process to remain that are large enough for a full-blown health crisis to emerge is contrary to the federal legislative intent and certainly contrary to public policy.

## V. REMEDIAL MEASURES

### A. SSI and SSDI Benefits

At the forefront of necessary remedial measures is the reenactment of state-provided-benefits to treat individuals with addiction disorders. This is a disability that can no longer be overlooked. Addiction is not a choice. Taking away benefits from a disabled person based on the notion that giving an individual with disabilities benefits is keeping him or her disabled is an irrational concept.<sup>137</sup> The Americans with Disabilities Act (ADA) defines the term disability to mean: (1) a physical or mental impairment that substantially limits one or more life activities of such individual; (2) a record of such impairment; or (3) being regarded as having such an impairment.<sup>138</sup> Under the Act, a disability is substantially limiting if it is an impairment that is episodic or in remission [such that] it would substantially limit a major life activity when active.<sup>139</sup> Under the definition of the ADA, an addiction disability should be a recognized class. State-funded programs such as SSI and SSDI should support and assist with the living expenses, medical treatment, and reemployment of individuals with addiction disability. Currently the deficit of this nation treating addiction-related issues is in the billions of dollars annually. Is this the best case solution for individuals living with addiction disability and society as a whole? If this same amount of money was spent for actual treatment, housing, and medical care, the impact on society would be substantial. As it stands, the billions of dollars lost each year are going to treat overdoses, babies born with addiction disorders, HIV infections, hepatitis C infections, and other severe medical problems resulting from opioid drug use, in addition to litigating and paying for criminal offenses attributed to addiction issues, and recouping losses incurred by local entities.<sup>140</sup> This figure does not factor in the losses suffered by family and friends of individuals with addiction disorders or by the individuals with the disability themselves. Proper resources and sufficient assistance to individuals with addiction disorders would have likely lessened the impact of the wrongdoing by opioid manufacturers and cost local governments far less.

136. Ams, *supra* note 121, at 781.

137. Slever, *supra* note 1, at 957. (“The statutory change aimed to eliminate what Congress saw as the ‘perverse incentive’ of encouraging drug and alcohol abuse by providing benefits solely on the basis of addiction teach welfare recipients some skill or something instead of killing them on the installment plan.”).

138. 42 U.S.C. § 12102 (2012).

139. *Id.* § 12102(4)(B).

140. See, e.g., Press Release, THE WHITE HOUSE, *supra* note 12.

## B. FDA Mandates

FDA regulations on new drug approvals for Schedule II drugs and the subsequent prescribing of the approved drugs need to be amended. The current standards for reformulations and off-label use of Schedule II drugs are not in accordance with public policy. Essentially, the current mandates allow Schedule II drugs to enter the marketplace without satisfactory clinical testing and to be prescribed for purposes unevaluated by the FDA.<sup>141</sup> For example, in June 2017, the FDA requested that Endo Pharmaceuticals remove reformulated Opana ER (a brand name of a popular pain medication) from the market due to an assessment that the benefits of the opioid based pain medication no longer outweighed the risk.<sup>142</sup> The original formulation of this drug was FDA approved for use in 2006; it was thereafter reformulated and marketed in 2011, but it was not until early 2017 that the independent advisory committee for the FDA convened to discuss abuse patterns and other safety concerns linked to its use.<sup>143</sup> Endo Pharmaceuticals did not remove it from the market until July 2017.<sup>144</sup> This computes to over a decade of distribution and consumer use in the United States of the original formulation and approximately six years of marketing and consumer use of the reformulated drug prior to the FDA's intervention.

Federal regulations are promulgated with the intent to protect consumers; however, very little protection is provided if the end user is taking drugs that a manufacturer did not have to adequately test or that a medical provider prescribes for purposes other than what the FDA approved them for. In accordance with the current FDA regulations, consumers are in the hands of manufacturers and medical prescribers without real protection from the FDA. The FDA needs to tighten the approval process to include long-term clinical testing of reformulated Schedule II narcotics. Additionally, the FDA needs to mandate that a medical prescriber be required to get approval to prescribe a Schedule II drug for anything other than its intended, and FDA approved, use. This process should result in further scientific medical data, literature, and studies performed by the FDA's independent advisory committee, or a designated medical team, before administration.

Manufacturers as well as medical prescribers should be held accountable for the repercussions of the products they manufacture, distribute, and prescribe until stricter federal regulations can be implemented. Federal legislation should be enacted to mandate that states remove the caps on recovery for Schedule II drugs and allow a broader interpretation of UDAP statutes (i.e., allowing anyone wronged to be able to bring a claim). The disparity between the different states' UDAP statutes is too great.<sup>145</sup> Each state's UDAP statutes should be comparable to the next in bringing claims for proper consumer protection.

Legislative policies need to be implemented to limit the number and types of opioids, and opioid-related drugs, approved by the FDA and made available in the United States. Allowing more opiates to be disbursed while in the midst of an opioid

141. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *supra* note 6, at 363.

142. *Oxymorphone (Marketed as Opana ER) Information*, U.S. Food & Drug Admin., <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm562339.htm>, (last updated Feb. 6, 2018).

143. *Id.*

144. *Id.*

145. *See, e.g., Carter, supra* note 99.

epidemic is counterproductive. If newer or reformulated versions of opioids can evidence greater efficacy, then those drugs need to replace existing opioids in the United States, and not add to the supply.

### C. Marketing and Incentives

Proper marketing campaigns need to be customary and frequent to deter the use of opioids. The outreach of the marketing campaigns needs to be far stretched, as to reach all corners of economic disparities. Educational institutions need to be equipped with propaganda that elicits the danger of opioids as well as the prevalence of addiction disability. Medical facilities need to be required to place addiction disability propaganda and material concerning the dangers of opioid addiction in conspicuous and common areas of their practices.

Most importantly, every prescriber of opiates should be required to provide adequate medical screening for addiction disability for each patient. Federal funding incentives should be provided to state and local governments for monitoring, tracking, and recording of compliance of every medical prescriber of opioids and other highly addictive and misused Schedule II narcotics.

### D. State and Local Government Pain Management Prescribing Policies

Every state needs to be equipped with the same pain management and prescribing policies to prevent hub locations, “doctor shopping,” “pill mills,” and trafficking. In 2016, only 23 states and the District of Columbia had guidelines in place that required prescribing physicians to have continued education hours related to prescribing controlled substances, pain management, or substance abuse and misuse.<sup>146</sup> Additionally, in 2016, only 32 states required an informed consent and agreement for treatment, and only 36 states required a documented treatment plan that set forth the actual treatment and goals to be achieved.<sup>147</sup> According to this same study, in 2016 only 32 states and the District of Columbia required or recommended that prescribers perform a physical examination and substance use disorder assessment prior to prescribing a controlled substance.<sup>148</sup> Most distressing is that in 2016 only ten states had regulations in place that limited the amount of pills a doctor can dispense in an individual prescription of opioids.<sup>149</sup>

### E. Administration of Legal Damages Awarded

If state and local governments do prevail in the courtroom, this could mean a large amount of funds being recovered by communities to help battle the opioid epidemic. Suitable placement of legal damages can have a substantial impact on how our nation recovers from this health crisis. It is essential that the individuals with addiction disorders are treated first and foremost.

146. *Overview of State Pain Management and Prescribing Policies*, NAT'L ALLIANCE FOR MODEL STATE DRUG LAWS 5 (Jan. 2016), <http://www.namsdl.org/library/74A8658B-E297-9B03-E9AE6218FA0F05B0/>.

147. *Id.* at 12.

148. *Id.* at 18.

149. *Id.* at 34.

Funds need to be allocated to community outreach programs, in-patient and out-patient treatment centers, and medication assisted treatment (MAT) programs. MAT programs should be inclusive of state and private detention facilities to help reintegrate non-violent inmates, incarcerated for drug-related-offenses, back into society. One prominent example of a MAT program is the Vivitrol Pilot Program offered in Orange County, Florida, in which 4,821 heroin users were identified in the correctional facility, 953 inmates were screened for interest, 92 qualified for the treatment, and 36 received the drug Vivitrol, which is used to counter addiction.<sup>150</sup> With a sufficient budget, this program could be expanded substantially. With adequate budgets, every state would have the potential to offer MAT programs in and outside of the criminal justice system.

Most importantly, every prescribing physician of opioids should be required to participate in MAT programs to counter the possible misuse and abuse of opioids. Funding in the form of tax breaks for medical prescribers to offer such programs would prove beneficial for both the provider and the end user.

## VI. CONCLUSION

In conclusion, the purpose of this article is to bring awareness to addiction disability and the role that the opioid epidemic has on the increasing number of individuals with addiction disorders; and moreover, to bring awareness to the changes that need to be considered to counter the issues the United States is facing today and to prevail in preventing future epidemics. State and local governments alike have the legal system as a tool to use to combat this issue and have the potential to recover enormous amounts of money. With precise budgeting as well as accurate placement and administration of damages awarded, possibilities for change in the way individuals with addiction disabilities are medically treated and the benefits they can recover will be immense, as will be the remuneration it will provide to communities as a whole.

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<sup>150</sup> Cornita A. Riley, Chief, Orange Cty. Corr. Dep't, Vivitrol Pilot & Other Substance Abuse Programs Presentation (June 2, 2017), <https://www.orangecountyfl.net/Portals/0/Library/Families-Health-Social%20Svcs/docs/OCCD%20Presentation.pdf>.