

# The Opioid Crisis and the Wrongful Conduct Rule: Does It Matter Who's to Blame?

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## ABSTRACT

As our nation continues to face the devastating opioid crisis, there is a desperate need to find a solution to the epidemic that is killing an average of 128 people per day. In an effort to hold someone liable for this deadly epidemic, some jurisdictions have abandoned the wrongful conduct rule, allowing opioid-addicted plaintiffs to sue their healthcare providers for contributing to their addiction. The focus of this paper is on the shortcomings of abandoning the wrongful conduct rule and how there are more effective strategies to overcoming the opioid crisis which will address the root of the problem.

## INTRODUCTION

The rampant misuse and overdose of opioids poses a significant issue in the United States, giving rise to a devastating opioid crisis that has undoubtedly progressed into an opioid epidemic. In 2017 alone, over 47,000 people died due to opioid overdoses.<sup>1</sup> Compared to the data from 2016, the number of deaths attributed to opioid overdoses increased by more than 5,000.<sup>2</sup> Since 2015, drug overdose deaths due to opioids, particularly synthetic opioids other than Methadone and heroin, have risen drastically.<sup>3</sup> Because of the substantial impact both prescription and illicit opioids have on public health due to increasing number of deaths and healthcare costs,<sup>4</sup> in October 2017, Eric D. Hargan, the Acting Secretary of the U.S. Department of Health and Human Services, officially declared the opioid crisis a national public health emergency on

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<sup>1</sup> *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> [<https://perma.cc/QA5B-JM6R>] (last updated Jan. 2019).

<sup>2</sup> Lawrence Scholl, Puja Seth, Mbabazi Kariisa, Nana Wilson & Grant Baldwin, *Drug and Opioid-Involved Overdose Deaths—United States, 2013–2017*, 67 MORBIDITY & MORTALITY WKLY. REP. 1419, 1420 (2019), <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm675152e1-H.pdf> [<https://perma.cc/YH5P-E2FJ>].

<sup>3</sup> Holly Hedegaard, Arialdi M. Miniño & Margaret Warner, *NCHS Data Brief No. 329*, NAT'L CTR FOR HEALTH STAT., at 4 (2018), <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf> [<https://perma.cc/J7EB-QPTH>].

<sup>4</sup> *Opioid Overdose Crisis*, *supra* note 1.

behalf of President Trump.<sup>5</sup> Taking into consideration the disastrous impact of the opioid crisis, there is a desperate need to find a solution for an epidemic that is killing an average of 128 people per day in the United States.<sup>6</sup>

Since the declaration of a national public health emergency in 2017, some commentators have highlighted the importance of recognizing addiction as a medical condition. These commentators also have recommended allowing opioid-addicted plaintiffs to sue their pharmacists and doctors for contributing to their addiction, even though those claims are traditionally barred by the wrongful conduct rule.<sup>7</sup> But abandoning the wrongful conduct rule would flood the court system with claims that could potentially hold healthcare professionals civilly, or even criminally, liable for exercising their professional judgment and discretion. As a practicing community pharmacist studying law, it is evident what the outcome will be by opening up opioid-related litigation against healthcare professionals. It will merely shift the blame between patients, pharmacists, and doctors, creating distrust between the three parties who need to work together not only to determine an appropriate method of pain management, but also to treat the underlying issue of substance use disorder and addiction.

As the devastating opioid crisis continues to affect Americans nationwide, multiple opioid manufacturers and distributors have attempted to evade liability with tactics such as delaying trials.<sup>8</sup> In an effort to hold *someone* liable for this deadly epidemic, the public has resorted to bringing lawsuits against doctors, pharmacists, and others in the healthcare system, drawing the focus away from the opioid manufacturers and distributors.<sup>9</sup> This has had the understandable triggering effect of causing major players in the healthcare system to begin pointing fingers at each other for causing the health crisis via litigation.<sup>10</sup>

Fundamentally, it is insignificant who is ultimately to blame for the opioid crisis between the prescribers, the dispensers, and the misusers. Rather than wasting valuable resources determining who is more at fault amongst these “bad players” via litigation, the more effective way to discourse the opioid crisis is to (1) prevent opioid-related deaths; (2) address the underlying issue of opioid addiction, such as by increasing access to Naloxone and increasing insurance coverage of Medication-Assisted

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<sup>5</sup> *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, U.S. DEP'T HEALTH & HUM. SERVS. (Oct. 26, 2017), <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html> [https://perma.cc/SP38-TE84].

<sup>6</sup> *Opioid Overdose Crisis*, *supra* note 1.

<sup>7</sup> *Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo Cty.*, 773 S.E.2d 627, 636 (2015).

<sup>8</sup> Letitia James, *Opioid Manufacturers and Distributors Denied in Effort to Push Back Opioid Trial*, N.Y. ST. OFF. ATT'Y GEN. (Mar. 4, 2020), <https://ag.ny.gov/press-release/2020/opioid-manufacturers-and-distributors-denied-effort-push-back-opioid-trial> [https://perma.cc/N62A-U953].

<sup>9</sup> See generally Joyce Frieden, *Don't Just Blame Drug Companies for the Opioid Crisis . . .*, MEDPAGE TODAY (Apr. 14, 2019), <https://www.medpagetoday.com/meetingcoverage/acp/79220> [https://perma.cc/V7J8-S4Z4]; see also Maia Anderson, *18 Recent Legal Actions Involving Pharmacists, Drugmakers*, BECKER'S HOSP. REV. (June 18, 2020), <https://www.beckershospitalreview.com/pharmacy/18-recent-legal-actions-involving-pharmacists-drugmakers.html> [https://perma.cc/B2QR-PCTR].

<sup>10</sup> See generally Lenny Bernstein, *Major Drugstore Chains Sue Doctors in Sprawling Federal Opioid Case*, WASH. POST, Jan. 8, 2020, [https://www.washingtonpost.com/health/major-drugstore-chains-sue-doctors-in-sprawling-federal-opioid-case/2020/01/07/3ac9cd70-317d-11ea-9313-6c8a89b1b9fb\\_story.html](https://www.washingtonpost.com/health/major-drugstore-chains-sue-doctors-in-sprawling-federal-opioid-case/2020/01/07/3ac9cd70-317d-11ea-9313-6c8a89b1b9fb_story.html) [https://perma.cc/UQ9A-XR26].

Therapy; and (3) increase education within the healthcare community of proper prescribing practices.

## I. BACKGROUND

This section provides an overview of how opioids became such a readily obtainable drug for non-cancer patients, how the government attempted to circumvent the issue by re-classifying a heavily used opioid to increase its regulation, and how there is the complex underlying issues of addiction and dependency that complicates many attempts to regulate opioids.

### A. Pain and Opioids

In the 1980s, opioids became the standard treatment for moderate to severe pain in cancer patients.<sup>11</sup> Then in 1990, the World Health Organization published guidelines on cancer pain treatment, which included recommendations of opioids.<sup>12</sup> From 1996 to 2000, opioid manufacturers took advantage of the increased recognition of opioid use and developed targeted marketing plans to influence physicians who had large numbers of chronic pain patients to prescribe their products to non-cancer pain patients by offering coupons for free limited-time prescriptions.<sup>13</sup> Then in 2001, the Joint Commission introduced new standards for pain assessment and management to address undertreated pain, which said that “[p]ain is considered a ‘fifth’ vital sign.”<sup>14</sup> In 2002, however, the Joint Commission changed this language to say “[p]ain used to be considered the fifth vital sign.”<sup>15</sup> Still, opioid manufacturers continued to aggressively advertise and deviously market the use of their products, misrepresenting the risk of addiction particularly in the use of opioids in chronic, non-cancer pain.<sup>16</sup> It was not until 2016 that the Centers for Disease Control and Prevention published guidelines for opioid prescribing and monitoring.<sup>17</sup>

### B. Classification of Opioids

Congress enacted the Controlled Substances Act of 1970 in an effort to classify all controlled substances, both prescription and illicit street drugs, into one of five established Schedules based on a drug’s potential for abuse, its recognized medical

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<sup>11</sup> Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL’Y 231, 266–67 (2008).

<sup>12</sup> *Id.*

<sup>13</sup> Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 222 (2009).

<sup>14</sup> DAVID W. BAKER, THE JOINT COMM’N, THE JOINT COMMISSION’S PAIN STANDARDS: ORIGINS AND EVOLUTION 5–6 (2017), [https://www.jointcommission.org/assets/1/6/Pain\\_Std\\_History\\_Web\\_Version\\_05122017.pdf](https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf) [<https://perma.cc/WRJ7-FWSK>].

<sup>15</sup> *Id.*

<sup>16</sup> Van Zee, *supra* note 13, at 222–23; *see also* U.S. FOOD & DRUG ADMIN., TIMELINE OF SELECTED FDA ACTIVITIES & SIGNIFICANT EVENTS ADDRESSING OPIOID MISUSE & ABUSE 3, <https://www.fda.gov/media/106638/download> [<https://perma.cc/QSG4-K24Q>] (2020) (citing that in 2003, FDA issued a Warning Letter to OxyContin’s manufacturer for misleading advertisements, which left out and minimized the harms associated with its use and promoted its use beyond what has been proven safe and effective).

<sup>17</sup> Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 MORBIDITY & MORTALITY WKLY. REP. 1 (Mar. 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf> [<https://perma.cc/QF2R-T4WS>].

benefits, and the level of dependency that could result from its abuse.<sup>18</sup> Schedule I controlled substances, which include illicit street drugs, have “a high potential for abuse,” “no currently accepted medical use in treatment,” and “a lack of accepted safety for the use of the drug . . . under medical supervision.”<sup>19</sup> In comparison, Schedule II controlled substances have “a high potential for abuse,” “a currently accepted medical use in treatment,” and their “abuse may lead to severe psychological or physical dependence.”<sup>20</sup> On the other hand, Schedule III controlled substances have a lower potential for abuse, but may result in “moderate or low physical dependence or high psychological dependence.”<sup>21</sup>

There are specific rules and regulations that the Attorney General must follow when adding a controlled substance to a Schedule or transferring between Schedules.<sup>22</sup> In 2014, in response to a petition made by the Department of Health and Human Services (HHS), the Drug Enforcement Administration published a final ruling rescheduling Hydrocodone, the most frequently prescribed opioid in the United States at the time,<sup>23</sup> from Schedule III to Schedule II.<sup>24</sup> The major factors that influenced HHS’s final ruling was the high abuse and addiction potential of Hydrocodone combination products.<sup>25</sup> The abundant availability, the relative ease of access, and the perceived safety of Hydrocodone suggested by the opioid manufacturers caused every age, ethnic, and economic group to be affected.<sup>26</sup>

### C. Opioid Addiction and Dependency

The American Psychiatric Association describes addiction as “a complex condition, a brain disease that is manifested by compulsive substance use despite harmful consequence” and that “[p]eople with addiction . . . have an intense focus on using certain substance(s) . . . to the point that it takes over their life.”<sup>27</sup> Those suffering from addiction seek the effects of a particular substance for several reasons: to feel good, to feel better, to do better, out of curiosity, or in response to social pressure.<sup>28</sup> Addicts may be aware of their problem, but are often unable to stop due to intense cravings for the substance.<sup>29</sup> Opioid Use Disorder is a subset of Substance Use Disorder that can simply be described as an addiction to opioids. It is recognized as a disorder in the

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<sup>18</sup> 21 U.S.C. § 812 (2018).

<sup>19</sup> 21 U.S.C. § 812(1) (2018).

<sup>20</sup> 21 U.S.C. § 812(2) (2018).

<sup>21</sup> 21 U.S.C. § 812(3) (2018).

<sup>22</sup> 21 U.S.C. § 811(a) (2015).

<sup>23</sup> DRUG ENFORCEMENT ADMIN., HYDROCODONE (2019), [https://www.deadiversion.usdoj.gov/drug\\_chem\\_info/hydrocodone.pdf](https://www.deadiversion.usdoj.gov/drug_chem_info/hydrocodone.pdf) [<https://perma.cc/9CHK-RWRP>].

<sup>24</sup> Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49661, 49662 (Aug. 22, 2014) (to be codified at 21. C.F.R. pt. 1308).

<sup>25</sup> *Id.*

<sup>26</sup> DRUG ENFORCEMENT ADMIN., *supra* note 23.

<sup>27</sup> Hector Colon-Rivera & Alëna Balasanova, *What Is a Substance Use Disorder?*, AM. PSYCHIATRIC ASS’N (Dec. 2020), <https://www.psychiatry.org/patients-families/addiction/what-is-addiction> [<https://perma.cc/Q8LV-QBQ7>].

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

DSM–5, the most current *Diagnostic and Statistical Manual of Mental Disorders*, which is a manual used by clinicians, such as psychiatrists, to accurately diagnose mental disorders.<sup>30</sup>

Every person has a different susceptibility to developing a substance use disorder or addiction. Not all people develop addiction, but some develop addiction to certain substances after even a single use of the substance.<sup>31</sup> The more risk factors a person has, the greater chance taking a drug will lead to addiction, even after just the first dose.<sup>32</sup> Addiction can lead to a dependence on the substance, which further perpetuates its abuse. The main difference between addiction and dependence is that “addiction encompasses both a mental and physical reliance on a given substance,” while dependence refers to more of the physical dependence “characterized by the symptoms of tolerance and withdrawal.”<sup>33</sup> Therefore, a person with addiction can also exhibit signs of physical dependence, but not all persons who are physically dependent have addiction.<sup>34</sup>

## II. CHANGING ROLE OF THE PHARMACIST

### A. *The Pharmacist’s Duty of Care*

In California, a pharmacist has a duty to dispense prescription drugs that are legally prescribed for that patient, and if a prescription is legally prescribed, a pharmacist must not obstruct a patient from obtaining that prescription.<sup>35</sup> There are only limited circumstances when a pharmacist may refuse to fill a prescription. For example, federal statutes provide health care professionals with conscience protections, which allows them to refuse to perform certain health care services on religious or moral grounds.<sup>36</sup> California’s equivalent to the conscience clause allows a pharmacist to refuse to fill a lawful prescription based on “ethical, moral, or religious grounds,” subject to additional requirements.<sup>37</sup>

Pharmacists commonly exercise this right when faced with having to dispense prescriptions for emergency contraceptives, which may be against their own personal

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<sup>30</sup> *Id.* See also DSM–5: *Frequently Asked Questions*, AM. PSYCHIATRIC ASS’N, <https://www.psychiatry.org/psychiatrists/practice/dsm/feedback-and-questions/frequently-asked-questions> [<https://perma.cc/Z5VP-4QJR>] (last visited Oct. 18, 2019).

<sup>31</sup> Destiny Bezruczyk, *Can You Become Addicted to Heroin on the First Try?*, ADDICTIONCENTER, <https://www.addictioncenter.com/community/addicted-heroin-first-try/> [<https://perma.cc/GT3Y-VXSN>] (last edited Nov. 20, 2020).

<sup>32</sup> *Id.*; NAT’L INST. ON DRUG ABUSE, DRUGS, BRAINS, AND BEHAVIOR: THE SCIENCE OF ADDICTION 6 (2020), <https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/soa.pdf> [<https://perma.cc/N72X-4UJU>].

<sup>33</sup> Jeffrey Juergens, *Addiction vs. Dependence*, ADDICTIONCENTER, <https://www.addictioncenter.com/addiction/addiction-vs-dependence/> [<https://perma.cc/ZQ5U-WM7N>] (last edited Nov. 30, 2020).

<sup>34</sup> *Id.*

<sup>35</sup> CAL. BUS. & PROF. CODE § 733 (2019).

<sup>36</sup> *Conscience Protections for Health Care Providers*, OFF. FOR CIVIL RIGHTS, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/conscience/conscience-protections/index.html> [<https://perma.cc/E8F7-DC2A>] (last edited Mar. 22, 2018).

<sup>37</sup> CAL. BUS. & PROF. CODE § 733(b)(3) (2019).

beliefs.<sup>38</sup> But even when a pharmacist seeks to exercise their right based on ethical, moral, or religious grounds, the statute's requirements make it challenging for a pharmacist to lawfully refuse to fill the prescription.<sup>39</sup> Hence, the minimum duty of care required by a pharmacist before the 1990s was to merely ensure clerical accuracy before dispensing a prescription.

In 1990, Congress enacted the Omnibus Budget Reconciliation Act, establishing the minimum standard of care for pharmacists.<sup>40</sup> This Act required a more active role from the pharmacist, imposing a duty to warn of a drug's potential harm and side effects to patients.<sup>41</sup> This meant that although a pharmacist correctly fills a prescription that is lawfully prescribed by a doctor, the pharmacist can still be found liable if they do not warn the patient of potential harm.<sup>42</sup> This federal Act expanded the clinical role of a pharmacist and required pharmacists to be more than mere dispensers of drugs.

### *B. Corresponding Responsibility Doctrine*

In August 2013, the pharmacist's duty of care continued to evolve when the California State Board of Pharmacy made a precedential decision to revoke a pharmacist's license for failing to exercise the "corresponding responsibility" placed on pharmacists as required by California Health and Safety Code § 11153(a), which mirrors the language of Title 21 Code of Federal Regulations § 1306.04.<sup>43</sup> In *Accusation Against Pacifica Pharmacy*, the precedential case, the Board of Pharmacy found that pharmacist Thang Tran engaged in unprofessional conduct by failing to exercise the "corresponding responsibility . . . to determine the legitimate medical purpose of controlled substance prescriptions before dispensing."<sup>44</sup>

With regard to controlled substances, the Board of Pharmacy investigation revealed that the pharmacist believed merely confirming the script with the prescriber satisfied his role in verifying the legitimacy of the prescription.<sup>45</sup> The Board of Pharmacy found that a pharmacist must exercise their professional judgment when dispensing controlled substance prescriptions, and this required more than simply ensuring clerical accuracy.<sup>46</sup> The Board's Decision and Order identified "red flags" that

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<sup>38</sup> See Janice Hopkins Tanne, *Emergency Contraception Is under Attack by US Pharmacists*, 330 *BMJ* 983 (2005), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC557172/pdf/bmj3300983a.pdf> [<https://perma.cc/EGM4-99CE>].

<sup>39</sup> CAL. BUS. & PROF. CODE § 733(b)(3) (2019).

<sup>40</sup> Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 1927(g)(2)(A)(ii), 104 Stat. 1388-1, 1388-152.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Accusation Against Pacifica Pharmacy*, No. 3802, slip op. at 1 (Cal. Bd. of Pharmacy Aug. 9, 2013), <https://www.pharmacy.ca.gov/enforcement/fy1011/ac103802> [<https://perma.cc/MC93-5KPP>] [hereinafter *Pacifica Pharmacy*]; see also CAL. HEALTH & SAFETY CODE § 11153(a) (West 2020) ("A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. [A] corresponding responsibility rests with the pharmacist who fills the prescription.").

<sup>44</sup> *Pacifica Pharmacy*, *supra* note 43.

<sup>45</sup> *Id.* at 2.

<sup>46</sup> *Id.*

pharmacists are now required to consider before dispensing a controlled substance prescription.<sup>47</sup>

As a result of the precedential decision, pharmacists in California now have a corresponding responsibility to further inquire whenever they believe that a prescription is not issued for a legitimate medical purpose.<sup>48</sup> Although the California Board of Pharmacy came to its decision by interpreting California Health and Safety Code § 11153(a), the language is identical to the Code of Federal Regulations § 1306.04(a), promulgated by the U.S. Drug Enforcement Administration, and therefore the decision is persuasive in all jurisdictions.<sup>49</sup> Now, pharmacists not only have a right to deny a prescription based on their professional judgment if it does not seem legitimate, but a corresponding responsibility to do so.<sup>50</sup>

### III. WRONGFUL CONDUCT RULE

This Part covers the wrongful conduct rule in jurisdictions that adopt and abandon it, the respective cases that analyze the rule, and the effect and flaws of adopting or abandoning the rule.

#### A. Majority Jurisdictions

While not every jurisdiction has directly addressed the issue, a majority of the states that have addressed the issue recognize the wrongful conduct rule as an affirmative defense to medical negligence claims.<sup>51</sup> At least thirteen other jurisdictions have adopted the common law rule “to bar recovery in claims for drug addiction.”<sup>52</sup> More specifically, in claims where a plaintiff attempts to recover for injuries received in the course of their own wrongdoing, the wrongful conduct rule applies to bar their claim.<sup>53</sup> The rationale for supporting the wrongful conduct rule is not that the defendants are *right* and deserve to be shielded from litigation, but that the plaintiffs bringing the claim are *wrong* and have contributed to their own injury, and thus must not gain profit for the wrongful act or shift liability to another.<sup>54</sup>

Although the opioid crisis was not declared a public health emergency until 2017, litigation involving opioid-addicted plaintiffs and dispensing pharmacists or pharmacies pre-dates that by decades. Typically, in cases involving these parties, courts have held that a plaintiff cannot recover damages against defendant pharmacists and pharmacies where the plaintiff himself wrongfully obtained, abused, or otherwise

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<sup>47</sup> *Id.* (including, but not limited to, irregularities on the face of the prescription itself, nervous patient demeanor, age or presentation of patient, cash payments, requests for early refills, and long distances traveled from patient’s home to the prescriber’s office or pharmacy).

<sup>48</sup> CAL. BD. OF PHARMACY, A PHARMACIST HAS A CORRESPONDING RESPONSIBILITY, [https://www.pharmacy.ca.gov/publications/corresponding\\_responsibility.pdf](https://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf) [<https://perma.cc/F572-SDPV>] (last visited Sept. 8, 2020)

<sup>49</sup> 21 C.F.R. § 1306.04 (West 2020).

<sup>50</sup> *Id.*

<sup>51</sup> See David B. Brushwood, *West Virginia Rejects Wrongful Conduct Rule in Pharmacy Case*, AM. PHARMACISTS ASS’N (July 1, 2015), <https://www.pharmacist.com/west-virginia-rejects-wrongful-conduct-rule-pharmacy-case> [<https://perma.cc/6HQR-MH3L>].

<sup>52</sup> *Id.*

<sup>53</sup> *Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo Cty.*, 235 W. Va. 283, 295 (2015).

<sup>54</sup> *Id.*

misused the prescription opioid drug.<sup>55</sup> The following two cases are examples of jurisdictions that considered the application of the wrongful conduct rule to bar the plaintiff's recovery.

*I. Orzel v. Scott Drug Co.*

The Michigan Supreme Court held that a plaintiff who illegitimately obtains a prescription for a controlled substance through misrepresentation cannot recover damages from a pharmacy for contributing to his addiction by dispensing the medication.<sup>56</sup> In *Orzel v. Scott Drug Co.*, the plaintiff filed a negligence action against several defendants including Scott Drug Co., the pharmacy that filled his prescription for Desoxyn.<sup>57</sup> In his complaint, the plaintiff claimed that he became physically and psychologically addicted to Desoxyn,<sup>58</sup> a Schedule II controlled substance medication that contains methamphetamine, which is indicated for the treatment of a particular type of obesity.<sup>59</sup> He further claimed that as a result of this addiction, he suffered from hallucinations and mental illness including paranoid schizophrenia.<sup>60</sup>

The plaintiff alleged that Scott Drug Co. breached its duty when the pharmacy dispensed Desoxyn to him without asking for identification or allowing enough time in between fills. But he admitted in his deposition that he used Desoxyn even before the pharmacy ever filled the prescription for him, and “testified that he knew that his purchase and use of Desoxyn was illegal.”<sup>61</sup> His consumption of the prescription opioid drastically increased from one tablet a day in November 1980 to around ten tablets a day by June 1981.<sup>62</sup> To satisfy his addiction, the plaintiff misrepresented to the physicians at a weight loss clinic that he wanted to lose weight so that the doctors would prescribe him Desoxyn for weight control.<sup>63</sup> The pharmacy did not fill the plaintiff's prescriptions until August 1981.<sup>64</sup> To make matters worse, the plaintiff even filled some of his prescriptions at other pharmacies and continued to purchase the drug illegally from street sources.<sup>65</sup>

The trial court initially denied the pharmacy's motions to have the case dismissed, but after the plaintiff testified to illegally obtaining Desoxyn, the trial court took the renewed motion for summary judgment under advisement.<sup>66</sup> The trial court moved forward and instructed the jury to apply comparative negligence principles to determine damages.<sup>67</sup> The jury found the defendant pharmacy negligent, but also

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<sup>55</sup> See, e.g., *Pappas v. Clark*, 494 N.W.2d 245 (Iowa Ct. App. 1992).

<sup>56</sup> *Orzel v. Scott Drug Co.*, 449 Mich. 550, 569–570 (1995).

<sup>57</sup> *Id.* at 552.

<sup>58</sup> *Id.* at 553.

<sup>59</sup> U.S. FOOD & DRUG ADMIN., DESOXYN® (rev. Oct. 2013), [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/005378s028lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/005378s028lbl.pdf) [<https://perma.cc/73UG-Y8JQ>].

<sup>60</sup> *Orzel*, 449 Mich. at 553.

<sup>61</sup> *Id.* at 554.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 555.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at 556.

<sup>67</sup> *Id.*

found the plaintiff to be 50% negligent, thus reducing the verdict by half to \$1.9 million.<sup>68</sup> The defendant moved for a judgment notwithstanding the verdict, and the trial court granted the motion because the plaintiff's illegal acts barred his claim.<sup>69</sup> The lower appellate court reversed this decision, finding that "John Orzel's illegal conduct should not [bar his] claim and that comparative negligence principles should apply to determine the extent of [his] potential recovery."<sup>70</sup>

The Michigan Supreme Court reversed the lower appellate court's decision, holding that the plaintiff's claim for recovery was barred because none of the limitations or exceptions to the wrongful conduct rule apply.<sup>71</sup> The court clarified that the wrongful conduct rule is just a general rule, and it has its limitations and exceptions which takes into consideration: (1) the nature of the wrongful conduct; (2) causation; (3) the varying degrees of culpability; and (4) any statutory basis for recovery.<sup>72</sup> These limitations and exceptions are summarized below.

One limitation to the wrongful conduct rule is that the plaintiff's illegal conduct must be serious. Just because a plaintiff engages in illegal conduct does not necessarily mean that his claim is automatically barred.<sup>73</sup> The plaintiff's conduct must be prohibited under a penal or criminal statute for the wrongful conduct rule to apply. But if the illegal act is simply a violation of a safety statute, then the violation does not rise to the level of seriousness that warrants the application of the wrongful conduct rule.<sup>74</sup> Another limitation to the wrongful conduct rule is that there must be a causal connection between the plaintiff's illegal conduct and the plaintiff's asserted damages.<sup>75</sup> A plaintiff's injury "must be traceable to his own breach of the law and such breach must be an integral and essential part of his case" to bar his recovery.<sup>76</sup>

One exception to the wrongful conduct rule is that a plaintiff can recover against the defendant if the defendant's culpability is greater than that of the plaintiff.<sup>77</sup> Another exception is that where a statute explicitly or implicitly allows for a plaintiff to recover damages for injuries, the plaintiff's claim is not barred.

To summarize, Michigan adopted the wrongful conduct rule, and after reconsideration, its Supreme Court sustained the application of the rule to bar a plaintiff's recovery in claims seeking damages for drug addiction, even when the defendant contributed equally in the illegal activity as determined by the jury verdict.<sup>78</sup>

## 2. *Inge v. McClelland*

The United States District Court for the District of New Mexico held that the wrongful conduct rule bars a plaintiff who admits his own illegal conduct from

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<sup>68</sup> *Id.* at 557.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 561–70.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.* at 564.

<sup>76</sup> *Id.* at 565.

<sup>77</sup> *Id.* at 569.

<sup>78</sup> *Id.* at 550; *see also id.* at 558.

recovering damages.<sup>79</sup> In *Inge v. McClelland*, the plaintiff sued a pharmacist and his pharmacy for allegedly filling improper and dangerous amounts of opioids, claiming damages under federal and New Mexico State law.<sup>80</sup>

In his complaint, the plaintiff alleged that a nurse practitioner proposed a deal where the nurse practitioner would prescribe a large amount of tramadol, a prescription narcotic for pain, so long as the plaintiff would share half the quantity with the nurse practitioner.<sup>81</sup> The original pharmacy refused to fill the plaintiff's tramadol prescription due to the large quantity.<sup>82</sup> The plaintiff then took the prescription to the defendant's pharmacy, who dispensed the medication despite allegedly knowing that the narcotic prescription was improper for a healthy person.<sup>83</sup> The plaintiff alleged that as a result of obtaining the powerful narcotic dispensed by the defendant pharmacy, he became addicted to the drug and suffered many losses.<sup>84</sup>

The plaintiff asserted a claim for damages under federal law and claims for negligence and breach of fiduciary duty under state tort laws.<sup>85</sup> For the federal law claim, the district court held that the defendant met its burden of proving its defense and the case must be dismissed.<sup>86</sup>

As for the state tort law claims, the district court held that the plaintiff was barred from recovery under the wrongful conduct rule.<sup>87</sup> The court found that because the plaintiff admitted to scheming with the nurse practitioner to present illegitimate prescriptions to a pharmacy and to then share the medications, the conduct was illegal under both state and federal law.<sup>88</sup> Since New Mexico has adopted the wrongful conduct rule, and since the plaintiff was at least equally responsible for causing his injuries, the wrongful conduct rule barred his claims.<sup>89</sup>

To summarize, New Mexico also reconsidered and sustained the application of the wrongful conduct rule when the plaintiff admitted to illegal activity either under state or federal law and was at least equally responsible for his harm.

### 3. *The Effect and Flaws of the Majority Rule*

The effect of the wrongful conduct rule is that plaintiffs who are at least equally culpable for their illegal conduct cannot recover for actual harm resulting from their addiction. This seems especially harsh when considering that their addiction may not have been a matter of free choice and that they could have become addicted after just a single use of a substance.<sup>90</sup> It also seems unfair when considering there are doctors, clinics, and pharmacies that are prescribing and dispensing narcotics for non-medical

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<sup>79</sup> *Inge v. McClelland*, 257 F. Supp. 3d 1159, 1167 (D.N.M. 2017).

<sup>80</sup> *Id.* at 1161.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* at 1162.

<sup>86</sup> *Id.* at 1165.

<sup>87</sup> *Id.* at 1167.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 1168.

<sup>90</sup> *See supra* Part I.C.

reasons, colloquially referred to as “pill mills,” contributing to a nationwide problem of prescription drug abuse and diversion while escaping liability.<sup>91</sup> For these reasons, certain jurisdictions have rejected the wrongful conduct rule to address a much larger public policy issue of penalizing healthcare professionals contributing to the opioid crisis.<sup>92</sup>

### B. *Minority Jurisdictions*

To penalize the “bad actors” in the healthcare profession who are contributing to the opioid crisis and holding them liable, some jurisdictions have departed from the wrongful conduct rule.<sup>93</sup>

#### 1. *Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo County*

The West Virginia Supreme Court rejected the wrongful conduct rule in cases involving opioid-addicted plaintiffs and instead applied comparative fault principles to hold defendant medical providers liable for contributing to the plaintiffs’ addiction.<sup>94</sup> In *Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo County*, twenty-nine plaintiffs filed eight separate civil actions in the Circuit Court of Mingo County against four physicians, three pharmacies, and a medical center alleging the defendants caused or contributed to the plaintiffs’ addiction to controlled substances.<sup>95</sup> The Circuit Court of Mingo County presented a certified question before the Supreme Court of Appeals of West Virginia regarding whether the plaintiffs may maintain a cause of action against the defendants for contributing to their addiction to controlled substances where the defendants admit to engaging in criminal conduct.<sup>96</sup>

Most of the plaintiffs in the lawsuit admitted that their abuse of controlled substances started before ever receiving treatment at the defendant medical facilities.<sup>97</sup> Some of the illegal activities to which the plaintiffs admitted and engaged in included: criminally distributing, purchasing, and receiving medications “off the street”; criminally obtaining prescription narcotics through misrepresentation, fraud, forgery, and deception; “doctor shopping” to criminally obtain prescriptions for narcotics from multiple doctors at once; and abusing or misusing the medication by not taking it as directed.<sup>98</sup> Despite clearly engaging in illegal conduct, the plaintiffs argued that the defendants’ “pill mill” activities contributed to the plaintiffs’ addiction and abuse of the controlled substances and therefore should have been found liable.<sup>99</sup>

The defendant medical providers urged the court to follow the holding in *Orzel*, arguing that the wrongful conduct rule barred the plaintiffs’ claim since they admitted

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<sup>91</sup> Pia Malbran, *What’s a Pill Mill?*, CBS NEWS (May 31, 2007), <https://www.cbsnews.com/news/whats-a-pill-mill/> [https://perma.cc/W72B-HNDB].

<sup>92</sup> *See infra* Part III.B.

<sup>93</sup> *Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo Cty.*, 235 W. Va. 283, 283 (2015).

<sup>94</sup> *Id.* at 284.

<sup>95</sup> *Id.* at 284.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 285.

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

to engaging in criminal activity.<sup>100</sup> In the alternative, the defendants argued that the doctrine of *in pari delicto* (which lays blame on both parties) barred the plaintiffs' recovery when they were equally at fault.<sup>101</sup> The circuit court rejected the defendants' arguments and submitted two certified questions to the Supreme Court of Appeals of West Virginia, asking the court whether it adopted the wrongful conduct rule or the doctrine of *in pari delicto*.<sup>102</sup> The court only addressed the first certified question.

The Supreme Court of Appeals of West Virginia criticized the lack of "lucid, predictable, or workable standards" in the application of the wrongful conduct rule, concluding that the rule's ambiguous limitations and exceptions served to "obliterate the rule altogether," essentially causing the rule to "collapse[ ] on itself."<sup>103</sup> The court thus certified to the circuit court that West Virginia declined to adopt the wrongful conduct rule.<sup>104</sup> But the court clarified that this holding did not necessarily mean that a plaintiff who "substantially contributes to his own injuries" can recover.<sup>105</sup> Instead, the court held that a plaintiff's wrongful conduct does not automatically bar his recovery for damages resulting partially from a negligent defendant, but that the plaintiff's conduct must be assessed under the principle of comparative fault to determine the extent of his recovery.<sup>106</sup>

Two justices dissented, each expressing their vehement disapproval of the majority's decision to break precedent, ultimately wasting court resources and allowing criminal wrongdoers to profit from their crimes.<sup>107</sup> The dissenting justices also declined to accept the majority opinion that the wrongful conduct rule was confusing or unworkable, opining that the rule simply required a court "to exercise its basic common sense" in its application for it to work.<sup>108</sup> To emphasize his point that the wrongful conduct rule was indeed workable, dissenting Justice Loughry explained that thirteen other jurisdictions had adopted the rule, and that five federal courts had also applied the rule to bar claims of drug addiction.<sup>109</sup>

## 2. *The Effect and Flaws of the Minority Rule*

The potential effect of abandoning the traditional wrongful conduct rule is exactly what the dissenting justices in *Tug Valley Pharmacy* feared—the courts will be overcrowded, court resources will be wasted, and criminal wrongdoers will profit from their crimes. Moreover, there is a risk that healthcare professionals who merely made a bad judgment call on a controlled substance prescription would have to invest time and money to face litigation. Although, in such circumstances, the "bad" plaintiffs' conduct would outweigh the conduct of the healthcare professional (likely resulting in

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<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *Id.* at 285–86.

<sup>103</sup> *Id.* at 288–89.

<sup>104</sup> *Id.* at 289.

<sup>105</sup> *Id.* at 292.

<sup>106</sup> *Id.* at 292.

<sup>107</sup> *Id.* at 293.

<sup>108</sup> *Id.* at 294.

<sup>109</sup> *Id.* at 294–95.

no civil liability), the defendant would still be at a loss of time and money spent to defend against threatened litigation.

Policy reasons that support abandoning the wrongful conduct rule include attempting to change the views of the general public towards addiction, recognizing it as a legitimate health issue, and attempting to target the “pill mill” operations that have significantly contributed to the opioid crisis.<sup>110</sup> It is understandable that a jurisdiction such as West Virginia—that is most significantly impacted by the opioid crisis—would want to target the entities responsible for supplying the substance at issue and to threaten them with civil liability.<sup>111</sup> But threatening all healthcare professionals with potential civil liability will only create animosity between patients, prescribers, and pharmacists, and create distrust amongst the healthcare professionals. It is important to understand that this is not the best solution for every jurisdiction.

#### IV. THE WRONG SOLUTION

##### A. Recent Recommendations

In recent years since the declaration of a public health emergency, for the purpose of finding a solution for the opioid crisis, some commentators have begun to place great emphasis in recognizing addiction as a brain disease, arguing that because opioid addiction is “not a matter of free choice” and “often arises out of legitimate prescription drug use,” modern courts should reject the wrongful conduct rule “in cases where plaintiffs seek recovery from those who caused or contributed to their addiction.”<sup>112</sup> However, allowing plaintiffs to bring traditionally barred claims against healthcare professionals will only result in the shifting of blame between the opioid-addicted plaintiff, the doctor who prescribed the opioid, and the pharmacist who dispensed the opioid.

The value in eliminating the wrongful conduct rule is limited to determining who will pay for the harm—the medical costs associated with addiction—but does not solve the problem or have long term value in overcoming the opioid crisis. Rather, the effect of eliminating the wrongful conduct rule and allowing opioid-addicted plaintiffs to sue would be that healthcare professionals will face litigation for exercising their professional judgment in cases involving opioids. Threatening healthcare professionals with potential litigation will only result in an impaired patient-provider relationship.

Rather than having the desired effect of reduced opioid prescribing and dispensing, eliminating the wrongful conduct rule will only cause the healthcare professionals to distrust and doubt all patients out of fear of potential litigation. And the fear of unwarranted litigation will cause distrust amongst the healthcare professionals because pharmacists will have to second guess every opioid prescription that comes into their pharmacy. Relationships in healthcare should not be rooted in distrust like this.

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<sup>110</sup> See Lauren Rousseau & I. Eric Nordan, *Tug v. Mingo: Let the Plaintiffs Sue—Opioid Addiction, the Wrongful Conduct Rule, and the Culpability Exception*, 34 T.M. COOLEY L. REV. 33, 71–72 (2017).

<sup>111</sup> See *id.* at 72; see also *Opioid Summaries by State*, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state> (last visited Apr. 16, 2020) (demonstrating that West Virginia has the highest rate of opioid-involved overdose deaths out of all states based on available data from 2018) [<https://perma.cc/S3HQ-HPH4>].

<sup>112</sup> Samuel Fresher, Comment, *Opioid Addiction Litigation and the Wrongful Conduct Rule*, 89 U. COLO. L. REV. 1311, 1315 (2018).

### *B. A Balancing Act—My Own Experience*

As a practicing community pharmacist, I am constantly challenged to balance fulfilling my duty to dispense and my corresponding responsibility to refuse illegitimate prescriptions when a patient presents with an opioid prescription. Before I check the inventory for the controlled substance medication or even allow a patient to leave their prescription at my pharmacy, I have the duty and responsibility to investigate.<sup>113</sup> I consider many factors, including: where the patient lives, where the doctor's office is located, where my pharmacy is located, the patient's age, the patient's demeanor, other medications prescribed in addition to the opioid medication, the patient's diagnosis, the patient's medication history, the patient's controlled substance medication dispensing history (by checking the Controlled Substance Utilization Review and Evaluation System, or commonly referred to as CURES), the quantity and strength of the prescription, and the integrity of the prescription itself (by testing the security features).<sup>114</sup>

Exercising my professional judgment in deciding whether to dispense an opioid prescription involves consideration of many factors. Consider the following hypothetical: an opioid-addicted patient goes to the emergency room and claims he is in pain with a ten out of ten on the pain scale. A physical examination reveals he has an infected wound in his lower abdomen. The emergency room physician prescribes the patient an antibiotic, to treat the infection, and Hydrocodone, an opioid, to relieve the pain. The patient takes the prescription and presents it to my pharmacy.

At my pharmacy, I ask the patient to write his date of birth, address, and phone number on the prescription. The patient claims he has no address because he is homeless. I understand, and I ask him to write "homeless" in place of an address. I ask for his identification, since my pharmacy has a strict policy that requires a person to present a valid identification to pick up any controlled substance prescription. He produces an expired identification and explains he has no money to renew his license. I check CURES and notice no issues. The patient asks only for the pain medication, and not the antibiotic. I explain that I cannot fill only the pain medication, because while it may give him temporary pain relief, the antibiotic is what will treat the underlying cause of pain, if pain was the actual purpose for the emergency room visit. The patient instantly changes his demeanor and gets angry, screaming at me and asking me if I am denying him his care. I explain further that since he also does not have a valid form of identification, he would not be able to pick up his medication. The patient gets even more angry and furiously begins to unbuckle his belt and lower his pants, revealing a severely infected wound in the lower abdomen. As I call over for security, the patient screams at me, "is this identification enough for you?" All the while I try to get the patient to get re-dressed, I explain to the patient that I understand he might legitimately be in pain, and that I will accept his expired identification considering the circumstances, but that he must get both the antibiotic and pain medication so that his infection can heal.

Now consider the following: the homeless man is actually an opioid addict who is purposely going in and out of the emergency room seeking treatment for the infection, knowing he will only take the pain medication and not the antibiotic. Imagine that the patient decided to sue me, the first pharmacist to fill his opioid prescription, for

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<sup>113</sup> See CAL. BD. OF PHARMACY, *supra* note 48.

<sup>114</sup> *Id.*

contributing to his addiction. Although the patient contributed himself to his own addiction by obtaining a prescription for opioids through deceit, his claim could proceed without the wrongful conduct rule. I would face legal consequences, not just potential administrative consequences from the Board of Pharmacy or the Drug Enforcement Administration, all because I exercised my professional judgment and made the decision to fill the pain medication for him. It is not clear what the value is in allowing the opioid-addicted plaintiff to sue me in this circumstance, or what behavior of mine it would deter. This hypothetical merely illustrates one flaw associated with eliminating the wrongful conduct rule.

## V. A DIFFERENT APPROACH

Rather than relying solely on litigation to resolve the opioid crisis by threatening the “bad” plaintiffs with no means of recovery of damages or the “bad” healthcare professionals with the threat of litigation, the more effective approach is to focus attention and resources on: (1) preventing deaths by increasing access to Naloxone; (2) treating the addiction; and (3) better educating healthcare professionals on the proper prescribing and dispensing of opioids and Naloxone.

### A. *Emergency Overdose Treatment*

Opioids are extremely dangerous, and one of the reasons that our nation faces an opioid crisis is due to an opioid’s mechanism of action—how the opioid works in the human body. Opioids bind to all different types of opioid receptors including mu receptors that are found throughout our central nervous system, which consists of the brain and spinal cord.<sup>115</sup> Opioid receptors are found in areas of the central nervous system that are associated with pain perception.<sup>116</sup> Some opioids partially bind to the receptors, while others fully bind, or even block, these receptors.<sup>117</sup> When opioids bind to a subtype called mu<sub>1</sub> receptors in particular, a person experiences the desired therapeutic effects of analgesia and euphoria. When opioids bind to other opioid receptors, a person experiences the undesired side effects of constipation, sedation, nausea, vomiting, and even respiratory depression.<sup>118</sup> When respiratory depression occurs, a person’s breathing slows down, which in turn causes less oxygen to be delivered to the different organs throughout the body, in essence causing the body to shut down.<sup>119</sup> In sum, because of the way opioids work—causing euphoria, which is the desired effect in addiction—addicts misuse opioids, which can stimulate respiratory depression and ultimately cause death.

One approach to mitigating the effect of this devastating epidemic taking the lives of thousands every year is to first prevent the deaths. A way to prevent these deaths

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<sup>115</sup> Yvette C. Terry, *An Overview of Opioids*, PHARMACY TIMES (June 13, 2011), <https://www.pharmacytimes.com/publications/issue/2011/june2011/an-overview-of-opioids> [https://perma.cc/6Z5H-ZFXH].

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

due to opioid-overdose is to increase accessibility to Naloxone.<sup>120</sup> Naloxone is an emergency overdose treatment that will save lives.<sup>121</sup> It is a reversal agent that binds to opioid receptors at a higher affinity than the opioid itself, temporarily reversing the effects of an opioid overdose.<sup>122</sup>

A significant barrier to expanding the use of Naloxone is the stigma associated with the treatment and with the addiction itself.<sup>123</sup> For this reason, those who actually need Naloxone are the last to reach out to their healthcare providers to ask for a prescription. To overcome this obstacle, and in an attempt to increase access to a medication that is not only effective but also vital,<sup>124</sup> a majority of states passed laws related to prescribing or administering Naloxone. Many states have passed legislation related to Naloxone, allowing for professional immunity, layperson immunity, and third-party prescribing.<sup>125</sup> Furthermore, some states have passed laws allowing for pharmacists to dispense Naloxone without a physician's prescription.<sup>126</sup>

When granted professional immunity, a person acting in his professional capacity will not be held liable for prescribing, dispensing, distributing, or administering Naloxone to a layperson.<sup>127</sup> Likewise, when granted layperson immunity, a person without professional or specialized knowledge will not be held liable for administering Naloxone to a person suffering from an overdose.<sup>128</sup> Third-party prescribing allows healthcare providers to lawfully prescribe, dispense, distribute, or administer Naloxone to family members and friends of those at risk of opioid overdose.<sup>129</sup> These statutes generally serve the purpose of encouraging health care professionals and

<sup>120</sup> See *U.S. Surgeon General's Advisory on Naloxone & Opioid Overdose*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html> (last visited Oct. 4, 2019) [<https://perma.cc/YG7K-DW52>].

<sup>121</sup> See *Naloxone: The Opioid Reversal Drug that Saves Lives*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf> (last visited Oct. 4, 2019) [<https://perma.cc/UUZ5-WAY5>].

<sup>122</sup> *Naloxone*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone> (last visited Oct. 4, 2019) [<https://perma.cc/V8L4-EUVV>]; *NARCAN® Highlights of Prescribing Info.*, U.S. FOOD & DRUG ADMIN. (Nov. 2015), [https://www.access.data.fda.gov/drugsatfda\\_docs/label/2015/208411lbl.pdf](https://www.access.data.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf) [<https://perma.cc/5JER-P9T4>].

<sup>123</sup> See Lawrence Yang, Liang Y. Wong, Margaux M. Grivel & Deborah S. Hasin, *Stigma and Substance Use Disorders: An International Phenomenon*, 30 *CURRENT OP. PSYCHIATRY* 378 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5854406/pdf/nihms943463.pdf> [<https://perma.cc/AQB8-2VSV>].

<sup>124</sup> See Sarah Follman, *Naloxone Prescriptions Among Commercially Insured Individuals at High Risk of Opioid Overdose*, *JAMA NETWORK OPEN*, May 3, 2019, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2732332> [<https://perma.cc/5RES-K2RK>].

<sup>125</sup> *Naloxone Access Statutes*, NAT'L ALLIANCE MODEL ST. DRUG L. 2, <https://namsdl.org/wp-content/uploads/Naloxone-Access-Statutes.pdf> [<https://perma.cc/TK93-6ELJ>] (research current through Mar. 1, 2016).

<sup>126</sup> See Rachel Balick, *Pharmacists Can Get—and Pharmacists Can Provide—Naloxone at the Pharmacy. Why Don't They?*, AM. PHARMACISTS ASS'N, July 10, 2018, <https://www.pharmacist.com/article/patients-can-get-and-pharmacists-can-provide-naloxone-pharmacy-why-dont-they> [<https://perma.cc/HYP7-NGJT>].

<sup>127</sup> *Naloxone Access Statutes*, *supra* note 125, at 2.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*; see also Corey Davis, *State Legal Innovations to Encourage Naloxone Dispensing*, 57 *J. AM. PHARMACISTS ASS'N* S180, S181 (2016), [https://www.japha.org/article/S1544-3191\(16\)30890-1/pdf](https://www.japha.org/article/S1544-3191(16)30890-1/pdf) [<https://perma.cc/B8JP-SCRW>].



Another way to increase access that could also overcome the stigma issue is to make Naloxone available over-the-counter (OTC). Countries such as Australia and Canada have already taken this step to make Naloxone available OTC without a prescription.<sup>138</sup>

A substantial challenge to making Naloxone available OTC in the United States is the difficult process of getting Naloxone approved for OTC dispensing by the U.S. Food and Drug Administration (FDA). For a medication to be available OTC, FDA requires an OTC drug monograph that “define[s] the safety, effectiveness, and labeling” of all active ingredients.<sup>139</sup> Once FDA publishes a final OTC drug monograph in the Federal Register, drug manufacturers can make and market the product as OTC.<sup>140</sup>

In late 2018, FDA took an unprecedented step of proactively developing and testing a consumer-friendly Drug Facts Label (DFL) for Naloxone in the pivotal Comprehension for OTC Naloxone (CONFER) label comprehension study.<sup>141</sup> The CONFER study concluded the Naloxone DFL tested in the study was acceptable as is, although there was room for improvement in outcomes such as comprehension of instructions to call 911 immediately.<sup>142</sup> This unprecedented action by FDA eliminated the most onerous challenge to making Naloxone available OTC by developing and testing a key component necessary for OTC availability, and the only step that remains is encouraging manufacturers to develop OTC Naloxone using FDA-approved labeling.<sup>143</sup>

Rather than allowing for increased opioid litigation against healthcare providers and wasting valuable resources to merely determine which “bad” party is at greater fault, a more sensible approach to overcoming the opioid crisis would be to increase Naloxone accessibility in order to prevent opioid overdoses.

### *B. Medication-Assisted Therapy*

Another essential step in overcoming the opioid crisis is to treat the underlying opioid addiction. Medication-assisted therapy (MAT) is a form of treatment that uses

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<sup>138</sup> See Simon R. Lenton, Paul M. Dietze & Marianne Jauncey, *Australia Reschedules Naloxone for Opioid Overdose*, 204 MED. J. AUSTRAL. 146, 146–47 (2016); see also CAN. PHARMACISTS ASS’N, ENVIRONMENTAL SCAN—ACCESS TO NALOXONE ACROSS CANADA 5 (Nov. 2017), [https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Environmental%20Scan%20%20Access%20o%20Naloxone%20Across%20Canada\\_Final.pdf](https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Environmental%20Scan%20%20Access%20o%20Naloxone%20Across%20Canada_Final.pdf) [<https://perma.cc/P8Q8-HGAS>].

<sup>139</sup> U.S. FOOD & DRUG ADMIN., DRUG APPLICATIONS FOR OVER-THE-COUNTER (OTC) DRUGS, <https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs> [<https://perma.cc/9XPT-MEF2>] (last edited Jan. 7, 2015).

<sup>140</sup> *Id.*; see also Press Release, Scott Gottlieb, FDA Commissioner, Statement from FDA Commissioner Scott Gottlieb, M.D., on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths (Jan. 17, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-suport-development-over> [<https://perma.cc/BB4S-VHBG>].

<sup>141</sup> U.S. FOOD & DRUG ADMIN., COMPREHENSION FOR OTC NALOXONE (CONFER): PIVOTAL LABEL COMPREHENSION STUDY – TASK 3 STUDY REPORT 1, <https://www.fda.gov/media/119745/download> [<https://perma.cc/SU3C-W775>] (accessed Sept. 9, 2020).

<sup>142</sup> *Id.* at 28.

<sup>143</sup> See Press Release, Norman E. Sharpless, FDA Commissioner, Statement on continued efforts to increase availability of all forms of naloxone to help reduce opioid overdose deaths (Sept. 20, 2019), <https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose> [<https://perma.cc/6EGF-W8UD>].

medications in combination with counseling and behavioral therapies to treat Substance Use Disorder, but primarily a subset of the disorder called Opioid Use Disorder.<sup>144</sup>

FDA approved three medications for the treatment of Opioid Use Disorder: Methadone, Buprenorphine, and Naltrexone.<sup>145</sup> Methadone, Buprenorphine, and Naltrexone are all types of opioids that bind to and displace opioid drugs from the opioid receptors. These medications work to block the euphoric and sedative effects of opioids, either by activating opioid receptors that suppress cravings or by blocking opioid receptors, which relieves the physical cravings often associated with opioid withdrawal.<sup>146</sup>

In 2010, a systematic review studying the effectiveness of MAT yielded promising results, finding that “all of the psychopharmacological medications discussed in [the] review appear to have a place in the treatment of opioid dependence.”<sup>147</sup> Particularly, the review found that buprenorphine is an effective agent for opioid detoxification and that methadone is an effective agent for long-term maintenance of opioid dependence.<sup>148</sup> Other studies showed that patients who use medications to treat their Opioid Use Disorder remain on therapy longer than those who don’t and are less likely to use illicit opioids.<sup>149</sup> Additionally, MAT has been recognized as an effective treatment for Opioid Use Disorder in combination with counseling and behavioral therapies in the National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use.<sup>150</sup> Not only is MAT proven to be clinically effective, but it also reduces the need for inpatient detoxification, which can cost anywhere from \$6,000 to \$20,000 for a thirty-day program.<sup>151</sup>

Despite the positive outcomes, one particular outcome variable recognized by the systematic review that most significantly impacted all treatment strategies and

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<sup>144</sup> *Medication-Assisted Treatment (MAT)*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/medication-assisted-treatment> [<https://perma.cc/EL77-9D3Z>] (last updated Sept. 1, 2020).

<sup>145</sup> *Information about Medication-Assisted Treatment (MAT)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat> [<https://perma.cc/P9AT-YP6T>] (last updated Feb. 14, 2019).

<sup>146</sup> *See What Is Naltrexone?*, PSYCHIATRIC RES. INST., U. OF ARK. FOR MED. SCI., <https://psychiatry.uams.edu/clinical-care/cast/what-is-naltrexone/> [<https://perma.cc/P569-D786>] (last visited Feb. 12, 2021).

<sup>147</sup> Jennifer C. Veilleux, Peter J. Colvin, Jennifer Anderson, Catherine York & Adrienne J. Heinz, *A Review of Opioid Dependence Treatment: Pharmacological and Psychosocial Interventions to Treat Opioid Addiction*, 30 *CLINICAL PSYCHOL. REV.* 155, 163 (Mar. 2010), <https://www.sciencedirect.com/science/article/pii/S0272735809001421?via%3Dihub> [<https://perma.cc/3AE6-J9C2>].

<sup>148</sup> *Id.*

<sup>149</sup> *The Case for Medication-Assisted Treatment*, THE PEW CHARITABLE TRUSTS 2 (Feb. 2017), <https://www.pewtrusts.org/-/media/assets/2017/02/thecasemedicationassistedtreatment.pdf> [<https://perma.cc/EH4K-6RA4>].

<sup>150</sup> *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, AM. SOC’Y OF ADDICTION MED. 8 (2015), <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24> [<https://perma.cc/CGJ2-D8KC>].

<sup>151</sup> *See supra* note 144; *see also* Jeffrey Juergens, *Understanding the Cost of Rehab*, ADDICTION CENTER, <https://www.addictioncenter.com/rehab-questions/cost-of-drug-and-alcohol-treatment/> [<https://perma.cc/R3D3-MXFH>] (last edited June 18, 2020).

warranted attention was treatment retention.<sup>152</sup> Given the complex nature of addiction, effective treatment of Opioid Use Disorder demands treatment in multiple phases: the initial detoxification phase as well as the subsequent rehabilitation phase.<sup>153</sup> In order to demonstrate the maximum potential of MAT, our resources and efforts must be dedicated to assisting physicians and treatment facilities with developing interventions that will not only help those with Opioid Use Disorder detoxify from opioids with minimum withdrawal symptoms, but also sustain recovery and ultimately achieve drug abstinence to restore them to a normal, healthy life.<sup>154</sup>

Currently, many insurance companies do not cover these treatments for Opioid Use Disorder.<sup>155</sup> The Affordable Care Act sought to expand access to Substance Use Disorder treatments, but because the Act did not explicitly define which Substance Use Disorder benefits must be covered, insurance companies offered coverage with excessive treatment limitations.<sup>156</sup> Insurance companies either limited the spectrum of drugs covered or only covered treatment for a short period of time, limiting its effectiveness.<sup>157</sup> All state Medicaid programs have moved in the right direction by covering at least two out of three FDA-approved MAT medications, with most covering all three, and covering a range of treatment services such as detoxification and rehabilitation.<sup>158</sup> Now, other insurance companies must follow suit and cover all FDA-approved medications for the treatment of addiction and remove their excessive treatment limitations.<sup>159</sup>

Encouraging health insurances to cover MAT will surmount a huge step in eradicating the opioid crisis because they address the root of the problem—the underlying addiction. By making opioid addiction treatment affordable and readily available, there will be one less barrier for a person who genuinely wants help for his or her addiction.

### C. Healthcare Professional Education

Finally, another approach to overcoming the opioid crisis is to prevent over-prescribing and over-dispensing of opioids. An effective way to do so is to educate the healthcare professionals involved in the process.

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<sup>152</sup> Veilleux et al., *supra* note 147, at 163.

<sup>153</sup> *See generally id.*

<sup>154</sup> *See generally* Veilleux et al., *supra* note 147, at 164.

<sup>155</sup> *See Cover MAT and Stabilize Formularies, AAFP Tells CMS*, AM. ACAD. OF FAMILY PHYSICIANS (Mar. 1, 2019), <https://www.aafp.org/news/government-medicine/20190301payment2020.html> [<https://perma.cc/37VQ-ZVB5>].

<sup>156</sup> *Uncovering Coverage Gaps: A Review of Addiction Benefits in ACA Plans*, THE NAT'L CTR ON ADDICTION & SUBSTANCE ABUSE (June 7, 2016), [https://drugfree.org/reports/uncovering-coverage-gaps-a-review-of-addiction-benefits-in-aca-plans/#:~:text=Uncovering%20Coverage%20Gaps%3A%20A%20Review%20of%20Addiction%20Benefits%20in%20ACA%20Plans,-Published%3A%20June%202016&text=This%20comprehensive%20review%20of%20the,Affordable%20Care%20Act%20\(ACA\)](https://drugfree.org/reports/uncovering-coverage-gaps-a-review-of-addiction-benefits-in-aca-plans/#:~:text=Uncovering%20Coverage%20Gaps%3A%20A%20Review%20of%20Addiction%20Benefits%20in%20ACA%20Plans,-Published%3A%20June%202016&text=This%20comprehensive%20review%20of%20the,Affordable%20Care%20Act%20(ACA)) [<https://perma.cc/UX5E-3EDW>] [hereinafter *Uncovering Coverage Gaps*].

<sup>157</sup> *See The Case for Medication-Assisted Treatment*, *supra* note 149, at 2.

<sup>158</sup> *Medicaid's Role in Addressing the Opioid Epidemic*, KAISER FAMILY FOUND. (June 3, 2019), <https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/> [<https://perma.cc/PVT7-F6E4>].

<sup>159</sup> *Uncovering Coverage Gaps*, *supra* note 156, at 23.

According to a Consensus Study Report conducted by the National Academies of Sciences, Engineering, and Medicine, strategies for addressing the opioid epidemic include (1) restricting the lawful supply of opioids; (2) influencing prescribing practices; (3) reducing demand; and (4) reducing harm.<sup>160</sup> The Committee tasked with conducting this study concluded that “[c]urrent efforts to improve pain education and knowledge about prescription opioid misuse and [Opioid Use Disorder] among prescribers are inadequate.”<sup>161</sup> Accordingly, the Committee recommended establishing comprehensive pain education materials and curricula for health care providers in order to influence opioid prescribing practices.<sup>162</sup> Furthermore, despite the fact that MAT is the standard of care for Opioid Use Disorder, the Committee found that MAT was severely underutilized.<sup>163</sup> Thus, the Committee recommended improving education in the appropriate treatment of Opioid Use Disorder for healthcare providers.<sup>164</sup>

Utilizing healthcare professionals to educate other healthcare professionals so that they work together in addressing the opioid crisis is a healthier approach than having them blame each other in litigation for creating the problem. South Carolina promoted the proper use of opioids across the state by utilizing pharmacists and other educational services, and effectively reduced the number of opioid prescriptions in the state.<sup>165</sup> The role of the educating pharmacists was to “promote a change in prescribing practices to limit the supply of prescription opioids in circulation; raise awareness of the risk of opioid addiction; [and] help properly identify and treat opioid-dependent patients” by providing education to healthcare providers and the community.<sup>166</sup> With an influx of pharmacists available in the workforce in California, and with pharmacists’ newfound provider status,<sup>167</sup> California has sufficient resources to effectively reduce the number of opioid prescriptions in a similar fashion.

Pharmacists can also play a significant role in destigmatizing Naloxone use by encouraging prescribers to have a conversation with patients seeking opioid prescriptions. One suggestion is to have an effective screening mechanism in place to identify patients at risk of an opioid overdose so those patients can be given a prescription for Naloxone along with their prescription for an opioid. Pharmacists can provide in-service training at emergency and urgent care facilities, educating

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<sup>160</sup> Richard J. Bonnie, Morgan A. Ford & Jonathan K. Phillips, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, NAT’L ACADS. OF SCIS., ENG’G & MED. (July 13, 2017), <https://www.nap.edu/catalog/24781/pain-management-and-the-opioid-epidemic-balancing-societal-and-individual> [<https://perma.cc/9PQT-8YNY>].

<sup>161</sup> *Id.* at 12.

<sup>162</sup> *Id.*

<sup>163</sup> *Id.* at 13–14.

<sup>164</sup> *Id.* at 14.

<sup>165</sup> Kayce M. Shealy, Erika E. Tillery, Cheryl A. Anderson & Katelyn L. Cheek, *Utilizing Pharmacists and Educational Services to Promote Proper Use of Opioids Across South Carolina*, 70 S.C. L. REV. 877, 878, 883 (2019).

<sup>166</sup> *Id.* at 880.

<sup>167</sup> Loren Bonner, *California’s SB 493 Implementation: Three, Two, One . . . Blast-Off!*, AM. PHARMACISTS ASS’N (July 1, 2015), <https://www.pharmacist.com/california-s-sb-493-implementation-three-two-one-blast> [<https://perma.cc/9ZHT-7QYJ>].

healthcare professionals about Naloxone and its various formulations,<sup>168</sup> and encourage prescribers to employ the Controlled Substance Utilization Review and Evaluation System<sup>169</sup> (CURES) before prescribing any opioids to patients. New pharmacists can also educate pharmacists who have been in practice for a while and are unfamiliar with their provider status, encouraging them to receive continuing education about Naloxone so that all pharmacists may offer it under a statewide protocol.<sup>170</sup>

Enhancing education among healthcare professionals on appropriate prescribing for pain management and Opioid Use Disorder itself will ultimately reduce the overall dispensing of opioid prescriptions. It will lessen the amount of inappropriately prescribed opioids and increase utilization of MAT, which will also lessen opioid prescribing in due course. Educating healthcare professionals about Naloxone will allow them to be more comfortable with co-prescribing Naloxone with opioid prescriptions to help increase access to the life-saving medication. Encouraging prescribers to check the CURES database prior to prescribing opioids will eliminate unnecessary opioid prescriptions. Educating healthcare professionals alone can make a significant impact by reducing the supply of opioids and increasing access to life-saving medications.

## CONCLUSION

Although there are shortcomings associated with the application of the wrongful conduct rule in opioid litigations involving “pill mills” and “bad” healthcare professionals, encouraging jurisdictions to abandon the rule for the purpose of addressing the opioid crisis is not only uneconomical, but also ineffective. There are more effective ways to overcome the opioid crisis than to point fingers and merely shift the blame, which is all that eliminating the wrongful conduct rule would achieve. There are tremendously underutilized resources that can prevent deaths due to opioid overdose, treat opioid addiction, and educate healthcare professionals and the public about the proper use of opioids. Destigmatizing the use of Naloxone and increasing its accessibility will prevent deaths due to opioid overdose. Encouraging insurance companies to add medication-assisted therapies to their formularies will eliminate the first of many barriers for opioid-addicted patients who may want to seek help for their addiction. Educating healthcare professionals on the proper use of opioids will reduce the number of opioids prescribed, which will further reduce the supply available for potential misuse or abuse. These solutions can make a tremendous impact on the opioid crisis by addressing the root of the problem.

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<sup>168</sup> FDA-approved forms of Naloxone are injectable, auto-injector, and nasal spray. *See* Sharpless, *supra* note 143, at 1–2.

<sup>169</sup> The Controlled Substance Utilization Review and Evaluation System (CURES) is California’s prescription drug monitoring program, which allows prescribers and dispensers to review an individual’s controlled substance dispensing history. *See Controlled Substance Utilization Review and Evaluation System*, OFF. OF THE ATT’Y GEN., STATE OF CALI. DEP’T OF JUSTICE, <https://oag.ca.gov/cures> [<https://perma.cc/D8YM-G7LW>] (last visited Sept. 9, 2020).

<sup>170</sup> *Expanding Pharmacist Services*, CAL. PHARMACISTS ASS’N, <https://cpha.com/advocacy/provider-status/expanding-pharmacist-services/> [<https://perma.cc/8UWR-XV6Y>] (last visited Dec. 21, 2019).