IN THE CIRCUIT COURT OF BOONE COUNTY, WEST VIRGINIA

STATE OF WEST VIRGINIA ex rel.
PATRICK MORRISEY, Attorney General,

Plaintiff,

v.

CIVIL ACTION NO. _____
JUDGE _____

PURDUE PHARMA, L.P., a Delaware limited partnership,
PURDUE PHARMA INC., a New York corporation, and
RICHARD SACKLER, M.D.

Defendants.

COMPLAINT

This action is brought in the name of the State of West Virginia in its sovereign capacity by Patrick Morrisey, Attorney General, pursuant to W. Va. Code § 46A-7-108 of the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101 *et seq.* ("WVCCPA"), against Purdue Pharma L.P., Purdue Pharma Inc., and Richard Sackler, M.D., to protect consumers and the integrity of the commercial marketplace in West Virginia. This action is brought against Richard Sackler individually and as a director on the Board of Purdue Pharma, Inc. The State also brings suit pursuant to the Attorney General's common law police power to abate and remedy the statewide public nuisance created by the Defendants' interference with the commercial marketplace and endangerment of the public health.

BACKGROUND

1. In June 2001, the State of West Virginia, the Bureau of Employment Programs, West Virginia Department of Health and Human Services and the West Virginia Public Employees Insurance Agency sued Purdue Pharma L.P., Purdue Pharma Inc., and Purdue Frederick Company

in the Circuit Court of McDowell County, West Virginia, Civil Action No. 01-C-137-S, for violations of the WVCCPA, in connection with the sale and marketing of OxyContin®. The parties entered into a settlement agreement that was approved by Final Order dated December 22, 2004 ("2004 Settlement"). In the settlement agreement, the State agreed to "absolutely, unconditionally, and irrevocably release, remise, acquit, and forever discharge Purdue . . . of and from any and all claims of whatsoever kind or nature relating to, whether now arisen or hereafter to arise, that were asserted or which could have been asserted in [Civil Action No. 01-C-137-S]."

2. In 2010, Purdue Pharma, L.P. removed the OxyContin® Tablets which were the subject of the 2004 settlement from the market. On August 8, 2010, it introduced and began marketing a new reformulated oxycodone time-released tablet that it also labeled OxyContin. See https://ndclist.com/ndc/59011-460. Purdue also registered a new NDC (National Drug Code) for this reformulated medication. The OxyContin® Tablets that were the subject of the 2004 settlement had NDCs 59011-0100, -0103, -105, -107. The number 59011 identifies the "labeler" of the drug, meaning the manufacturer, repackager, or distributer. The second number identifies the product -- OxyContin® Tablets. In 2010, Purdue registered its reformulated Oxycontin product as new to the market under an "approved new drug application." This new Oxycontin was assigned NDCs for each strength of this new drug. For example, 59011-490 is the NDC for the 2010 Oxycontin 80 mg tablet. See https://www.accessdata.fda.gov/scripts. The OxyContin® Tablets which were the subject of the 2004 settlement are no longer manufactured. Therefore, the State does not violate the 2004 Settlement by bringing this action against the Defendants for its violations of state law in its marketing and sale of this new drug, in addition to its other opioid pain medications.

3. The Attorney General has been thoroughly investigating Purdue Pharma for several years and this lawsuit reveals a number of the findings from his office's investigation.

I. GENERAL FACTUAL ALLEGATIONS

4. Opioids are synthetic or semi-synthetic drugs derived from opium. Historically, opioids were prescribed in limited circumstances due to long-standing and well-founded fears about their addictive potential and safety. Then came Purdue.[1] Purdue created a false narrative to reverse these attitudes among public health care providers and other stakeholders in order to increase sales of its opioid products and its own market share.

5. Purdue violated the WVCCPA by making a series of misleading safety, comparative, and benefit claims about its opioid products and unfairly targeting vulnerable populations such as the elderly. Purdue advanced the deceptive narrative that its opioid products were safer than they actually were, its competitors' products were more dangerous or less effective than they actually were, its opioid products had certain qualities or benefits for which it lacked adequate substantiation, and its opioid products were safer for elderly patients than they actually were.

6. Purdue's actions and omissions concerning its highly addictive narcotics have helped create and fuel a public nuisance in West Virginia by significantly interfering with the commercial marketplace and endangering the life and health of the state's residents.

PARTIES

7. The Plaintiff, the State of West Virginia ex rel. Patrick Morrisey, Attorney General, is charged with enforcing the WVCCPA. Pursuant to W. Va. Code § 46A-7-108, the Attorney

[1] Unless otherwise stated, the term "Purdue" shall mean and include Purdue Pharma L.P. Purdue Pharma Inc. and Richard Sackler, M.D.

General is authorized to bring a civil action for violations of the WVCCPA and for other appropriate relief. The Attorney General has all common law powers except as restricted by statute or court decision. Syl. pt. 3, *State ex rel. Discover Financial Services, Inc., et al. v. Nibert*, 744 S.E.2d 625, 231 W. Va. 227 (2013).

8. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Connecticut.

9. Defendant Purdue Pharma Inc. is a privately owned company incorporated in New York with its principal place of business in Connecticut.

10. Defendant Purdue Pharma Inc. is the general partner of Purdue Pharma L.P.

11. Defendant Richard Sackler, M.D. is a former officer and member of the board of directors of Purdue Pharma, Inc. where he was intimately involved in directing the operation of the company including making decisions as to the sales and marketing practices of Purdue Pharma, L.P.

12. This Court has jurisdiction over the Defendants for the reasons set forth below.

STATE COURT JURISDICTION

13. The causes of action asserted and the remedies sought in this Complaint are based exclusively on West Virginia statutory, common, or decisional law.

14. This Complaint does not confer diversity jurisdiction upon federal courts pursuant to 28 U.S.C. § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdictional provisions of the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d). Federal question subject matter jurisdiction under 28 U.S.C. § 1331 is not invoked by this Complaint. Nowhere does the State plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not

implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. There is no federal issue important to the federal system as a whole as set forth in *Gunn v. Minton*, 568 U.S. 251, 258 (2013).

15. In this Complaint, the State occasionally references federal statutes, regulations, or actions, but does so only to establish the Defendants' knowledge or to explain how the Defendants' conduct has not been approved by federal regulatory agencies.

JURISDICTION

16. As a court of general jurisdiction, the circuit court is authorized to hear this matter based on the WVCCPA and nuisance claims, the amount at issue, and the relief sought pursuant to W. Va. Code § 56-3-33(a).

VENUE

17. Venue is proper in Boone County pursuant to W. Va. Code § 46A-7-114.

TIME PERIOD

18. This enforcement action concerns violations of law from the date a particular opioid was introduced to the market. In the case of OxyContin, this action concerns violations that occurred after August 8, 2010, the date the reformulated drug was introduced to the market. References in the Complaint to conduct that occurred before this date are mentioned to establish Purdue's knowledge, a pattern of behavior, other facts that are relevant to conduct occurring after the 2004 Settlement, or other opioids sold and marketed by Purdue.

APPLICABLE LAW

19. West Virginia Code § 46A-6-102(6) defines "trade" or "commerce" to mean "the advertising, offering for sale, sale or distribution of any goods or services and shall include any trade or commerce, *directly or indirectly*, affecting the people of this state." (Emphasis added.)

20. West Virginia Code § 46A-6-104 provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of *any trade or commerce* are hereby declared unlawful." (Emphasis added.)

21. West Virginia Code § 46A-6-102(7) defines unfair methods of competition and unfair or deceptive acts or practices to mean and include, but not be limited to:

> (E) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have . . . .
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> * * *
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> (L) Engaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding;
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> (M) The act, use or employment by any person of any deception, . . . false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby.

W. Va. Code § § 46A-6-102(7)(E), (L), and (M).

II. SPECIFIC FACTUAL ALLEGATIONS

Purdue's Opioid Products

22. Purdue owns and manufactures several different extended release opioid products that it marketed in West Virginia. These products include OxyContin, Butrans, and Hysingla ER, among others. As the name suggests, extended release opioids differ from immediate release

opioids in that they have a concentrated active ingredient that is supposed to be released over a period of time.

23. OxyContin, Purdue's highest selling and most profitable drug, is the brand name for oxycodone hydrochloride, a potent extended release opioid delivered in tablet form in 10, 15, 20, 30, 40, 60, 80, and, at one time, 160 mg doses. Butrans is the brand name for Purdue's buprenorphine skin patch that is available in five different strengths: 5, 7.5, 10, 15, and 20 mcg/hour doses. Hysingla ER is the brand name for Purdue's hydrocodone bitartrate, an extended release opioid delivered in 20, 30, 40, 60, 80, 100, and 120 mg film-coated tablets. Ryzolt, which Purdue no longer sells, was the brand name for tramadol hydrochloride, an opioid that had both immediate and extended release characteristics and was available in 100 mg dosing increments.

Purdue's Reliance on Continued Users and High-Dose Opioids

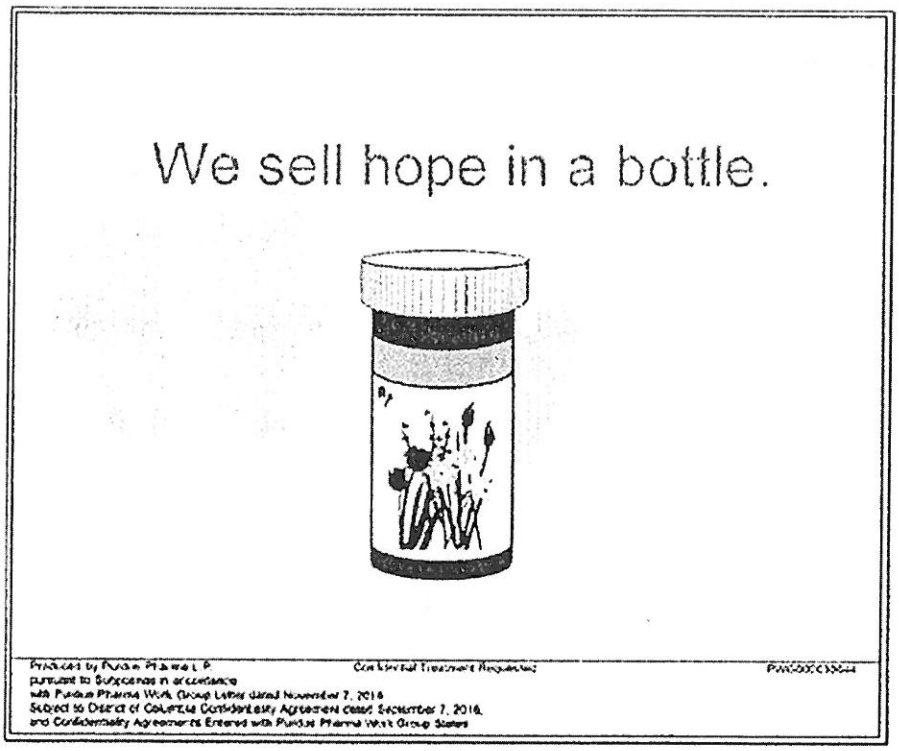
Purdue's Sales Model

24. Purdue created a sales structure that led to and fostered the proliferation of deceptive marketing claims which was implemented by trainings in which Purdue instructed sales representatives to make select prohibited claims, combined with lax compliance enforcement, a heavy emphasis on sales performance for compensation, and otherwise inadequate instruction.

25. Between 2006 and 2016, Purdue dramatically increased its sales force to market its opioid products to health care providers, pharmacies, and health care institutions in West Virginia. Purdue directed the marketing efforts of its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and feedback on sales representatives' "call notes" from sales visits.

26. Purdue spent significant sums of money to promote its opioid products to providers because it had evidence that increased sales calls were "highly correlated" with more prescriptions for its products[2]—particularly among the top prescribers of those products.[3]

27. Purdue summarized the marketing for its opioid products with the tagline "We sell hope in a bottle,"[4] shown below, in one of the company's hiring guides for incoming marketing employees.



[2] See, e.g., PWG000324250; PWG000447858 (Collectively attached hereto and incorporated herein as Ex. 1).

[3] PWG000447879 (See Ex, 2, attached hereto and incorporated herein).

[4] PWG000030644 (Ex. 3, attached hereto and incorporated herein).

28. Purdue trained its sales representatives about how to overcome a provider's objections, such as a provider expressing concern about the abuse of opioids or a provider stating he or she does not treat chronic pain[5]—pushing these providers to write more Purdue prescriptions.

29. Many of Purdue's West Virginia sales representatives devoted half of their sales calls in a given scheduling period to visit primary care physicians, family doctors, nurse practitioners, or physician assistants.[6] Purdue knew or should have known that these prescribers frequently had limited resources or time to scrutinize the company's claims or to conduct the necessary research regarding the efficacy and risks of high doses of extended release opioids.[7]

30. Purdue specifically targeted nurse practitioners and physician assistants to increase prescribing of its opioid products. In a 2015-2016 OxyContin Brand Strategy training session, Purdue instructed its sales representatives that "NP/PAs [are] critical to our success; contributing to both volume and growth."[8] Likewise, in a sales and marketing PowerPoint focusing on strategies for 2012, Purdue included a "Strategic Imperative" that the company should *"[i]ncrease/maintain volume with high value [oxycodone extended release] prescribers — These high value OxyContin prescribers will include NPs and PAs*"[9] and "[i]dentify & engage, next tier of 'rising stars' to expand roster."[10] As part of its 2013 Annual Marketing Plan for OxyContin, Purdue analyzed marketing data and concluded that "[t]he only specialties still growing are NPs and PAs, which make up the fastest-growing group in both the [extended release opioid] market and the industry

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[5] PWG000303245-51(Ex. 4, attached hereto and incorporated herein).
[6] PWG000071980-72025 (Ex. 5, attached hereto and incorporated herein).
[7] David Ollier Weber, *How Many Patients Can a Primary Care Physician Treat*?, American Association for Physician Leadership (2/11/19); Altschuler J, et al., *Estimating a reasonable patient panel size for primary care physicians with team-based task delegation. Ann Fam Med.* 2012;10(5):396–400. doi:10.1370/afm.1400 (Collectively attached hereto and incorporated herein as Ex. 6).
[8] PWG000435504 (Ex. 7, attached hereto and incorporated herein).
[9] PWG000062476 (emphasis added); PWG000437024. (Collectively attached hereto and incorporated herein as Ex. 8).
[10] PWG000062490 (Ex. 9, attached hereto and incorporated herein).

in general."[11] In the same 2013 marketing plan, Purdue also included a "market insight" that "NPs and PAs desperately seek information, typically from sales representatives."[12]

31. Purdue's marketing strategies to target generalists, nurse practitioners and physician assistants worked.

32. By at least 2014, Purdue was aware that prescribers often relied upon the company for information.

33. Purdue compensated its sales representatives through a salary and bonus structure that incentivized its sales representatives to make frequent sales calls to the highest volume prescribers of its opioid products, which it termed "super core" and "core" prescribers.[13] These prescribers were also more likely to be the most problematic concerning the abuse and diversion of its opioid products.

34. Many of Purdue sales representatives' bonuses were based entirely on the number of prescriptions generated. Purdue expressly told its sales representatives to focus on physicians who were potentially high prescribers.[14] Sales representatives whose numbers lagged were subject to disciplinary actions which included further sales training and strict managerial oversight, while disciplinary actions for noncompliant sales calls were less frequent.

35. This sales structure resulted in the dissemination of misleading claims by Purdue as set forth below.

36. Purdue's sales representatives misrepresented the safety, efficacy, and benefits of its opioid products and those of its competitors to providers in West Virginia. They did not provide

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[11] PWG003874196; see also PWG000447819 (Collectively attached hereto and incorporated herein as Ex. 10).
[12] PWG00062560 (Ex. 11, attached hereto and incorporated herein).
[13] PWG003874461 (Ex. 12, attached hereto and incorporated herein).
[14] PWG000063003; *See also* PTN000116388 (describing 80/20 rule that 20% of clinicians will write 80% of the business.) (Collectively attached hereto and incorporated herein as Ex. 13).

adequate warnings to these providers and marketed the company's opioid products to providers who were not experienced in prescribing them.

37. A 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[15]

Purdue's Branded and Unbranded Marketing

38. Purdue created, used, and widely-disseminated a significant number of written marketing materials for its opioid products in West Virginia.

39. Purdue required its sales representatives to use sales aids during sales calls with prescribers. These sales aids were reviewed, approved, and supplied by the company. These sales aids included both branded and unbranded materials. Branded materials referred to one of Purdue's opioid products by name; unbranded materials referred to opioids generally or a class of opioids, such as extended release opioids (for which Purdue was brand leader).

40. Purdue's unbranded advertising was also designed to influence the prescription writing habits of providers, to increase sales of its branded opioid products, and to restore "Purdue's diminished reputation as the leader in pain management."[16]

41. Unbranded sales aids were integral to Purdue's overall marketing strategy. Purdue created its own specific marketing plans for its unbranded campaigns, like *Partners Against Pain*,[17] kept track of advertising metrics for these campaigns,[18] evaluated its unbranded campaigns versus those of its competitors,[19] and had its marketing team play a key role in creating unbranded content.

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[15] HAZELDEN BETTY FORD FOUNDATION, *Missed Questions, Missed Opportunities*, (Jan. 27, 2016) http://www.hazeldenbettyford.org/about-us/news-and-media/press-release/doctors-missing-questions-that-could-prevent-opiod-addiction.
[16] PWG000209984 (Ex. 14, attached hereto and incorporated herein).
[17] PWG000209977 (Ex. 15, attached hereto and incorporated herein).
[18] PWG000209980 (Ex. 16, attached hereto and incorporated herein).
[19] PWG000209986 (Ex. 17, attached hereto and incorporated herein).

For example, *Partners Against Pain* ran in various forms from 1993 to 2016. Unbranded marketing pieces were handed out or promoted by Purdue's West Virginia sales representatives as part of sales calls for specific branded products. Purdue's unbranded materials also acted as a point-of-entry for sales representatives to make contact with a provider for a sales call for a branded product.

42. Unbranded materials were supposed to be left behind or referenced in sales calls. Some unbranded materials were also designed to reach the general public. For example, Purdue's *Partners Against Pain* campaign featured celebrities such as Naomi Judd and Jennifer Grey to generate more attention for Purdue's opioid messaging.[20]

43. Purdue referred to unbranded materials as a "key tactic" to "driv[e] brand differentiation while re-energizing [the extended release opioid] market,"[21] and used "unbranded HCP promotion to dispel the misperception of [extended release opioids],"[22] as part of Purdue/s Sales and Marketing Department's focus to "bring Value to customers."[23]

44. Purdue expressly referenced some of these offerings in sales calls for specific branded products and even instructed compensated physician speakers about specific marketing terms that would benefit the company.

45. Another example of Purdue's use of educational pieces to advance its marketing message was the *Complexities of Caring for People in Pain* brochure. This brochure overstated the dangers of non-steroidal anti-inflammatory drugs (NSAIDs) that contain acetaminophen and minimized the dangers of single-entity opioids like OxyContin.

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[20] PVT0054030 (Ex. 18, attached hereto and incorporated herein).
[21] PWG000062804 (Ex. 19, hereto and incorporated herein).
[22] PWG000062007 (Ex. 20, attached hereto and incorporated herein).
[23] PWG000063003 (Ex. 21, attached hereto and incorporated herein).

46. Purdue's unbranded pieces were designed to increase both a health care provider's receptiveness to its sales messages for its branded products and to advocate for pain management policies that were most beneficial for sales of Purdue's opioid products.

Sales Calls

47. One of the primary ways that Purdue marketed its opioid products in West Virginia was through in-person sales calls to health care providers, pharmacies, managed care companies, and others. Purdue required its sales representatives to document each interaction through call notes—the contents and accuracy of which Purdue relied on and used as a key part of its business.

48. Purdue trained its sales representatives to "[p]repare a concise call note that captures the key points of the dialogue between the Representative and Customer,"[24] to "ensure that call reporting clearly reflects the sales presentation,"[25] to "[r]e-read every word of your call report to make sure that it is clear and accurate,"[26] to "[a]lways review a call note before saving the record to ensure that it accurately reflects the important events that took place during the call,"[27] and to complete the call note shortly after the sales call to ensure accuracy.[28]

49. Purdue required its district managers to certify that they had carefully reviewed call notes from sales representatives, and to use a software program to track the number and percentage of sales representative call notes that were reviewed.

A. DECEPTIVE SAFETY CLAIMS AND MATERIAL OMISSIONS

50. When marketing in West Virginia, Purdue misrepresented the safety and potential adverse health risks of its opioid products. Specifically, Purdue misrepresented the increased risk

[24] PWG000035025 (Ex. 22, attached hereto and incorporated herein).
[25] PWG000035028 (Ex. 23, attached hereto and incorporated herein).
[26] PWG000035035 (Ex. 24, attached hereto and incorporated herein).
[27] PWG000035041 (Ex. 25, attached hereto and incorporated herein).
[28] PTN000001729 (Ex. 26, attached hereto and incorporated herein).

of addiction, which it sought to minimize or failed to disclose entirely. Purdue misrepresented its opioid products in numerous ways, including, but not limited to: (1) representing without qualification that OxyContin did not have a dose ceiling[29]; (2) advancing the concept of pseudoaddiction; (3) representing that its opioid products produced fewer peaks and valleys than short acting opioids leading to less euphoria or more effective pain relief; (4) misrepresenting the abuse-deterrence properties of OxyContin and Hysingla ER; (5) understating the risk of addiction; (6) failing to disclose the increased risk of addiction at higher doses of its opioid products; (7) failing to disclose the lack of evidence concerning the effectiveness of long-term use of opioids; and (8) making sweeping, unqualified safety claims about its opioid products.

Safety Claims: Unqualified No Dose Ceiling Claims

51. Purdue represented without qualification that OxyContin did not have a dose ceiling when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

52. OxyContin has a dose ceiling that is imposed by adverse reactions to patients taking increased doses of the drug, including overdose, respiratory depression, somnolence, addiction, and other serious adverse effects.

53. While the FDA approved a limited statement on OxyContin's Full Prescribing Information making clear that OxyContin's dose ceiling was imposed by adverse reactions, Purdue's West Virginia sales representatives routinely asserted that OxyContin had no dose ceiling at all. Furthermore, Purdue failed to discipline or correct sales representatives who made such claims.

[29] "Dosage ceiling" or "ceiling effect" refers to the phenomenon in which a drug reaches a maximum effect, so that increasing the drug dosage does not increase its effectiveness.

Safety Claims: Pseudoaddiction

54. Purdue downplayed the problem of addiction by simply re-labeling it as "pseudoaddiction." Purdue promoted this concept as part of its marketing for its opioid products in West Virginia when it was false, deceptive, and/or unsubstantiated at the time the claims were made.

55. The term "pseudoaddiction" was coined by Dr. David Haddox, who later became Purdue's vice president of health policy. The term was popularized for opioid treatment by Purdue. The term originated in 1989 based upon a single case report of a 17 year old leukemia patient whom Haddox determined was exhibiting behaviors associated with opioid addiction – requesting medication before scheduled dosing time and complaining of pain.[30] It referred to patients who exhibited drug-seeking behavior due to undertreated or uncontrolled pain, as opposed to addiction. Purdue consistently used this concept in sales calls and written educational materials to teach providers in West Virginia to actually prescribe more or higher doses of opioids for purportedly "pseudoaddicted" patients, who would then allegedly cease drug-seeking behavior once their pain was controlled. This concept has "not been empirically verified. No evidence supports its existence . . . ." (See n. 28.)

56. Some doctors hired by Purdue to help spread Purdue's marketing messages to other providers concede that pseudoaddiction is not a valid concept. In 2012, Dr. Lynn Webster acknowledged: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something we are debunking as a

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[30] Greene MS, Chambers RA. *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature. Curr Addict Rep.* 2015;2(4):310–317. doi:10.1007/s40429-015-0074-7 (Oct. 1, 2015) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4628053/ (Ex. 27, attached hereto and incorporated herein.)

concept."[31] Likewise, Dr. Russell Portenoy, a pain specialist with close ties to Purdue, later admitted that the concept of pseudoaddiction in chronic pain was not supported by the evidence. He stated, "The term has taken on a bit of life of its own. That's a mistake."[32]

57. In the second edition of Providing Relief Preventing Abuse, Purdue asserts:

> Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. The term pseudoaddiction has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated. Pseudoaddiction can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.[33]

58. While Purdue did not use the term "pseudoaddiction" in the third edition of Purdue's *Providing Relief Preventing Abuse*, it still advanced the concept of pseudoaddiction by stating:

> [s]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.[34]

59. Purdue also advanced the notion of pseudoaddiction in numerous other ways. In 2013, Purdue, through its partnersagainstpain.com website, linked to materials that included a consensus document created by the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM), that defined pseudoaddiction as:

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[31] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).
[32] See n. 30.
[33] PTN00003542 (emphasis in original) (Ex. 28, attached hereto and incorporated herein).
[34] PTN000003632 (Ex. 29, attached hereto and incorporated herein).

> [A] term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated.[35]

Safety Claims: Misrepresentations as to "Peaks and Valleys"

60. Purdue sought to minimize the true addictive potential of its opioid products by representing that its products provide a slow-onset, stable dose without the "peaks and valleys." Purdue thus encouraged health care providers to infer that these opioids were safer because they did not produce the euphoric high that fosters addiction. Purdue used the term "peaks and valleys," or similar words to overstate a limited finding about OxyContin's steady-state in blood levels and turned this limited finding into a claim about the purported continuous pain relief and reduced euphoric effect of its opioid products and highlighted the converse effects of its competitors' products. These statements were false, deceptive, and/or unsubstantiated at the time they were made.

61. In its 2012 and 2013 Promotional Guidelines, which were supposed to be followed by Purdue's sales representatives, Purdue stated that the claims discussed above were prohibited.[36] Contrary to these guidelines, Purdue sales representatives in West Virginia continued to represent that its products provided a slow-onset, stable dose without euphoric "peaks and valleys."

62. *In the Face of Pain* was another unbranded marketing piece that was referenced by Purdue sales representatives during sales calls with West Virginia providers. This marketing piece told pain sufferers the following:

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[35] PWG000085183 (Ex. 30, attached hereto and incorporated herein).

[36] PWG000008024-64 (p. 41 of 71); PVT0058288-323 (36 of 64) (Collectively attached hereto and incorporated herein as Ex. 31).

> Knowledge is power. Many people living with pain and even some health care providers believe that opioid medications are addictive. The truth is that when properly prescribed by a health care professional and taken as directed, these medications give relief — not a "high."[37]

Safety Claims: Abuse-Deterrence Misrepresentations

63. Opioid abuse takes several forms. The most common is oral abuse which can range from using drugs without a prescription, to swallowing higher or more frequent doses than prescribed. Other forms of opioid abuse include crushing or liquefying the drug in order to snort or inject it.

64. Purdue falsely represented that OxyContin could not be abused in certain ways.

65. In 2010, Purdue received approval from the FDA for a new formulation of OxyContin that had certain abuse-deterrent properties (ADPs) that resisted abuse from snorting or injecting. However, in its medical review of Purdue's application, the FDA found that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HC1 is still relatively easily extracted."[38]

66. After OxyContin and Hysingla ER were reformulated to include limited abuse-deterrent properties, Purdue used these features as primary selling points but failed to disclose that the abuse-deterrent properties of its opioids did not impact or prevent the most common form of abuse—oral ingestion.

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[37] PVT0037244 (emphasis added) (Ex. 32, attached hereto and incorporated herein).
[38] New Drug App. 22-272, OxyContin, Center for Drug Eval. and Research, at p. 7 (Dec. 30, 2009) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf

67. In sales calls with West Virginia health care providers, Purdue misrepresented the extent of the abuse-deterrent properties of its opioids. Purdue's representations exceeded those permitted by the FDA in 2013.[39]

68. Purdue failed to disclose that the ADPs of OxyContin and Hysingla ER did not impact oral abuse despite knowledge that its consultant conducted interviews in which some prescribers voiced concerns that the "technology does not address oral abuse."[40]

69. In 2011, Purdue published a version of *Providing Relief Preventing Abuse* that it distributed in sales calls for its opioid products and by mail.[41] Purdue's pamphlet deceptively depicted the signs of addiction by emphasizing the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa without clearly disclosing that the most common way to abuse opioids is through oral use.[42]

Safety Claims: Understating the Risk of Addiction

70. The vast majority of the "source of business" for OxyContin came from patients who continued to use the product. For example, from August 2009 to March 2011, over 80% of Purdue's business for OxyContin came from continued users.[43] For a six month period later in 2011, 86.3% of Purdue's business from OxyContin sales came from continuing prescriptions.[44] During an eight-month period in 2015, 87% of Purdue's business for OxyContin sales came from patients who continued to use the product.[45]

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[39] PWG003788164 (Ex. 33, attached hereto and incorporated herein).
[40] PWG000447841 (document is referenced both as a final report and working draft) (Ex. 34, attached hereto and incorporated herein).
[41] PWG004285193_A (Ex. 35, attached hereto and incorporated herein).
[42] PTN000003544 (Ex. 36, attached hereto and incorporated herein).
[43] PVT0026754; PWG000324280 (Collectively attached hereto and incorporated herein as Ex. 37).
[44] PWG00004088 (Ex. 38, attached hereto and incorporated herein).
[45] PWG000435505 (Ex. 39, attached hereto and incorporated herein).

71. In order to sell more of its opioid products and keep continued users on its products, Purdue sought to change the narrative about the addictive potential of its opioids in ways that would generate less scrutiny. On a Purdue controlled website, Purdue promoted material from a third-party pain advocacy group that grossly misrepresented the risks of addiction from opioids. Purdue made significant financial contributions to this pain advocacy group by specially funding its projects. These statements were false, deceptive, and/or unsubstantiated at the time they were made.

72. Exit Wounds a Survival Guide to Pain Management for Returning Veterans & Their Families, D. McGinnis (2009) was a publication, which Purdue specifically funded,[46] that was targeted to veterans seeking pain relief. The publication could be directly accessed through a Purdue website, www.inthefaceofpain.com,[47] and was attributed to the American Pain Foundation (APF), which Purdue also substantially funded.

73. On www.inthefaceofpain.com, Purdue held Exit Wounds out as an authoritative resource for veterans seeking pain relief. Purdue promoted its *In the Face of Pain* campaign and website on written material that contained express references to Purdue's opioid products including Butrans.[48] Purdue also promoted *In the Face of Pain* and linked to the website, www.inthefaceofpain.com, on Purdue's more comprehensive corporate website, www.pharma.com,[49] and its mobile-friendly version,[50] both of which also contained marketing for Purdue's opioid products, by brand name.

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[46] PTN000023060; PWG000048316 (Collectively attached hereto and incorporated herein as Ex. 40).
[47] PWG000190216, -305 (Ex. 41, attached hereto and incorporated herein).
[48] PWG000088580-85 (Ex. 42, attached hereto and incorporated herein).
[49] PWG000126647 (Ex. 43, attached hereto and incorporated herein).
[50] PWG000131838; PWG000131841 (Collectively attached hereto and incorporated herein as Ex. 44).

74. Exit Wounds contained numerous misrepresentations about the addictive potential of opioid products. For example, Exit Wounds states:

> The pain-relieving properties of opioids are unsurpassed; they are today considered the "gold standard" of pain medications, and so are often the main medications used in the treatment of chronic pain. Yet, despite their great benefits, opioids are often underused. For a number of reasons, healthcare providers may be afraid to prescribe them, and patients may be afraid to take them. At the core of this wariness is the fear of addiction, so I want to tackle this issue head-on.
>
> If your body adjusts to a drug or medication, it may become less effective over time. This is called tolerance. This is simply a physiological process that doesn't occur for all people or with all medications. Many people with persistent pain, for example, don't develop tolerance and stay on the same dose of opioids for a long time....
>
> Opioid medications can, however, be abused or used as recreational drugs, and some people who use these drugs this way will become addicted....
>
> Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications. When used correctly, opioid pain medications increase a person's level of functioning; conversely, when a drug is used by somebody who is addicted, his or her function decreases.[51]

Failing to Disclose Increased Risk of Addiction at Higher Doses

75. Taking opioids for longer periods of time or in higher doses increases the risk of addiction, as well as other serious risks and side effects.[52]

76. Aside from express representations, Purdue also downplayed the increased risk of addiction from higher doses of its opioid products through material omissions, which the company has recognized are actionable in sales trainings.[53]

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[51] PTN000023114 (emphasis in original) (Ex. 45, attached hereto and incorporated herein).
[52] *Opioid Prescribing: Where You Live Matters*, Centers for Disease Control and Prevention (visited May 7, 2019) https://www.cdc.gov/vitalsigns/opioids/index.html.
[53] PWG000190154 (Ex. 46, attached hereto and incorporated herein).

77. In its marketing, including branded materials, unbranded materials, and sales calls with providers and others in West Virginia, Purdue failed to disclose the material fact that there is an increased risk of addiction at higher doses of its opioid products.

78. The ability to escalate doses was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Unless health care providers felt comfortable prescribing increasingly higher doses of opioids to counter their patients' building of tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all. Moreover, without disclosing the increased risk of addiction, Purdue regularly encouraged providers in West Virginia to increase the dose of its opioids, or "titrate up," products like OxyContin rather than prescribe them more frequently.

79. High dose opioids have continuously been a significant part of Purdue's business in West Virginia particularly for OxyContin. While Purdue instructed sales representatives to emphasize low-dose starts, Purdue sold disproportionately high amounts of its 40 mg and above tablets of OxyContin.

80. To put this in context, one OxyContin 40 mg tablet taken every 12 hours equates to 120 MMEs (the morphine milligram equivalency) per day, a standardized unit of opioid potency. The CDC states providers should avoid or carefully justify a daily threshold above 90 MMEs.[54]

81. Purdue made the escalating dosing strengths a centerpiece of its marketing for OxyContin, stating, "OxyContin is the only ER oxycodone available in 7 tablet strengths."[55]

82. Another version of Purdue's Conversion and Titration Guide for OxyContin also claims that the "7 tablet strengths [of OxyContin] offer dosing flexibility" and features a stair-step

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[54] *Calculating Total Daily Dosage of Opioids for Safer Dosage* (visited May 7, 2019) https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

[55] PTN000072961 (Ex. 47, attached hereto and incorporated herein).

titration graphic going only upwards, and contains a reference to titration above 80 mg every 12 hours—without disclosing the increased risk of addiction from higher doses of OxyContin.

83. Purdue's West Virginia sales representatives frequently referred to high doses of OxyContin or other opioids without disclosing the increased risk of addiction at higher doses.

84. Purdue taught West Virginia sales representatives at national meetings to "close" with questions to providers about the benefit of OxyContin at higher doses.

Failing to Disclose Lack of Evidence for Long-Term Use of Opioids

85. To convince West Virginia prescribers and patients that opioids should be used to treat chronic pain, despite the unavoidable risk of addiction, Purdue had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials < 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[56] Moreover, the FDA stated in 2013 that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[57]

86. Similarly, an Evidence Report by the U.S. Health and Human Services Agency for Healthcare Research and Quality assessed the current evidence on effectiveness and harms of

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[56] CDC Guideline for Prescribing Opioids for Chronic Pain – U.S. 2016, pp. 15, 19 (March 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.

[57] Ltr. from U.S. Food and Drug Admin.to Andrew Kolodny, M.D., Physicians for Responsible Opioid Prescribing, (Sept. 10, 2013), http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

opioid therapy for chronic pain focusing on long-term (>1 year) outcomes and concluded that the evidence regarding long-term opioid therapy for chronic pain is "very limited but suggests an increased risk of serious harms that appears to be dose-dependent."[58]

87. Purdue has long been aware of the disconnect between the academic literature, which assesses efficacy of extended release opioids only as far out as 12 weeks, and the reality—which it helped create—that many patients use OxyContin and other opioids for months or years. For example, a 2011 internal email among Purdue researchers discussed the need for "new research studies of not less than 12 months duration to determine the long-term effectiveness of opioids for chronic non-cancer pain"[59]—an acknowledgment that such evidence did not exist.

88. Nevertheless, Purdue has continued to tout the purported benefits of long-term opioid use, while falsely and misleadingly implying that these benefits are supported by scientific evidence. Purdue sales representatives do not disclose the lack of evidence supporting long-term use. Purdue promotional materials likewise promote long-term use without disclosing the absence of long-term studies.

Safety Claims: General Safety Claims

89. Purdue made a series of unqualified safety claims in West Virginia that represented that the company's opioid products were safer than they actually were. These claims were false, deceptive, and/or unsubstantiated at the time they were made. Purdue also promoted OxyContin's time on the market as an implied safety claim.

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[58] Roger Chou, M.D., F.A.C.P., *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain,* Agency for Healthcare Research and Quality; U.S. Department Of Health And Humans Services, abstract available at https://www.ncbi.nlm.nih.gov/books/NBK258809/.

[59] PTN000022184 (Ex. 48, attached hereto and incorporated herein).

B. DECEPTIVE COMPARATIVE CLAIMS

90. Purdue does not possess substantiated data, comparative trials, or head-to-head studies evaluating its products versus other products.

91. For example, in 2011 Purdue indicated to sales representatives that "Statements cannot represent or suggest that a drug is safer/more effective (or make any other sort of comparative claim) unless there is substantial evidence/clinical trials supporting the statement — We have no drugs that satisfy this standard[.]"[60]

92. In spite of this, Purdue made claims that competing products were more dangerous than they actually were, less effective than they actually were, or that its products were equivalent to or superior to competing opioids and non-opioids when these claims were false, deceptive, and/or unsubstantiated at the time they were made.

93. Purdue did this in eight main ways, namely: (1) broadly representing that its own products were superior to competing opioid products; (2) representing that OxyContin was safer, more effective, as effective, or superior to other extended release opioids such as (a) Opana, (b) Duragesic, (c) methadone, and (d) Avinza; (3) representing that OxyContin was safer, more effective, as effective, or superior to immediate release opioids generally as well as (a) Dilaudid, (b) hydrocodone, (c) immediate release opioids containing acetaminophen, (d) hydrocodone combinations, (e) Lortab and Vicodin, and (f) Percocet; (4) representing that OxyContin was safer, more effective, as effective, or superior to non-opioids; (5) representing that Butrans was safer, more effective, as effective, or superior to immediate release opioids such as hydrocodone, hydrocodone combinations, Darvocet, tramadol, and Lortab; (6) representing that Ryzolt was safer, more effective, as effective, or superior to immediate release opioids generally, as well as

[60] PWG000190160 (emphasis in original) (Ex. 49, attached hereto and incorporated herein).

Percocet and Lortab specifically; (7) representing that Ryzolt was safer, more effective, as effective, or superior to other tramadol products including tramadol and Ultram ER; and (8) representing that Hysingla ER was safer, more effective, as effective, or superior to immediate release opioids including hydrocodone combinations and those containing acetaminophen.

Comparative Claims: OxyContin's General Superiority over Other Products

94. Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to other products when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

Comparative Claims: OxyContin v. Other ER Opioids

OxyContin v. Opana

95. In West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Opana ER, an extended release opioid analgesic tablet containing oxymorphone hydrochloride when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

96. Purdue's West Virginia sales representatives were taught to differentiate OxyContin from Opana ER in sales calls to providers based on (1) the warning on Opana ER's label for the consumption of alcohol; (2) the effect of food on Opana ER; and (3) the 3-7 day titration period for Opana ER compared with the 1-2 day period for OxyContin.

OxyContin v. Duragesic

97. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Duragesic, the brand name for an extended release fentanyl skin patch, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

OxyContin v. Methadone

98. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to methadone, another Schedule II extended release opioid used primarily for opioid addition treatment, but also prescribed to treat pain, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

OxyContin v. Avinza

99. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Avinza, the brand name for an extended release morphine sulfate drug that was discontinued in 2015, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

Comparative Claims: OxyContin v. Immediate Release Opioids

100. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to immediate release, also known as short-acting, opioids when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

101. Substantiation aside, comparing OxyContin to immediate release opioids made financial sense. Purdue closely tracked and monitored those providers in West Virginia who were most likely to switch a patient from an immediate release opioid to an extended release opioid.

102. At a national sales meeting, Purdue trained its sales staff to ask the following question of a provider:

> **Positioning:**
>
> "Doctor, do you realize (or are you aware) that initiating 10 mg q12h of OxyContin is comparable to initiating a 5 mg hydrocodone/oxycodone q4-6h after trying tramadol, while also giving the patient all the benefits of less frequent dosing and providing a single entity opioid?

> You will be providing a more convenient q 1 2h dosing regimen. Doctor since these are established opioid patients with persistent ATC moderate to severe pain doesn't this make sense?[61]

OxyContin v. Dilaudid

103. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Dilaudid, the brand name of an immediate release opioid consisting of hydromorphone that is manufactured by Purdue among others and which has been on the market since 1984, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

104. Substantiation aside, comparing OxyContin to an immediate release opioid Purdue also owned made financial sense because it encouraged the use of more expensive opioid products that would have to be taken over a longer time period.

OxyContin v. Hydrocodone

105. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to immediate release hydrocodone when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

OxyContin v. Products Containing Acetaminophen

106. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to other pain-relieving products containing acetaminophen when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

107. Despite not having head-to-head studies comparing the safety of its opioid products with those containing acetaminophen, Purdue emphasized the dangers of excessive levels of

[61] PWG000109649 (emphasis added) (Ex. 50, attached hereto and incorporated herein).

acetaminophen in the context of promoting its opioid products despite repeatedly recognizing that such claims were unsubstantiated comparative claims.

108. Purdue admitted in its Guidelines on Product Promotion that referring to OxyContin's "No Defined Maximum Dose" or "Single Entity Opioid Status" "could imply superiority of OxyContin® to non-opioid/opioid combination products"[62] despite having a marketing piece titled "OxyContin Single-Entity Opioid Flashcard," which was created "[t]o help communicate to prescribers that OxyContin® is a single-entity opioid that does not contain acetaminophen, aspirin, or ibuprofen[.]"[63]

109. Purdue's 2013 Guidelines on Product Promotion stated, "Any discussion or reference to dosing limitations of another agent may lead to a claim of implied superiority."[64]

110. In its 2013 Guidelines on Product Promotion, Purdue specifically listed unsubstantiated superiority claims as including:

> Asking the HCP if they could think of 1-2 Percocet® around-the-clock patients who could benefit from no acetaminophen.
>
> Stating to an HCP that they should start a patient on Butrans® or OxyContin® when they want to get patients off of acetaminophen.
>
> Discussing the benefits of no acetaminophen and q 1 2h dosing with OxyContin® or 7 day dosing with Butrans®.[65]

111. Yet, Purdue's marketing materials widely disseminated these same unsubstantiated claims in West Virginia.

112. One of these unbranded marketing pieces distributed by Purdue, titled "Maximum Recommended Daily Doses of Opioid Analgesics Containing APAP (acetaminophen) or ASA

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[62] PVT0058322 (Ex. 51, attached hereto and incorporated herein).
[63] PWG000099907 (Ex. 52, attached hereto and incorporated herein).
[64] PWG000008057 (Ex. 53, attached hereto and incorporated herein).
[65] PWG000008059 (Ex. 54, attached hereto and incorporated herein).

(aspirin)," listed the maximum dosage of competing opioid products[66] and was often used by Purdue sales representatives to emphasize, explicitly and implicitly, that OxyContin had no maximum dosage.

113. On websites that it controlled, Purdue linked to materials that misrepresented the potential dangers between both non-opioid and opioid products containing acetaminophen and opioid products like OxyContin that do not contain acetaminophen. For example, on Purdue's *In the Face of Pain* website, it linked to the APF guide for veterans, Exit Wounds, which misrepresented these potential dangers.

114. Exit Wounds stated in relevant part:

> [A]ceteminophen can relieve mild to moderate pain and treat fever; but it is not an NSAID and will not reduce swelling. It produces few, if any, side effects at the doses that can relieve pain, **but it can damage the liver when used in large doses, especially if used with alcohol**.
>
> * * *
>
> [A]cetaminophen is often combined with an opioid medication—usually, in the same pill or capsule—to treat moderate to severe pain. Be sure to check the amount with your doctor or pharmacist. Don't decide on your own to take extra acetaminophen if a combination pain medicine is not controlling your pain, you could end up using too much acetaminophen, and that could cause liver damage. **Currently, there is concern in the medical community about the growing rate of liver damage associated with large doses of acetaminophen.**
>
> * * *
>
> **Possible side effects of acetaminophen include: Possible liver damage at high doses[;] — Liver damage and stomach bleeding if used in combination with alcohol[.]**
>
> * * *
>
> **The pain-relieving properties of opioids are unsurpassed; they are today considered the "gold standard" of pain medications, and so are often the main medications used in the treatment of chronic pain**. Yet,

[66] PWG000089678 (Ex. 55, attached hereto and incorporated herein).

> despite their great benefits, opioids are often underused. For a number of reasons, healthcare providers may be afraid to take them. At the core of this wariness is the fear of addiction, so I want to tackle this issue head-on.
>
> * * *
>
> Opioid medications can, however, be abused or used as recreational drugs, and some people who use these drugs this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing harm. They continue to crave and use the drug despite the harm it may be causing to their health, their relationships, or their ability to function in other spheres of life.
>
> * * *
>
> Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid medications. When used correctly, opioid pain medications *increase* a person's level of functioning; conversely, when a drug is used by somebody who is addicted, his or her function decreases.[67]

115. Purdue's West Virginia sales representatives likewise made claims comparing OxyContin and other products containing acetaminophen.

OxyContin v. Hydrocodone Combinations

116. As the name suggests, hydrocodone combinations are opioids containing hydrocodone and other active ingredients such as acetaminophen, aspirin, or other compounds. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to hydrocodone combinations when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

OxyContin v. Lortab or Vicodin

117. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Lortab or Vicodin, two brand name

[67] PTN0000023114 (bold emphasis added, italicized emphasis in original) (Ex. 56, attached hereto and incorporated herein).

examples of hydrocodone combination products, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

OxyContin v. Percocet

118. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Percocet, the brand name for a combination of short-acting opioid product containing oxycodone and acetaminophen, when those claims were false, deceptive, and/or unsubstantiated at the time they were made

Comparative Claims: OxyContin v. Non-opioids

119. In its marketing in West Virginia, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to non-opioids for the treatment of pain when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

Comparative Claims: Butrans v. Immediate Release Opioids

Hydrocodone and Hydrocodone Combinations

120. In its marketing in West Virginia, Purdue represented that Butrans, its buprenorphine opioid product prescribed to treat pain, was safer than, more effective than, as effective as, or superior to hydrocodone and hydrocodone combinations when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

121. Purdue's sales representatives generally claimed that Butrans was better than hydrocodone or hydrocodone combinations because of its lack of acetaminophen—especially for the elderly.

Comparative Claims: Butrans v. Darvocet or Tramadol

122. In its marketing in West Virginia, Purdue represented that Butrans was safer than, more effective than, as effective as, or superior to other opioids including Darvocet, a combination

narcotic pain reliever and fever reducer consisting of propoxyphene and acetaminophen, or tramadol when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

Comparative Claims: Butrans v. Lortab

123. In its marketing in West Virginia, Purdue represented that Butrans was safer than, more effective than, as effective as, or superior to Lortab when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

Comparative Claims: Ryzolt v. Other Tramadol Products

124. In its marketing in West Virginia, Purdue represented that Ryzolt, a branded tramadol product, was safer than, more effective than, as effective as, or superior to other tramadol products, such as generic tramadol and branded Ultram ER, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

Comparative Claims: Hysingla ER v. Acetaminophen Products and Hydrocodone Combinations

125. In its marketing in West Virginia, Purdue represented that Hysingla ER, its branded hydrocodone hydrochloride drug that did not contain acetaminophen, was safer than, more effective than, as effective as, or superior to opioids containing acetaminophen products and hydrocodone combinations when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

C. DECEPTIVE BENEFIT CLAIMS

126. In its marketing materials, Purdue made a series of representations about the benefits and characteristics of its opioid products that were not approved by the FDA and for which it lacked substantiation. Purdue did this in three main ways, namely by (1) representing that its

products improved a patient's quality of life; (2) representing that its products would improve a patient's function; and (3) representing that its opioid products helped a patient sleep.

Benefit Claims: Quality of Life

127. Purdue sales representatives in West Virginia claimed that Purdue's opioid products could improve a patient's quality of life when these claims were false, deceptive, and/or unsubstantiated at the time they were made.

128. The CDC Guideline concluded that after a "systematic review of the best available evidence," by an expert panel free of conflicts of interest, that no study exists to show opioids are effective for outcomes related to quality of life.[68] Furthermore, powerful narcotics that can kill patients and commit them to a life of addiction or recovery cannot be said to broadly improve a patient's quality of life.

129. In its 2012 Guidelines on Product Promotion, Purdue stated and trained its sales representatives that "[y]ou cannot make a quality of life claim unless supported by substantial evidence — We have no drugs that meet this standard," and "[y]ou cannot ask a question of the HCP that causes him/her to make a quality of life conclusion about a Purdue product."[69]

130. In its 2013 Guidelines on Product Promotion, Purdue stated and trained its sales representatives that: "A quality of life claim is a claim that a person's well-being, or certain aspects of a person's well-being, will be improved by using a certain product. You cannot make a quality of life claim unless supported by substantial evidence. We have no drugs with clinical studies that satisfy this standard."[70]

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[68] CDC Guideline for Prescribing Opioids for Chronic Pain – U.S. 2016, p. 9 (March 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.

[69] PVT0058330 (Ex. 57, attached hereto and incorporated herein).

[70] PWG000008070 (emphasis added) (Ex. 58, attached hereto and incorporated herein).

131. Despite having no evidence to support these claims, Purdue trained its West Virginia sales representatives to make quality of life claims in sales calls to health care providers, which they did routinely.[71]

Benefit Claims: Improved Function

132. Purdue represented that its opioid products would improve a patient's function when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

133. While opioids may initially improve function by providing pain relief in the short term, Purdue's claim that opioids improve patients' function in the long term is unsubstantiated.

134. The 2016 CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use." The CDC reinforced this conclusion throughout the Guideline, finding that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later," "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term therapy," and "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[72]

135. Despite the lack of evidence, Purdue represented in its written marketing materials that its opioid products could improve patients' function.

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[71] PWG000007356 (Introduction to Pain Management 2013 Level 100 Sales Training) (Jan. 9, 2013) (stating in a Purdue sales training presentation that a "Comprehensive Evaluation" includes, among other things, a "Pain Assessment" in which one should "Discuss qualities of pain" and "Evaluate impact of pain on physical and psychological function") (Ex. 59, attached hereto and incorporated herein).

[72] CDC Guideline for Prescribing Opioids for Chronic Pain – U.S. 2016, pp. 12, 15, 18, 20 (March 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.

136. In an advertisement originally posted on The Atlantic magazine's website in 2015 titled *Take My Pain Away . . . A Physician's Perspective of Prescription Opioids and Pain Management*, Purdue made the unsubstantiated claim that all physicians who treat chronic pain with opioids have a significant number of patients that experience quality of life improvements. Purdue used a paid consultant and past president of the American Academy of Pain Medicine, a third party pain advocacy group that Purdue substantially funded, to author this sponsored content.

137. Specifically, Purdue stated in *Take My Pain Away*:

> Today, all physicians who treat chronic pain with opioids have a significant number of patients in our practices that are back at work as full-time employees or back at school as full-time students because their pain is tolerable and under control. I have a group of patients who take opioids on a regular, sustained basis, and no one could pick them out of any group of their friends, neighbors, or coworkers. They look and act like anyone else. They have no cognitive impairment and no sign of sedation or drowsiness because their treatment is under control, they are appropriate patients for the treatment, and they are monitored by their treating physician or healthcare professional.
>
> * * *
>
> Pain makes people less able to continue their normal activities and, eventually, if untreated, pain can ruin their lives. . . . Pain can make a patient depressed, and depression leads to more physical pain.
>
> * * *
>
> But for patients who don't respond to other pharmacological agents, or to physical or complementary therapies, it is very good to know that there is a class of potent medications [high-dose opioids1 that, when used carefully with the right patients, might allow them to live more comfortable, active, and normal lives.[73]

[73]https://web.archive.org/web/20170906232515/www.theatlantic.com/sponsored/purdue-health/take-my-pain-away/202/(emphasis added); PWG000214678 (2014 draft with revisions, p. 3) (Ex. 60, attached hereto and incorporated herein).

138. While the piece did not mention OxyContin by name, Purdue used *Take My Pain Away* as an advertisement for OxyContin that was consistent with Purdue's brand strategy for OxyContin to "[e]levate the importance of abuse deterrence as key driver for ERO prescribing"[74] and "[g]enerate supporting data and related promotional materials on abuse deterrence."[75]

139. *Take My Pain Away* recommended opioids with abuse deterrent properties, a category in which OxyContin was the clear market-leader[76] and the first opioid to receive "Tier 1 and Tier 3 labeling that describes abuse-deterrent characteristics."[77]

140. The emphasis on abuse deterrent properties within the piece was amplified in tag-along correspondence in which Purdue encouraged recipients to read and share *The Atlantic* articles including the *Take My Pain Away* piece and emphasized "recent technological approaches to developing opioid medications with abuse-deterrent properties."[78]

141. As of March 2015, Purdue's *Take My Pain Away* had at least 26,236 page views, 21,998 unique visitors to the website, and led to 37,681 impressions on Twitter.[79] Purdue's *Take my Pain Away* is currently still online.

142. Likewise, Purdue's West Virginia sales representatives claimed in sales calls that its opioid products could improve a patient's function.

Benefit Claims: Sleep Aid

143. Purdue represented that its opioid products would act as a sleep aid when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

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[74] PWG000029073 (Ex. 61, attached hereto and incorporated herein).
[75] PWG000063473 (Ex. 62, attached hereto and incorporated herein).
[76] See n. 73.
[77] PWG000029079 (Ex. 63, attached hereto and incorporated herein).
[78] PWG000133628 (Ex. 64, attached hereto and incorporated herein).
[79] PWG000204609 (Ex. 65, attached hereto and incorporated herein).

144. While Purdue's opioids may relieve pain, and some are dosed every 12 hours as opposed to shorter intervals, the claim that opioids improve a patient's sleep is unsubstantiated. Indeed, one of the most significant risks of OxyContin and other opioids is respiratory depression, which is more difficult to detect or counteract during sleep.

D. DECEPTIVE CLAIMS ABOUT OPIOID USE IN THE ELDERLY

145. Purdue misrepresented the safety of OxyContin in the elderly through a series of affirmative statements and material omissions. Purdue specifically and unfairly targeted providers who worked with nursing homes or who had large elderly patient populations.

146. Purdue likewise misrepresented the safety of Butrans in elderly patients with affirmative statements and material omissions. The label for Butrans states "[w]hile no dose adjustment is recommended on the basis of age, administer Butrans with caution in elderly patients."[80]

147. Purdue designated providers "LTC" for long term care, included these providers on target lists for sales representatives to visit, and established prescribing goals for LTC providers that sales representatives were supposed to meet.

148. Purdue's sales representatives called on nursing homes and Purdue instructed them to have a specific business plan in place to maximize demand for its opioid products.

149. Purdue misrepresented the safety of its products in the elderly by (1) omitting the material fact that there is a greater risk of respiratory depression from OxyContin and Butrans in elderly patients; (2) omitting the material fact that low-dose starts of OxyContin in elderly patients most often lead to higher doses of OxyContin where risks are increased; (3) making unsubstantiated comparative claims about OxyContin and its extended release competitor,

[80] PWG003467787 (Ex. 66, attached hereto and incorporated herein).

Duragesic, which was popular for providers to prescribe to elderly patients; and (4) making unsubstantiated comparative claims about Butrans and competing products with acetaminophen.

E. OMISSIONS OF MATERIAL CONNECTIONS

150. Purdue routinely referred to positions that third party pain advocacy groups would take with respect to a health care issue without clearly and conspicuously disclosing the material fact that Purdue was a substantial financial contributor to the third party group.

151. This material omission had the effect of making the third party pain advocacy group's position appear more credible or more neutral than it otherwise would have had the material fact of Purdue's substantial monetary contribution been disclosed.

152. Purdue was the predominant financial contributor to the American Pain Society (APS). Between 2012 and 2017, Purdue gave APS $542,259.52, 56% of its total funding, while combined contributions from four other opioid manufacturers totaled $420,465.[81] From 2006 to 2016, Purdue gave APS at least $628,925 in educational grants. Between 1997 and 2012, Purdue gave APS $3,091,264.[82]

153. Purdue was also the predominant financial contributor of the American Academy for Pain Medicine (AAPM). Between 2012 and 2017, Purdue provided 60% of AAPM's total funding, providing $725,584.95 compared with just $473,825 AAPM received from four other large branded-opioid manufacturers combined.[83]

154. Purdue also significantly funded the American Pain Foundation (APF), which was highly dependent on pharmaceutical company funding and produced numerous publications

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[81] PWG004285195 (Ex. 67, attached hereto and incorporated herein); Senate Report available at: https://www.mccaskill.senate.gov/media-center/news-releases/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.

[82] PTN000017361 (Ex. 68, attached hereto and incorporated herein).

[83] See n. 80.

touting the use of opioids to treat chronic pain. Between 2006 and 2016, Purdue gave APF $1,356,000. Between 1999 and 2012, Purdue was one of APF's biggest donors, with donations totaling $3.6 million.[84]

155. With Purdue's financial backing, APF created several documents that advanced messages that were favorable to Purdue. For example, APF published Treatment Options: A Guide for People Living with Pain[85] that downplayed and omitted the serious risks of opioids while overstating the risks of non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen.[86]

156. APF took actions that were directly in Purdue's interest. As shown in internal emails, Purdue even worried that APF would be perceived as acting too much on its behalf where APF's position was consistent with branded manufacturers, as opposed to positions more consistent with general pain patient advocacy.[87]

157. APF took action that directly benefited Purdue.

158. APF and Purdue were so connected that Dr. Richard Sackler even e-mailed Dr. David Haddox, Purdue's Vice President of Health Policy, upon learning that APF shut down in May 2012 after a Congressional investigation launched, stating "What is the story here? We were founding funders."[88]

159. Purdue referred to third party groups in its marketing materials without disclosing its financial connection to the groups alongside authoritative, unbiased sources.

160. *Providing Relief, Preventing Abuse* brochures, were handed out to the general public in West Virginia, included APS and the AAPM along with references to federal regulatory

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[84] See n. 81.
[85] PWG009243973 (Ex. 69, attached hereto and incorporated herein).
[86] PWG009243990-91 (Ex. 70, attached hereto and incorporated herein).
[87] PTN000024706 (Ex. 71, attached hereto and incorporated herein).
[88] PTN000023246 (emphasis added) (Ex. 72, attached hereto and incorporated herein).

and law enforcement agencies such as the DEA and FDA without disclosing Purdue's funding connection to APS or AAPM.[89]

161. In standardized presentations Purdue created to give to health care providers and other groups, Purdue held out APS and AAPM, among others as "Resources for Appropriate Pain Management and Responsible Prescribing Practices" without disclosing Purdue's funding connection to these groups.[90]

162. Purdue also linked to deceptive APF materials like Exit Wounds on its pain advocacy website, www.inthefaceofpain.com, without disclosing Purdue's significant funding of the group.[91]

163. Purdue's West Virginia sales representatives frequently referenced recommendations from other pain advocacy groups that Purdue significantly funded without clearly and conspicuously disclosing this material fact.

164. For example, Purdue instructed its sales representatives to use the APS guidelines to advance its own branded marketing message. As with materials published by other pain advocacy groups, the APS guidelines advanced Purdue's position by emphasizing the superiority of delivery of the opioid by oral use and attempting to legitimize high doses of opioids, defining a "high" dose to be > 200 MME per day.[92]

F. PURDUE BEARS SIGNIFICANT RESPONSIBILITY FOR THE OPIOID EPIDEMIC IN WEST VIRGINIA

165. The United States has approximately 4.4% of the world's population, but accounts for the vast majority of opioids consumed globally, including oxycodone, which is the

[89] PWG003738850,-61 (Ex. 73, attached hereto and incorporated herein).
[90] PWG000290879 (Ex. 74, attached hereto and incorporated herein).
[91] PWG000058550 (Ex. 75, attached hereto and incorporated herein).
[92] PWG000225448 (Ex. 76, attached hereto and incorporated herein).

concentrated active ingredient in OxyContin. In 2014, the United States accounted for 81% of the global total consumption of oxycodone.[93] A 2017 United Nations report estimated that the United States consumed 99% of the world's opioid production.[94] Within the United States, West Virginia accounts for disproportionately high rates of opioid consumption generally and oxycodone consumption specifically for its population.

166. A cause for this imbalance is not that Americans and West Virginians experience pain at higher rates than their global or national peers or have greater access to healthcare. Rather, one of contributing factors to the severity of the current opioid crisis is "aggressive marketing by pharmaceutical companies" as recognized by the Director to the National Institute on Drug Abuse within the National Institutes of Health in a 2014 report to the United States Senate.[95]

167. Purdue's aggressive marketing and other conduct played a substantial role in creating and prolonging the opioid crisis in West Virginia. Purdue's conduct helped lead to addiction, abuse, diversion, and other negative outcomes that have caused the State to spend substantial resources in attempts to address the epidemic.

168. Purdue's OxyContin is the branded opioid that is most associated with the opioid crisis nationally and in West Virginia. Purdue created the market for a highly potent, extended release single entity opioid consisting of oxycodone that was easily manipulated by misrepresenting OxyContin's potential for addiction and abuse through an unprecedented

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[93] Nora Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Nat'l Institute on Drug Abuse (May 14, 2014) https://www.drugabuse. gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (internal citations omitted).

[94]https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/Narcotic_drugs_ technical_publication_2017.pdf

[95] Nora Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Nat'l Institute on Drug Abuse (May 14, 2014) https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-op io id s-hero in-prescription-drug-abuse.

marketing campaign for a Schedule II narcotic that targeted some of the highest prescribing providers and pharmacies of opioids and OxyContin in West Virginia.

169. In many cases, Purdue had knowledge of signs of abuse or diversion from the West Virginia providers and pharmacies that its sales representatives called upon yet Purdue ignored these red flags.

170. Purdue's marketing was effective. Purdue's sales calls to providers generated more prescriptions for OxyContin and its other opioid products.

171. Purdue knew that more sales calls, to the top prescribers of its opioid products, led to more prescriptions. A Purdue consultant found: "For all deciles, increased calls are associated with higher OxyContin TRx growth—a sign of promotional sensitivity" in a marketing document from 2013 titled "OxyContin Growth Opportunities."[96] Similarly, Purdue had evidence that "[r]eps who make more OxyContin P1s on high-decile prescribers generate more OxyContin growth in their territory."[97] P1 denotes first priority or presenting OxyContin first in a sales call.

172. As part of these sales calls, Purdue emphasized "new to brand" starts and trained its West Virginia sales representatives to ensure that doctors started new patients on OxyContin.

173. Purdue worked with distributors to ensure that pharmacies had the maximum supply of OxyContin. Distributors set threshold limits for a pharmacy's opioid supply that are supposed to serve as a protection against abuse or diversion. However, as a self-described "strategic imperative," Purdue sought to have distributors create separate threshold limits for oxycodone and OxyContin, instead of one for oxycodone generally, and to create separate

[96] PWG000447858 (referencing both a final report and working draft) (Ex. 77, attached hereto and incorporated herein).
[97] PWG000447879 (Ex. 78, attached hereto and incorporated herein).

threshold limits for oxycodone immediate release 30 mg in order to ensure that pharmacies carried more OxyContin.[98]

174. Purdue sales representatives made sales calls to, and used, pharmacies as a source of information regarding problematic prescribers. Purdue also used pharmacies as a source of information to track down high-prescribing doctors as well as to identify new prescribers to call on.

175. Purdue ignored red flags for abuse or diversion at West Virginia pharmacies and continued to push OxyContin.

176. Purdue also made sales calls to pharmacies that it knew from internal data to dispense both significant quantities of and high percentages of high dose OxyContin.

177. The large number of OxyContin prescriptions, especially at high doses, has helped drive a substantial number of residents to become addicted in West Virginia. A 2015 meta-analysis of 38 studies evaluating opioid misuse, abuse, and addiction in chronic pain patients found rates of addiction averaging between 8-12%[99] though the actual percentage is most likely higher because of those misclassified as physically tolerant.

178. A study of 3,520 opioid-dependent individuals conducted by clinical investigators from Washington University in St. Louis and others found that oxycodone and hydrocodone are "by far" the most popular drugs of choice among prescription opioid abusers.[100] Within that subset, oxycodone was the choice of significantly more users (44.7%) than hydrocodone (29.4%) because

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[98] PWG000212739 (Ex. 79, attached hereto and incorporated herein).

[99] Kevin E. Vowles, *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review and Data Synthesis*, PAIN, 569, 156:4 (April 2015).

[100] Theodore Cicero, PhD, *Factors Influencing the Selection of Hydrocodone and Oxycodone as Primary Opioids in Substance Abusers Seeking Treatment in the United States*, PAIN, 154:12 (2013).http://cicero.wustl.edu/skip/publications/documents/Factorsinfluencingtheselectionofhydrocodone andoxycodoneaspr imaryopioidsinsubstanceabuserssee.pdf.

the quality of the high was viewed to be much better by oxycodone users (54%) than hydrocodone users (20%).[101] The study found "that hydrocodone was less attractive than oxycodone because of hydrocodone's frequent combination with other products like acetaminophen."[102]

179. Oxycodone's popularity over other opioids is supported elsewhere in the literature. For example, another study found that oxycodone scored most favorably among patients dependent on heroin compared with fentanyl, buprenorphine, and morphine.[103]

180. Given this preference for oxycodone, it is no surprise that OxyContin, which offered concentrated oxycodone that could be easily manipulated to access, was popular and a substantial contributor to the opioid epidemic in West Virginia.

181. OxyContin's addictive qualities and easy manipulation led a subset of addicts to turn to heroin, which was cheaper, when the old formulation of OxyContin was removed from the market on August 5, 2010, and replaced with the reformulated version beginning August 9, 2010.

182. Statistical evidence shows that the abrupt growth in the heroin death rate, which the CDC found to have increased by more than five times between 2010 and 2016,[104] was caused, in part, by the reformulated OxyContin. In West Virginia, heroin use in persons 12 years and older increased from .25% to .36% (3% higher than the national average).

183. A publication by the National Bureau of Economic Research reached this conclusion by analyzing time-series evidence that dated the changes in the heroin and opioid markets to the month in which reformulation occurred by analyzing the availability of heroin in

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[101] See n. 99.
[102] See n. 99.
[103] Corner, S.D. *Relative Abuse Liability of Prescription Opioids Compared to Heroin in Morphine-maintained Heroin Abusers*. Neuropsychopharmacology, 33(5):1179-1191 (2008) https://www.nap.edu/read/24781/chapter/8#190).
[104] *Heroin Overdose Data*, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/heroin.html.

local markets and by accounting for alternative theories.[105] The study also found that outcomes such as deaths, poisonings, emergency room visits, and enrollments in treatment programs from heroin abuse have all increased since August 2010.[106]

184. A similar working paper by the Rand Corporation in January 2017 stated "[o]ur results imply that a substantial share of the dramatic increase in heroin deaths since 2010 can be attributed to the reformulation of OxyContin."[107]

185. This conclusion is consistent with national data showing a spike in the number of overdose deaths involving heroin showing a four-fold increase from 2010.[108]

186. Likewise, the finding is consistent with data from West Virginia where deaths from heroin overdoses have increased from 28 in 2010 to 618 in 2017.[109, 110] This is three times the national rate of deaths. See n. 120.

187. This statistical evidence concerning heroin overdoses linked to the reformulation of OxyContin serves as a marker for those individuals addicted or otherwise impacted by the prior formulation of OxyContin.

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[105] William Evans, How the Reformulation of OxyContin Ignited the Heroin Epidemic, NATIONAL BUREAU OF ECONOMIC RESEARCH (hereinafter NBER) 6 (April 2018) https://www3.nd.edu/"-elieber/research/ELP.pdf

[106] Coplan, Paul M. *Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics*." Pharmacoepidemiology and Drug Safety Vol. 22,12 (2013): 1274-82, doi:10.1002/pds.3522; Theodore Cicero, *Effect of Abuse-Deterrent Formulation of OxyContin*, New England Journal of Medicine 367(2): 187-189 (2012); Theodore Cicero, *The Changing Face of Heroin Use in the United States: a Retrospective Analysis of the Past 50 Years*, JAMA PSYCHIATRY 71(7):821.826 (2014); Theodore Cicero, *Shifting Patterns of Prescription Opioid and Heroin Abuse in the United States*, New England Journal of Medicine, 373(18): 1789-1790 (2015); and Wilson Compton, *Relationship between Nonmedical Prescription-Opioid Use and Heroin Use*, New England Journal of Medicine 374(2): 154-163 (2016)).

[107] Abby Alpert, *Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids*, Rand Corporation (Jan. 2017).

[108] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (Rev. Jan. 2019).

[109] *West Virginia Opioid Summary*, National Institute on Drug Abuse (Ex. 80, attached hereto and incorporated by reference here.)

[110] See n. 108

188. Opioid use, morbidity, and mortality have increased exponentially nationwide and across West Virginia in the years since Purdue first began aggressively marketing opioids for long-term use.

189. In 2016, 2.08 million prescriptions were written to West Virginians for opioids – 110 prescriptions for every 100 people. During that same year, West Virginia had the highest rate of opioid-related overdose deaths than any state in the country – 43.4 per 100,000.[111]

190. In 2017, 81.3 opioid prescriptions were written for every 100 persons in West Virginia, compared to the national average of 58.7 prescriptions. See n. 113.

191. The Substance Abuse and Mental Health Services Administration ("SAMHSA") has stated that the number of individuals enrolled in substance use treatment in West Virginia has varied between 10,711 in 2011, 9,596 in 2012, 10,057 in 2013, and 10,099 in 2015.[112]

192. Similarly, SAMHSA has stated that in a single day approximately one-half of the West Virginians enrolled in substance abuse treatment receive methadone or buprenorphine as part of a substance abuse program.[113]

193. The opioid epidemic in West Virginia has also had a negative impact on infants, children, the elderly, and families generally.

194. Between 2014 and 2016 the rate of Neonatal Abstinence Syndrome increased from a rate of 33.4 per 1,000 births to 37 cases per 1,000 births. The southeastern region of West Virginia had an even higher rate of 48.76 per 1,000 births.[114]

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[111] See n. 108.
[112] *Behavioral Health Barometer West Virginia*, Vol. 4, Substance Abuse and Mental Health Services Admin. 13, (hereinafter Behavioral Health Barometer West Virginia) (Ex. 81, attached hereto and incorporated by reference herein.)
[113] See n. 108.
[114] See n. 108.

195. Unfair and deceptive marketing of opioids by Purdue also has a significant detrimental impact on children in West Virginia. Adolescent misuse of prescription opioids is particularly devastating because it is the peak period in life when people first misuse opioids. Purdue pushing the overprescribing of opioids has given more young children access to them.

196. Parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system. Children removed from their home as a result of parental substance abuse are likely to remain in foster care longer and have significantly higher rates of adoption than those in foster care for other reasons. A higher rate of adoption indicates that children removed from their homes remain in foster care longer and are less likely to exit from foster care to reunite with biological parents.

197. In February 2018, Purdue stated that it has ceased detailing (having sales representatives provide doctors with benefits, side effects, and other information specific to a particular drug) its opioid products to health care providers. Even if true, this does not affect the State's nuisance abatement action because the company could resume sales calls and other marketing, the effects of Purdue's conduct are long-term, pervasive, and continuous, and substantial equitable costs of abating the nuisance remain.

III. PURDUE PHARMA INC. AND PURDUE PHARMA L.P. ARE BOTH RESPONSIBLE FOR PURDUE PHARMA L.P.'S UNLAWFUL ACTS OR PRACTICES

198. Purdue Pharma Inc. and Purdue Pharma L.P. acted together to carry out all of the misconduct alleged in this Complaint.

199. According to its official corporate documents, Purdue Pharma Inc.'s purpose is manufacturing, sales, distribution, and research and development with respect to pharmaceutical, toiletry, chemical and cosmetic products, directly or as the general partner of a partnership engaged in those activities. That is the conduct at issue in this suit.

200. Purdue Pharma Inc. controlled Purdue Pharma L.P. as its general partner and is liable for the misconduct of the partnership as a matter of law. Purdue Pharma Inc. is also the general partner of Purdue Holdings L.P., which holds the sole limited partnership interest in Purdue Pharma L.P.

201. Purdue Pharma L.P. employed the sales representatives and paid the doctors to promote Purdue's drugs. That is a key element of the conduct at issue in this suit.

202. Purdue Pharma Inc. and Purdue Pharma L.P. shared the same physical offices, the same CEOs, and many of the same officers.

IV. RICHARD SACKLER, M.D. LED AND DIRECTED PURDUE'S MISCONDUCT

203. This section of the Complaint identifies an individual who is at least partially personally responsible for Purdue Pharma L.P.'s illegal scheme. An individual is personally liable if: (a) he participated in the misconduct; or (b) he knew about the misconduct and failed to stop it; or (c) he should have known about the misconduct and they failed to stop it. In this case, the individual defendant, Richard Sackler, M.D. made the decisions to break the law; he helped control the unfair and deceptive conduct; and he personally collected many millions of dollars from the deception.

Summary Richard Sackler's Misconduct

204. Richard Sackler was a chief architect of Purdue's deceptions. Richard Sackler and members of his family directly benefited from the profits derived from this deceptive conduct. In summary:

a. He controlled the misconduct described in the foregoing paragraphs.

b. He knew, or should have known, that sales representatives were sent to West Virginia to promote opioids to prescribers thousands of times.

c. He knew, or should have known, that the sales representatives in West Virginia would unfairly and deceptively promote opioid sales that are risky for patients, including by: falsely blaming the dangers of opioids on patients instead of the addictive drugs; pushing opioids for elderly patients without disclosing the higher risks; pushing opioids for patients who had never taken them before without disclosing the higher risks; pushing opioids as substitutes for safer medications, with improper comparative claims; falsely assuring doctors and patients that reformulated OxyContin was safe; pushing doctors and patients to use higher doses of opioids, without disclosing the higher risks; pushing doctors and patients to use opioids for longer periods of time without disclosing the higher risks; and pushing opioid prescriptions by doctors that Purdue knew were writing dangerous prescriptions.

205. He knowingly and intentionally took money derived from Purdue Pharma's deceptive business in West Virginia.

206. He knowingly and intentionally sought to conceal his misconduct.

207. He knew, or should have known, the sales representatives would conceal the facts about Purdue Pharma's opioids from West Virginia doctors and patients.

208. He knew, or should have known, that prescribers, pharmacists, and patients in West Virginia would rely on Purdue Pharma's deceptive sales campaign to prescribe, dispense, and take Purdue Pharma's opioids. Securing that reliance was the purpose of the sales campaigns.

209. He knew, or should have known, that staff reporting to him would reinforce these misleading acts through thousands of additional acts in West Virginia, including by sending deceptive publications to West Virginia doctors.

210. Richard Sackler made choices that caused part of the opioid epidemic. Richard Sackler is an owner of Purdue Pharma, Inc., and he served many years as an officer and as a member of its board of directors. Richard Sackler had the power to, and did, decide how addictive narcotics were sold. Through the deceptive marketing campaigns and sales tactics, which were approved by Richard Sackler, more patients were lured to opioids at higher doses for longer than ever before.

211. The misconduct of Richard Sackler was intentional and with full knowledge that those acts were unlawful, as illustrated by criminal convictions and judgments by other courts in consumer actions prior to 2007.

V. VIOLATIONS OF THE LAW

COUNT I
WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT
West Virginia Code § 46A-6-104

212. The Plaintiff, the State of West Virginia, incorporates by reference and re-alleges each and every allegation contained in paragraphs 1-211 of this Complaint.

213. The Defendants' advertising, promotion, and offering of its opioid products, as alleged herein, constitutes "trade" or "commerce" as defined in W. Va. Code § 46A-6-102(6).

214. As used in this Complaint, "unsubstantiated" means not possessing competent and reliable scientific evidence, defined as tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the

profession to yield accurate and reliable results, at the time a claim is made. In the alternative, the State submits that "unsubstantiated" means not possessing substantial evidence, defined as adequate and well-controlled investigations, at the time a claim is made. The State submits that as applied there is no difference between the standards and that, regardless, Purdue's unsubstantiated claims as referenced in this Complaint fail either standard.

215. By engaging in the act, use or employment of any deception, misrepresentation, or the concealment, suppression or omission of any material fact in connection with the sale of goods with the intent that a person relies upon the deception, misrepresentation, concealment suppression or omission, the Defendants have violated W. Va. Code § 46A-6-104.

216. By expressly claiming without qualification that OxyContin does not have a dose ceiling or through words or phrases of similar import when this is not the case or when this claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

217. By expressly referencing pseudoaddiction in its marketing or through words or phrases of similar import when this claim was deceptive or unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

218. By explicitly or implicitly claiming that OxyContin or Butrans did not produce peaks and valleys that led to feelings of euphoria or less effective pain relief or through words or phrases of similar import when this is not the case or when this claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code 46A-6-104.

219. By referring to the abuse-deterrent properties of OxyContin and Hysingla ER's post-2010 formulations and failing to disclose that these properties do not deter or otherwise

impact oral ingestion, the most common form of abuse, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

220. By explicitly or implicitly understating the risk of addiction from its opioid products, in each instance the Defendants have violated W. Va. Code 46A-6-104.

221. By referring to "seven dosing strengths of OxyContin," using a stair-step graphic for increased titration, or otherwise making claims about higher doses of its opioid products and failing to disclose the increased risk of addiction and other serious risks or side effects from higher doses of its opioid products, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

222. By promoting its opioids for long-term use and failing to disclose the lack of evidence for long-term use of its opioids, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

223. By explicitly or implicitly claiming without qualification that its opioid products were safer than they actually were or when this claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

224. By explicitly or implicitly claiming that OxyContin was safer, more effective, as effective, or superior to Opana, Duragesic, methadone, or Avinza, or through words or phrases of similar import, when this is not the case or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

225. By explicitly or implicitly claiming that OxyContin was safer, more effective, as effective, or superior to immediate release opioids generally or Dilaudid, hydrocodone, immediate release opioids containing acetaminophen, hydrocodone combinations, Lortab, Vicodin, and

Percocet specifically when this is not the case or when the claim was unsubstantiated at the time made, the Defendants have violated W. Va. Code § 46A-6-104.

226. By explicitly or implicitly claiming that OxyContin was safer, more effective, as effective, or superior to non-opioids when this is not the case or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

227. By explicitly or implicitly claiming that Butrans was safer, more effective, as effective, or superior to immediate release opioids such as hydrocodone, hydrocodone combinations, Darvocet, tramadol, and Lortab when this is not the case or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

228. By explicitly or implicitly claiming that Ryzolt was safer, more effective, as effective, or superior to immediate release opioids generally or Percocet specifically or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

229. By explicitly or implicitly claiming that Ryzolt was safer, more effective, as effective, or superior to opioids including immediate release tramadol generally or Ultram ER specifically or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

230. By explicitly or implicitly claiming that Hysingla ER was safer, more effective, as effective, or superior to immediate release opioids including hydrocodone combinations and those containing acetaminophen or through words or phrases of similar import when this is not the case

or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

231. By explicitly or implicitly representing that its opioid products improve a patient's quality of life, or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

232. By explicitly or implicitly representing that its opioid products improve a patient's function or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

233. By explicitly or implicitly representing that its opioid products act as a sleep aid, or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

234. By explicitly or implicitly misrepresenting the safety of OxyContin or Butrans when taken by the elderly, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

235. By targeting health care providers who worked in nursing homes or who otherwise had large elderly patient populations for sales calls for OxyContin and Butrans, both of which have an increased risk of respiratory depression in the elderly, the Defendants have violated W. Va. Code § 46A-6-104.

236. By referring to low-dose starts of OxyContin in elderly patients and failing to disclose that low dose starts most often lead to higher doses of OxyContin where safety risks in

the elderly are increased, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

237. By referring to recommendations or promotional, policy, educational, and other materials from the American Pain Society, the American Pain Foundation, the American Academy of Pain Medicine, or other pain advocacy groups that Purdue substantially funded and used in its marketing without disclosing this connection, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

238. By making sales calls to providers and pharmacies after knowing of likely indicators of abuse or diversion, in each instance the Defendants have violated W. Va. Code § 46A-6-104.

239. As part of its WVCCPA action, the State expressly does not seek any damages attributable to the Medicaid or Medicare programs.

COUNT II
COMMON LAW NUISANCE

240. The Plaintiff, the State of West Virginia, incorporates by references and re-alleges each and every allegation contained in paragraphs 1-211 of this Complaint.

241. Through the actions described above, the Defendants have contributed to and/or assisted in creating and maintaining a condition that has interfered with the operation of the commercial market, interfered with public health, and endangered the lives and health of West Virginia residents.

242. While the Defendants' degree of care is not relevant in a common law nuisance suit brought by the sovereign State, the Defendants behaved negligently, recklessly, or intentionally as set forth above.

243. Through the actions described above, Defendants have contributed to and/or assisted in creating and maintaining a condition that endangers the life or health of West Virginia residents and that unreasonably interferes with or obstructs rights common to the public.

244. Opioid use, abuse, addiction, and overdose deaths have increased throughout West Virginia. Locations such as the offices of high-prescribing health care providers and the pharmacies at which their patients fill opioid prescriptions have attracted drug dealers and those addicted to opioids.

245. The greater demand for emergency services, law enforcement, addiction treatment, and other social services places an unreasonable burden on governmental resources including the State and its political subdivisions.

246. Expanding the market for prescription opioids by making misrepresentations and omissions to health care providers, especially to general practitioners, nurse practitioners, and physician assistants, as well as targeting providers and pharmacies with practices that had actual abuse or diversion or signs indicative of abuse or diversion, created an abundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death.

247. The Defendants' actions described above were a substantial factor in opioids becoming widely available, used, and all too often abused.

248. But for the Defendants' actions, opioid use would not have become so widespread and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. The Defendants' actions have and will continue to injure and harm many residents throughout West Virginia for years to come.

249. While tort-based standards are not applicable to a public nuisance suit brought by the sovereign State, the public nuisance and associated financial and economic losses were

foreseeable to the Defendants, who knew or should have known that its unfair and deceptive business practices regarding the safety, purported benefits, and comparative superiority or equivalency of its opioid products, its continued sales targeting of providers and pharmacies with practices that had actual abuse or diversion or signs indicative of abuse or diversion of opioids, and its other conduct described herein were creating a public nuisance.

250. The Defendants intended health care providers to prescribe its extended release opioids for long-term use and for patients to fill those prescriptions and to keep filling those prescriptions at higher and higher doses. A reasonable person in the Defendants' position would foresee not only an expanded market but the other likely and foreseeable result of the Defendants' conduct - the widespread problems of opioid addiction and abuse, particularly given the easy manipulation of its prior formulation and its popularity among opioid abusers and those addicted.

251. The Defendants were on notice and aware of signs both that health care providers were prescribing unreasonably high numbers of opioids and that the broader use of opioids were causing the kinds of harm described in this Complaint.

252. The Defendants' business practices generated a new and very profitable circular market with the promotion of opioids—providing both the profitable supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand to buy more.

253. The Defendants acted without express authority of a statute in misrepresenting the safety, comparative superiority or equivalence of its opioids to other products, and benefits of its opioid products, failing to disclose the increased risk of addiction at higher doses, and failing to disclose the lack of substantiation for long-term use of opioids among other conduct.

254. The health and safety of West Virginia residents, including those who use, have used, or will use opioids, as well as those affected by users of opioids, is a matter of great public

interest and of legitimate concern to the State. West Virginians have a right to be free from conduct that endangers their health and safety and that interferes with the commercial marketplace. Purdue's conduct interfered in the enjoyment of these public rights.

255. As part of its nuisance action, the State expressly does not seek any damages attributable the Medicaid or Medicare programs.

III. PRAYER FOR RELIEF

WHEREFORE, the State prays that the Court grant the following relief:

1. Judgment against the Defendants, jointly and severally, in favor of the State;

2. Temporary relief, a preliminary injunction and permanent injunction ordering the Defendants to comply with W. Va. Code § 46A-6-104 and to cease the unlawful conduct;

3. Equitable relief, including, but not limited to, restitution and disgorgement;

4. Civil penalties of up to $5,000.00 for each repeated and willful violation of W. Va. Code § 46A-6-104, pursuant to W. Va. Code § 46A-7-111(2);

5. Pre- and post-judgment interest;

6. Costs and reasonable attorneys' fees; and,

7. Such other relief, fees and costs as shall be available under the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101, *et seq.*;

8. Such other and further relief as shall be deemed appropriate herein.

STATE OF WEST VIRGINIA ex rel.
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By Counsel

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VERIFICATION

STATE OF WEST VIRGINIA,
COUNTY OF KANAWHA, TO-WIT:

I, R. Stephen Jarrell, Assistant Attorney General, being duly sworn, depose and say that I am the counsel of record for the Plaintiff in the Complaint in the foregoing styled civil action; that I am familiar with the contents of the foregoing Complaint; and that the facts and allegations contained therein are true, except such as are therein stated upon information and belief, and that as to such allegations I believe them to be true.

R. Stephen Jarrell (WV State Bar # 6787)
Assistant Attorney General
Consumer Protection Division and
Antitrust Division

Taken, subscribed, and sworn to before me in the County and State aforesaid this 15th day of May, 2019.

My commission expires April 13, 2020.

OFFICIAL SEAL
NOTARY PUBLIC
STATE OF WEST VIRGINIA
Peggy S. Means
Office of the Attorney General
PO Box 1789
Charleston, WV 25326-1789
My Commission Expires April 13, 2020

NOTARY PUBLIC