IN THE CIRCUIT COURT OF BOONE COUNTY, WEST VIRGINIA

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

Plaintiff,

v.

CIVIL ACTION NO. 19-C-151
JUDGE William S Thompson

ENDO HEALTH SOLUTIONS INC.,
a Delaware corporation,
ENDO PHARMACEUTICALS INC.,
a Delaware corporation, and
PAR PHARMACEUTICAL, INC.,
a New York corporation,

Defendants.

COMPLAINT

Plaintiff, the State of West Virginia, by its Attorney General, Patrick Morrisey, sues Defendants, Endo Health Solutions Inc., Endo Pharmaceuticals Inc., and Par Pharmaceutical, Inc. (collectively "Endo" or "the Defendants"), and alleges as follows:

I. Introduction

1. The State of West Virginia is suffering from a devastating opioid crisis created, in part, by Endo. Opioids may kill as many as 500,000 people in the United States over the next ten years.

2. Opioids are powerful narcotic painkillers that include non-synthetic, partially synthetic, and fully-synthetic derivatives of the opium poppy. Endo has marketed and sold opioids under a variety of brand names.

3. The opioid epidemic did not happen by accident. Rather, the epidemic is the result of a carefully constructed plan to change the way opioids were viewed by the medical community and the public.

4. Until the mid-1990s, doctors believed that the risks of using opioids often dramatically exceeded their benefits—opioids were viewed as too addictive and debilitating to be used long-term and for less severe chronic pain conditions.

5. Endo, through predecessor companies, began to market and sell oxycodone combination products nearly seventy years ago. First, in 1950, was Percodan, an oxycodone and aspirin combination. In 1955, Endo obtained a patent for oxymorphone, a potent morphine-like opioid, which it marketed and sold in immediate-release tablet form under the brand name Numorphan from 1966-1971. Later, in 1976, came Percocet, an oxycodone and acetaminophen combination.[1] All three drugs were available only through a doctor's prescription. All three drugs were abused.

6. Percodan became a target for abuse and misuse shortly after it arrived on the market and was a recognized as a serious social problem by the early 1960s.[2] By 1964, Percodan abuse had become so widespread that the federal government was prompted to change it from a "class B" narcotic, capable of being phoned in to a pharmacist, to a "class A" narcotic, which required a written prescription.[3] But the change in class had little effect on preventing abuse. Percodan addiction and abuse continued well into the 1970s. A 1979 news article reported that "patients who take [Percodan] six to eight times a day for as little as three weeks can find themselves

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[1] ENDO-CHI_LIT-00543482.
[2] Edward Bloomquist, *The Addiction Potential of Oxycodone (Percodan)*, 99 California Medicine 127, 127–130 (1963), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1515192/pdf/califmed00086-0046.pdf.
[3] 29 Fed. Reg. 48.

unwittingly addicted."[4] In the same article, a recovering Percodan addict pleaded with readers not to take the drug, describing it as "a loaded gun in your head."

7. Abuse of Numorphan tablets via injection became a widespread problem shortly after Endo began to market the drug in 1966. Known on the street by the names "blue morphine" or "blues" for its blue color, Numorphan tablets were one of the most sought-after opioids because when cooked, strained, and injected, they were considered to be "especially euphoric; better than heroin or morphine."[5] An addiction study conducted in January 1970 indicated that abusers turned to Numorphan because "a 10-mg tablet of Numorphan reportedly has the same intensity of immediate effect—rush—as a $10 bag of heroin, but with twice the duration."[6] The widespread abuse of the drug later inspired, in part, the 1980s Hollywood blockbuster "Drugstore Cowboy."[7]

8. By 2002, approximately 9.7 million individuals over age 12 had used Percodan, Percocet, or Tylox, an oxycodone and acetaminophen combination manufactured by Janssen, for non-medical use at least once in their lifetime.[8]

9. Endo ceased production of Numorphan tablets in October 1971 and requested that FDA withdraw the New Drug Application (NDA) for the tablet form of the drug in October 1979.[9] Upon information and belief, Endo pulled Numorphan tablets from the market due to regulatory pressure after reports of abuse.[10]

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[4] *Unwitting Addicts Discover That the Painkiller Percodan Brings An Agony of Its Own*, PEOPLE.COM, Nov. 19, 1979, *available at* https://people.com/archive/unwitting-addicts-discover-that-the-painkiller-percodan-brings-an-agony-of-its-own-vol-12-no-21/.
[5] ENDO-OR-CID-00694085.
[6] Watkins, Torrington D. & Carl D. Chamber, Drug Abuse: Current Concepts and Research, 307 (Keup, Wolfram, Ed., 1972).
[7] EPI000443330.
[8] ENDO-CHI_LIT-00543482.
[9] ENDO-OPIOID_MDL-04093686.
[10] EPI000443330 ("Endo withdrew Numorphan from the market in 1972 due to regulatory pressure since it was so sought after by drug addicts."); ENDO-OPIOID_MDL-06246554 ("By the early 1970s, there was a really high

10. Then, in 1996, came a watershed event when Purdue launched OxyContin, a potent extended release oxycodone. Thanks to Purdue's aggressive marketing tactics, sales of OxyContin surged as had never been seen before for an opioid product. Eyeing Purdue's success, Endo wanted to establish a flagship extended release single-entity opioid tablet to compete with Purdue. Rather than go back to the drawing board, Endo turned to a drug it had sold in the past—Numorphan—and asked the FDA to reactivate the NDA for the tablet form of the drug in August, 1996.[11]

11. Endo knew that Numorphan would need a facelift if it was to compete with Purdue's OxyContin, fearing that the old name and the blue color of its tablets would resurrect memories of abuse and diversion.[12] Endo decided to re-brand its oxymorphone tablets under the brand name Opana.[13] Opana ER was first approved by the FDA in 2006, and a different formulation obtained approval in 2012. But Endo knew that re-branding its old, widely abused oxymorphone formula would not be enough—Endo had to help change the narrative about opioids in general if it was to maintain a leadership role in the opioid analgesic market.

12. For companies like Endo, doctors' long-held beliefs about the dangers of prescription opioids served to make the opioid analgesic market unacceptably small. Dramatic growth in sales and revenue would come only from the widespread, long-term use of opioids for common and chronic pain conditions like back pain, arthritis, and headaches.

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demand for 'blues' or 'Nu-blues' by our friends in the IV drug abuse world, so the drug got pulled in favor of restricting it to hospitals, and only in the IV and I think suppository formulations."); *see also* Ellen Fields, MD, MPH, *Regulatory History of Opana ER*, JOINT MEETING OF THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE AND THE ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE, U.S. FOOD AND DRUG ADMINISTRATION, (March 13-14, 2017), *available at* https://www.fda.gov/media/103920/download (slide 5).

[11] ENDO-OPIOID_MDL-04093687.

[12] ENDO-OPIOID_MDL-04927914; ENDO-OPIOID_MDL-04101352.

[13] ENDO-OPIOID_MDL-01407685.

13. To make that happen, Endo and other opioid makers had to turn the standard of care on its head—persuading doctors that drugs they had been unwilling to prescribe because of their risk of addiction were more effective and safe enough to use widely and long-term for relatively minor pain conditions. Patients were exposed to the same reassuring messages.

14. Opioid manufacturers are responsible, in part, for the State's opioid epidemic. Over time, opioid manufacturers overcame physicians' reluctance to prescribe opioid pain relievers ("OPRs"), due to concerns about addiction, tolerance and physiological dependence, through a variety programs.[14]

15. They claimed doctors were confusing addiction with physical dependence and stated that addiction was rare and completely distinct from physical dependence, and claimed that physical dependence was clinically unimportant.[15]

16. Endo specifically marketed to doctors and patients in West Virginia, misrepresented that their opioid medications were safer than other alternatives, disseminated misleading statements about opioids, furthered the concept of pseudoaddiction, misrepresented that opioids were "rarely addictive" when used for chronic (non-cancer) pain, and misrepresented the benefits of long-term use of opioids. They targeted particularly vulnerable populations, such as the elderly, even though opioid use in this population carries a heightened risk of overdose, injury, and death.

17. The long-term use of opioids is particularly dangerous because patients develop tolerance to the drugs over time, requiring higher doses to achieve any effect. Patients also quickly

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[14] Andrew Kolodny, *et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, ANN. REV. PUB. HEALTH 2015 36:1, 559–574, 562, *available at* https://bit.ly/2J5A9Tp.
[15] *Id.* at 562.

become dependent on opioids and will experience often-severe withdrawal symptoms if they stop using the drugs. That makes it very hard for patients to discontinue using opioids after even relatively short periods. The risks of addiction and overdose increase with dose and duration of use. At high doses, opioids depress the respiratory system, eventually causing the user to stop breathing, which can make opioids fatal. It is the interaction of tolerance, dependence, and addiction that made the use of opioids for chronic pain so lethal.

18. Since at least the 1950s, the scientific community has cautioned that long-term use of OPRs could lead to addiction with one study claiming that "there can be no doubt" that prolonged used of a particular potent opioid analgesic "represents considerable addiction liability."[16] As of 2015, "high-quality long-term clinical trials demonstrating the safety and efficacy of OPRs for chronic non-cancer pain [had] never been conducted."[17] Nevertheless, Endo and other opioid manufacturers promoted opioids for long term use, with great commercial success.

19. As a result, in part, of Endo's efforts, opioids are now the most prescribed class of drugs. Globally, opioids sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[18] But the rise in opioid sales corresponded to a dramatic rise in opioid abuse, addiction, and death.[19]

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[16] ENDO-OPIOID_MDL-03261993.
[17] Kolodny at 562–63.
[18] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, FINANCIAL TIMES (Aug. 10, 2016), https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.
[19] *See* Kolodny at 563.

20. The CDC has also identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers—which, at the molecular level and in their effect, closely resemble heroin—are four times more likely to become addicted to heroin.[20] According to a recent study, among young urban heroin users, 86% used opioid pain relievers prior to using heroin.[21] When individuals who are addicted to OPRs can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin, a fact which Endo has known since at least 2012.[22]

21. In 2012, a year when the rate of opioid overdose related deaths in West Virginia was among the highest in the nation, the director in charge of Endo's Mid-Atlantic region, which included most of West Virginia, callously joked that Endo should partner with Pepsicola to make "Pepsicontin" in order to boost sales.[23]

22. While opioid related deaths may be underreported by as much as 20%, the opioid epidemic is deadlier than the AIDS epidemic at its peak, and West Virginia suffered from the highest opioid mortality rate in the country in 2016.[24]

23. In 2017, over 1,000 West Virginia citizens died as the result of a drug overdose. Eighty-six percent (86%) of these overdose deaths involved an opioid. West Virginia led the

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[20] *See* Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last accessed October 4, 2019).
[21] Nat'l Inst. On Drug Abuse, *Prescription Opioids and Heroin* (Jan. 2018), https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use.
[22] EPI002276218 (slide 8).
[23] ENDO-OPIOID_MDL00760890.
[24] Christopher Ingraham, *CDC Releases Grim New Opioid Overdose Figures: 'We're Talking About More Than an Exponential Increase,'* WASH. POST., Dec. 12, 2017, https://wapo.st/2POdL3m.

nation with the highest rate of drug overdose deaths involving opioids (49.6 deaths per 100,000 people). This is threefold higher than the national rate of 14.6 deaths per 100,000 people.[25]

24. In 2017, West Virginia providers wrote 81.3 opioid prescriptions for every 100 people compared to the national average U.S. rate of 58.76 prescriptions.[26]

25. As reported in a special issue of the West Virginia Medical Journal, West Virginia has the 3rd highest non-heroin OPR treatment rate in the United States.[27]

26. In addition to the number of deaths caused by OPRs such as oxymorphone, oxycodone and hydromorphone, there has been an increase in overdose deaths caused by heroin, which dealers cut with fentanyl, an opioid 100 times stronger than morphine.[28]

27. Studies show a direct correlation between OPRs and heroin addiction with 4 out of 5 heroin users reporting their opioid use began with OPRs.[29]

28. Children are especially vulnerable to the opioid epidemic. West Virginia's rate of Neonatal Abstinence Syndrome ("NAS") is five times the national average and results in thousands of children being placed in foster care.[30] In 2017, the overall incidence rate of NAS was 50.6 cases

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[25] *See* Caity Coyne, *Number of Fatal Drug Overdoses in 2017 Surpasses 1,000 Mark in West Virginia*, CHARLESTON GAZETTE-MAIL, Aug. 30, 2018, https://bit.ly/2yLcxim; *see also*, Christopher Ingram, *Drugs are Killing so Many People in West Virginia that the State Can't Keep Up With the Funerals*, WASH. POST., Mar. 7, 2017, https://wapo.st/2GI9rk2; Christopher Ingram, *Fentanyl Use Drive Drug Overdose Deaths to a Record High in 2017*, CDC Estimates, WASH. POST., Aug. 15, 2018, https://wapo.st/2Ozn8b7; *see also West Virginia Opioid Summary*, NAT'L INST. ON DRUG ABUSE (Mar. 2019), https://bit.ly/2MzDsGn.

[26] *See West Virginia Opioid Summary*, NAT'L INST. ON DRUG ABUSE (Mar. 2019), https://bit.ly/2MzDsGn.

[27] Khalid M. Hasan, MD. & Omar K. Hasan, MD, *Opiate Addiction and Prescription Drug Abuse: A Pragmatic Approach*, W. VA. MED. J. (Special Edition) Jan. 2010, at 84.

[28] Dennis Thompson, *Drug OD Deaths Nearly Tripled Since 1999*, CBS NEWS, Feb. 24, 2017, https://cbsn.ws/2J4n90u.

[29] Andrew Kolodny, *et al.*, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, ANN. REV. PUB. HEALTH 2015 36:1, 559–574, 560, *available at* https://bit.ly/2J5A9Tp.

[30] *Proposed Opioid Response Plan for the State of West Virginia* 20, (Jan. 10, 2018), https://bit.ly/2Oyu48a.

per 1,000 live births for West Virginia residents. The highest incidence rate of NAS was 106.6 cases per 1,000 live births (10.66%) in Lincoln County.

29. In 2007, the cost for treating a NAS baby was approximately $36,000. In comparison, the cost for a healthy baby was approximately $3,600.[31]

30. Between 2006 and 2016, children entering the West Virginia foster care system due to parental addiction rose 124%. About 70% of referrals to Child Protective Services in 2017 had a substance abuse component according to the statistics from the Centralized Intake Unit of the West Virginia Bureau for Children and Families. The state court Child Abuse and Neglect database indicates that about 80% of referrals from family court and circuit court judges have a substance abuse factor.

31. Endo helped fuel the opioid epidemic by engaging in strategic campaigns of misrepresentations about the risks and benefits of opioid use to physicians, other prescribers, consumers, pharmacies, and state governmental agencies. Endo knew that opioids were dangerous and addictive; nevertheless, it used front organizations that they funded to disseminate misinformation about the use of opioids for chronic pain treatment. Endo also employed medical professionals known as key opinion leaders ("KOLs") and therapeutic experts ("TEs") to endorse and promote the use of opioids. The KOLs wrote articles and gave speeches touting the benefits of opioid use as if they were independent medical experts, but they actually served as Endo's mouthpieces.

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[31] Michael L. Stitely, MD, et al., *Prevalence of Drug Use in Pregnant West Virginia Patients*, W. VA. MED. J. (SPECIAL EDITION), Jan 2010, at 48.

32. Endo must now be held accountable for its role in helping to create the opioid epidemic ravaging the State of West Virginia.

II. State Court Jurisdiction

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

34. 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).

35. 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.

III. Jurisdiction

36. As a court of general jurisdiction, the circuit court is authorized to hear this matter, based on the West Virginia Consumer Credit and Protection Act W. Va. Code §§ 46A-1-101, *et seq*. ("WVCCPA") and nuisance claims, the amount at issue, and the relief sought pursuant to W. Va. Code § 56-3-33.

IV. Venue

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

V. Parties

38. The Plaintiff, the State of West Virginia ex rel. Patrick Morrisey, Attorney General, is charged with enforcing the West Virginia Consumer Credit and Protection Act, W. Va. §§ 46A-1-101, *et seq*. Pursuant to W. Va. Code § 46A-7-108, the Attorney 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 restricted by statute. Syl. pt. 3, *State ex rel. Discover Financial Services, Inc., et al. v. Nibert*, 744 S.E.2d 625, 231 W. Va. 227 (2013).

39. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. is a subsidiary of Endo International plc.

40. Defendant Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a subsidiary of Endo International plc. Endo Pharmaceuticals Inc. is registered with the West Virginia Board of Pharmacy.

41. Par Pharmaceutical, Inc. is a New York corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a subsidiary of Endo International plc. Par Pharmaceutical, Inc. is registered with the West Virginia Board of Pharmacy.

VI. Endo's False, Deceptive, and Unfair Marketing of Opioids

42. Endo conducted a marketing scheme designed to persuade prescribers, pharmacists, patients, and payors that opioids can and should be used for chronic pain, resulting

in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, Endo spent millions of dollars on promotional activities and materials that falsely deny, trivialize, or materially understate the risks of opioids while overstating the benefits of using them for chronic pain, and to "build need" for its products.[32]

43. Endo disseminated these messages to reverse the generally accepted medical understanding of opioids and risks of opioid use. Endo disseminated these messages directly, through its sales representatives, in speaker groups led by physicians that Endo, among other opioid manufacturers, recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

44. Endo provided millions of dollars to industry-funded front groups like the National Initiative on Pain Control ("NIPC"), American Pain Society ("APS"), and the American Pain Foundation ("APF") under the guise of independent education grants. These seemingly unbiased and independent third parties spread Endo's false and deceptive messages about the risks and benefits of opioids for the treatment of chronic pain nationwide.

45. Endo knew that its conduct as alleged herein was contributing to the opioid epidemic causing the harm alleged herein.

46. Endo's conduct, in part, created a public health crisis and a public nuisance. The harm and endangerment to the public health, safety, and the environment created by this public nuisance is ongoing and has not been abated.

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[32] END00000958.

47. The public nuisance – i.e., the opioid epidemic – created, perpetuated, and maintained, in part, by Endo can be abated and further recurrence of such harm can be avoided thereby ending the opioid epidemic.

48. The manufacturer of an opioid drug has a primary responsibility to ensure the safety, efficacy, and appropriateness of the drug's marketing and promotion. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that the drug is only distributed and dispensed to appropriate patients and not diverted. These responsibilities, to ensure that opioid products and promotional practices meet consumer protection laws and regulations, exist independent of any FDA or DEA regulation. As a registered manufacturer and distributor of controlled substances, Endo is uniquely positioned, based on its knowledge of prescribers and orders, to act as a first line of defense to prevent abuse of opioids.

A. Endo's False and Deceptive Statements About Opioids

49. Endo's misrepresentations include, but are not limited to, the following categories:

a. The risk of addiction from chronic opioid therapy is low;

b. Signs of addictive behavior are "pseudoaddiction" requiring more opioids;

c. Opioid doses can be increased without limit or greater risks of addiction;

d. Long-term opioid use improves patients' functioning;

e. Original Opana ER is not prone to abuse; and

f. New formulation of Opana ER successfully deterred abuse.

50. Endo set out to convince physicians, patients and the public at large of the truth of each of these propositions in order to expand the market for its opioids.

51. Endo's conduct, and each misrepresentation, contributed to an overall narrative that misled prescribers, pharmacists, patients, and payors about the risks and benefits of opioids. This is not an exhaustive list of the nature and manner of each deceptive misrepresentation by Endo.

a. False: The risk of addiction from chronic opioid therapy is low.

52. Endo's branded and unbranded marketing misrepresented the true risk of addiction for Endo's opioid products. These statements were false, deceptive, misleading and/or unsubstantiated at the time they were made.

53. Endo falsely represented that addiction is rare in patients who are prescribed opioids.

54. In a 2004 unbranded marketing piece titled "Understanding Your Pain" that was targeted towards patients, Endo misrepresented that:

- *"Taking opioids for pain relief is not addiction. People addicted to opioids crave the opioid and use it regularly for reasons other than pain relief."*
- *"Addiction also IS NOT what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain.* This normal 'tolerance' to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, *it does not mean you will 'run out' of pain relief.* Your dose can be adjusted or another medicine can be prescribed."
- "Is it wrong to take opioids for pain? No. Pain relief is an important medical reason to take opioids as prescribed by your doctor. *Addicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction."*
- "How can I be sure I'm not addicted? Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, *maybe just to escape from your problems*."

- "Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain *and improve your function. You are not addicted.*"[33]

55. Likewise in 2006, Endo trained its sale representatives to tell providers that "[t]olerance can be mistaken for addiction because the patient may ask for increasing doses of the opioid, which can be perceived as 'drug-seeking behavior'"[34] and "[a]ddiction is a disorder and not an expected consequence of taking an opioid."[35]

56. In sales calls, Endo sales representatives represented to providers that Opana ER had low addiction potential or otherwise understated the risk of addiction from Opana ER. As examples, Endo sales representatives stated that Opana ER "can provide pain relief throughout 24 hours, ensures good compliance, ensures low addiction potential,"[36] has "low risk of habituation,"[37] has "improved efficacy with less tolerance,"[38] has "less euphoria and maybe less addictive potential,"[39] or made similar statements.[40]

57. In 2009, Endo's branded website for Opana and Opana ER, www.opana.com, misrepresented the risk of addiction. It stated:

> Most doctors who treat patients with pain agree that patients treated with prolonged medicines usually do not become addicted. Physical dependence, which is different from addiction, may develop when taking opioids for pain relief for a long time. This means that your body adapts to the drug and you will have withdrawal symptoms if the medicine is stopped or decreased suddenly. Taking opioids for pain relief is NOT addiction.[41]

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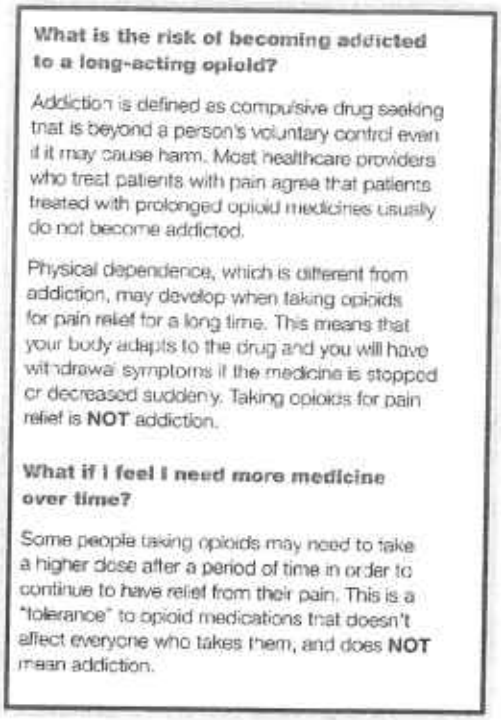
[33] ENDO PHARMACEUTICALS, *Understanding Your Pain* (2004), *available at* https://perma.cc/QN86-62PK (emphasis added); ENDO_OPIOID_MDL-00877545.
[34] ENDO-OR-CID-00409557.
[35] ENDO-OR-CID00409559.
[36] ENDO-CHI_LIT-00548030.
[37] ENDO-CHI_LIT-00548030.
[38] ENDO-CHI_LIT-00548034.
[39] ENDO-CHI_LIT-00548045.
[40] ENDO-CHI_LIT-00548030 (*e.g.* "Also low risk of habituation").
[41] ENDO-CHI_LIT-00537608.

58. Endo also widely circulated a promotional brochure for its opioids titled "Information on Taking a Long-Acting Opioid" in 2008 and 2009 that stated:[42]



What is the risk of becoming addicted to a long-acting opioid?

Addiction is defined as compulsive drug seeking that is beyond a person's voluntary control even if it may cause harm. Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.

Physical dependence, which is different from addiction, may develop when taking opioids for pain relief for a long time. This means that your body adapts to the drug and you will have withdrawal symptoms if the medicine is stopped or decreased suddenly. Taking opioids for pain relief is **NOT** addiction.

What if I feel I need more medicine over time?

Some people taking opioids may need to take a higher dose after a period of time in order to continue to have relief from their pain. This is a "tolerance" to opioid medications that doesn't affect everyone who takes them, and does **NOT** mean addiction.

59. This brochure was accessible to providers and patients nationwide and in West Virginia on its www.opana.com website until at least 2011.[43] It was also included in the Opana ER rebate kit that Endo distributed to providers, pharmacies, and ultimately consumers until at least March 31, 2011.[44]

60. Until at least December 2010, Endo represented on its www.opana.com website that "[m]ost doctors who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[45]

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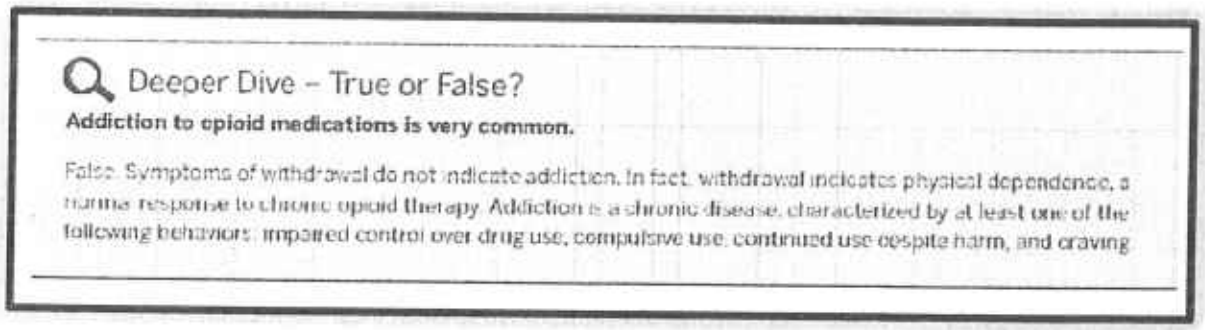
[42] ENDO-CHI_LIT-00538443, ENDO-CHI_LIT-00541197 (emphasis in original).
[43] ENDO-OR-CID-00089341.
[44] ENDO-OR-CID-00089341.
[45] *Opana ER*, Endo Pharmaceuticals (archived on Dec. 28, 2010), https://bit.ly/2mXjt9Q.

61. Endo never conducted a study or other survey with health care providers who treat patients with pain to determine whether the providers agreed with the claims that patients treated with prolonged opioid medicines usually do not become addicted. Endo did not have competent or reliable scientific evidence to support such claims at the time they were made.

62. Endo also deceptively trained its sales representatives that physical dependence and addiction could be easily distinguished from one another. Endo's sales representatives, in turn, trumpeted this message to health care providers.

63. For example, in a 2010 training guide, Endo instructed its sales representatives to inform providers that opioid analgesics were potentially addictive but "[l]ong-term opioid use can induce physical dependence and may induce tolerance to therapy. None of these physiological phenomenon cause addiction."[46]


Deeper Dive – True or False?

Addiction to opioid medications is very common.

False. Symptoms of withdrawal do not indicate addiction. In fact, withdrawal indicates physical dependence, a normal response to chronic opioid therapy. Addiction is a chronic disease, characterized by at least one of the following behaviors: impaired control over drug use, compulsive use, continued use despite harm, and craving

64. Endo's claims that understated the risk of addiction from opioids were widely disseminated to health care providers and the public in West Virginia.

65. Endo's claims understating the risk of addiction were false, misleading, or deceptive at the time they were made. Endo's claims led health care providers and the public to believe that Endo's opioid products were safer or less addictive than they actually were.

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[46] ENDO-CHI_LIT-00545277.

b. False: Signs of addictive behavior are "pseudoaddiction," requiring more opioids.

66. Endo instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became Purdue's vice president of health policy, published a study in 1989 coining the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[47] The term was 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.[48] The term referred to patients who exhibited drug-seeking behavior due to undertreated or uncontrolled pain, as opposed to addiction.

67. Endo consistently used this concept in sales calls and written educational materials to teach providers in West Virginia to prescribe more or higher doses of opioids for purportedly "pseudoaddicted" patients, who would then allegedly cease drug-seeking behavior once their pain was controlled.[49] The concept of pseudoaddiction has "not been empirically verified" and "no evidence supports its existence."[50]

68. Endo 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.

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[47] David E. Weissman & J. David Haddox, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) PAIN 363–66 (1989).
[48] Marion Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2015 CURRENT ADDICTION REPORTS, 310, 310–317 (Oct. 1, 2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4628053/#.
[49] ENDO-OPIOID_MDL-01605955; 2002702.
[50] *Id.*

69. From at least 2006 to 2013, Endo trained its sales representatives specifically to pitch pseudoaddiction,[51] which Endo's representatives then used in sales calls with providers.

70. In a 2006 sales training document, Endo taught its sales representatives that pseudoaddiction was a "term used to describe an iatrogenic phenomenon in which a patient with undertreated pain is perceived by healthcare professionals to exhibit behaviors similar to those seen in addiction but is not truly addicted[,]"[52] that "[t]he physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief[,]"[53] and that "[p]hysical dependence can be mistaken for addiction, because in some cases a patient may insist on continued use of the opioid even when pain has resolved, to avoid withdrawal symptoms experienced when they try to stop."[54]

71. Endo tested its sales representatives and stated that "clock watching when waiting for the next opioid dose is a good example of a patient with . . . pseudoaddiction."[55]

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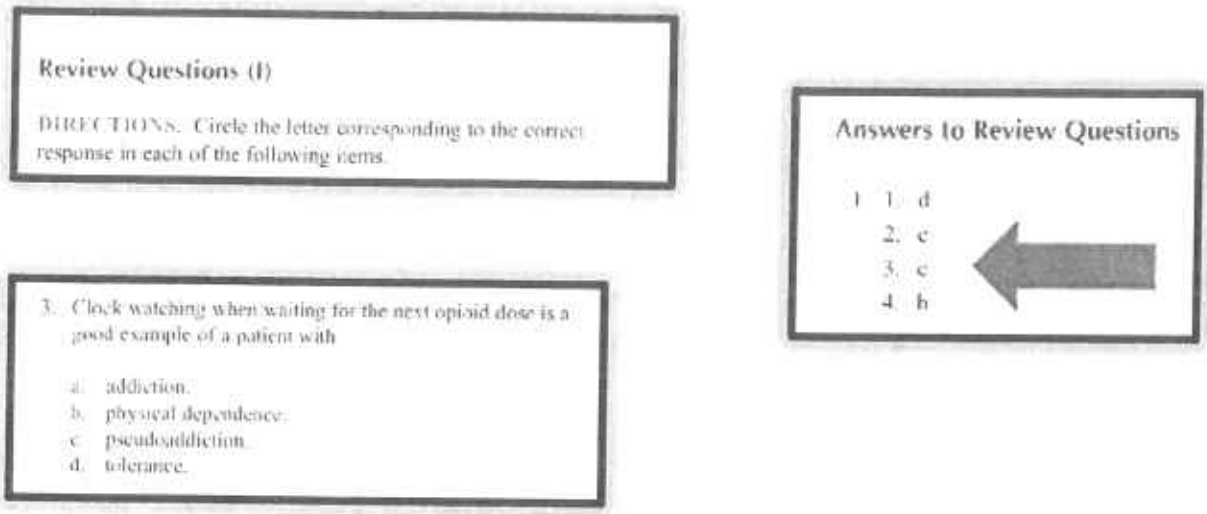
[51] *See, e.g.*, ENDO-OPIOID_MDL00647172.
[52] ENDO-OR-CID-00409556.
[53] ENDO-OPIOID-MDL_00647173.
[54] *Id.*
[55] ENDO-OPIOID_MDL00647180, 7203.



72. In a January 2011 sales training document, Endo instructed sales representatives that:

> Pseudoaddiction is a pattern of drug-seeking behavior among pain patients with unrelieved pain. Differentiating between addiction and pseudoaddiction can be challenging and may often take multiple patient encounters. One key difference from addiction is that in pseudoaddiction, the patient's drug-seeking behavior stops once his or her pain has been effectively treated.[56]

73. Endo's Vice President of Pharmacovigilance and Risk Management admitted that he was not aware of any research validating the "pseudoaddiction concept."[57]

74. In a sales training document dated May 2013, Endo trained its sales representatives, including those in West Virginia, that pseudoaddiction is "[a] pattern of drug-seeking behavior among pain patients with unrelieved pain, which can be differentiated from addiction by the stopping of the drug-seeking behavior once his or her pain has effectively been treated."[58]

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[56] END00014983.
[57] *In re Endo Health Solutions, Inc.*, Assurance of Discontinuance No. 15-228 (Mar. 1, 2016), *available at* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.
[58] ENDO-OR-CID-00002491.

75. Endo consistently used the pseudoaddiction concept in sales calls and written educational materials to teach providers in West Virginia to prescribe more or higher doses of opioids for their "pseudoaddicted" patients, who would then allegedly cease drug-seeking behavior once their pain was controlled. Endo taught its sales representatives, who in turn were teaching health care providers, that a "physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief."[59]

76. Endo also advanced the concept of pseudoaddiction through unbranded marketing and purported medical education. For example, APS, a pain advocacy group supported by Endo, included the concept of pseudoaddiction in an educational program it provided to medical residents.[60] Moreover, NIPC, a pain advocacy group solely supported by Endo,[61] promoted the concept of pseudoaddiction to physicians as late as 2012.[62]

77. The concept of pseudoaddiction was also advanced in an unbranded quick reference manual for prescribers titled "A Pocket Guide to Pain Management" which was distributed on the website www.painedu.org,[63] a third party pain organization whose development, maintenance, and continued enhancement was supported by Endo.[64] The manual remained available on the website until at least July 2015.[65]

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[59] ENDO-OR-CID-00409557.
[60] ENDO-OPIOID_MDL-05968066; 05968029.
[61] EPI000750029.
[62] ENDO-OR-CID-01254756.
[63] END00051543.
[64] EPI000750034; ENDO-OPIOID_MDL-01940511.
[65] *Improving Pain Treatment Through Education*, PAINEDU (archived on July 3, 2015), *available at* https://bit.ly/30Zsj5a.

78. Endo's claims about pseudoaddiction were widely disseminated to health care providers and the public in West Virginia.

79. Endo's claims about pseudoaddiction were false, misleading and deceptive because it led health care providers and the public to believe that the use of Endo's opioid products, and opioids as a class, carried less risk of addiction when such claims were not supported by competent or reliable scientific evidence at the time they were made.

c. False: Opioid doses can be increased without limit or greater risk of addiction.

80. Taking opioids for longer periods of time or in higher strength doses increases the risk of addiction, among other serious risks, and increases the likelihood of side effects like overdoses and death.[66]

81. These misrepresentations were integral to Endo's promotion of prescription opioids. Patients develop a tolerance to opioids' analgesic effects so that achieving long-term pain relief requires constantly increasing the dose. Patients who take larger doses, and who escalate to larger doses faster, are much more likely to remain on opioids for a longer period of time, resulting in repeat business and increased revenue.

82. Through materials it produced, sponsored, or controlled, Endo instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Endo's claims were deceptive in that Endo omitted warning of increased adverse effects that occur at higher doses, which had been confirmed by scientific evidence.

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[66] *Opioid Prescribing: Where You Live Matters*, CENTERS FOR DISEASE CONTROL AND PREVENTION, *available at* https://www.cdc.gov/vitalsigns/opioids/index.html; *Opioid Prescribers Can Play a Key Role in Stopping the Opioid Overdose Epidemic*, NAT'L INST. ON DRUG ABUSE, *available at* https://www.drugabuse.gov/publications/improving-opioid-prescribing/improving-opioid-prescribing.

83. Nevertheless, Endo represented that the dosage for its opioid products could be increased without disclosing the material fact that this would increase the risk of addiction, among other serious risks and side effects.

84. For example, Endo distributed a pamphlet in 2004 titled *Understanding Your Pain: Taking Oral Opioid Analgesics,* which targeted patients and stated that they "won't 'run out' of pain relief" so long as they increase their dosages, but did not disclose the increased risk of addiction, among other risks and side effects. The *Understanding Your Pain* pamphlet was intended to reach West Virginia prescribers and patients and was available on Endo's website.[67]

85. Endo distributed a book written by Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain*, which states that in the face of signs of aberrant behavior, increasing the dose, "*in most cases . . . should be the clinician's first response*,"[68] again without appropriately disclosing the increased risk of addiction from higher doses.

86. Endo made escalating dose strengths a core piece of its marketing for Opana ER stating, "[f]ive dosage strengths for individualized titration and dosing to help achieve adequate pain relief."[69] Endo encouraged providers to start patients at a 5 mg dose of Opana ER and titrate the dose upwards every 3-7 days by 5-10 mg every 12 hours[70] and pushed the idea that "[h]igher doses of oxymorphone ER did not appear to be associated with a marked worsening of tolerability."[71]

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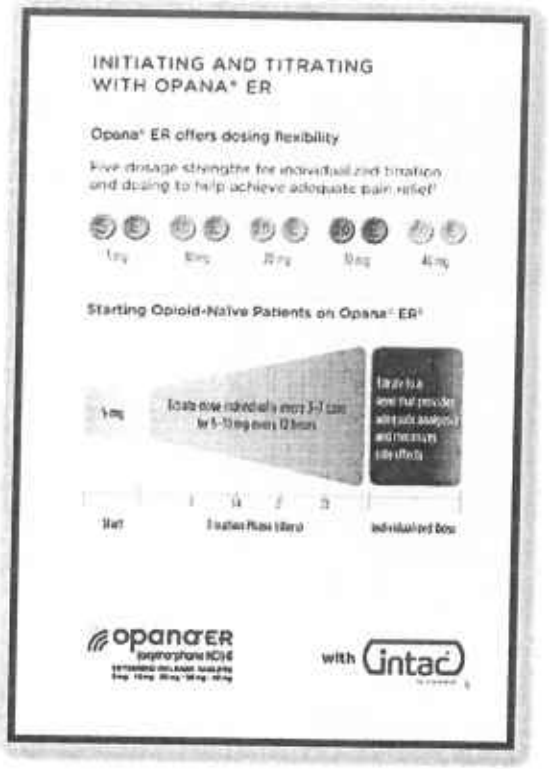
[67] ENDO PHARMACEUTICALS, *Understanding Your Pain* (2004), *available at* https://perma.cc/QN86-62PK.
[68] ENDO-CHI_LIT-00538765 (emphasis added).
[69] ENDO-OR-CID-00006271.
[70] ENDO-CHI_LIT-00549982.
[71] ENDO-OR-CID-00256541.

87. Numerous Endo marketing materials for Opana ER that were widely disseminated in West Virginia depict the different tablet strengths – in a line – and instruct health care providers that they can increase the dose by titrating upwards without disclosing the increased risk of addiction at higher doses.[72]



88. Endo failed to disclose the increased risk of addiction at higher opioid doses in marketing and promotional materials for its opioid products that were widely disseminated to health care providers and the public in West Virginia.

89. Endo's marketing and promotional materials that failed to disclose the increased risk of addiction at higher doses were false, misleading, and deceptive because they led health care

[72] ENDO-OR-CID-00006271.

providers and the public to believe that Endo's opioid products, and opioids as a class, were safer than they actually were and did not have an increased risk of addiction at higher doses.

d. False: Long-term opioid use improves patients' functioning.

90. Endo represented that patients' function and quality of life improved with long-term use of opioids despite the lack of evidence of improved function and despite the existence of evidence to the contrary.

91. For example, since at least May 2011, Endo distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER that included photographs depicting patients with physically demanding jobs, implying that the drug would provide long-term pain relief and functional improvement.

92. In a sales aid for Percocet, Endo instructed its sales representatives that the use of Percocet was shown to improve patient quality of life.[73] Similarly, in a brochure distributed to physicians, quality of life improvements were touted as a key benefit for Endo's Percocet products.[74]

93. Endo also instructed its sales representatives to make quality of life claims about its Opana products. As of at least 2012, the platform statement given to prescribers about Opana ER claimed that "Opana ER allows patients to function at a higher level, experience a better quality of sleep, and achieve the quality of life they desire with minimal cognitive and other side effects."[75]

94. Endo's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As of 2015, there were no controlled studies of the

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[73] ENDO-OPIOID_MDL-04908364 (slide 13-14).
[74] ENDO-OPIOID_MDL-04929193.
[75] ENDO-OR-CID-00218892.

efficacy or safety of long-term use of opioids, much less any evidence that opioids reduce patients' pain and improve function long term.[76] This fact was made all the more clear by the FDA through warning letters issued to manufacturers citing the lack of evidence that the use of opioids for chronic pain improves patients' function and quality of life.[77] Based upon a review of the existing scientific evidence, the CDC Guidelines concluded that "there is no good evidence that opioids improve pain or function with long-term use."[78]

95. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a few long-term studies of opioid use had "consistently poor results," and "several studies have showed that opioids for chronic pain may actually worsen pain and functioning . . ."[79] along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

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[76] Andrew Kolodny, *et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, ANN. REV. PUB. HEALTH 2015 36:1, 559–574, 562–3, *available at* https://bit.ly/2J5A9Tp.

[77] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claims that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities ... has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[78] Dowell D, Haegerich TM, Chou R., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, MORBIDITY AND MORTALITY WKLY. REP., Mar. 18, 2016, at 20, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

[79] Thomas Frieden &Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 NEW ENG. J. MED. 1501, 1503 (2016), *available at* https://www.nejm.org/doi/full/10.1056/NEJMp1515917.

96. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[80] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[81]

97. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[82] In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[83] Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six

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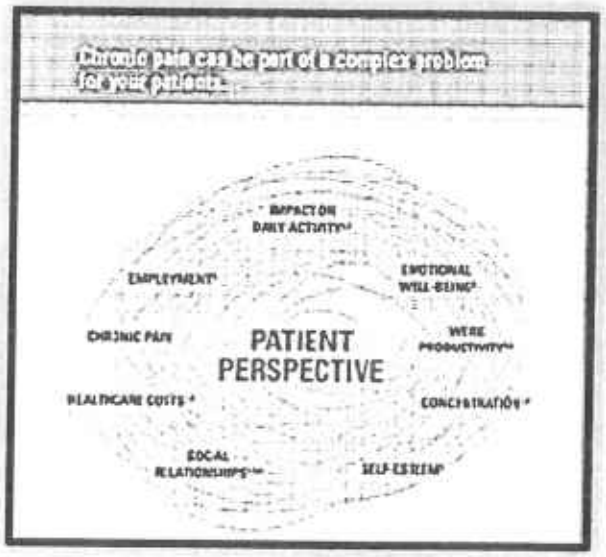
[80] Dowell D, Haegerich TM, Chou R., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, MORBIDITY AND MORTALITY WKLY. REP., Mar. 18, 2016, at 2, 18, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.
[81] Thomas Frieden &Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 NEW ENG. J. MED. 1501, 1503 (2016), *available at* https://www.nejm.org/doi/full/10.1056/NEJMp1515917.
[82] Andrea Rubinstein, *Are we Making Pain Patients Worse?*, SONOMA MED. (Fall 2009), *available at* http://www.nbcms.org/en-us/about-us/sonoma-county-medical-assoication/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.
[83] Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders,* 33 SPINE 2219-27 (Sept. 15, 2008).

weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.[84]

98. Nevertheless, Endo built on its earlier marketing and touted the purported benefits of long-term opioid use, while falsely and misleadingly implying that these benefits are supported by evidence.

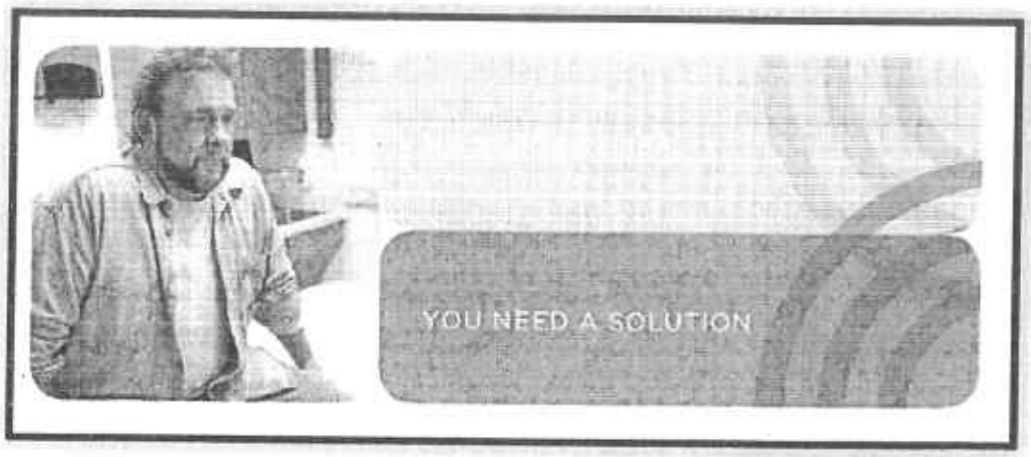
99. Endo used visual aids claiming that its opioids, such as Opana ER, would help with a patient's overall well-being. In one of its "master visual aids" distributed nationwide for Opana ER, Endo made implicit claims that its opioid products would help patients keep working and improve their daily activities, emotional well-being, work productivity, concentration, and self-esteem.[85]



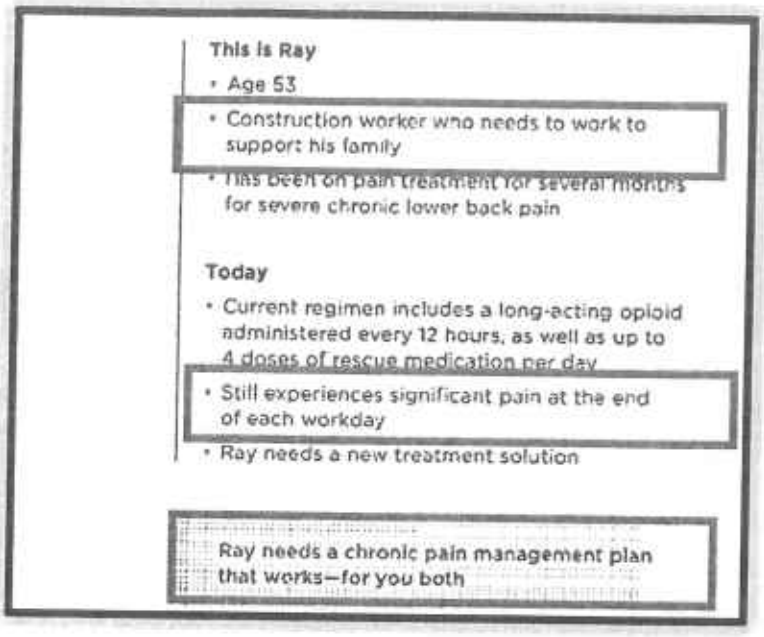
[84] Franklin, GM, et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 SPINE 199, 201-202 (Jan. 15, 2008), *available at* https://www.ncbi.nlm.nih.gov/pubmed/18197107.

[85] ENDO-OR-CID-00782399 (Patient Perspective from the Master Visual Aid).

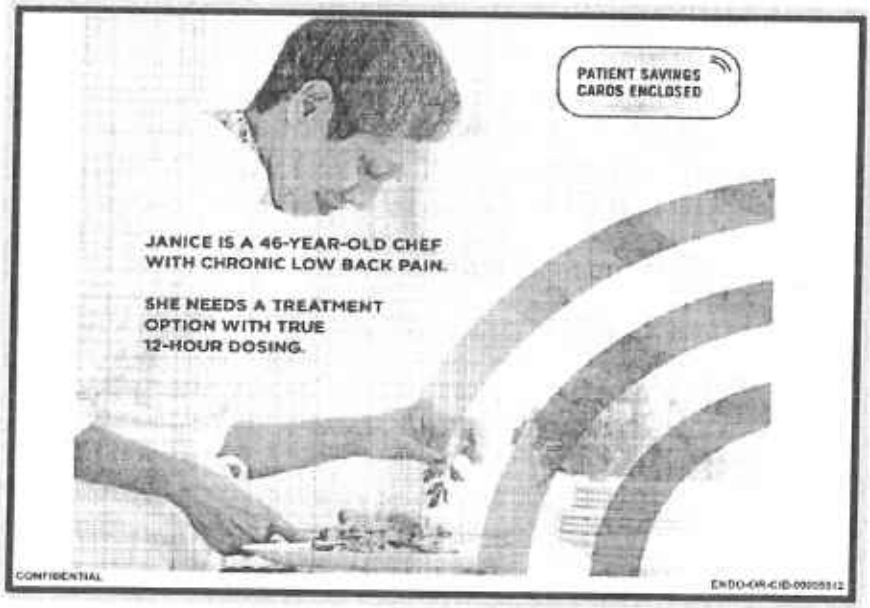
100. Endo also instructed its sales representatives to tell health care providers that opioids would improve patients' ability to function, allowing them to return to work and increase physical activity. For example, an Endo sales brochure with the tagline "HE NEEDS RELIEF[.] YOU NEED A SOLUTION," featured a fictional construction worker named Ray "who needs to work to support his family" and "still experiences significant pain at the end of each workday." The brochure ends by stating "Ray needs a chronic pain management plan *that works* – for you both."[86]



[86] ENT000051687 (emphasis added).



101. Another Endo advertisement featured a fictional chef named Janice and implied that Opana ER would improve her ability to function at work.[87]



[87] ENDO-OR-CID-00005512.

102. Endo's claims about its opioid products, including that they could improve one's function, quality of life, sleep, emotional well-being, work productivity, concentration, or self-esteem, were false, misleading, and deceptive because they led health care providers and the public to believe that Endo's opioid products, and opioids as a class, provided such benefits when this is not the case or when such claims were not supported by competent or reliable scientific evidence.

e. False: Original Opana ER is not prone to abuse.

103. Prescription opioid abuse takes several forms, the most common being oral abuse, which includes using drugs without a prescription, as well as swallowing higher or more frequent doses than prescribed. Other forms of opioid abuse include crushing, cutting, chewing, grinding, or liquefying the drug in order to snort or inject it.

104. Endo knew of the abuse and diversion problem that would come from the launch of its extremely potent opioid, Opana ER. Handwritten notes on internal documents from Endo dated before Opana ER's launch expressly state that Endo was aware of the problem of abuse and diversion.[88]

105. In a 2007 document titled "*Better the Devil You Know*... Inspiring Physicians to Do the Right Thing with Opana ER," Endo's marketing consultants identified "being the stigma-free pain medication" as a marketing opportunity and recommended that Endo advance the deceptive claims that Opana ER was "less attractive target to abusers,"[89] "less attractive to drug seekers," produced "less euphoria," and was a "responsible" choice.[90] Endo advanced these concepts for years.

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[88] ENDO-CHI_LIT-00543529.
[89] ENDO-OR-CID-01017684 (slides 7–9 of 120).
[90] ENDO-OR-CID-00733299 (slides 1, 14, 35 of 120).

106. Endo documented that its false and misleading claims about Opana ER's purported lower potential for abuse or diversion resonated with health care providers. In a 2007 internal marketing document, Endo stated that a "main message recall" for Opana ER for health care providers its sales representatives called upon was "[l]ow potential for abuse/diversion."[91]

107. Endo followed the recommendations of its consultants and internal marketing documents and repeatedly made low abuse potential or abuse deterrent messages to health care providers, including providers in West Virginia. Endo's sales representatives falsely represented to health care providers that the original formulation of Opana ER was "not prone to abuse,"[92] had "low incidence of euphoria,"[93] "[l]ow abuse potential,"[94] was "very hard to adulterate into making it an immediate release drug,"[95] was "very resistant to adulteration"[96] or made other similar statements.[97]

108. Likewise, in a 2008 internal marketing document, Endo emphasized the purported "[l]ow potential for abuse/street abuse/diversion" as the primary attribute of Opana ER that was most likely to increase prescriptions.[98]

109. Endo also made representations concerning the low abuse potential of Opana ER in West Virginia through letters signed by West Virginia physicians, which Endo would

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[91] ENDO-CHI_LIT-00547959 (slide 18 of 136).
[92] ENDO-CHI_LIT-00548031.
[93] ENDO-CHI_LIT-00548031, -045.
[94] ENDO-CHI_LIT-00548034, -041.
[95] ENDO-CHI_LIT-00547958; -8033.
[96] ENDO-CHI_LIT-00548046.
[97] ENDO-CHI_LIT-00548031, -041, -045, -115 ("Low incidence of abuse due to low incidence of euphoria."), - 117 ("less risk of narcotic related problematic [sic]"), -135 ("decreased potential for abuse"), -136 ("low abuse potential"), -146 ("Safety of immediate release Opana and pain control for breakthrough pain in almost all patients without significant abuse."), -198 ("[g]enerally has low abuse potential").
[98] ENDO-OR-CID-00130755.

periodically update.[99] For example, letters dating from 2009 suggested that Opana ER was abuse deterrent and made claims that Opana ER's delivery matrix "allows for the chance of less abuse and possible diversion,"[100] that the "design of the Opana ER molecule makes it less likely for the potential for abuse,"[101] and that "Opana ER has the potential for less addiction and has less abuse potential, which is (sic) appears to be an evident and ongoing problem."[102]

110. However, Endo knew that Opana ER was quickly becoming a drug of choice for abuse and diversion.[103] A January 2009 report issued by the Ohio Substance Abuse Monitoring Network reported that drug abusers had begun to turn to Opana as an alternative to OxyContin, commonly crushing the stop-sign shaped Opana tablets to inhale the drug intranasally.[104] Users indicated that the "Opana 'high' was comparable to or even better" than Purdue's flagship product, with one user commenting "[t]he oxymorphone is the best . . . even better than oxycodone."[105] Nevertheless, Endo continued to promote its product as not prone to abuse.

111. Endo's claims that its original formulation of Opana was not prone to abuse, misuse and diversion was false, misleading, and deceptive because it led health care providers and the public to believe that Opana ER had these attributes when this was not the case.

f. False: New formulation of Opana ER successfully deterred abuse.

112. By 2010, Endo knew that making abuse deterrent claims regarding its planned reformulation of Opana ER would be problematic because it had no evidence the reformulation

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[99] ENDO-OPIOID_MDL-00962354.
[100] ENDO-OPIOID_MDL-00962356.
[101] ENDO-OPIOID_MDL-00962357.
[102] ENDO-OPIOID_MDL-00962358.
[103] ENDO-OPIOID_MDL-02178254.
[104] ENDO-OPIOID_MDL-02178256.
[105] ENDO-OPIOID_MDL-02178256.

would actually deter abuse. In an internal e-mail on February 8, 2010, Endo's Vice President of Regulatory Affairs acknowledged the lack of data demonstrating that the reformulation would actually deter abuse:

> The modifier that I believe will be accepted is ER. Any other modifier that is descriptive of the [abuse deterrent] technology provides little, if any, useful information to the prescriber *because we don't have data to demonstrate that the technology conveys any benefit to the patient.* If FDA eventually describes the characteristics and minimum requirements of a tamper resistant or abuse deterrent formulation they may establish an appropriate suffix at that time.[106]

113. In fact, Endo knew that its reformulated Opana ER was likely to be subject to even more abuse than its original formulation. As early as August 30, 2010, Endo's own *in vitro* studies showed that reformulated Opana ER had "much higher" "syringeability" than the original formulation. Endo anticipated that the FDA would inquire why the studies showed such a result for the new purported tamper resistant formula and crafted a response which explained that, at best, reformulated Opana ER (referred to in the graphic below as "TRF" and "EN3288") carried the same potential for intravenous abuse as the original formulation (referred to below as "Opana ER").[107]

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[106] ENDO-OR-CID-00448291 (emphasis added).
[107] ENDO-OR-CID-00082756.

Q6. Why is your in-vitro syringability data for TRF is much higher than Opana ER?

Responder: Frank

Answer (Headline): Why is your in-vitro syringability data for TRF is much higher than Opana ER?

Answer (Support Data):
The in-vitro syringability test results show the standardized laboratory test procedures do not always simulate the real-life situation, which is demonstrated by the bench-top tampering study 901. Study 901 results indicate that both EN3288 and Opana ER tablets are difficult to extract for IV abuse by experienced abusers. (901)
This difference observed in the in-vitro syringability test was artificially due to the attempt to standardize the experimental procedures. In the standardized testing procedures for syringability test, both EN3288 and Opana ER tablets were crushed first. After crushing with a pill crusher, EN3288 was only flattened but Opana ER was practically pulverized. The crushed samples were extracted with 5 mL of water with 5 min of boiling. After boiling, the evaporated water was replaced with fresh water, and then filtered and withdrawn into a syringe. The difference in amount extracted reflected the more gelling of the Opana ER powder than the flattened EN3288 tablet, and the lower concentration of the Opana ER extract could be that freshly added water was filtered and drawn into syringe. (Phast report)
When the syringability study was conducted with tampered EN3288 and Opana ER samples having similar particle sizes, the results were similar to the finding of study 901. (GRT/Phast make up studies, TBD, not in the NDA)

Bridge to Key Message: EN3288 is as difficulty to abuse IV as Opana ER

114. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating which the company claimed made it crush resistant.

115. However, prior to its approval, the FDA advised Endo that it could not market the new Opana ER as abuse deterrent. The FDA told Endo:

> While the new formulation has demonstrated a minimal improvement in resistance to tampering by crushing, thereby limiting the likelihood of abuse by crushing followed by ingestion, and by insufflation (snorting) to some degree, *it can still be . . . cut . . . rendering it readily abusable by ingestion and intravenous injection, and possibly still by insufflation* [snorting]; although whether . . . tablets can be snorted was not studied. *Of more concern, when chewed . . . the new formulation essentially dose dumps like an immediate-release formulation.*[108]

[108] FDA Center for Drug Evaluation and Research, Summary Review 3–4, Dec. 9, 2011, *available at* www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000SumR.pdf (emphasis added); *see also* ENDO-OR-CID-00073848 (citing this language from Dec. 9, 2011 decision).

116. Nevertheless, Endo sought to establish reformulated Opana ER as the leading abuse-deterrent opioid product.[109]

117. Endo used "with INTAC Technology" as its most prominent abuse deterrent message by making it part of the brand name for the reformulated Opana ER. Endo employed the phrase "with INTAC Technology" whenever it mentioned the brand name – something Endo did repeatedly to drive the false claim home. Endo made this claim nationwide, including in West Virginia.[110]

118. In February 2012, Endo began marketing and selling the reformulated Opana ER under the rebranded name "Opana ER with INTAC Technology" despite the fact that the FDA never approved abuse deterrence labeling for the reformulated Opana ER.

119. Two months later, in April 2012, Endo received a response letter from the FDA explicitly stating that Endo's claims about Opana ER's INTAC technology were misleading, despite an included disclaimer. The FDA stated that "these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's 'INTAC™ technology' confers some form of abuse deterrence properties when this has not been demonstrated by substantial evidence."[111]

120. Nevertheless, Endo continued promoting Opana ER as "crush resistant" even though Endo anticipated it could receive a "Warning Letter" from the FDA for doing so.[112] Endo knew that unless it was able to distinguish its reformulated Opana ER there would be no reason to prescribe it over generic versions of the old formulation, which were substantially cheaper.

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[109] ENDO-OR-CID-00223057.
[110] ENDO-OR-CID-00117276 (documenting INTAC claim with WV doctor on March 30, 2012).
[111] ENDO-OR-CID-00009163, -164 (emphasis added).
[112] ENDO-OR-CID-00345837.

121. During the third week of June 2012, Endo trained all its Opana ER sales representatives, including those in West Virginia, to advance the claim that the reformulated Opana ER was "designed to be crush-resistant" and "the INTAC Technology is included in the new formulation for that purpose" in sales calls with providers.[113]

122. For example, on July 11, 2012, USA Today published a story titled "Opana Abuse in USA Overtakes OxyContin," which as the headline indicates, described the rise of Opana ER abuse following OxyContin's reformulation.[114] The story revealed that hot spots for OxyContin abuse had become hot spots for Opana ER abuse.

123. That same day, Endo's marketing department instructed *all* its sales representatives nationwide to respond to health care providers' questions about the USA Today Opana ER story with, among other things, the following:

> Endo discontinued the manufacturing of the original formulation of Opana ER in early 2012 and *now only manufactures the new formulation of Opana ER with INTAC™ technology which is designed to be crush-resistant.*[115]

124. Endo also directed its promotional speakers, who were usually doctors, to make similar comments in response to questions about the USA Today story, including that Opana ER with INTAC Technology was crush resistant.[116]

125. In an internal memorandum dated January 2013, Endo's Opana ER Brand and Sales Training Team sent the following to "all customer facing roles," including Endo's sales representatives:

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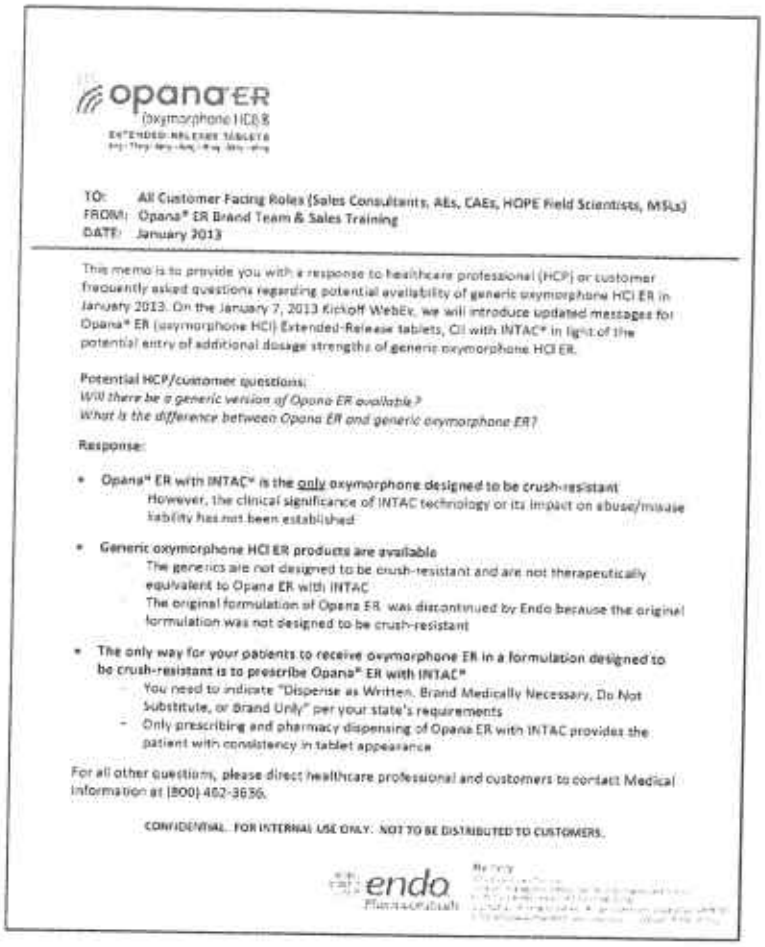
[113] ENDO-OR-CID-00770083.
[114] ENDO-OR-CID-00839051.
[115] ENDO-OR-CID-00009156 (emphasis added).
[116] ENDO-OR-CID-00430776.



opana ER
(oxymorphone HCl) 5
EXTENDED-RELEASE TABLETS
Rx Only

TO: All Customer Facing Roles (Sales Consultants, AEs, CAEs, HOPE Field Scientists, MSLs)
FROM: Opana® ER Brand Team & Sales Training
DATE: January 2013

This memo is to provide you with a response to healthcare professional (HCP) or customer frequently asked questions regarding potential availability of generic oxymorphone HCl ER in January 2013. On the January 7, 2013 Kickoff WebEx, we will introduce updated messages for Opana® ER (oxymorphone HCl) Extended-Release tablets, CII with INTAC® in light of the potential entry of additional dosage strengths of generic oxymorphone HCl ER.

Potential HCP/customer questions:
Will there be a generic version of Opana ER available?
What is the difference between Opana ER and generic oxymorphone ER?

Response:

- Opana® ER with INTAC® is the only oxymorphone designed to be crush-resistant
  - However, the clinical significance of INTAC technology or its impact on abuse/misuse liability has not been established
- Generic oxymorphone HCl ER products are available
  - The generics are not designed to be crush-resistant and are not therapeutically equivalent to Opana ER with INTAC
  - The original formulation of Opana ER was discontinued by Endo because the original formulation was not designed to be crush-resistant
- The only way for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe Opana® ER with INTAC®
  - You need to indicate "Dispense as Written, Brand Medically Necessary, Do Not Substitute, or Brand Only" per your state's requirements
  - Only prescribing and pharmacy dispensing of Opana ER with INTAC provides the patient with consistency in tablet appearance

For all other questions, please direct healthcare professional and customers to contact Medical Information at (800) 462-3636.

CONFIDENTIAL. FOR INTERNAL USE ONLY. NOT TO BE DISTRIBUTED TO CUSTOMERS.

endo Pharmaceuticals

CONFIDENTIAL ENDO-OR-CID-00015474

126. Endo also instructed its sales representatives to distinguish reformulated Opana ER from its original formula and competing generics by giving providers a new sales message: "The only way for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe Opana® ER with INTAC®."[117]

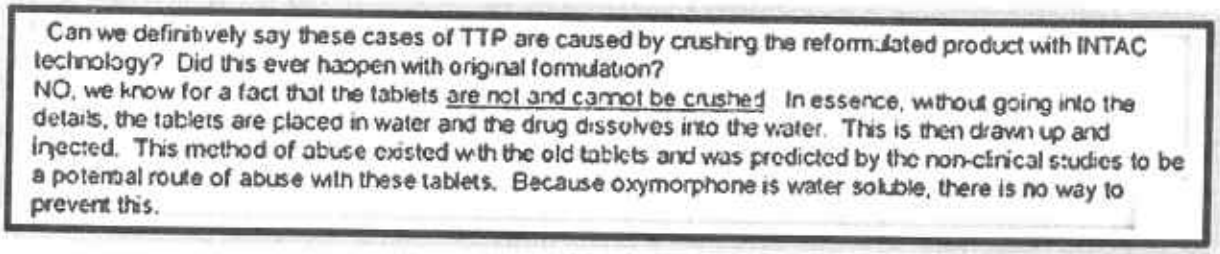
127. Endo continued to promote the abuse deterrence claims even after having actual knowledge of significant abuse soon after the launch of reformulated Opana ER, including in West

[117] EPI000421543.

Virginia.[118] In 2009, only 3% of Opana ER abuse was by intravenous means. After reformulation, injection of Opana ER increased substantially. Endo's own data, presented in 2014, found that between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.[119]

128. Endo also made its abuse deterrence claims despite actual knowledge that there was no way to prevent intravenous injection *in the first place* because oxymorphone easily dissolves in water. In a public relations presentation, Endo's Vice President of Pharmacovigilance and Risk Management & Senior Clinical Advisor responded to internal questions and admitted to the intravenous injection form of abuse:

> [Intravenous] abuse existed with the old tablets and was predicted by the non-clinical studies to be a potential route of abuse *with these tablets*. ***Because oxymorphone is water soluble, there is no way to prevent this.***[120]


Can we definitively say these cases of TTP are caused by crushing the reformulated product with INTAC technology? Did this ever happen with original formulation?
NO, we know for a fact that the tablets are not and cannot be crushed In essence, without going into the details, the tablets are placed in water and the drug dissolves into the water. This is then drawn up and injected. This method of abuse existed with the old tablets and was predicted by the non-clinical studies to be a potential route of abuse with these tablets. Because oxymorphone is water soluble, there is no way to prevent this.

129. Endo instructed its sales representatives to provide health care providers with messages that were deceptive in multiple ways. *First*, the brand name "Opana ER with INTAC" is an abuse-deterrence claim that the Opana ER pill remains intact at all times, when this is not

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[118] EPI002276216, -218; ENDO-OPIOID_MDL-6249371; EPI002276220; ENDO-OR-CID-01181060.
[119] Theresa Cassidy, et al., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations,* IBH (Sept. 7, 2014), https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxymorphone/.
[120] ENDO-OR-CID-00848440 (highlighted, bold, and italicized emphasis added) (The next question and response reads: "[I]s it accurate to say our reformulated product is successfully demonstrating the crush-resistant properties for which it was designed? YES; the tablets cannot be crushed.").

true. *Second*, the phrase "designed to be crush-resistant" misleads or tends to mislead consumers that reformulated Opana ER is more resistant to abuse or manipulation than it actually is. *Third*, as the FDA warned Endo, including a disclaimer that "the clinical significance of INTAC technology or its impact on abuse/misuse liability has not been established" does not mitigate the overall deception of the ad or the express deceptive claims made. *Fourth*, Endo's memorandum claims that reformulated Opana ER is superior to generic Opana ER under the old formulation when Endo's own data showed that reformulated Opana ER was as bad as or worse than the old formulation for common forms of abuse. *Fifth*, Endo did not discontinue the original formulation because it was susceptible to abuse or for safety reasons—it did so because it feared that generic competition would cost Endo millions of dollars in revenue.[121]

B. Endo's Deceptive Comparative Claims: *Opana ER v. OxyContin*

130. From the beginning, Endo worried that its opioids, including Opana ER, would be perceived as "me too" drugs that would have trouble establishing market share.[122] By the time Endo launched Opana ER in 2006, Purdue had created the extended release opioid market for chronic pain through OxyContin and had a 10-year head start. Thus, Endo made unsubstantiated comparative claims about its competitors' opioids to try to increase market share within the long-acting opioid segment—a market that Endo defined as including OxyContin, generic controlled release oxycodone, Avinza, Kadian, and all other Sustained Release Morphine.[123]

131. Endo knew that it was deceptive to make unsubstantiated comparative claims. In internal documents, the company acknowledged:

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[121] Decl. of Julie H. McHugh, Chief Operating Officer for Endo Pharm. Inc., at ¶ 6, *Endo Pharm Inc. v. FDA*, Case No. 1:12-cv-01936-RBW (Dec. 18, 2012), ECF No. 287, *available at* https://bit.ly/2OFmAih.
[122] ENDO-CHI_LIT-00545916 (slide 22 of 65); *see* also, ENDO-CHI_LIT-00543590.
[123] ENDO-CHI_LIT-00545553 (slide 14 of 38).

> Sales representatives should not make comparative claims unless such claims have been approved by the Marketing & Advertising Review Committee (MARC). Examples of inappropriate comparative claims include:
>
> - Label-to-label comparisons (e.g., 'Drug A's clinical study showed 80% clinical response but Drug B's clinical study showed 65% clinical response if you look at their respective labeling')[;]
>
> - Comparisons of pharmacokinetic or pharmacodynamics effects to show greater efficacy (e.g. "Drug A works better, because it has a longer half-life than Drug B')[;]
>
> - Comparisons or pharmacokinetic or pharmacodynamics effects to show greater safety (e.g., 'Drug A is safer than Drug B, because it has a shorter half-life than drug B')[; and]
>
> - Claims about drug's uniqueness to imply superior efficacy or safety without a head-to-head trial comparing your drug to the drug(s) it is unique compared to (e.g., 'unique efficacy in elderly patients')[.][124]

132. Throughout Opana ER's product life, Endo sought to distinguish it from OxyContin specifically.[125] Endo "hyper targeted" some of the highest OxyContin prescribers, including some in West Virginia, and instructed its sales representatives to "[t]ake business from OxyContin where we have good access" with these prescribers.[126]

133. In 2007, Endo's marketing department recognized that "differentiat[ing] OPANA ER vs. OxyContin" was a "critical success factor"[127] and stated that it would "[c]ontinue to differentiate Opana ER vs. OxyContin" as part of its strategic plan.[128]

134. In another 2007 document, Endo again identified its ability to "[d]ifferentiate OPANA ER vs. OxyContin" as a "Critical Success Factor" and reiterated that one of its primary

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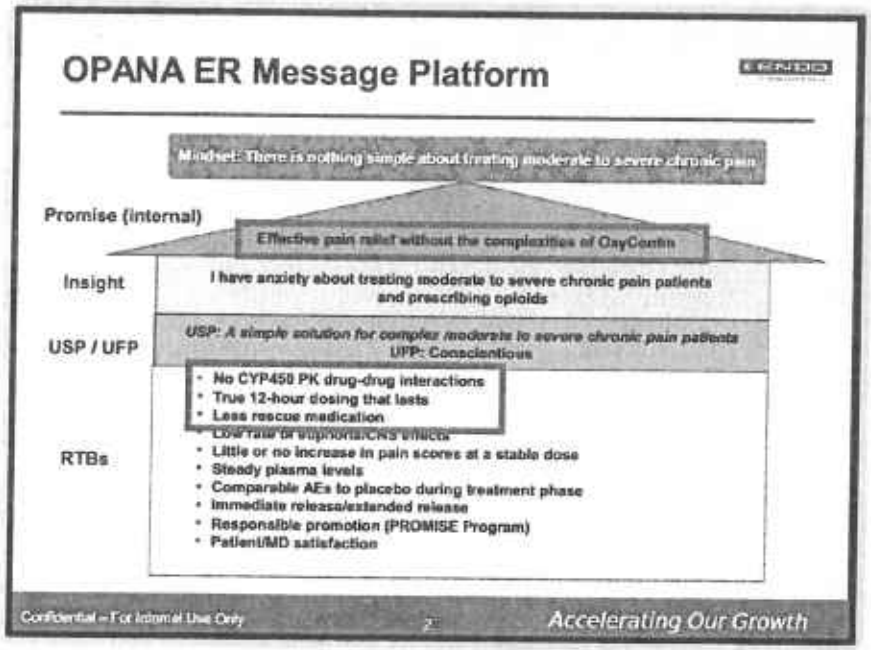
[124] ENDO-OR-CID-00782391.
[125] *See, e.g.*, ENDO-OR-CID-00343598 (slides 24, 28, 38 of 74); ENDO-CHI_LIT-556197 (slide 22 of 38).
[126] ENDO-OR-CID-00963215 (slide 1 of 2); *see also*, ENDO-CHI_LIT-556197 (slide 26 of 38).
[127] ENDO-CHI_LIT-00541043. ENDO-CHI_LIT-00545558 (slide 2 of 48).
[128] ENDO-CHI_LIT-00545558 (slide 2 of 48).

marketing objectives was to "[c]ontinue to *differentiate* OPANA ER based on its *durable efficacy and dosing advantages.*"[129]

135. Endo selected "[e]ffective pain relief without the complexities of OxyContin" as the central promise of Endo's "OPANA ER Message Platform." Endo identified the following, among other things, as claims that would provide an entry point for Endo to compare Opana ER with OxyContin:

- No CYP450 PK drug-drug interactions
- True 12-hour dosing that lasts
- Low rate of euphoria/CNS effects
- Comparable adverse events to placebo during treatment phase.[130]



[129] ENDO-CHI_LIT-00541043, -061, -062 (emphasis added).
[130] ENDO-CHI_LIT-00545559 (slides 2-3); *see also*, ENDO-CHI_LIT-00547048; ENDO-CHI_LIT-00547838 (slide 9 of 20); ENDO-CHI_LIT-00547715 (slide 9 of 18).

136. Endo advanced the "internal" promise externally and implemented it in actual sales calls. Endo training documents taught sale representatives to position Opana ER as easier to manage than OxyContin and requiring fewer rescue medications.[131] In sales calls, Endo positioned Opana ER as safer than other long acting pain relievers[132] and represented that it had fewer drug interactions and required less rescue medication.[133]

137. Endo's sales representatives made the claim of "no known CYP450 drug/drug interactions at clinically relevant doses" a "primary selling message for Opana ER"[134] and used the message as an entry point to make superiority claims of Opana ER over OxyContin.

138. Endo also touted that Opana ER had more "durable" and effective pain relief than OxyContin. Endo even ran Opana ER advertisements that referred to "real" 12-hour dosing and "uniquely engineered for true 12-hour dosing that lasts" as an entry point to make comparative claims about OxyContin, which had the widespread reputation among providers of not lasting for 12 hours.[135]

139. Endo made this 12-hour dosing message a core comparative claim in sales calls. In internal documents, Endo had evidence that:

> *77% of HCP's recalled on an aided basis "true every 12 hour dosing" as the primary message of the OPANA ER sales rep detail.*[136]

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[131] *See* ENDO-CHI_LIT-00545558 (slide 25 of 47); ENDO-CHI_LIT-00547715; ENDO-OR-CID-00782393, -422.
[132] ENDO-CHI_LIT-00547959 (slide 96 of 135).
[133] ENDO-OR-CID-00459065 (Opana ER tab).
[134] ENDO-OR-CID-00431119; ENDO-OR-CID-00782488; ENDO-OR-CID-00782405, -445; ENDO-OR-CID-00782443.
[135] ENDO-CHI_LIT-00541049.
[136] ENDO-OR-CID-01228484 (emphasis added).

140. Endo knew through audits of sales calls that its sales representatives made comparative claims which amplified many of its other deceptive safety, efficacy, and benefit claims. As illustrative examples, Endo knew in 2007 that its sales representatives:

- said Opana ER has a "steadier release of the medication than most of the other medications out on the market[;]"[137]
- made "comparisons with other medications including OxyContin and generic morphine sulfate[;]"[138]
- said Opana ER "has less side effects, including nausea[;]"[139]
- said Opana ER had "less side effect profile[;]"[140]
- said that Opana ER provided "[b]etter control pain, *less risk of abuse*[;]"[141]
- said that Opana ER is a "new long acting pain medication that doesn't have the negative press of OxyContin and is an effective agent, something to try for people not controlled on their current regiment[;]"[142]
- said that Opana ER had "less side effects and easier to take medication than OxyContin[;]"[143] and
- said that Opana ER had "[l]ess euphoria and maybe *less addictive potential*[.]"[144]

141. In June 2012, part of Endo's "Opana ER Action Plan" was to focus on converting OxyContin and MS Contin prescribers to the reformulated Opana ER.[145]

142. Endo's comparative claims about OxyContin were false, deceptive, misleading and/or unsubstantiated at the time they were made.

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[137] ENDO-CHI_LIT-00548027.
[138] ENDO-CHI_LIT-00548039.
[139] ENDO-CHI_LIT-00548027.
[140] ENDO-CHI_LIT-00548039.
[141] ENDO-CHI_LIT-00548028.
[142] ENDO-CHI_LIT-00548029.
[143] ENDO-CHI_LIT-00548029.
[144] ENDO-CHI_LIT-00548045.
[145] ENDO-OR-CID-01311385 (emphasis added).

C. Endo Disseminated its False, Deceptive and Misleading Messages About Opioids Through Multiple Direct and Indirect Channels

143. Endo spread its false and deceptive messages by marketing its opioids directly to doctors and patients throughout the United States. Endo also deployed seemingly unbiased and independent third parties it controlled to spread their false and deceptive messages about the risks and benefits of opioids for the treatment of chronic pain throughout the country, including throughout West Virginia.

144. Endo ensured marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speak training; single sets of visual aids, speak slide decks, and sales training materials; and nationally coordinated advertising.[146]

145. Endo utilized various channels to carry out its marketing scheme of targeting the medical community and patients with deceptive information about its opioids: (1) direct, targeted communications with prescribers by sales representatives or "detailers;" (2) third party groups with the appearance of independence from Endo; (3) KOLs and TEs, doctors who were paid by Endo to promote its pro-opioid message; (4) disseminating their misleading messages through reputable organizations; (5) CME programs controlled and/or funded by Endo; (6) branded advertising; (7) unbranded advertising; (8) publications; and (9) speakers bureaus and programs.

a. Endo used "detailers" to directly disseminate their misrepresentations to prescribers.

146. As illustrated herein, Endo's sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted

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[146] ENDO-MSAG_TR-00005524 at 282:11-283:3.

prescribers with centrally orchestrated messages. Endo's sales representatives also distributed third-party marketing material to their target audience that was deceptive. Endo's direct contact with prescribers was its most important means of disseminating the false narrative and increasing opioid prescriptions, and accordingly, its sales.

147. Endo promoted opioids through sales representatives (also called "detailers") and small group speaker programs designed to reach out to individual prescribers. By establishing close relationships with doctors, Endo was able to disseminate its misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

b. Endo deceptively directed third-party groups to promote opioid use.

148. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Endo exerted influence and effective control, in part, over the messaging by these groups. These groups put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated the benefits of opioids, and understated their risks.

149. Endo's consultant recommended to Endo that it should "Review All Sources and Amounts of Funding to Third-Party Groups" and "Anticipate [the] Funding Needs of Organizations" because "*To Get, You've Got to Give.*"[147]

150. Endo incorporated publications from these third-party pain advocacy groups into the company's marketing for its branded opioid products like Opana ER. One of the most

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[147] ENDO-CHI_LIT-00543595, at slide 8 (emphasis added).

significant types of third-party publications that Endo touted in its marketing were treatment guidelines, which the CDC has recognized can "change prescribing practices."[148]

151. Endo knew how influential treatment guidelines could be for providers and used "Appropriate Use Guidelines for P[rimary] C[are] P[hysician]s" to help "[e]ntrench OPANA ER as a preferred therapy based on durable efficacy and unique set of dosing advantages."[149]

152. APF developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC was a continuing medical education program that published prescriber education programs, including a series of "dinner dialogues."[150] In addition to live educational events, it reached prescribers through webcasts and printed materials.[151] NIPC estimated that over 1.2 million prescribers participated in its programs.[152]

153. Endo was NIPC's only financial contributor.[153] Between 2003 and 2012, Endo provided NIPC $31 million.[154] Endo substantially controlled NIPC by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan

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[148] Dowell D, Haegerich TM, Chou R., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, MORBIDITY AND MORTALITY WKLY. REP., Mar. 18, 2016, at 2, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.
[149] ENDO-CHI_LIT-00546179 (slides 13, 17).
[150] ENDO-OR-CID-00640194.
[151] ENDO-OPIOID_MDL-01940510; ENDO-OR-CID-00640194.
[152] ENDO-OPIOID_MDL-01940510.
[153] ENDO-OR-CID-00640194.
[154] ENDO_OPIOID_DEPMAT-000033799.

Endo submitted to the FDA,[155] yet Endo's involvement in NIPC was not disclosed on the website pages describing NIPC or on www.painknowledge.org.

154. Endo used the American Geriatric Society (AGS) Guidelines in branded marketing for its opioids, including Opana ER. Following focus groups with health care providers in 2009, Endo identified "[a] clear opportunity for messaging to older patients based on AGS Guidelines for opioid use[.]"[156] Endo also referenced the *AGS Guidelines on Opioid Use in Elderly Patients* in its own marketing materials without disclosing its financial connection to the group.[157]

155. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy."[158] The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.[159] These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication.

156. The American Academy of Pain Medicine (AAPM) and the American Pain Society (APS) issued their own guidelines in 2009 ("2009 Guidelines"). AAPM, with the assistance,

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[155] END00358522.
[156] ENDO-OR-CID-00136446.
[157] ENDO-OR-CID-00364928 (slide 49-50).
[158] *Pharmalogical Management of Persistent Pain in Older Persons*, 10 Pain Medicine 1062–83, 1076 (Sept. 16, 2009) *available at* https://academic.oup.com/painmedicine/article/10/6/1062/1843022.
[159] *Id.*

prompting, involvement, and funding of Endo, in part, issued the treatment guidelines and continued to recommend the use of opioids to treat chronic pain.[160]

157. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Endo promoted opioids and whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."[161]

158. Endo widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support its conclusions and its involvement in the development of the Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS 2009 Guidelines while omitting its disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

159. Endo's control of APS and other so-called pain advocacy groups is illustrated by Endo's active role in recommending content for APS's medical resident training program.[162]

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[160] ENDO-OPIOID_MDL-06234663.
[161] Dowell D, Haegerich TM, Chou R., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, MORBIDITY AND MORTALITY WKLY. REP., Mar. 18, 2016, at 2, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.
[162] ENDO_OPIOID_MDL-01928252.

160. Endo widely disseminated and promoted guidelines and educational materials to health care providers and to the public. Endo did not disclose its financial connection to the third-party advocacy groups that published the guidelines and educational materials it disseminated.

161. Endo's use of guidelines and educational materials from third-party advocacy groups in marketing its opioid products without clear and conspicuous disclosure of its monetary contribution to the groups was false, deceptive, and misleading because the practice misled health care providers and the public to believe that the information or advice contained in the guidelines was neutral and unbiased.

D. Endo Fueled and Profited From a Public Health Epidemic That Has Significantly Harmed West Virginia and Devastated Thousands of Its Citizens.

162. Opioids became a common treatment for chronic pain, in part, because of Endo's campaign of misrepresentations. As a result, opioid usage rates—and opioid abuse rates—have skyrocketed in West Virginia and in the United States. Between 1999 and 2014, sales of opioids nearly quadrupled, according to the CDC. Nearly 259 million opioid prescriptions were written in the United States in 2012 alone. This equates to more than one opioid prescription for every American adult. At the same time, diagnoses of opioid addiction increased nearly 500% from 2010 to 2016. Many tens of thousands of West Virginians are currently addicted to opioids.

163. The United States has approximately 4.4% of the world's population, but accounts for the vast majority of opioids consumed globally, including oxymorphone, which is the concentrated active ingredient in Opana ER.

164. This imbalance occurs not because Americans experience pain at higher rates than their global or national peers or have greater access to healthcare. Rather, it is due in large part to "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 U.S. Senate.[163]

165. In 2006, the opioid prescribing rate in West Virginia was 129.9 for every 100 people. In 2011, it increased to 139.6 prescriptions for every 100 people. In Boone County in 2006, the prescribing rate was 176.56 per 100 people and rose to 205.1 per 100 people by 2011.[164]

166. In 2017, West Virginia ranked highest in deaths due to drug overdose at 57.8 per 100,000 people. Between 2016 and 2017, the incidence rate of overdose deaths increased in West Virginia by 11.2 percent.[165]

167. 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.[166]

168. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing.[167] He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any

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[163] Nora Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, NATIONAL INSTITUTE ON DRUG ABUSE (May 14, 2014) *available at* https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[164] *U.S. Opioid Prescribing Rate* Maps, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

[165] *Drug Overdose Deaths*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[166] *Behavioral Health Barometer West Virginia, Volume 4*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN. 13, *available at* http://www.wvpti-inc.org/uploads/files/WV%20HEALTH%20BAROMETER%20(2).pdf

[167] *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, Centers for Disease Control and Prevention (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, (Aug. 2016), *available at* https://www.aafp.org/patient-care/public-health/pain-opioids/turn_the_tide.html.

of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[168]

169. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[169] In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[170]

170. The FDA also has made clear that "most opioid drugs have 'high potential for abuse,'" and "the *serious risks* of misuse, abuse, neonatal opioid withdrawal syndrome (NOWS), addiction, overdose, and death [are] associated with the use of ER/LA opioids overall, and during pregnancy."[171] According to the FDA, because of the "*known* serious risks" associated with extended-release opioid use, including "risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[172]

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[168] *Id.*
[169] Theodore J. Cicero, et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, Pharmacoepidemiology & Drug Safety, 827-40 (Jul. 18, 2007), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1002/pds.1452.
[170] *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, Centers for Disease Control and Prevention (Jan. 1, 2016), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w.
[171] ENDO-OPIOID_MDL-01321423 (emphasis added).
[172] ENDO-OPIOID_MDL-01391441 (emphasis added).

171. Upon information and belief, the escalating number of opioid prescriptions written by doctors who were deceived by Endo's deceptive marketing scheme is a cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout West Virginia.

172. Addiction has consumed the lives of countless West Virginians exposed to opioids prescribed by doctors either directly, from their own prescriptions, or indirectly, from prescription drugs obtained by others and found in family medicine cabinets. It is difficult to describe the lifelong struggle individuals addicted to opioids will face. The desire to get drugs becomes so consuming that addicts can no longer work or care for their children, and will resort to desperate means to persuade doctors to provide their next prescription—even pulling their own teeth.

173. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin when they can no longer get access to or afford the pills. It was foreseeable that users who became addicted to a particular prescription opioid, such as Opana ER, would migrate to another drug (including heroin) if those drugs became less expensive or more readily available. In fact, some users migrate to heroin (sometimes with fentanyl) they buy on the street.

174. Nationally, roughly 80% of heroin users previously used prescription opioids. From 2010 to 2017, heroin related overdose deaths increased by more than five (5) times. Social service agencies report being overwhelmed by the number of overdose and addiction cases in West

Virginia. In the city of Huntington (population 49,000), for instance, authorities responded to 26 heroin overdose cases in one four-hour span in 2017.[173]

175. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose.

176. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a 2017 study by a Princeton economist, the increase in opioid prescriptions from 1999 to 2015 could account for roughly 43% of the decline in labor force participation for men and 25% for women. Two-thirds of the surveyed men not in the labor force said they took prescription painkillers—compared to just 20% of employed men. Many of those taking painkillers still said they experienced pain daily.[174]

177. The abuse of opioids, including Opana ER, and the resulting increase in heroin use and addiction have caused outbreaks of HIV, chronic hepatitis C, and thrombotic thrombocytopenic purpura ("TTP").

178. In 2015, statistics from the Centers for Disease Control and Prevention, as well as the West Virginia Department of Health, showed that West Virginia has the highest rates of hepatitis B and hepatitis C cases in the United States. In 2012, West Virginia's hepatitis C rate was reported at 3.1 cases per 100,000 people, compared with 0.7 cases per 100,000 nationally.

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[173] *See The latest overdose outbreak shows just how dangerous the heroin epidemic has gotten*, WASH. POST, Aug. 17, 2017, https://www.washingtonpost.com/news/wonk/wp/2016/08/17/the-latest-overdose-outbreak-shows-just-how-dangerous-the-heroin-epidemic-has-gotten/?noredirect=on.

[174] *See* Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, BROOKINGS PAPERS ON ECONOMIC ACTIVITY, BPEA Conference Drafts, Sept. 7-8, 2017), *available at* https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf.

Reports show about two-thirds of people with hepatitis in West Virginia identify themselves as drug users.[175]

179. Children have not been spared by the opioid crisis. Between 2006 and 2016, children entering the West Virginia foster care system due to parental addiction rose 124%. About 70% of referrals to Child Protective Services in 2017 had a substance abuse component according to the statistics from the Centralized Intake Unit of the West Virginia Bureau for Children and Families. The state court Child Abuse and Neglect database indicates that about 80% of referrals from family court and circuit court judges have a substance abuse factor. As of July 2019, there were 6,940 children placed in foster care.[176]

180. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from NAS. These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

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[175] *See West Virginia Faces Epidemic of Hepatitis B and Hepatitis* C, HEP, April 17, 2015, https://www.hepmag.com/article/west-virginia-hepatitis-27088-916981843.
[176] *See Foster Care Placements Report*, W. VA. DEP'T. OF HEALTH AND HUMAN SERV., Jul. 31, 2019, https://dhhr.wv.gov/bcf/Reports/Documents/2019%20August%20Legislative%20Foster%20Care%20Placement%20Report.pdf.

181. NAS has become a great source of concern in West Virginia. West Virginia's rate of NAS is five times the national average.[177] In 2017, the overall incidence rate of NAS was 50.6 cases per 1,000 live births for West Virginia residents. The incidence rate of NAS in 2000 was only 0.5 cases per 1,000.[178]

182. While the use of opioids has taken an enormous toll on the state of West Virginia and its residents, Endo has realized millions of dollars in revenue from use of its opioids for chronic pain as a result of its deceptive, unfair, and unlawful conduct.

183. Endo's actions alleged in this Complaint have caused numerous societal and economic injuries to the State of West Virginia. The Defendants' conduct has contributed to deaths, drug addiction, personal injuries, child neglect, children placed in foster care, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and lost productivity, among others. The State of West Virginia is expending its resources to address these and other social problems resulting from the opioid crisis and will continue to expend resources addressing these problems.

COUNT I
Violation of the West Virginia Consumer Credit and Protection Act

184. Plaintiff adopts, realleges, and incorporates by reference paragraphs 1 through 183 above as if fully set forth herein.

185. Endo's acts or practices alleged herein are unfair, deceptive, and/or unconscionable in violation of the WVCCPA.

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[177] *See Proposed Opioid Response Plan for the State of West Virginia* 20, (Jan. 10, 2018), https://bit.ly/2Oyu48a.
[178] *See* Jean Y. Ko, et. al, *Incidence of Neonatal Abstinence Syndrome —28 States, 1999–2013*, 65 MORBIDITY & MORTALITY WKLY. REP. 799–802 (Aug. 12, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6531a2.pdf.

186. Endo's sale, promotion, marketing, advertising, distribution, and manufacturing of opioid products in the State of West Virginia involves trade or commerce within the meaning of the WVCCPA.

187. Endo sold, promoted, marketed, distributed, and advertised opioid products to the State of West Virginia and its consumers.

188. Endo's misrepresentations and omissions of material facts, as detailed above, constitute deceptive acts or practices that are prohibited by the WVCCPA.

189. Endo's unfair, deceptive, and unconscionable acts or practices, or the effects thereof, are continuing, will continue, and are likely to recur unless permanently restrained and enjoined.

190. Consequently, the Plaintiff seeks all available relief under the WVCCPA, including but not limited to disgorgement, restitution, civil penalties, equitable relief, injunctive relief, and attorneys' fees and costs.

191. As part of this action, the State expressly does not raise any conduct related to, nor seek any damages, attributable to the Medicare or Medicaid programs. As to manufacturers, the state reserves the right to file a separate action to claim damages attributable to the Medicare or Medicaid programs.

COUNT II
Common Law Public Nuisance

192. Plaintiff adopts, realleges, and incorporates by reference paragraphs 1 through 183 above as if fully set forth herein.

193. Through the actions described above, Endo has 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.

194. The expansion of the market for prescription opioids because of Endo's misrepresentations and omissions to health care providers, especially to general practitioners, nurse practitioners, and physician assistants, as well as targeting providers and pharmacies with actual or signs indicative of abuse or diversion, facilitated an overabundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death.

195. Opioid use, abuse, addiction, and overdose deaths have increased dramatically in West Virginia as a result of Endo's conduct. 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.

196. Endo's actions described above were a substantial factor in opioids becoming widely available, used, and abused.

197. But for Endo's actions, opioid use would not have become so widespread and the enormous public health hazards of opioid overuse, abuse, addiction, and death that now exists would have been averted. Endo's actions have and will continue to injure and harm the citizens and the State of West Virginia for many years to come.

198. 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.

199. Endo 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 Endo's position would foresee not only an expanded market but the other likely and foreseeable result of Endo's 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.

200. Endo was 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.

201. Endo's 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.

202. Endo 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.

203. 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. Endo's conduct interfered in the enjoyment of these public rights.

204. As part of this action, the State expressly does not raise any conduct related to, nor seek any damages, attributable to the Medicare or Medicaid programs. As to manufacturers, the state reserves the right to file a separate action to claim damages attributable to the Medicare or Medicaid programs.

Prayer for Relief

WHEREFORE, Plaintiff prays for the following relief:

a. Judgment against the Defendants in favor of the State;

b. 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;

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

d. 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);

e. Pre- and post-judgment interest;

f. Costs and reasonable attorneys' fees; and,

g. 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.*;

h. An order abating the public nuisance and ordering any injunctive relief that the Court finds appropriate under law; and

i. An order awarding such other and further relief as the Court deems appropriate.

STATE OF WEST VIRGINIA ex rel.
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Attorney General

By Counsel

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VERIFICATION

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

I, Michelle L. Bradley, Assistant Attorney General, being duly sworn, depose and say that I am the counsel of record for Plaintiff 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.

Michelle L Bradley
MICHELLE L. BRADLEY (WV State Bar # 10129)
ASSISTANT ATTORNEY GENERAL

Taken, subscribed, and sworn to before me in the County and State aforesaid this 19th day of November, 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

Peggy S Means
NOTARY PUBLIC