IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

STATE OF OREGON ex rel. ELLEN F. ROSENBLUM, Attorney General for the State of Oregon, Plaintiff, vs. ENDO HEALTH SOLUTIONS, INC., a Delaware corporation; and ENDO PHARMACEUTICALS, INC.; a Delaware corporation, Defendants.	No. _____ **COMPLAINT** **Unlawful Trade Practices Act; Oregon Racketeer Influenced and Corrupt Organizations Act; Elderly Persons and Persons with Disabilities Abuse Prevention Act; Negligence; Nuisance** **(Not Subject to Mandatory Arbitration – Prayer in excess of $51,000)** **Filing Fee not collectible pursuant to ORS 21.259.** **DEMAND FOR A JURY TRIAL** **Priority hearing and determination requested pursuant to ORS 166.725(5)**

Plaintiff for her complaint against defendants alleges as follows:

INTRODUCTION

1.

Oregon, along with the rest of the United States, remains in an opioid crisis. Deaths caused by opioid overdose are increasing every year—in 2010, there were 21,088 opioid-involved overdose deaths. In 2011, the United States comprised 4.6% of the world's

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population, but consumed 80% of the world's opioids.[1] By 2017, the opioid crisis had cost an estimated $1 trillion in the United States in lost wages, productivity, and tax revenue and additional health care, social services, and criminal justice spending.[2] By 2019, the number of opioid-involved overdose deaths had increased by over 200%—there were 49,860 deaths.[3] In 2020, the crisis became significantly worse. Nearly 70,000 Americans died from an opioid overdose.[4]

2.

Oregon has not been immune from the effects of the opioid crisis; if anything, Oregon is among the hardest hit states. Oregon has one of the highest rates of misuse of prescription opioids in the county.[5] In 2018, Oregon providers wrote 57.3 opioid prescriptions for every 100 persons, higher than the national average.[6] Last year, 2020, was particularly devasting. Preliminary data from the Oregon Health Authority shows that opioid-related deaths increased by 40% from 2019 to 2020. In May 2020, 63 people suffered opioid-related overdose deaths, compared to 15 people in May 2019.[7]

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[1] Donald Teater, The Phycological and Physical Side Effects of Pain Medications, Nat'l Safety Council (2014), https://www.nsc.org/getmedia/0113f259-d2c5-4a3e-abca-f05299f65ec2/adv-rx-side-effects-wp.pdf.

[2] Altarum Institute, *Economic Toll of Opioid Crisis in U.S. Exceeded $1 Trillion Since 2001* (Feb. 13, 2018), https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001.

[3] National Institute on Drug Abuse, *Overdose Death Rates* (Jan. 29, 2021), https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates.

[4] National Center for Health Statistics, *Provisional Drug Overdose Death Counts*, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

[5] Oregon Health Authority, *Reducing Opioid Overdose and Misuse*, https://www.oregon.gov/oha/ph/preventionwellness/substanceuse/opioids/pages/index.aspx.

[6] National Institute of Health, *Drug-Involved Overdose Deaths*, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/oregon-opioid-involved-deaths-related-harms.

[7] KGW8, *CDC: Record number of Americans suffered drug overdose deaths in 2020* (Jul. 14, 2021), https://www.kgw.com/article/news/local/cdc-record-number-of-americans-suffered-drug-overdose-deaths-in-2020/283-24d226e6-c2d8-4196-af07-c231789fd410#:~:text=PORTLAND%2C%20Ore.,compared%20to%20the%20year%20before.

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3.

The link between prescription opioids, opioid abuse, and opioid overdose is well documented. The most important risk factor for opioid overdose is not a feature of any individual patient; it is receiving a prescription for opioids.[8] Those with a prescription tend to take the medication over a longer period and in higher doses, which can also lead to addiction.[9]

4.

Historically, opioids were prescribed in limited circumstances because of long-standing and well-established risks of addiction and overdose. Opioid manufacturers, including defendants Endo Health Solutions and Endo Pharmaceuticals, Inc. ("Endo"), sought to reverse that historical practice through sustained campaigns of deceptive, misleading, and aggressive marketing practices.

5.

Purdue Pharma ("Purdue") created the playbook for those deceptive and aggressive marketing practices in the 1990s. When Purdue released OxyContin—a potent prescription opioid drug—in 1996, Purdue spent millions of dollars on aggressive marketing campaigns promoting its message that opioids were safe and effective treatments for chronic pain. That marketing campaign was based on deceptive practices, including misrepresentations about the risks of addiction associated with prescribing opioids for the treatment of chronic pain. Purdue falsely claimed that OxyContin posed a lower threat of abuse and addiction than other painkillers, and it falsely claimed that OxyContin increased function for patients with chronic pain.

[8] Deborah Dowell, Hillary V. Kunins, Thomas A. Farley, *Opioid Analgesics—Risky Drugs, Not Risky Patients*, JAMA, Mar. 9, 2013 at E1.

[9] Centers for Disease Control and Prevention, *Prescribing Practices* (Aug. 13, 2019), https://www.cdc.gov/drugoverdose/deaths/prescription/practices.html.

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6.

In 2007, The United States Department of Justice took Purdue to court to stop its false, deceptive, and misleading marketing. Three of Purdue's top executives pleaded guilty to federal criminal charges based on their actions which misled regulators, doctors, and patients about OxyContin's risk of addiction and potential for abuse. Purdue itself plead guilty to felony misbranding of a drug. The fines incurred by Purdue were, at the time, among the largest ever imposed against a pharmaceutical company.

7.

The same year, the Oregon Attorney General also took Purdue to court, obtaining a judgment against the company that strictly limited its deceptive practices and assessed substantial fines.

8.

In 2010, Purdue changed its OxyContin formula in a way that purportedly made it more resistant to certain forms of abuse.

9.

Although Purdue's actions leading up to 2010 were illegal and wrong, Endo saw the situation as a financial opportunity. Defendants knew that in the aftermath of Purdue and its executive's crimes, health care providers would be wary about prescribing Purdue's drug, OxyContin. Endo wanted its drug, Opana ER, to be the opioid to replace it.

10.

Thus, while Oregon and the rest of the country were dealing with the continued effects of Purdue's criminal activities, Endo profited doing the same things that Purdue had done. Knowing that it stood to gain from Purdue's loss, and knowing that the spotlight was on Purdue, Endo continued to employ deceptive and misleading marketing practices.

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11.

As set forth below, Endo engaged in a deceptive, misleading, and false marketing campaign lasting over a decade. Defendants misrepresented the risks and benefits of opioids to health care providers in the face of scientific evidence and repeated rulings by the FDA informing defendants that those claims were misleading and false.

12.

Specifically, Endo, among other things, promoted Opana ER as having lower potential for abuse despite knowing that such claims were false. Endo also targeted continued users of opioids while at the same time implementing a marketing campaign aimed at spreading the false message that most patients who take prescribed opioids for long periods of time do not become addicted. Endo used front groups, third-party advocacy groups, and individual practitioners to spread its false claims. Endo funded those groups and individuals but did not disclose its financial connection to them so that they would appear more credible.

13.

Endo's deceptive and misleading marketing practices often specifically targeted vulnerable and elderly populations. Endo misleadingly marketed its opioids to elderly patients without disclosing serious dangers.

14.

Endo employed its deceptive, misleading, and false marketing strategies in Oregon. Endo ignored evidence of opioid abuse occurring in Oregon and elsewhere and continued its deceptive marketing practices.

15.

Endo has also engaged in a concerted effort to cover-up its illegal conduct. In 2016, the Oregon Attorney General began investigating Endo's deceptive, misleading, and false marketing strategies and issued a comprehensive civil investigative demand. Endo failed to

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produce marketing records from before 2008, even though those records were responsive to the demand. Endo's attorneys falsely asserted that "data does not exist for the time period prior to 2008." Years later, it became clear that such data does exist. Endo's failure to produce relevant discovery is not limited to Oregon. Earlier this year a Tennessee court entered a default liability judgment against Endo for discovery misconduct. In its opinion accompanying the judgment, the court stated that there had been a "coordinated strategy between Endo and its counsel to … interfere with the administration of justice."

16.

Endo now faces inquiries into its litigation conduct across the nation. In New York, a court appointed a retired judge to investigate Endo and its counsel's failure to produce highly relevant documents before trial. The retired judge concluded that Endo's counsel had engaged in sanctionable conduct. An Illinois federal court appointed a special master to investigate Endo's compliance with discovery rules in a case brought by the City of Chicago. Inquires were also launched into Endo's litigation ethics in Arkansas, Texas, and California.

17.

All told, Endo's conduct in Oregon was negligent and a public nuisance and violates the Oregon Unlawful Trade Practices Act, the Elderly Persons and Persons with Disabilities Abuse Prevention Act, and the Oregon Racketeer Influenced and Corrupt Organizations Act. Accordingly, plaintiff Ellen Rosenblum, the Attorney General for the State of Oregon, brings this lawsuit to hold Endo accountable for its violations of the state law and to enjoin Endo's continued false, deceptive, and misleading conduct.

PARTIES, JURISDICTION, AND VENUE

18.

Plaintiff Ellen Rosenblum is the Attorney General of Oregon. She is authorized to bring this action pursuant to ORS 124.125, ORS 166.725(5), ORS 180.060(1)(d), and ORS

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646.632(1). She brings the claims stated herein on her own behalf, on behalf of the affected State agencies, and for the benefit of the people of Oregon.

19.

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

20.

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.

21.

Subject matter jurisdiction is conferred on this Court by ORS 14.030.

22.

Venue in Multnomah County is proper pursuant to ORS 14.080(1) because the cause of action arose in Multnomah County.

23.

This Court has personal jurisdiction over Endo based on its contacts with Oregon. Endo has promoted, marketed, advertised, and sold its opioid products in Oregon. Endo has also engaged in business transactions in Oregon, including transactions through its sales representatives who made sales calls to health care providers in Oregon. Additionally, Endo has mailed, delivered, or otherwise made marketing materials for its opioid products available to health care providers and consumers in Oregon.

24.

The State also brings this action in its *parens patriae* capacity and thereby acts on behalf of all Oregonians affected by Endo's false, misleading, and reckless marketing, promotion, and distribution of opioids in Oregon. The State has a quasi-sovereign interest in the well-being, health, and safety of all Oregonians who have been injured and continue to be

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threatened by Endo's conduct. Such injuries include harm to Oregonians' health, harm to Oregon businesses, harm to public safety, and harm to Oregon's health care systems.

25.

Prior to the filing of this complaint, the Attorney General notified Endo of its unlawful trade practices, as required by ORS 646.632(2). The Attorney General provided that notice on October 4, 2021. Endo failed to deliver an Assurance of Voluntary Compliance in response.

SUMMARY OF THE ACTION

I. Endo manufactures, markets, sells, and distributes prescription opioids.

26.

Endo has manufactured, marketed, sold, and distributed the following opioid drugs in Oregon:

Drug	Chemical Name
Opana ER	oxymorphone hydrochloride, extended release
Opana	oxymorphone hydrochloride
Percodan	oxymorphone hydrochloride and aspirin
Percocet	oxymorphone hydrochloride and acetaminophen
Generic	oxycodone
Generic	oxymorphone
Generic	hydromorphone
Generic	hydrocodone

27.

Opana ER contained an active ingredient that was twice as potent as OxyContin's active ingredient.

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28.

In addition to the opioids listed above, in 2011, Endo released a reformulated version of Opana ER. Reformulated Opana ER is bio-equivalent to the original formulation.

29.

In addition to manufacturing and selling opioids, Endo manufactured and sold its name-brand drug, Narcan (chemical name: naloxone hydrochlorine) until July 2013. Narcan is used to temporarily reverse the effects of an opioid overdose.

II. Endo engaged in an aggressive, deceptive, and misleading marketing practices in order to sell its opioids.

A. Endo marketed Opana ER using deceptive and misleading claims about its safety and effectiveness.

30.

Endo marketed Opana ER as an alternative to other opioids that creates "less euphoria." Endo claimed that Opana ER created less euphoria because it led providers to believe that Opana ER was less susceptible to abuse and less addictive.

31.

Endo's claims that Opana ER created "less euphoria" than other opioids was deceptive and misleading. Opana ER does not create less euphoria than other opioids; it is just as susceptible to abuse as other opioids and just as addictive.

32.

Endo marketed Opana ER as an alternative to other opioids by claiming that it had fewer strong side effects.

33.

Endo sales representatives informed health care providers that Opana ER provided "24-hour pain relief so patients can function normally," that Opana ER "[r]eturns patients more rapidly and more fully to their usual activities of daily life," that a "12 hour drug[] improves sleep for the patient," and that "improvement in physical and social functioning as

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well as sleep and true 12-hour pain control to keep patients active and return to their work and daily activities."

34.

Endo's claim that Opana ER had fewer strong side effects than other opioids was deceptive and misleading. Opana ER does not have fewer strong side effects than other opioids.

35.

Endo's claims suggesting that Opana ER allows patients to function normally in their day-to-day activities is also deceptive and misleading. The side effects of Opana ER, like any opioid, make it difficult to carry out daily activities normally.

36.

Endo's business depended on continued users of opioids. Continued users represented 88% of Endo's total business from Opana ER.

37.

Endo needed to convince health care providers that prescribing opioids for longer periods of time was safe. On its website, www.opana.com, Endo stated that "[m]ost doctors 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."

38.

Despite claiming in its marketing materials that "most doctors who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," Endo never conducted any study or survey to determine whether that was true.

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39.

Endo's claims about taking opioids for a prolonged period were deceptive and misleading. Endo knew that the longer a person takes opioids, the higher the risk is for addiction. Thus, continued users of opioids face the highest risk of becoming addicted. Endo was aware that continued users of opioids were most likely to become addicted and overdose. But Endo relied on continued users for its business, so it downplayed those risks in its marketing strategy.

40.

To address health care providers' concerns about addiction, Endo developed a marketing strategy around the false concept of "pseudoaddiction."

41.

Endo used aggressive marketing techniques to convince practitioners that "pseudoaddiction" is a "pattern of drug seeking behavior among pain patients with unrelieved pain," and that the difference between real addiction and "pseudoaddiction" is that "in pseudoaddiction, the patient's drug-seeking behavior stops once his or her pain has been effectively treated."

42.

Endo's claims about pseudoaddiction were deceptive and misleading. Endo knew that its claims about pseudoaddiction were false at the times it made them. Endo's own doctors publicly disavowed the concept of pseudoaddiction in February 2012. Endo trained its sales representatives to pitch claims about pseudoaddiction from 2006 to 2013.

43.

Endo continued making claims about pseudoaddiction because its business from Opana ER relied on continued users of opioids, who often became addicted.

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44.

Endo's strategy to downplay and minimize the risks of addiction worked. In 2008, Endo confirmed that health care providers perceived "safety/tolerability/fewer side effects" as an advantage of Opana ER, including that it had a purported low abuse potential, lower incidence of side effects, and lower drug interactions. Endos sales and revenue increased, including in Oregon.

45.

Endo used aggressive marketing techniques to disseminate the deceptive and misleading claims outlined above. Endo used front organizations and individuals to disseminate deceptive information about the safety and effectiveness of opioids, it used sales calls to reach out to health care providers directly, and it specifically targeted health care providers who had less experience in pain management or who prescribed large numbers of opioids in high doses.

B. Endo used front organizations and individuals to disseminate deceptive and misleading information about the safety and effectiveness of opioids.

46.

For years, Endo contributed significant amounts of money to both the American Academy of Pain Medicine and the American Pain Society. Endo representatives also attended meetings with the American Academy of Pain Medicine, which those representatives considered to be "promotional activity."

47.

In 2009, the American Academy of Pain Medicine and the American Pain Society jointly published guidelines for opioid treatment. Endo then trained its sales representatives to discuss those guidelines in sales calls with providers. Endo used the guidelines as part of Endo's marketing campaign for Opana ER without disclosing Endo's financial connections to the groups.

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48.

The American Academy of Pain Medicine and the American Pain Society guidelines failed to address the risks of long-term dependence on opioids, addiction, and cessation of opioid therapy.

49.

When Endo did not disclose information about its financial connection to both the American Academy of Pain Medicine and the American Pain Society, it made those groups' recommendations and guidelines look more credible.

50.

In addition to the contributions Endo made to the American Academy of Pain Medicine and the American Pain Society, Endo also contributed over $1,000,000 to the American Pain Foundation. Endo was the American Pain Foundation's biggest donor.

51.

The American Pain Foundation issued guidelines that downplayed the risks associated with opioids. Its guidelines also embellished and exaggerated the benefits of taking opioids. Endo then used those guidelines in its marketing efforts.

52.

With the American Pain Foundation, Endo funded the development of a website called painknowledge.org to advance claims of pseudoaddiction. The website stated that it was part of the National Initiative on Pain Control ("NIPC"), and the website claimed that "[s]ometimes people behave as if they are addicted, when they are really in need of more medication. This can be treated with higher doses of medicine." Endo was NIPC's only financial contributor. Between 2003 and 2012, Endo provided NIPC $31 million.

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53.

In May 2012, the American Pain Foundation disbanded after the United States Senate Finance Committee sent it a letter in connection with the committee's investigation into the connections between opioid manufacturers and pain advocacy groups.

54.

Painknowledge.org also published a guide for patients called "Pain: Opioid Therapy." The guide listed the "common side effects" of opioids, but it did not include addiction.

55.

The guide "Pain: Opioid Therapy" contained misleading and deceptive information about the risks and benefits of taking opioids.

56.

The American Pain Foundation's National Initiative on Pain Control hosted a series of CME's (Continuing Medical Education classes) titled "Persistent Pain in the Older Patient," which deceptively and misleadingly claimed that continued use of opioids had been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

57.

Endo also contributed financially to the American Geriatric Society, which is a trade organization made up of health care providers who serve the elderly.

58.

Endo followed the same pattern with The American Geriatric Society: The society issued guidelines for opioid treatment, Endo used those guidelines in its marketing efforts, and in doing so, Endo did not disclose its financial connection to the group.

59.

The American Geriatric Society's guidelines contained misleading and deceptive information about the risks and benefits of taking opioids.

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60.

When front groups with financial ties to Endo spread deceptive and misleading information without disclosing the groups' connections to Endo, the information appeared more credible. By using third parties to spread deceptive and misleading messages about opioids, the claims Endo's sales associates made on sales calls also looked more credible, even when they also were deceptive and misleading.

C. Endo engaged in an aggressive sales call strategy, and during sales calls, Endo's sales representatives spread deceptive and misleading information about the safety and effectiveness of its prescription opioids.

61.

According to Endo's own internal documents, Endo made more sales calls in 2007 than other major competitors in the opioid market. Endo made thousands of sales calls to hundreds of health care professionals in Oregon. Between 2008 and 2016, Endo made more than 40,000 sales calls to Oregon health care professionals. Endo's marketing in Oregon was particularly successful. From 2007-2011, Endo's relative sales of opioids in Oregon were higher than Oregon's relative share of the national population.

62.

Endo also focused it sales efforts on targeting physician assistants and nurse practitioners. Endo was aware that physician assistants and nurse practitioners typically have less pain management experience, but it focused on those providers because they were "key driver[s] of [sales] performance."

63.

For example, Endo targeted Briana Aspy, a nurse practitioner who worked in the Portland area from 2008 to 2011. Ms. Aspy's patients redeemed Endo's patient savings program, which offered patients $25 off per prescription for a year, at significant rates.

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64.

Endo's data showed that physician assistants and nurse practitioners were "3x times more responsive than MDs to details" and "96% of prescriptions are written without physician consult (60% are for therapy initiation)."

65.

Endo's sales callers targeted the highest prescribers of opioids, noting that it was key to "[u]nderstand[] who is generating significant profit, and profit growth, for OPANA ER." To effectuate that plan, Endo gave health care providers letter grades corresponding with how often they prescribed Opana ER so that its sales callers could easily target high subscribers.

66.

Endo's sales efforts also included focusing its marketing on convincing providers to prescribe higher doses of Opana ER, because higher doses generated more money for Endo than low strength doses.

67.

Endo's high-strength doses of Opana ER were 20, 30, and 40 mg tablets. A 20 mg tablet of Opana ER, taken as Endo directed every 12 hours, is about 120 MME's per day. An "MME" is a standardized unit of opioid potency; it stands for Morphine Milligram Equivalent.

68.

The CDC recommends 90 MME daily as a maximum. The CDC states that prescribers should avoid it or carefully justify exceeding that limit. Opana's 20 mg tablet exceeded that dosage by 30 MMEs, and its 40 mg tablet exceeded that dosage by 150 MMEs.

69.

Higher doses of opioids increase a patient's risk of overdose and death. Higher dosages have also not been shown to reduce pain in the long term. In fact, even a dose as

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low as 20-50 MME's per day can increase risk of overdose and death. According to the CDC, at least one study "found no difference in pain or function between a more liberal opioid dose escalation strategy (with an average dosage of 52 MME) and maintenance of current dosage (average final dosage 40 MME)."

70.

Endo knew or should have known that increased doses increase a patient's risk of overdose and death, but it maintained its marketing strategy aimed at convincing health care providers to prescribe higher doses anyway.

D. Endo's marketing strategy also targeted consumers directly.

71.

Endo's marketing consultants advised Endo to position Opana ER as a safer alternative to OxyContin that "enables a better lifestyle to keep patients healthier" with "fewer strong side effects," "less euphoria," less abuse, and without OxyContin's "baggage," as documented in excerpts of an Endo presentation titled "Better the Devil you Know . . . Inspiring Physicians to Do the Right Thing with Opana ER."

72.

The presentation advised that Endo's sales representatives should tell physicians that "Opana ER is different. It's designed so you can do the right for your patients in pain." It also advised sales representatives to state that "Opana is responsible."

73.

The presentation also advised Endo to implement a program called "Titration Phase is On US" in which Endo paid for a patient's first trial phase of Opana ER. The pack included four levels of doses so that the patient could figure out the right dosage "without office visits or multiple trips to the pharmacy."

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74.

Endo used speaker programs to promote positive messaging about Endo and its opioid products. Those speaker programs typically featured doctors who advanced claims about the safety and efficacy of Opana ER.

75.

Endo's messaging with patients included deceptive and misleading claims about the safety and effectiveness of Opana ER. Endo marketed opioids to patients for conditions such as chronic lower back pain and osteoarthritis, even though the risks of taking opioids for conditions such as chronic lower back pain and osteoarthritis far outweigh any benefits.

76.

Opioids are not safe for chronic lower back pain and osteoarthritis. The American Board of Internal Medicine recommends opioids only for severe pain that lasts a short time and does not recommend the use of opioids for lower back pain. Additionally, according to the American Association of Hip and Knee Surgeons, the use of opioids for osteoarthritis should be avoided except in exceptional circumstances.

77.

Endo pursued seniors for its opioids, as well. Endo established a "[s]trategic imperative" to "[i]ncrease the profitability through most valuable customer segments" which included "patient share in . . . [osteoarthritis]."

78.

Endo also marketed opioids as safe to take continuously. It provided patients with coupons through its Opana ER savings card, which permitted savings of $300 per year, up to $25 per prescription. To reap the benefit of that program, patients needed to take opioids continuously for a year, which substantially increases the risk of addiction.

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III. Endo knowingly promoted its opioids to dangerous prescribers.

79.

After Purdue's executives pled guilty to felonies, Endo's marketing department noted that differentiating Opana ER from OxyContin was critical to its sale success.

80.

In 2010, Purdue pulled its old formulation of OxyContin from the market and replaced it with a reformulated version. The reformulated version, according to Purdue, was less prone to some forms abuse. Endo knew it could capitalize on that—it knew prescribers were looking for a replacement opioid after the 2010 reformulation of OxyContin.

81.

Endo knew that the same pill mills who had sold the old formulation of OxyContin were looking for a replacement. Endo specifically targeted those pill mills. Endo did so even though Endo knew that opioids prescribed by pill mills were being abused in large numbers.

82.

Immediately after the reformulated version of OxyContin was released, sales of Opana ER significantly increased. The increase was driven by "customer" dissatisfaction with the new OxyContin formula—just as Endo's sales team expected.

83.

Endo trained its sales representatives to portray Opana ER as easier to manage than OxyContin and to require fewer rescue medications.

84.

Endo sales representatives claimed in sales calls that Opana ER had fewer side effects than OxyContin, including less nausea.

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85.

Endo sales representatives claimed in sales calls that Opana ER provided "less risk of abuse" than OxyContin.

86.

Endo was aware that Opana ER was being abused. Endo noted later in an internal document that "[t]he introduction of an abuse-deterrent formulation of OxyContin in August 2010 coincided with a documented increase in reported abuse rates of Opana ER."

87.

By the end of 2010, Endo's own analysis showed that its success was due in part to the introduction of a taper resistant formulation of OxyContin. Endo knew that "abuse behavior" was driving decline in OxyContin use.

88.

Endo was undeterred by evidence of abuse—by the end of 2010, revenue from Opana ER soared.

IV. When the FDA was set to approve generic versions of Opana ER in 2010, Endo stepped up its misleading and deceptive marketing strategies.

89.

In December of 2010, the FDA approved to two generic versions of Opana ER. The companies that obtained FDA approval were Impax and Actavis. Actavis began marketing its generic version of Opana ER on July 15, 2011.

90.

As set forth below, to ward off competition from generic versions of Opana ER, Endo used three strategies: First, Endo submitted an application for FDA approval for a reformulated version of Opana ER. Second, Endo submitted a citizen's petition to the FDA claiming that it had pulled the original version of Opana ER from the market because of health and safety concerns. Third, Endo deceptively and misleadingly employed a marketing

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campaign promoting reformulated Opana ER as being safer and more abuse-deterrent, than the original Opana ER.

91.

If its strategies were successful, Endo could then remove the original formulation from the market for safety concerns. Because a generic drug's FDA approval is tied to the name-brand drug's FDA approval, if the original name brand drug loses FDA approval due to safety concerns, the generic version will also lose its FDA approval. And, if Endo convinced the FDA that its new drug was different from its original version, Endo's patent exclusivity for that new version would continue, even though patent exclusivity for the original version was set to expire. Thus, if Endo created a safer version of Opana ER and then convinced the FDA that its original formula was not safe, Endo would be able to continue selling its new version of Opana ER without generic competition.

92.

As explained below, Endo was not successful in convincing the FDA that its reformulated version of Opana ER was different from its original version. Thus, Endo resorted to making false claims about the reformulated version of Opana ER, because it could not otherwise distinguish it from generic versions.

A. Endo submitted an application for FDA approval for a reformulated version of Opana ER.

93.

To maintain its revenue in the face of the new generic competitors, in July of 2010, Endo submitted an application for FDA approval of a reformulated version of Opana ER.

94.

In its application, Endo sought to establish that the active ingredients in the reformulated Opana ER were safe and effective by relying on the "bioequivalence" of the reformulated version and the original version. The only issue for FDA approval, therefore,

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was whether Endo's claims that the reformulated version contained better abuse-deterrent properties.

95.

On January 7, 2011, an FDA panel concluded that the reformulated Opana ER had only "minimal improvement in resistance to tampering by crushing." The panel also concluded that the reformulated version could still be tampered with, "rendering it readily abusable by ingestion and intravenous injection, and possibly still by insufflation [(snorting)]." The panel found that, "[o]f more concern, when chewed [redacted] the new formulation essentially dose dumps like an immediate release formulation."

96.

The FDA panel noted that:

> "While the label and MedGuide would certainly carry warnings against chewing, some concern exists that any language in the label noting the reduced crushability of this formulation could be misleading and result in health care practitioners or patients thinking that it is safer than the old formulation, and that it is safe to chew the product; or that it is safe to give the new product to a cognitively impaired patient who may chew the product if not adequately supervised."

97.

The FDA panel noted that one study showed that "it might be easier to prepare a solution for injection when using [the reformulated Opana ER] than when using [the original] Opana ER."

98.

The Controlled Substances Staff team recommended that the label "not include language that [redacted] provides resistance to crushing." The team disagreed with Endo's claims that the reformulated version of Opana ER was resistant to crushing because "the extended-release characteristics of the formulation are comprised by cutting, chewing or grinding."

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99.

Endo contemplated funding its own study about the differences between Opana ER and the reformulated version. However, the idea was met with "strong resistance." Endo's Director of Project Management explained in an email that Endo "fear[ed] that there will be little differentiation between [reformulated Opana ER] and Opana ER in an intranasal abuse study." The email explained that "FDA deemed that there was no difference," so "[i]f the intranasal abuse liability study fails, then we would have yet a third study which shows no real incremental difference between old and new."

100.

On December 9, 2011, the FDA approved the reformulated version of Opana ER, with the caveat that it "did not meet the agency's standards for being considered abuse-deterrent."

101.

The FDA did not approve Endo's request to include a description of abuse-deterrent properties in its product label, package insert, Medication Guide, or promotional materials.

B. Endo filed a citizen petition to the FDA stating that it had removed the original version of Opana ER from the market due to safety concerns.

102.

After the reformulated version of Opana ER was approved, Endo sought to have the FDA revoke FDA approval of the original formulation so that generic versions of the original version would also lose FDA approval.

103.

On August 13, 2012, Endo filed a citizen petition to the FDA stating that it had removed the old version of Opana ER from the market due to safety concerns. It requested that the FDA suspend and withdraw the approval of any generic Opana ER.

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104.

In its petition, Endo stated that its data "suggests that, among intentional abusers of opioids, the difficulty in abusing the new formulation of OxyContin has driven abusers to formulations that lack similar abuse-deterrent technologies. The increase in Opana ER abuse rates are attributed to the ease of defeating the extended release properties of Opana ER."

105.

Despite its purported safety concerns, Endo never recalled any product that was already in the distribution channel as of May 31, 2012.

106.

On May 10, 2013, the FDA denied Endo's citizen petition. As part of its denial, the FDA found that Endo had not withdrawn the original Opana ER formulation for safety reasons. It also reiterated its findings that the reformulated version of Opana ER was not safer than the original version. In fact, the FDA stated that there was a "troubling possibility that a higher (and rising) percentage of [reformulated Opana ER] abuse is occurring via injection that was the case with [the original version]."

107.

On the same day that the FDA issued its denial of Endo's citizen petition, the FDA told Endo that all Endo had done was replace the original version, which was susceptible to crushing, with a new version, which was more susceptible to intravenous abuse. The FDA also explained that that was more dangerous, as "intravenous abuse is associated with a greater risk of infection, including hepatitis, HIV and bacterial pathogens, along with a greater risk for overdose and death."

C. Because Endo failed to convince the FDA to revoke FDA approval of the original formulation, Endo resorted to making false, deceptive, and misleading marketing claims about the reformulated version of Opana ER.

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108.

At the same time Endo was seeking FDA approval of its citizen petition, internally, Endo began to cover up any data showing that the reformulated Opana ER raised the same risks for consumers. During the time when Endo was marketing and selling both the original and reformulated versions of Opana ER, Endo coded all adverse event reports that it received that did not specify a formulation as being associated with the original version.

109.

In July 2013, Endo's "Government Affairs Strategic Plan" was to "[p]rovide data and supporting information to Agency officials to identify increased rates of abuse for generic oxymorphone."

110.

Endo also marketed the reformulated Opana ER as being safer than the original version despite the FDA's repeated findings that it was not. Because Endo was facing competition from generic opioids, Endo's strategy for marketing reformulated Opana ER was to market the reformulated Opana ER as being safer than other products.

111.

After the FDA denied Endo's request to include abuse deterrence language in the reformulated Opana ER's label, package insert, and Medication Guide, Endo rebranded Opana ER as "Opana ER with INTAC technology."

112.

As part of that rebranding, Endo included statements that Opana ER was "designed to be crush resistant."

113.

From around February of 2012, Endo used the phrase "Opana ER with INTAC technology" whenever it mentioned Opana ER by brand name.

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114.

On April 30, 2012, the FDA informed Endo that its claims about "INTAC technology" "misleadingly minimize the risks associated with Opana ER by suggesting that INTAC technology confers some form of abuse deterrence properties when this has not been demonstrated by substantial evidence."

115.

Endo continued making those claims anyway. Internal financial analysis showed that, financially, it was more beneficial to make the claims. On May 15, 2012, William Best, Endo's Director of Promotional Regulatory Affairs sent an email to Bob Barto, Endo's Vice President of Regulatory Affairs stating that he was "OK" with going forward with "INTAC technology" messaging. Mr. Best acknowledged that the FDA had not approved those claims, but stated that "[i]f [the FDA] do[es] send a letter it is likely to be a warning letter."

116.

On May 17, 2012, Endo rolled out its marketing campaign based on the abuse deterrence messaging, including messaging about INTAC technology, nationwide.

117.

In June 2012, Endo stated in its "Opana ER Action Plan" that included an "INTAC Sell Sheet." It planned to quickly distribute the INTAC Sell Sheet to its sales representatives because it was a "key resource."

118.

Endo trained its sales associates to claim that the reformulated Opana ER was "designed to be crush resistant" and that "the INTAC Technology is included in the new formulation for that purpose."

119.

In July 2012, USA Today published a story titled "Opana Abuse in USA Overtakes OxyContin." The day the story came out, Endo's marketing department told its sales

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associates nationwide to respond to the story by stating that "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."

120.

Endo also instructed its promotional speakers to make similar claims. Specifically, Endo instructed its speakers to state that "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."

121.

Additionally, in July 2012, Endo expressed regret for not using the "INTAC technology" messaging earlier. Endo's internal quarterly review cited the "[l]ack of specific INTAC technology messaging at product availability" slowed performance. According to the review, demand creation began in late May, not mid-April.

122.

In December 2012, Endo sent a "Dear Doctor" letter to health care providers nationwide, including in Oregon, that contained at least five abuse-deterrent claims or references to INTAC Technology.

123.

In January 2013, Endo instructed all Endo representatives in "customer facing roles," including Endo's sales team, that when asked what the differences were between reformulated Opana ER and generic versions, sales associates should say that "Opana ER with INTAC is the only oxymorphone designed to be crush-resistant" and that "[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe Opana ER with INTAC."

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124.

In May 2013, after the FDA denied its citizen petition, Endo temporarily stopped using "Opana ER with INTAC." But that did not last long.

125.

In September 2015, Endo began using "Opana ER with INTAC" messaging. Endo sales representatives began distributing a "sell sheet" to health care providers nationwide, including in Oregon, and the sell sheet used the term "Opana with INTAC" seven times. Although the sheet contained a disclaimer that "the clinical significance of INTAC technology or its impact on abuse/misuse has not been established," the sheet also conveyed that the Opana ER tablet stayed intact was abuse-deterrent. The overall impression of the sheet was misleading.

126.

Endo continued to use claims about "INTAC technology" and its abuse-deterrent properties in marketing in 2017.

127.

Endo's claims about INTAC technology and its abuse-deterrent properties were deceptive and misleading. Such claims led health care providers and patients to believe that the reformulated version of Opana ER was crush resistant, or had abuse-deterrent properties, when it did not.

V. Endo knew that reformulated Opana ER was being abused.

128.

On June 8, 2017, the FDA took a nearly unprecedented step: It requested that Endo remove reformulated Opana ER from the market. The FDA did so "due to public health consequences of abuse." The FDA based its decision "on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation."

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129.

Before the FDA asked Endo to remove reformulated Opana ER from the market, Opana knew it was being abused. Continued users of reformulated Opana ER were the source of the majority of Endo's revenue from the drug.

130.

As compared to the original version of Opana ER, Endo generated even more business from high doses of reformulated Opana ER. The increased use of high doses should have been a red flag for Endo that its sales were coming from abuse.

131.

Endo ignored red flags and continued deceptively and misleadingly marketing reformulated Opana ER.

132.

Some health care providers who were frequently targeted by Endo sales representatives ultimately were disciplined by the Oregon medical board for conduct relating to their prescribing of controlled substances and opioids.

133.

Endo targeted Dr. Roy Blackburn with its marketing efforts. Dr. Blackburn specialized in Physical Medicine and Rehabilitation (PM&R), and Dr. Blackburn and his clinic—Oregon TLC Pain management—have been repeatedly investigated and disciplined by the Oregon medical board for unsafe prescribing of opioids, among other things. In April 2011, one of his patients, a young woman, died of an opioid overdose.

134.

Endo also targeted Dr. James Gallant with its marketing efforts. Dr. Gallant specialized in internal medicine and has been repeatedly investigated and disciplined by the Oregon medical board for unsafe prescribing of opioids. The Oregon Medical Board reprimanded Dr. Gallant in 1997 and again in 2001. Yet, between 2008 and 2013, Endo paid

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at least 188 sales calls on Dr. Gallant. Endo also involved Dr. Gallant in its speakers program and entered an advisory board agreement with him. Dr. Gallant's prescribing of opioids was so reckless and dangerous that the Oregon Medical Board entered a stipulated order with him for unprofessional and dishonorable conduct, retiring his medical license.

135.

Endo targeted Dr. Stuart Rosenblum. Dr. Rosenblum is a pain medicine doctor who has ties to many pharmaceutical companies who manufacture and sell opioids and frequently would speak at pharmaceutical company's marketing events about the safety and effectiveness of opioids.

136.

Although it did not happen often, if a sales representative did report a health care provider for abuse, Endo usually did nothing about it.

137.

Nonetheless, in February 2016, Endo International's CEO and President, Rajiv Silva, announced that the company would again seek FDA approval for abuse-deterrent labeling for reformulated Opana ER.

VI. Endo made false representations to the State of Oregon to obtain Pharmacy Board Registrations.

138.

The Oregon State Board of Pharmacy (the "Pharmacy Board") regulates the sale of drugs in Oregon. Under Oregon law, all manufacturers and wholesalers of drugs must register annually with the Pharmacy Board. To register, a manufacturer or wholesaler must complete a form provided by the Pharmacy Board. Application forms that do not contain all the required information are incomplete. A manufacturer or wholesaler may not operate in Oregon unless it is registered with the Pharmacy Board. Moreover, the Pharmacy Board may revoke or refuse to issue a registration to a manufacturer or wholesaler that has violated state or federal law or made intentional misrepresentations on an application for issuance or

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renewal of a registration. The Pharmacy Board gave direct and indirect benefits to Endo because by being registered with the Pharmacy Board Endo was able to sell its opioids in Oregon.

139.

Endo qualifies as a manufacturer according to the Pharmacy Board's rules and governing statute and, accordingly, Endo must register as such and renew its registration each year to operate in Oregon.

140.

Since at least 2017, Endo has submitted applications to renew its registration with the Pharmacy Board to operate as a drug manufacturer or wholesaler in Oregon. Endo has repeatedly submitted applications to the Pharmacy Board containing materially false representations about the existence of state and federal drug law investigations into Endo.

141.

Endo has been under investigation by the Oregon Attorney General for its marketing and promotion of opioids since 2016. The Oregon Attorney General has also led a multistate investigation since 2017. Endo has been fully aware of these investigations. Multiple states counties, and cities throughout the United States have also sued Endo for its marketing and promotion of opioids. The City of Chicago sued Endo in 2014. The City of Seattle sued in 2017. The State of Ohio filed a lawsuit against Endo in 2017. Dozens of other states followed. Endo has paid tens of millions to settle these suits, including $50 million in New York, $35 million in Tennessee, and nearly $9 million in Oklahoma, all in this year alone.

142.

In a 2017 manufacturer renewal application, which Endo signed on August 23, 2017, Endo falsely answered "No" to the question, "Since the date of your last renewal, has disciplinary action been taken, or is any such action currently pending against any of the persons or establishments listed on this application, by any State or Federal Authority in

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connection with a violation of any federal or state drug law or regulation?" Endo's response was false because Endo knew as of at least 2016 it was under investigation by the Oregon Attorney General and other states for its marketing and promotion of opioids.

143.

In a 2019 manufacturer renewal application, which Endo submitted online, Endo falsely answered "No" to the question, "Since the date of your last renewal, has disciplinary action been taken, or is any such action currently pending or proposed, against any of the persons or establishments listed on this application, by any State or Federal Authority in connection with a violation of any federal or state drug law or regulation"? Endo's response was false because Endo knew as of at least 2016 it was under investigation by the Oregon Attorney General and other states for its marketing and promotion of opioids.

144.

In a 2020 manufacturer renewal application, which Endo submitted online, Endo falsely answered "No" to the question, "Since the date of your last renewal has any investigation been initiated, or has any pharmacy or drug related disciplinary action been taken, or is any such action currently pending against any of the persons or facilities listed on this renewal application by any State (other than Oregon) or Federal Authority?" Endo's response was false because Endo knew as of at least 2016 it was under investigation by the Oregon Attorney General and other states for its marketing and promotion of opioids.

145.

In a 2021 manufacturer renewal application, which Endo submitted online, Endo falsely answered "No" to the question, "Since the date of your last renewal has any investigation been initiated, or has any pharmacy or drug related disciplinary action been taken, or is any such action currently pending against any of the persons or facilities listed on this renewal application by any State (other than Oregon) or Federal Authority?" Endo's

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response was false because Endo knew as of at least 2016 it was under investigation by the Oregon Attorney General and other states for its marketing and promotion of opioids.

VII. Endo's deceptive, misleading, and false marketing of its opioids harmed thousands or Oregonians and caused more than a billion dollars in past and future costs to the State.

146.

Endo's actions have contributed to and worsened the opioid epidemic.

147.

The opioid epidemic has cost the State of Oregon billions of dollars, including millions of dollars spent on health care costs of treating patients with opioid use disorder, rehab costs, and treatment of infants born with neonatal abstinence syndrome. The opioid epidemic has cost Oregon $31 million in healthcare costs from 2007 to 2019, and is projected to cost another $61 million in health care costs from 2020 to 2040.

148.

The opioid epidemic has cost Oregon millions of dollars in spending through its criminal justice system. From 2007 to 2019, Oregon has spent $159 million on policing due to the opioid epidemic, $340 million on judicial and legal expenditures, and $376 million on corrections expenditures. Those numbers are projected to increase: From 2020 to 2040, Oregon is projected to spend $197 million on policing, $626 million on judicial and legal expenditures, and $742 million on corrections.

149.

Because of the opioid epidemic, Oregon has spent millions of dollars on its child welfare system. From 2007 to 2019, Oregon spent $224 million on child protective services, $496 million on its foster care system, and $389 on educational expenses. From 2020 to 2040, Oregon is projected to spend $426 million on child protective services, $961 million on its foster care system, and $655 million on educational expenses.

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150.

In addition to the expenditures listed above, the opioid epidemic has diminished Oregon's labor force, which costs Oregon lost income from income taxes. The estimated tax revenue lost from labor force exits due to opioid abuse from 2007 to 2019 is $1.7 billion, and is projected to cost the state another $1.7 billion in 2020 to 2040. People have also left the labor force because they die from an opioid overdose, and that has cost the state $188 million from 2007 to 2019 and will cost $298 million from 2020 to 2040. When Oregonians leave the labor force due to incarceration, it costs: From 2007 to 2019, lost tax revenue from reduced labor force because of incarcerations cost the state $109 million and will cost the state another $135 million from 2020 to 2040.

151.

All in all, from 2007 to 2040, the opioid epidemic will cost the State of Oregon around $13 billion dollars.

152.

Meanwhile, Endo has profited from both sides of the opioid epidemic. As noted, in addition to manufacturing and selling opioids, Endo manufactured and sold its name-brand drug, Narcan (naloxone hydrochlorine) until July 2013.

153.

According to the United States Attorney General, "[e]xpanding the awareness and availability of [naloxone hydrochlorine] is a key part of the public health response to the opioid epidemic." That is because Narcan can temporarily reverse the effects of an opioid overdose.

154.

Endo was not making enough money from Narcan, so it discontinued manufacturing the drug in July 2013. Endo's decision to discontinue manufacturing Narcan contributed to a

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naloxone shortage in the United States during 2013, which reduced the ability to adequately respond to opioid overdose incidents.

155.

In July 2015, Endo licensed the brand name "Narcan" to another pharmaceutical company—Adapt Pharma—so that it could sell its naloxone hydrochlorine nasal spray under a widely-known and established brand name.

VIII. The Attorney General's claims are timely.

156.

Endo and the Attorney General entered a tolling agreement effective March 14, 2016. That agreement tolls the statute of limitations and all other time-related defenses, effective March 14, 2016, for "any civil cause of action under ORS § 646.605 to § 606.656, including any related common law claims, ORS § 180.750 to § 180.785, ORS § 166.715 to § 166.735, and ORS 165.692 against [Endo] arising out of or relating to" Endo's "promotion and marketing" of Opana ER and its related formulations. The Attorney General terminated the tolling agreement on October 28, 2021.

157.

The Attorney General's claims under the Unlawful Trade Practices Act, Elderly Persons and Persons with Disabilities Abuse Prevention Act, and the Oregon Racketeer Influenced and Corrupt Organizations Act are timely. The Unlawful Trade Practices Act does not contain a statute of limitations for actions brought by the Attorney General.

158.

The Attorney General may initiate an Oregon Racketeer Influenced and Corrupt Organizations Act action at any time within five years of the last act that violated the statute. ORS 166.725(11). The Attorney General's claim against Endo is timely because Endo's pattern of racketeering activity is ongoing and continues at least through 2021, when Endo

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submitted a false application to the Oregon Board of Pharmacy. Furthermore, all racketeering claims were tolled from March 14, 2016.

159.

Endo concealed its dangerous and deceptive conduct. In addition to the allegations that Endo deliberately coded reports of abuse incorrectly as part of its government affairs strategy, most of Endo's dangerous and deceptive sales strategies were described only in internal documents and never shared with the public. Thus, the discovery rule also tolls the statute of limitations and all other time-related defenses, if any, for all the claims the Attorney General alleges in this complaint.

FIRST CLAIM FOR RELIEF

(Unlawful Trade Practices Act)

160.

The Attorney General realleges the proceeding paragraphs, and incorporates the allegations herein, as if fully set forth.

Count 1—Violation of ORS 646.607(1)

161.

Endo violated ORS 646.607(1) by employing unconscionable tactics in connection with the sale of its opioids by:

a. Recklessly, falsely, and deceptively minimizing the risks and warning signs of addiction;

b. Recklessly, falsely, and deceptively promoting high doses of Opana ER, despite scientific evidence that high doses of opioids increase the risk of overdose and death and do not improve patient well being;

c. Recklessly, falsely, and deceptively promoting continued use of Opana ER, despite scientific evidence that continued use of opioids increase the risk of addiction, overdose, and death;

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d. Making false, deceptive, and reckless claims about pseudoaddiction;

e. Falsely, misleadingly, and deceptively marketing Opana ER's opioids as effective at improving patient's quality of life;

f. Falsely, deceptively, and misleadingly marketing Opana ER as having fewer strong side effects than other opioids;

g. Funding and working in concert with the American Pain Foundation, American Academy of Pain Medicine, and the American Pain Society to establish guidelines that downplayed the risks for opioid treatment, which Endo then used in sales calls in Oregon without disclosing its ties to the group;

h. Funding the American Pain Foundation, which developed a website called painknowledge.org to advance claims of pseudoaddiction and to promote higher doses of opioids when a patient was displaying signs of addiction;

i. Targeting high prescribers in its sale efforts, despite knowing that opioids from high prescribers are frequently abused;

j. Telling health care providers that Opana ER had less risk of abuse and fewer side effects than OxyContin, even though those claims were false, deceptive, and misleading;

k. Marketing reformulated Opana ER and "INTAC technology" as being safer than the original despite the FDA's repeated findings that it was not safe;

l. Continuing to use claims about "INTAC technology" in its marketing despite the FDA's warning that those claims misleadingly minimize risks;

m. Instructing its sales associates that the reformulated version of Opana ER was designed to be crush resistant, even though the FDA had informed Endo that such claims were deceptive and misleading; and

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n. Instructing its promotional speakers to claim that the reformulated version of Opana ER was designed to be crush resistant, even though the FDA had informed Endo that such claims were deceptive and misleading.

162.

Pursuant to ORS 646.632(1), the Attorney General seeks an injunction prohibiting Endo from continuing to market any of its opioids in Oregon.

163.

Pursuant to ORS 646.642(3), the Attorney General seeks a civil penalty of up to $25,000 for each violation of ORS 646.607(1) described above.

164.

Pursuant to ORS 646.632(8), the Attorney General seeks her reasonable attorney fees incurred in bringing this count.

Count 2—Violation of ORS 646.608(1)(b)

165.

Endo violated ORS 646.608(1)(b) by causing the likelihood of confusion or misunderstanding as to the extent of FDA approval of the reformulated Opana ER by:

a. Marketing reformulated Opana ER and "INTAC technology" as being safer than the original despite the FDA's repeated findings that it was not safe;

b. Continuing to use claims about "INTAC technology" in its marketing despite the FDA's warning that those claims misleadingly minimize risks;

c. Instructing its sales associates that the reformulated version of Opana ER was designed to be crush resistant, even though the FDA had informed Endo that such claims were deceptive and misleading; and

d. Instructing its promotional speakers to claim that the reformulated version of Opana ER was designed to be crush resistant, even though the FDA had informed Endo that such claims were deceptive and misleading.

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166.

Pursuant to ORS 646.632(1), the Attorney General seeks an injunction prohibiting Endo from continuing to market any of its opioids in Oregon.

167.

Pursuant to ORS 646.642(3), the Attorney General seeks a civil penalty of up to $25,000 for each violation of ORS 646.608(1)(b) described above.

168.

Pursuant to ORS 646.632(8), the Attorney General seeks her reasonable attorney fees incurred in bringing this count.

Count 3—Violation of ORS 646.608(1)(e)

169.

Endo violated ORS 646.608(1)(e) by representing that Endo's opioids had sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities that they do not have by:

a. Falsely, misleadingly, and deceptively marketing Opana ER's opioids as effective at improving patient's quality of life;

b. Telling health care providers that Opana ER had less risk of abuse and fewer side effects than OxyContin, even though those claims were false, deceptive, and misleading;

c. Marketing reformulated Opana ER and "INTAC technology" as being safer than the original despite the FDA's repeated findings that it was not safe;

d. Continuing to use claims about "INTAC technology" in its marketing despite the FDA's warning that those claims misleadingly minimize risks;

e. Instructing its sales associates that the reformulated version of Opana ER was designed to be crush resistant, even though the FDA had informed Endo that such claims were deceptive and misleading; and

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f. Instructing its promotional speakers to claim that the reformulated version of Opana ER was designed to be crush resistant, even though the FDA had informed Endo that such claims were deceptive and misleading.

170.

Pursuant to ORS 646.632(1), the Attorney General seeks an injunction prohibiting Endo from continuing to market any of its opioids in Oregon.

171.

Pursuant to ORS 646.642(3), the Attorney General seeks a civil penalty of up to $25,000 for each violation of ORS 646.608(1)(e) described above.

172.

Pursuant to ORS 646.632(8), the Attorney General seeks her reasonable attorney fees incurred in bringing this count.

SECOND CLAIM FOR RELIEF

(Oregon Racketeer Influenced and Corrupt Organizations Act)

173.

The Attorney General realleges the proceeding paragraphs, and incorporates the allegations herein, as if fully set forth.

174.

Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., the American Academy of Pain Medicine, the American Pain Society, American Pain Foundation, and the American Geriatric Society have operated continuously as an enterprise from 2006 until present. The enterprise has a common purpose to increase the sale of Endo's opioids.

175.

Defendants participated in the enterprise through a pattern of racketeering activity by committing, attempting to commit, or conspiring to commit crimes of (1) unsworn

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falsification, ORS 162.085; (2) fraudulently obtaining a signature, ORS 165.042; and (3) wire fraud, 18 U.S.C. § 1343.

176.

Endo committed, attempted to commit, or conspired to commit the crime of unsworn falsification, ORS 162.085(1), by (1) falsely stating that it had produced all responsive records to the Oregon Attorney General, in response to the Attorney General's civil investigative demand, and (2) failing to timely correct its false statements. Endo committed the crime of unsworn falsification each and every time it submitted a false statement to the Attorney General and each time it communicated with the Attorney General and failed to correct its earlier false statements.

177.

Endo further committed, attempted to commit, or conspired to commit the crime of unsworn falsification, ORS 162.085(1), by making false written statements to the Pharmacy Board in connection with Endo's applications for the benefit of registration under Oregon's statutes governing pharmacy. Endo committed the crime of unsworn falsification each and every time it submitted a false application for registration or renewal.

178.

Endo attempted to commit the crime of fraudulently obtaining a signature, ORS 165.042(1), by, with intent to defraud, knowingly misrepresenting the facts about its opioids, including both the original and reformulated versions of Opana ER, and to obtain the signatures of health care professionals on prescriptions. Endo knowingly misrepresented facts about its opioids in an attempt to obtain signatures on prescriptions by:

a. Falsely, misleadingly, and deceptively marketing Opana ER's opioids as effective at improving patient's quality of life;

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b. Telling health care providers that Opana ER had less risk of abuse and fewer side effects than OxyContin, even though those claims were false, deceptive, and misleading;

c. Telling health care providers that Opana ER had less risk of abuse and fewer side effects than OxyContin, even though those claims were false, deceptive, and misleading;

d. Marketing reformulated Opana ER and "INTAC technology" as being safer than the original despite the FDA's repeated findings that it was not safe;

e. Continuing to use claims about "INTAC technology" in its marketing despite the FDA's warning that those claims misleadingly minimize risks;

f. Instructing its sales associates that the reformulated version of Opana ER was designed to be crush resistant, even though the FDA had informed Endo that such claims were deceptive and misleading; and

g. Training its promotional speakers to claim that the reformulated version of Opana ER was designed to be crush resistant, even though the FDA had informed Endo that such claims were deceptive and misleading.

179.

Endo committed, attempted to commit, and conspired to commit the crime of wire fraud by:

a. Engaging in a scheme to defraud Oregonians by disseminating marketing materials to its sales representatives, such as the "INTAC Sell Sheet," which contained false representations about the safety and abuse-deterrent properties of Opana ER;

b. Engaging in a scheme to defraud Oregonians by working with and funding the American Academy of Pain Medicine, the American Pain Society, and the American Pain Foundation to publish and disseminate guidelines for opioid

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treatment, when those guidelines contained false and misleading representations about the safety and effectiveness of opioids; and

c. Engaging in these schemes with the specific intent of obtaining money from Oregonians and their insurers from the sale of Purdue's opioids.

180.

The predicate crimes described above were not isolated. They occurred continuously for more than 10 years, beginning before 2011 and continuing after 2017. These crimes had the same intent and results: To increase Endo's sales of its opioids. The victims were the same: The people of the State of Oregon. The methods were the same: The use of sales representatives, marketing material, and false, misleading, and deceptive information about the safety and efficacy of Endo's opioids and to market and sell those opioids in Oregon.

181.

Endo violated ORS 166.720(3) by participating both directly and in indirectly with the enterprise through the pattern of racketeering activity. Endo violated ORS 166.720(3) each time it committed, attempted to commit, or conspired to commit one of the predicate acts described above.

182.

For Endo's violations of ORS 166.720(3), the Attorney General seeks an injunction pursuant to ORS 166.725(1) prohibiting Purdue from marketing its opioids in Oregon.

183.

For Endo's violations of ORS 166.720(3), the Attorney General seeks civil forfeiture pursuant to ORS 166.725(2) of all money and property Endo has obtained from its violations of ORS 166.720(3), from January 2007 to present, including all revenue generated from the sale of opioids in Oregon.

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184.

For each of Endo's violations of ORS 166.720(3), the Attorney General seeks a civil penalty of up to $250,000, pursuant to ORS 166.725(8).

185.

Pursuant to ORS 166.725(5), the Attorney General seeks an award of the cost of investigation and reasonable attorney fees incurred in connection with this claim.

THIRD CLAIM FOR RELIEF

(Abuse of Vulnerable Persons)

186.

The Attorney General re-alleges the preceding paragraphs and incorporates the allegations herein as if fully set forth.

187.

Endo recklessly created a substantial risk of serious physical injury to elderly and disabled Oregonians by:

a. Recklessly, falsely, and deceptively minimizing the risks and warning signs of addiction;

b. Recklessly, falsely, and deceptively promoted continued use of its opioids, despite the scientific evidence that continued use of opioids increase the risk of addiction and death and do not improve patient well being;

c. Specifically targeting seniors and promoting its opioids for conditions like osteoarthritis without disclosing serious risks; and

d. Failing to inform health care professionals that Endo's opioids increased the risks of falls, fractures, and confusion.

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188.

Pursuant to ORS 124.120, the Attorney General seeks a permanent injunction prohibiting Endo from marketing its opioids to individuals over 65 years of age or disabled individuals.

189.

In addition, pursuant to ORS 124.125(1), the Attorney General seeks a civil penalty of up to $25,000 for each vulnerable person placed in danger by Endo's reckless conduct.

190.

Pursuant to ORS 124.100(2)(c) and 124.125(1), the Attorney General is entitled to reasonable attorney fees related to this claim and the costs of investigation.

FOURTH CLAIM FOR RELIEF

(Negligence)

191.

The Attorney General incorporates by reference the allegations in the above paragraphs as if fully set forth herein.

192.

Endo created an unreasonable risk of foreseeable harm by:

a. Hiring an enormous sales force and pressuring it to recklessly, falsely, deceptively, and misleadingly market Endo's opioids in Oregon;

b. Directing its sales force to promote high doses of opioids, minimize the risk of addiction, encourage continued use, and blame individuals suffering from the disease of addiction for abuse when marketing opioids in Oregon;

c. Creating a reformulated version of Opana ER that was just as susceptible to abuse and recklessly, falsely, receptively, and misleadingly marketing it as safer than earlier versions and other opioids;

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d. Funding supposedly independent, third-party organizations to create reckless, false, misleading, and deceptive information about opioids; and

e. Creating and disseminating reckless, false, misleading, and deceptive marketing materials to Oregonians.

193.

As a result of Endo's negligent conduct, the State suffered enormous damages, including the deaths of its citizens, the medical costs for unnecessary prescriptions for opioids, and the resulting costs of abuse, addiction, and injury caused by the unnecessary use of opioids. Damages are as much as $1 billion.

194.

Plaintiff intends to amend this Complaint to seek punitive damages pursuant to ORS 31.725.

FIFTH CLAIM FOR RELIEF

(Public Nuisance)

195.

The Attorney General re-alleges the preceding paragraphs and incorporates the allegations herein as if fully set forth.

196.

As described above, Endo has helped create and maintain a continuous and unreasonable interference with public health and safety in the State of Oregon. Doing so has endangered the lives and health of Oregonians.

197.

As early as 2007, Endo knew, should have known, or was reckless in not knowing that opioids should not be prescribed for continuous use because continuous use increases the risk of addiction. Endo also should have known as early as 2007 that opioids carry a high risk of abuse, which can lead to addiction, overdose, and death.

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198.

As early as 2011, Endo knew, should have known, or was reckless in not knowing that the reformulated version of Opana ER was not abuse-deterrent and that marketing it as such was reckless, misleading, false, and dangerous to public health.

199.

Nonetheless, as detailed above, Endo continued to recklessly, falsely, deceptively, and misleadingly market Endo's opioids. Endo's marketing strategies continued to minimize the risks of addiction, encouraged continued use of its opioids, and claimed that the reformulated version of Opana ER had abuse-deterrent properties.

200.

Endo engaged in its reckless, false, deceptive, and misleading marketing practices in a manner that was consciously indifferent to the health, safety, and welfare of the general public of the State of Oregon.

201.

Endo's reckless, false, deceptive, and misleading marketing practices have caused addiction, abuse, injury, and death across Oregon. Endo's actions were a substantial factor in opioids becoming widely available, widely used, and widely abused in Oregon.

202.

As a result of Endo's conduct, plaintiff has incurred damages and is entitled to compensation therefor. Plaintiff also seeks compensation sufficient to abate the nuisance caused by defendants. That amount will be at least $1 billion.

PRAYER

WHEREFORE, plaintiff Attorney General Rosenblum prays for relief against defendants as follows:

A. On the first claim for relief:

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1. On count 1, for a judgment in favor of Attorney General Rosenblum and against Endo in the amount of up to $25,000 for each violation of the Unlawful Trade Practices Act;

2. On count 2, for a judgment in favor of Attorney General Rosenblum and against Endo in the amount of up to $25,000 for each violation of the Unlawful Trade Practices Act;

3. On count 3, for a judgment in favor of Attorney General Rosenblum and against Endo in the amount of up to $25,000 for each violation of the Unlawful Trade Practices Act;

4. On counts 1, 2, and 3, for an injunction prohibiting Endo from continuing to market its opioids in Oregon;

B. On the second claim for relief, for a judgment in favor of Attorney General Rosenblum and against Endo in the amount of $250,000 for each violation of ORS 166.720(3); an injunction prohibiting Endo from marketing its opioids in Oregon; and the civil forfeiture of all money and property Endo has derived from or realized through conduct in violation of ORS 166.715 to 166.735;

C. On the third claim for relief, for a judgment in favor of Attorney General Rosenblum and against Endo in the amount of $25,000 for each violation of the Elderly Persons and Persons with Disabilities Abuse Prevention Act and an injunction prohibiting Endo from marketing its opioids to individuals over 65 or disabled individuals in Oregon;

D. On the fourth claim for relief, for a judgment in favor of Attorney General Rosenblum and against Endo in an amount to be determined at trial;

E. On the fifth claim for relief, for a judgment in favor of Attorney General Rosenblum and against Endo in an amount to be determined at trial;

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F. An award of reasonable attorney fees and costs of the investigation, preparation, and litigation, pursuant to ORS 124.100(2)(c), 124.125(1), 166.725(5), and 646.632(8); and

G. Such other relief as the Court deems appropriate.

DATED this 10th day of November, 2021.

ELLEN ROSENBLUM
ATTORNEY GENERAL
FOR THE STATE OF OREGON

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