COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION NO. __
CIVIL ACTION NO. _____

COMMONWEALTH OF KENTUCKY, *ex rel.*, ANDY BESHEAR, ATTORNEY GENERAL, Plaintiff. v. ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; Defendants.	**COMPLAINT** JURY TRIAL DEMANDED

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I. PRELIMINARY STATEMENT

1. Until relatively recently, doctors prescribed, and patients used, opioids only for short-term acute pain, for cancer, or end-of-life pain. Opioids were seen as too addictive and debilitating to be used long-term, and, for less severe chronic pain conditions, doctors knew that the risks of using opioids dramatically exceeded their benefits.[1]

2. For companies like Endo and other opioid makers, the market for opioids defined by medical consensus was 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.

3. 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

[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

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.

4. 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 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 of time. 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.

5. Although the use of opioids is addicting and possibly lethal, Endo's marketing worked, and helped build the far larger market for the chronic use of opioids. [redacted]; virtually all of Endo's opioid sales—and profits—were from a market that did not exist ten years earlier. This is the case even though Opana ER is a particularly powerful opioid—oxymorphone—that is three times stronger than morphine, which made its long-term daily use even more dangerous.

6. Having first helped create the market for the widespread use of opioids to treat chronic pain, Endo, and its prescribers, were soon confronted with evidence that Opana ER was being widely abused—just as doctors had originally feared. Concerned that doctors' prescribing would be chilled by evidence of addiction and abuse and seizing on a chance to protect its sales, Endo launched a reformulated Opana ER, which it promised would deter abuse. Even though the FDA and Endo's own studies and data rejected that claim, Endo promoted reformulated Opana ER--like its predecessor--as safe. But, contrary to Endo's marketing, Opana ER is readily

injectable by opioid addicts, which makes its widespread prescribing for chronic pain especially inappropriate and dangerous. In fact, Opana ER has been linked to a wave of infections transmitted through intravenous drug use, including Hepatitis C and HIV.

7. At each juncture, Endo put its own profits ahead of public health and patient safety. And, rather than help limit the opioid epidemic by reporting potential diversion through illicit prescribing, as it is obligated to do on under federal and state law, Endo looked the other way.

8. Drug overdoses have become the leading cause of accidental death in the Commonwealth. In 2016 alone, 1,404 people died from fatal drug overdoses in Kentucky—almost four people every day. Oxymorphone claimed at least 191 of these lives. Many of those victims were service members or veterans, who accounted for 452 drug overdoses between 2010 and 2015. As Kentucky citizens who have become addicted to prescription opioids predictably migrate to illicit, but less expensive, opioids, namely heroin and fentanyl, overdoses have dramatically increased.

9. In addition to opioid-related fatalities, the Commonwealth has suffered other serious injuries. Kentucky has seen a dramatic increase in opioid addiction, reflected, in part, in the increase in Medicaid spending for medications to treat opioids, which doubled in just two years--from $56 million in 2014 to $117 million in 2016.

10. The widespread use of opioids and corresponding increases in addiction and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians' administration of Naloxone—the antidote to opioid overdose. In Louisville, the police force administered 123 doses of Naloxone in just the first six weeks of the year—representing 3 overdoses each day. It also has resulted in dramatic growth in drug-

related crimes. In one Kentucky county, roughly 90% of prosecutions are related to prescription drug abuse or diversion. Across the Commonwealth, there have been increases in domestic violence, robberies, burglaries, and thefts, among other crimes.

11. Opioids have endangered public health in Kentucky even beyond addiction and overdose. Intravenous use of opioids, which has been a particular problem with easy-to-inject Opana ER has led to a surge in Hepatitis C in the state and created a risk of an even broader epidemic. After a surge of HIV cases in Scott County, Indiana tied specifically to the injection of Opana ER, the U.S. Centers for Disease Control and Prevention ("CDC") identified 220 counties across the country at greatest risk for similar outbreaks; 54 of those counties—roughly 25% of the total—were in Kentucky. Just last year, the state Medicaid program spent nearly $50 million on drug treatment for Hepatitis C.

12. Children has been especially vulnerable to the opioid epidemic. In just one 12-month period between August 1, 2014 until July 31, 2015, 1,234 infants in Kentucky were born addicted to opioids, more than 100 newborns per month. These infants will spend weeks in neonatal intensive care units while they painfully withdraw from the drugs—a process so painful that it traps many adults on opioids. Children are also injured by the removal from their homes due to opioid abuse and addiction. *See infra* ¶ 149.

13. As startling as these statistics are, they cannot fully convey the harm that the opioid epidemic has visited on individuals and families in Kentucky. One mother interviewed by the Attorney General's Office lost her son, a member of the Kentucky National Guard, to an Opana ER overdose. While he was not prescribed Opana ER, he was able to obtain pills from someone who obtained them through a prescription. He began using Opana ER when he was 18 years old and became addicted within weeks. He moved from taking it orally to snorting it. His

mother emailed Endo using a form on the company's website reporting his addiction and pleading for help. Despite treatment to overcome his addiction, he relapsed. He overdosed on Opana ER and died shortly before being deployed in 2012. One month after his death—a full year after she had emailed Endo—the company finally responded to ask for her information so that it could file a report with the FDA.

14. The Attorney General brings this public-interest lawsuit to hold Endo accountable for its violations of the Consumer Protection Act ("KCPA"), KRS 367.110 *et seq.*; the Kentucky Medicaid Fraud Statute, KRS 205.8463, the Kentucky Assistance Program Fraud Statute, KRS 194A.505; and Kentucky's Fraudulent Insurance Acts statute, KRS 304.47-020. The Attorney General also seeks remedies for the creation and maintenance of a continuing public nuisance, fraud, and unjust enrichment. This action seeks repayment of the Commonwealth's spending on opioids, disgorgement of Endo's unjust profits, civil penalties for its egregious violation of law, compensatory and punitive damages, injunctive relief, and abatement of the public nuisance Endo has helped create.

II. PARTIES

15. The Plaintiff, Commonwealth of Kentucky, brings this action, by and through its Attorney General, Andy Beshear, in its sovereign capacity in order to protect the interests of the Commonwealth and its citizens. This suit concerns matters of state-wide interest. Andy Beshear is the duly elected Attorney General of Kentucky, an independent constitutional officer of the Commonwealth and its chief law enforcement officer, with full authority to initiate and prosecute all cases in which the Commonwealth has an interest. The Attorney General is vested with specific constitutional, statutory and common law authority to commence proceedings to enforce KRS § 367.110 *et seq.,* KRS 205.8451 through KRS 205.8483, KRS 194A.505, and KRS 304.47-020, to exercise all common law duties and authority pertaining to the office of the

Attorney General under the common law pursuant to KRS 15.020, and pursuant to the Attorney General's authority, to bring an action on behalf of the Commonwealth. The Attorney General has determined that these proceedings are in the public interest.

16. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. 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 Health Solutions Inc. and Endo Pharmaceuticals, Inc. collectively are referred to herein as "Endo.")

17. Endo has developed, marketed, and sold prescription drugs, including the following opioids, in Kentucky:

a. Opana (oxymorphone hydrochloride) and Opana ER (oxymorphone hydrochloride extended release) are Schedule II[2] opioid agonist tablets first approved in 2006. In 2017, the U.S. Food & Drug Administration ("FDA") asked that Endo remove Opana ER from the market. Opana, and particularly Opana ER, represent the focus of Endo's marketing efforts.

b. Percodan (oxycodone hydrochloride and aspirin) is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004.

c. Percocet (oxycodone hydrochloride and acetaminophen) is a Schedule II opioid agonist tablet first approved in 1999 and first marketed by Endo in 2006.

[2] Since 1970, opioids have been regulated under the Controlled Substances Act ("CSA"). Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I the highest. The CSA and Kentucky law impose a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812; KRS 218A.060; KRS 218A .080. As noted above, all of Endo's opioids are classified as Schedule II drugs.

18. Although Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER, it continues to promote Opana ER through a dedicated website and to list Opana ER on the company's website among its other drugs. Endo also continues to market and sell Percodan, Percocet, and other generic opioids.

19. Endo's opioids consist of both long- and short-acting opioids (sometimes referred to as extended release or ER opioids and immediate release or IR opioids). Long-acting or extended release opioids like Opana ER are, in theory, supposed to provide continuous opioid therapy for 12 hours. In contrast, short acting opioid formulations last between 4-6 hours. Extended release opioids typically carry higher concentrations of the active pharmaceutical ingredient (the opioid).

20. Opioids made up roughly $403 million of Endo's overall revenues in 2012, peaked at $657 million in 2014, and fell to $486 million of Endo's $4 billion in sales in 2016. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it alone accounted for 10% of Endo's total revenue in 2012.

III. JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over the Commonwealth's claims pursuant to KRS 23A.010, KRS 194A.505(8), KRS 205.8469, KRS 367.190 as the claims enumerated herein arise exclusively under Kentucky statutory and common law and from the *parens patriae* authority of the Attorney General to act on behalf of the Commonwealth of Kentucky and its citizens. The Commonwealth's claims are in excess of any minimum dollar amount necessary to establish the jurisdiction of this Court.

22. This Court has personal jurisdiction over the Defendants pursuant to KRS 454.210 because the Defendants have regularly transacted and/or solicited business in the Commonwealth and/or derived substantial revenue from goods used or consumed or services

rendered in the Commonwealth and/or contracted to supply good or services in the Commonwealth and/or caused injury by an act or omission in the Commonwealth and/or caused injury in the Commonwealth by an act or omission outside the Commonwealth.

23. The Complaint herein sets forth exclusively state law claims against the Defendants. Nowhere does the Commonwealth plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law. The Commonwealth expressly asserts that the only causes of action asserted and the only remedies sought herein are founded upon the statutory, regulatory, common, and decisional laws of the Commonwealth of Kentucky.

24. The claims asserted herein by the Commonwealth of Kentucky consist of claims on behalf of the Commonwealth of Kentucky, and the Commonwealth does not assert any cause of action herein on behalf of any individual or any purported class of individuals.

25. Venue is proper in Franklin County pursuant to KRS 452.450 and 452.460 because injuries to the Commonwealth occurred in Franklin County and pursuant to KRS 367.190(1) because unlawful methods, acts and/or practices of Endo were committed in Franklin County.

IV. FACTUAL ALLEGATIONS

A. Endo Executed a Comprehensive Strategy to Deceptively Market Opioids, Especially Opana ER, in Kentucky by Falsely Downplaying the Risks and Overstating the Benefits of Using These Drugs for the Long-Term Treatment of Chronic Pain.

26. In promoting its opioids in Kentucky, Endo made claims it knew were contrary to or unsupported by scientific evidence. Endo's misrepresentations and omissions—which are described below—reinforced each other and created the dangerously misleading impression that:

a. starting patients on opioids was low-risk because most patients would not become addicted;

b. doctors could identify patients who were at greatest risk of addiction and manage their use to avoid addiction;

c. doctors could disregard what might otherwise appear to be signs of addiction as "pseudoaddiction;"

d. if opioid therapy was not successful, patients could easily be weaned from the drugs;

e. prescribers need not be concerned about higher doses, which many patients need to try to sustain pain relief as they develop tolerance to opioids;

f. the abuse-deterrent features of reformulated Opana ER made it safer and prevented abuse; and

g. long-term opioid therapy would help chronic pain patients regain resume their daily lives.

27. Endo also misleadingly portrayed and overstated the risks of competing products, such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen), which do not impose a risk of addiction, and made unsubstantiated claims, either directly or implicitly, that opioids were superior to NSAIDs.

28. Endo directly spread these deceptive messages through websites, publications, and sales representatives who visited individual doctors. Door-to-door visits to prescribers, also known as detailing, were particularly important because they allowed Endo's sales representatives to address potential prescribers' individual questions, concerns, and practices. Endo also could direct its sales representatives to target the highest prescribers of its or competitors' drugs. Endo directed the majority of its marketing budget to sales representatives—with good results: [redacted]

29. To ensure that its sales representatives delivered messages that were consistent with its overall marketing plans and strategy, [redacted]

[redacted]

30. Endo also channeled part of its [redacted] to seemingly independent and trustworthy third parties—respected physicians or researchers (known within the industry as "key opinion leaders" or "KOLs" for their ability to influence other doctors) and patient and professional organizations—to spread the same message.

31. Endo's KOLs delivered talks and continuing medical education programs (or "CMEs") paid for by Endo that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from Endo, and the CMEs were often sponsored by Endo—giving Endo considerable influence over the messenger, the message, and its means of distribution. They served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs and other "educational" materials. Only doctors supportive of opioids for chronic pain received these funding and speaking opportunities. Through KOLs, Endo could direct and guide these activities to serve its marketing purposes.

32. KOLs also served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society. Endo and other opioid makers exerted influence over these groups by providing major funding directly to them, as well. These "front groups" for the opioid industry published treatment guidelines and patient education materials, often funded, directed, reviewed, or edited by Endo, that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. [redacted]

[redacted]

33. Front groups also conducted outreach to groups targeted by Endo, such as veterans and the elderly. Some of their CMEs, for example, specifically promoted the use of opioids in elderly populations. [redacted] However, Opana ER poses even greater risks to elderly patients. In 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded: "[f]or patients 65 and older these medications are not safe, so consult your doctor."

34. [redacted] Endo also set out to reach veterans directly. For instance, *Exit Wounds*, a publication aimed at veterans distributed by the American Pain Foundation ("APF"), a purportedly pro-patient advocacy group, with grants from Endo, described opioids as "under-used" and the "gold standard of pain medications" without adequately warning of their risks, including the risk of addiction and their potentially fatal interaction with benzodiazepines, a medication often prescribed for post-traumatic stress disorder.

35. Endo relied on KOLs and front groups to defend it and its opioids from public relations threats. Internal documents reveal that Endo acted proactively to line up these allies to give supporting statements in the event of the "death of teen abuser or celebrity death."

36. The use of third-party, unbranded marketing not only created the false impression that materials requested, reviewed, edited, and distributed by Endo came from objective and disinterested sources, it allowed Endo to avoid regulatory scrutiny, as such advertising typically is not reviewed by the FDA. The same is true of the messages conveyed to prescribers by Endo's sales representatives.

37. As confirmed by Kentucky prescribers and upon information and belief, based on the centralized, national strategy and messages Endo used for marketing its opioids, all of the messages, materials, and programs described below were disseminated to Kentucky prescribers and patients.

38. For the most part, Endo's misrepresentations and omissions were directed to prescribers, particularly primary care physicians, internal medicine doctors, and others who lacked the specialized expertise in pain management, opioids, and addiction to independently assess Endo's promotional claims. Endo's comprehensive efforts to mislead doctors, tainting virtually every source of information they relied on—treatment guidelines, speaker programs, CMEs, websites, and detailing visits, among others—made it difficult even for doctors with specialized expertise to identify their deceptions. The Complaint also identifies patient education material and websites that would have been available to, and often were directed at, consumers.

B. Endo Downplayed the Risk of Addiction.

39. In promoting its opioids in Kentucky, Endo falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed by a doctor, and failed to disclose the greater risk of addiction with prolonged use of opioids.

40. Contrary to Endo's misrepresentations, pain patients who use opioids precisely as prescribed by a doctor can—and do—become addicted. Addiction is the result of using opioids,

not just misusing or abusing them. As many as one in four patients who receive prescription opioids long-term for chronic pain in primary care settings will become addicted.

41. The risk of addiction is—unequivocally—a clinically significant risk that should be disclosed—prominently and accurately—to prescribers and patients. One out of every 550 patients started on opioid therapy die of opioid-related causes a median of 2.6 years after their first opioid prescription. The CDC director recently declared: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[3]

42. Kentucky doctors were told that legitimate patients were unlikely to become addicted unless they intentionally sought out opioids illicitly, and that opioids prescribed properly would not result in addiction. Substance abuse treatment providers in Kentucky also confirm that patients report not having been warned of the risk of addiction by their doctors when they were prescribed opioids.

43. Marketing materials that Endo distributed and made available to Kentucky prescribers and patients also conveyed misrepresentations regarding the risk of addiction.

44. For example, until April 2012, Endo stated on its website, www.opana.com, which was available to both prescribers and patients, that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." Upon information and belief, Endo has not conducted and does not possess a survey that shows that this is true. In any event, this statement is misleading because it suggests that opioids are not addictive.

[3] Frieden and Houry, Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline, NEJM, 4/21/16, at 1503.

45. [redacted] Upon information and belief,[4] sales representatives conveyed this information to Kentucky prescribers in their visits.

46. Endo worked closely with APF to promote the message that opioids were not addictive. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007-2012. APF ultimately closed its doors in 2012, after the Senate Finance Committee began an investigation of industry influence of its activities and its role in creating the opioid crisis.

47. Endo exerted special control of the National Initiative on Pain Control ("NIPC"), an APF initiative that included the website www.painknowledge.org, which was available to patients and prescribers.[5] NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." Endo substantially controlled NIPC by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. [redacted] Yet,

[4] Unless otherwise indicated, allegations made upon information and belief rely upon the inference that, consistent with its centralized planning and implementation of its marketing efforts, Endo's conduct in Kentucky conformed with its actions nationally.

[5] APF internal documents include a grant proposal to Endo to allow APF to assume sponsorship of NIPC and pointed out that "[f]or the past 9 years, the NIPC has been supported by unrestricted annual grants from Endo Pharmaceuticals, Inc." APF regarded its sponsorship of the NIPC as an "opportunity to generate new revenue, as Endo has earmarked substantial funding" of $1.2 million "to continue the NIPC." APF's dependence on Endo for its operating funds made it particularly likely to support Endo's promotional efforts and messages.

Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or www.painknowledge.org. [redacted]

48. By virtue of its control over APF and NIPC, Endo was responsible for the assertion at www.painknowledge.org that "[p]eople who take opioids as prescribed usually do not become addicted."

49. The American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). Treatment guidelines, like those produced by AGS, are especially influential with primary care physicians and family doctors to whom Endo promoted opioids, 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 U.S. Centers for Disease Control and Prevention has recognized that treatment guidelines can "change prescribing practices."[6]

50. The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "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 450 times in Google Scholar (which allows users to search scholarly publications that would

[6] 2016 CDC Guideline at 2.

have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

51. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[7] Five of the ten experts on the 2009 AGS Guidelines panel also disclosed financial ties to Endo. These doctors served as paid speakers and consultants, presented CMEs sponsored by Endo, and received grants from Endo. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

52. Endo and other drug companies also supported the 2009 guidelines of the American Academy of Pain Medicine and the American Pain Society, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain* (hereinafter the "AAPM/APS Guidelines"). Of the 21 panelists, nine had at some point received financial support from Endo (14 from the pharmaceutical industry in total). [redacted] The AAPM/APS Guidelines promoted opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence for their use, and concluded that the risk of addiction is manageable for patients regardless of past abuse histories. A Kentucky doctor recalled a high-level representative of the American Pain Society ("APS") within the last few years advising that opioids were not addictive.

53. Doctors also served to spread Endo's deceptive messages through Endo's speaker programs, which, based on their use nationally, were given in Kentucky and to Kentucky

[7] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

prescribers. These programs, which featured well-respected doctors paid by Endo speaking to audiences of colleagues, provided: (1) an incentive for doctors to prescribe a particular opioid (a prerequisite for being selected as a speaker); (2) recognition and compensation for the doctors selected as speakers; and (3) more effective peer-to-peer marketing. These speaker programs had significant reach and influence on prescribers' decisions to prescribe Endo's opioids and, upon information and belief based on Endo's other marketing themes, contained the same deceptive messages Endo disseminated through other vehicles.

54. [redacted]

55. [redacted] Given Endo's centralized promotional messages and materials, its use of the AAPM/APS Guidelines in these contexts suggests that Endo more broadly referenced and promoted the AAPM/APS Guidelines without disclosing the acknowledged lack of evidence to support them. According to Google Scholar, the AAPM/APS Guidelines have been cited 1,185 times, with as many as 100 citations already this year.

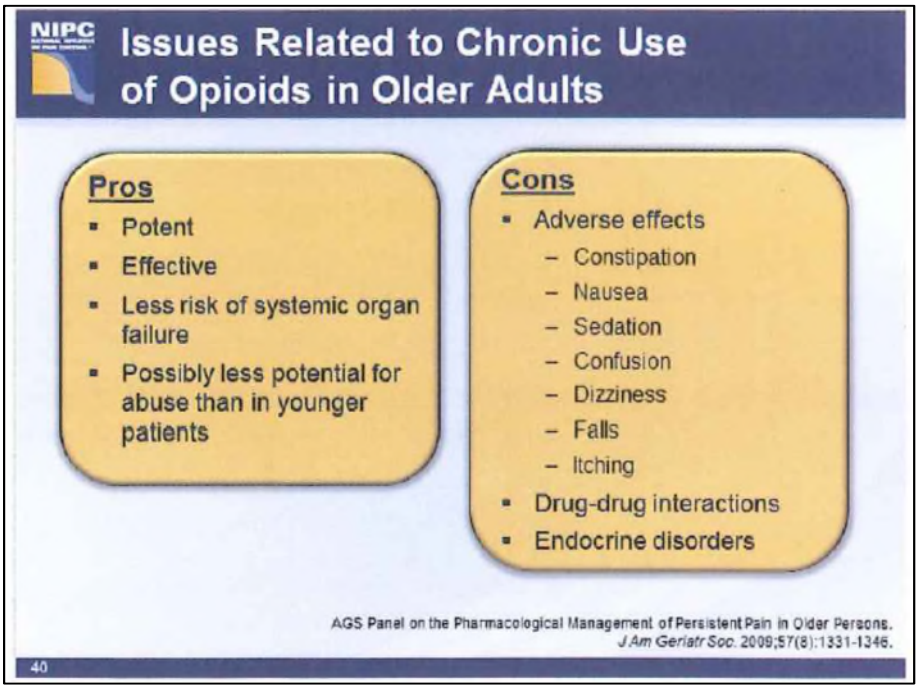
56. KOLs provided Endo with written materials, in addition to their talks. For example, a 2004 Endo patient education publication, edited by a leading KOL Dr. Russell

Portenoy and titled, *Understanding Your Pain: Taking Oral Opioid Analgesics*, provides a representative example. This publication answers the hypothetical patient question—"What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." Thus, the publication strongly and deceptively suggests that pain patients will not become addicted to opioids. This publication is still available online.

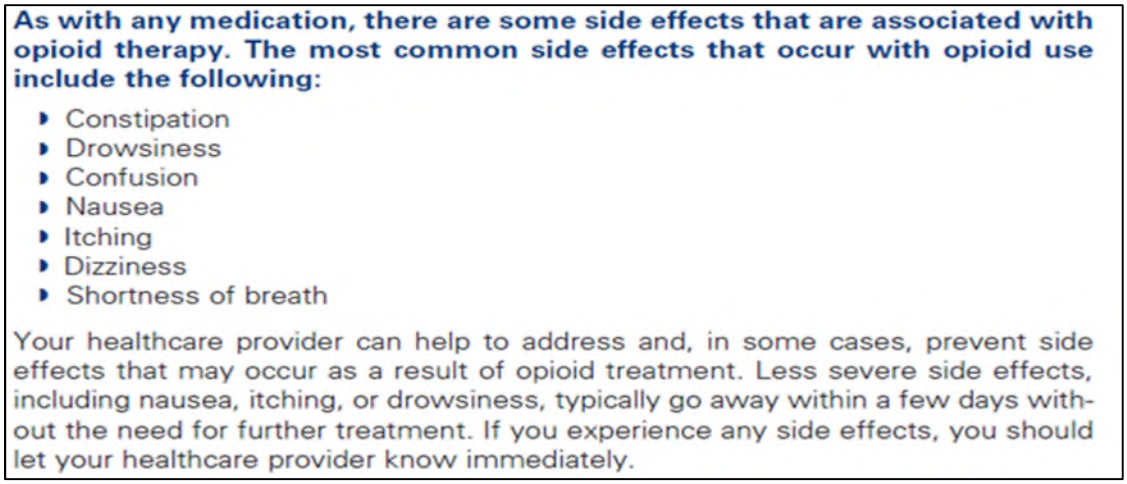
57. Dr. Portenoy has received grants and research contracts from Endo, among others, and published some of the earliest articles promoting the use of opioids for chronic pain. These articles were limited in scope—one such article was titled *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases* and recognized evidence that opioids improved patients' function was lacking and that doses should be low. However, over time, Dr. Portenoy's statements on opioids became more sweeping, including claims that doctors can be "very assured" patients without family history of substance abuse would not become addicted, and that the rate of addiction was as low as 1%.

58. Endo also spread its deceptive messages, and co-opted the traditional sources on which doctors relied for information, through CMEs. For example, an Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, included dangerous misrepresentations about the risk of addiction to opioids. The CME describes fear of addiction, safe use, and drug interactions—all legitimate factors relating to addiction, abuse, and overdose—as mere barriers to treating "persistent" or chronic pain in the elderly. Citing the 2009 AGS Guidelines as its sole support, the CME describes the "chronic use of opioids in older adults" as "effective" and,

without foundation, notes "possibly less potential for abuse than in younger patients." The CME lists adverse outcomes that include minor adverse effects, like constipation and nausea, but omits addiction, overdose, respiratory depression, or death, among others. The slides also note that tolerance to opioids' more mild side effects (such as dizziness or nausea) "develops within days to weeks." The CME never discloses the heightened risks opioids pose to elderly patients (see below).



59. Endo sponsored materials aimed not only at doctors, but also at patients. As an example, a 2009 patient education publication, *Pain: Opioid Therapy*, posted on painknowledge.org and funded by Endo, omitted addiction from the "common risks" of opioids, as shown below:



As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

60. As noted above, Endo's misrepresentations and omissions of the risk of addiction are contrary to longstanding scientific evidence. In 2013, the FDA emphasized the "known serious risk[] of . . . addiction"—"even at recommended doses"—of all opioids."[8] The risk of addiction and overdose, particularly with chronic use, is well-established.

61. The FDA also has made clear that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a serious risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome, also known as neonatal abstinence syndrome or NAS], addiction, overdose, and death." (Emphasis added.) According to the FDA, because of the "known serious risks" associated with long-term 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. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

[8] FDA CDER Response to Physicians for Responsible Opioid Prescribing Partial Petition Approval and Denial, September 10, 2013.

62. The warnings on Endo's own FDA-approved drug labels caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids. (Emphasis added.) Endo's marketing of opioids contradicted, and thus neutralized, its own labels.

C. Endo Created a False Sense of Security by Misleadingly Portraying the Efficacy of Screening Tools.

63. Endo falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allowed them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Endo aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Confidence that doctors could, without much effort, identify patients not at risk of addiction was an important step in making prescribers comfortable with long-term opioid therapy.

64. Endo sales representatives suggested or implied to Kentucky prescribers that if patients were screened and monitored, they could be safeguarded from addiction.

65. An Endo-sponsored 2007 supplement to the *Journal of Family Practice* contained an article, *Pain Management Dilemmas in Primary Care: Use of Opioids*, which recommended risk screening. Supplements are paid sections of medical journals that do not require peer - review, but can be influential with doctors because of their inclusion in otherwise validated scientific journals. The article claimed that even patients at high risk of addiction could be safely treated with opioids through "a maximally structured approach" including toxicology screens and pill counts. The supplement recommended the Opioid Risk Tool (ORT) a five-question test developed by Endo-supported KOL Dr. Lynn Webster, which, unreliably, relied on patients to

self-identify current or past substance abuse, sexual abuse, or mental illness. The ORT was linked to by Endo-supported websites, as well. Upon information and belief, given that the Journal of Family Practice is a nationally-distributed journal, this misrepresentation would have reached Kentucky prescribers.

66. These claims were false and unsupported at the time they were made by Endo. There have been no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—for improving outcomes related to overdose, addiction, abuse, or misuse. Endo Encouraged Doctors to Disregard Addiction as "Pseudoaddiction."

67. Dr. Russell Portenoy, a KOL for Endo and other manufacturers popularized the term "pseudoaddiction"—used to describe a purported phenomenon in which signs of addiction are actually signs of undertreated pain. Thus, doctors who encounter patients on opioids who seem unduly focused on their drugs should respond not by assessing or addressing potential addiction, should prescribe additional opioids. Thus, pseudoaddiction, which has no competent scientific support and was based only on the observation of a single patient in a hospital setting, served two marketing purposes. First, it persuaded doctors who observed signs of addiction that patients were not actually addicted—allowing them to feel comfortable continuing to prescribe opioids. Second, it turned doctors' observations of addiction—the very fear that limited the prescribing of opioids—into cause to sell even more drugs, since the response to "pseudoaddiction" is more opioids. This is the medical equivalent of fighting fire by adding fuel.

68. [redacted]

[redacted]

69. Consistent with that training, Endo has described pseudoaddiction as a true phenomenon in detailing in Kentucky.

70. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo went as far as to list "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.

71. Upon information and belief, Endo itself has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the New York Attorney General, in a 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in

distinguishing "between addiction and 'pseudoaddiction.'"[9] Endo thereafter agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

D. Endo Downplayed the Difficulty of Opioid Withdrawal.

72. To downplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Endo had to make it appear that doctors could also easily end opioid therapy. Endo falsely claimed that withdrawal from opioids could be managed by gradually reducing patients' doses, and failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

73. Withdrawal symptoms include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction. Patients' experience of withdrawal, and their extreme fear of it, makes it very difficult for them to cease using opioids, especially after they have used them for any significant period of time.

74. However, Endo sales representatives failed to disclose the difficulty of withdrawal when detailing doctors in Kentucky, even though Endo knew of scientific evidence that patients experienced withdrawal, and grossly understated the difficulty of tapering doses after chronic use.

75. In addition, Endo sponsored an unaccredited 2011 CME, titled *Persistent Pain in the Older Adult*, which claimed that withdrawal symptoms could be avoided entirely by tapering a patient's opioid dose by 10%-20% for 10 days. However, particularly after high-dose, long-term use, withdrawal from opioids can be extremely difficult, both psychologically and

[9] Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.: 15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

physically, and, upon information and belief, Endo had no evidence to indicate that gradually reducing opioid doses would avoid those difficulties.

E. Endo Omitted or Misrepresented the Risks of Higher Doses.

76. The ability to escalate doses was critical to Endo's efforts to market opioids for chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower doses did not provide pain relief. [redacted] Thus, it was in Endo's interest not to disclose the greater risks of high dose opioids, and Endo falsely claimed that doctors and patients could increase opioid doses indefinitely without added risk and failed to disclose the greater risks to patients at higher doses.

77. In detailing doctors in Kentucky, Endo failed to disclose that patients faced greater risks of addiction, overdose, and other adverse effects at higher doses. Endo's exhortations to doctors not to undertreat pain—which would require prescribing opioids at higher and higher doses as patients build up tolerance, show signs of "pseudoaddiction," or otherwise fail to benefit from the drugs—made Endo's omission of the risks of high-dose opioids particularly dangerous and misleading.

78. Painknowledge.com, the NIPC website sponsored by Endo, claimed in 2009 in a piece aimed at patients, that opioid doses may be increased until "you are on the right dose of medication for your pain." The website was accessible online until at least 2012.

79. Endo distributed a pamphlet for patients, *Understanding Your Pain: Taking Oral Opioid Analgesics*, which is available online. In question and answer format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be

increased . . . You won't 'run out' of pain relief." The pamphlet does not disclose greater risks as patients' doses are increased.

80. Endo was aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

F. Endo Overstated the Benefits and Failed to Disclose the Lack of Evidence for Long-Term Opioid Therapy for Chronic Pain.

81. To convince doctors and patients that opioids should be used to treat chronic pain, Endo also had to persuade them that there was a significant upside to long-term opioid use. To that end, Endo's branded advertisements deceptively portrayed the benefits of opioids for chronic pain and failed to disclose the lack of evidence for long-term opioid therapy for chronic pain.

82. In detailing doctors in Kentucky, Endo claimed that its opioids were for or would provide functional improvement and failed to disclose the lack of evidence for long-term opioid therapy.

83. [redacted]

84. Painknowledge.org, the NIPC website sponsored by Endo, promised patients that, on opioids, "your level of function should improve; you may find you are now able to participate

in activities of daily living such as work and hobbies, that you were not able to enjoy when your pain was worse." The website also listed improved quality of life and "improved function" as benefits of opioid therapy.

85. Not only did Endo not have evidence to support its functional-improvement claims, Endo knew that a study had shown that, for some chronic pain patients treated with opioids, their pain became worse, not better.

86. A roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."[10] APF failed to disclose these reservations in its highly pro-opioid materials.

87. No reliable evidence establishes that opioids improve patients' chronic pain or function over the long-term or that opioids work better than alternative, less risky treatments. There are no studies that follow patients for more than a year, and most randomized controlled trials (considered the benchmark for medical studies) are for six weeks or less. The FDA has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."

88. The most recent Diagnostic and Statistical Manual of Mental Disorders, or DSM, classifies opioid use disorder (or addiction) as a problematic pattern of use that can cause distress or clinically significant impairment, such as inability to fulfill major role obligations. As a

[10] Micke A. Brown and Amanda Crowe, Highlights from the American Pain Foundation's Roundtable. Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management, 2(2) Advances in Pain Mgmt. 93, 94 (2008).

matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

89. Despite this, Endo falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

G. Endo Exaggerated the Side Effects of Competing Products While Downplaying or Failing to Disclose Side Effects of Opioids.

90. Endo also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain.

91. [redacted]

92. As another example, the Endo-sponsored a CME put on by NIPC, *Persistent Pain in the Older Adult*, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have "possibly less potential for abuse than in younger patients," and does not list respiratory depression among the adverse effects.

93. Endo routinely failed to disclose in its educational and marketing materials the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[11] in which the patient becomes more sensitive to certain painful stimuli over time; or experiences hormonal or endocrine dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome ("NAS") (when an infant exposed to opioids prenatally painfully withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are often also used by pain patients to treat post-traumatic stress disorder and anxiety.

94. Once again, these misrepresentations and omissions contravene findings by and guidance from the FDA based on the scientific evidence. Indeed, the FDA changed the labels for ER (extended release) opioids in 2013 and IR (immediate release) opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate."

H. Endo Revived Its Sales, and Endangered Patients, by Deceptively Portraying Reformulated Opana ER as Abuse Deterrent.

95. [redacted] While the marketing, use, and abuse of Endo's opioids were not the only causes of the opioid epidemic, Endo was conscious of the impact that the epidemic would have on its sales. In addition, Endo was aware that it would soon face generic competition[12] for Opana ER and that it needed to be able to compete with other opioids, like OxyContin, that were being introduced in abuse-deterrent

[11] *See* n. 8, *supra*.
[12] Generic versions of Opana ER did appear at certain strengths in July 2011 and at others in January 2013.

formulations. [redacted]

96. However, Opana ER was particularly likely to be the tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanisms remain intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%, a phenomenon sometimes called "dose-dumping." [redacted]

97. In December 2011, Endo obtained approval for a new formulation of Opana ER that it claimed was crush-resistant. The new version had the same oxymorphone as the active ingredient and, like the original versions, was an extended release pill. Its inactive ingredients differed, with the main feature being a hard coating. Endo "did not submit any new clinical safety or efficacy data" as part of its application, but rather relied entirely on the "bioequivalence" of the new and old formulations of Opana. Obtaining approval of reformulated Opana ER on this basis allowed Endo to rely on the original version of the drug as the basis for approval of the reformulated version.[13] The FDA told Endo, however, in January 2011 that it

[13] Intervenor Impax Laboratories, Inc.'s (1) Cross-Motion to Dismiss; or, in the Alternative, (2) Opposition to Plaintiff's Motion for a Preliminary Injunction, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.* ("Impax Br."), No. 1:12-cv-01936 Doc. 18 at 7 (D.D.C. Dec.9, 2012); *see also* FDA Summary Review for Regulatory Action, NDA 201655 (Dec. 9, 2011) (stating that "[n]o new safety data were included in this submission" and "[n]o efficacy studies were submitted in this application.").

could not market Opana ER, even after the reformulation, as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. In December 2011, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

98. [redacted]

99. Endo also was well aware that once a person becomes addicted and begins to abuse opioids, crush or tamper-resistant features would not prevent them from abusing Opana ER. [redacted]

100. [redacted]

[redacted]

101. On August 10, 2012, the company submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER and help preserve +

102. the market for reformulated Opana ER, which could be sold at non-competitive prices. (A second, similar Citizen Petition and supplements to the petition followed in 2012 and 2013.) This was not a theoretical concern: Impax Laboratories ("Impax") had sought FDA approval to sell a generic version of Opana ER.[14] Endo claimed, however, that original Opana ER, was being withdrawn for safety reasons because of its potential for abuse.

103. Endo acknowledged its true motivation in court filings seeking to expedite the FDA's ruling on the Citizen Petition. In a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's

[14] Litigation between Impax and Endo followed, culminating in a settlement in which Impax agreed to delay its generic competitor to Opana ER until 2013. Despite Endo's prior objections that a generic copy of Opana ER would be unsafe, Endo's agreement with Impax enabled it to share profits from those generic sales. In March of 2016, the Federal Trade Commission filed a complaint against Endo, alleging that Endo's agreement with Impax was an unlawful pay-for-delay agreement in violation of the antitrust laws.

revenue by up to $135 million per year.[15] Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.[16] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[17]

104. Meanwhile, despite Endo's purported concern with public safety, court filings indicate that not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers.[18] In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[19]

105. In its Citizen Petition, Endo claimed redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when

[15] Decl. of Julie H. McHugh in Support of Plaintiff's Motion for Preliminary Injunction and Opposition to Defendants' Motions to Dismiss, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 28 (D.D.C. Dec. 18, 2012)

[16] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[17] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[18] Impax Br., Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.., No. 1:12-cv-01936 Doc. 18 at 1 (D.D.C. Dec.9, 2012).

[19] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER also be "readily prepared for injections and more easily injected[.]" Finally, the FDA warned that preliminary data—including in Endo's own studies—suggested the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.[20]

106. Over time, evidence confirmed that injection was becoming the preferred means of abusing Opana ER, which made Opana ER *less safe* than the original formulation. This occurred both because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.[21] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500% according to data gathered in 2017. [redacted]

107. Despite having only about 10% of the sales of OxyContin, abuse of Opana ER surpassed abuse of OxyContin by 2012, and was particularly pronounced in Kentucky. FDA data demonstrated, that per dosing unit, Opana ER had four-times as many incidents of

[20] *See* May 10, 2013 FDA Decision, at 8 n.25 (post-marketing data available at that time (May 2013) "appear to suggest that a greater (and rising) percentage of Opana ER abusers are abusing Opana ER via injection since the replacement of [original Opana ER] with [Reformulated Opana ER] in the market.")

[21] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

intentional abuse than OxyContin between 2013 and 2016. In 2015, Opana ER commanded as much as $100 to $150 per pill on the street – a strong sign of its attractiveness to abusers.[22]

108. [redacted]

109. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to “a very, very distinct area of the country."

110. Yet, Endo itself presented data in 2014 that found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% of the old formulation.[23]

111. Neither its actual awareness of high rates of injecting Opana ER, nor the FDA’s denial of its abuse-deterrent labeling or Citizen Petition stopped Endo from continuing to market the drug in Kentucky, as elsewhere, as tamper-resistant and effective in reducing or stopping abuse.

[22] Deborah Highland, Opana Brings Deadly Threat, Bowling Green Daily News (Jul 23, 2015), Heroin in Kentucky: Drug surges as Kentucky cracks down on pain pills, Courier-Journal, May 16, 2014.

[23] Theresa Cassidy, The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations,” Pain Week Abstract 2014, available at: https://www.painweek.org/assets/documents/general/724-painweek2014acceptedabstracts.pdf

112. In detailing doctors in Kentucky after the reformulation, Endo promoted reformulated Opana ER as safer than original Opana ER and other opioids and less likely to be abused or diverted. In fact, numerous Kentucky prescribers recall its abuse-deterrence as Endo's primary marketing message for Opana ER. One prescriber, for instance, reported that doctors who had stopped prescribing Opana ER because of its abuse, considered prescribing it again once it was marketed as abuse-deterrent.

113. A review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

114. The message reached the general public, too. The Bowling Green Daily News reported as recently as July 2015 that "Opana [ER], the brand name medication, contains an abuse-deterrent feature that prevents users from crushing the pill for snorting or injecting. Many generics don't have this feature." One substance abuse provider recalled that Opana ER was supposed to be a "wonder drug" that could not be injected, but that clients showed her how easily the pills could be prepared for injection.

115. In its written materials, Endo continued to market Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush

resistant."[24] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[25] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[26] Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." [redacted] Endo branded promotional materials, including its promotional website for Opana ER, which was accessible to and designed for both patients and providers, also failed to disclose the FDA's denial of its abuse-deterrent labeling, Endo's own studies showing that Opana ER was susceptible and in fact continued to be abused, and the FDA's findings that Opana ER is easier to inject than original Opana ER. At no time during this period, did Endo correct its misrepresentations to Kentucky prescribers or disclose the evidence that Opana ER was not only no safer than original Opana ER, but less safe.

117. Rather than correct the record, sales representatives were given the following talking points in an internal email in July 2012 to use for doctors who asked about news reports of addiction and abuse:

[24] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[25] *Id*.

[26] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

- "Endo takes the problem of prescription drug abuse very seriously and is strongly committed to providing solutions to the medical needs of patients who suffer from chronic pain[;]" and

- "Part of [Endo's] corporate mission is a commitment to educating physicians and patients about the appropriate and responsible use of pain management therapies."

Nowhere in these talking points was any recognition of the growing problem of Opana ER abuse.

118. In March 2017, because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.[27] Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER. However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."[28]

I. Endo Fraudulently Concealed Its Misconduct.

119. Endo made, promoted, and profited from deceptive marketing about the risks and benefits of opioids for chronic pain even though it knew that its misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes.

120. Over the past decade, the Commonwealth has continued to aggressively work to combat the opioid epidemic within its borders. It has targeted pill mills, disciplined doctors,

[27] Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, *available at*: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm

[28] July 6, 2017 press release, Endo Provides Update on Opana ER, http://www.endo.com/news-events/press-releases

nurses, and pharmacists, and worked to provide support and treatment services to individuals and families affected by addiction and overdoses.

121. Meanwhile, Endo, shrouded by its promises of relieving suffering and preventing abuse, has profited from the crisis.

122. Endo had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use, and Opana ER in particular, that patients were suffering from addiction, overdoses, and death in alarming numbers.

123. Rather than disclose that information, Endo took steps to avoid detection of and to fraudulently conceal its deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Endo disguised its own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like front groups and KOLs. Endo also manipulated its promotional materials and messages to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. It also failed, until required by its settlement with the New York Attorney General, to disclose studies, such as Study 108 and Study 109, regarding Opana ER's crushability that undermined its promotional claims.[29]

124. The lack of support for Endo's deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could the Commonwealth have reasonably been expected to detect Endo's deception.

[29] http://www.endo.com/endopharma/r-d/clinical-research/clinical-trial-study-results (last visited Oct. 23, 2017)

125. Thus, Endo successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the Commonwealth now asserts.

J. Endo Fueled and Profited from a Public Health Epidemic That Has Significantly Harmed the Commonwealth and Devastated Thousands of Its Citizens.

126. The vast market for opioids was created and sustained in significant part by Endo's deceptive marketing in establishing opioids as a first-line treatment for chronic pain and its equally deceptive promotion of reformulated Opana ER as abuse-deterrent. Endo's deceptive marketing caused patients to believe they would not become addicted, addicted patients to seek out more drugs, and health care providers to make and refill opioid prescriptions that maintain dependence and addiction.

127. Endo's marketing, and especially its detailing to doctors, has been effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Endo necessarily expected a return on its multi-million dollar investment in opioid marketing, and carefully calibrated its promotional efforts to serve that end.

128. Overall sales of prescription opioids in Kentucky have skyrocketed. From 2006 to 2015, the Commonwealth had more opioid prescriptions than people. In 2015, Kentucky ranked sixth in the nation in opioid-related deaths.[30] In 2016, 97.2 opioid prescriptions were written for every 100 Kentucky residents.

[30] Dan Clark, *Do Some States Have More Opioid Prescriptions than Residents?*, Politifact New York (Sept. 19, 2017); *see also* CDC prescribing data listing 122.6 as the prescription rate for KY in 2006, 130.8 in 2007, 136.6 in 2008, 135.2 in 2009, 136.5 in 2010, 137 in 2011, 127.9 in 2012, 111.7 in 2013, 110 in 2014, and 102.6 in 2015: https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

129. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are now the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

130. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

131. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."

132. 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."[31] 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."

[31] Theodore J Cicero *et al*., *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban Locations* in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

133. Most opioid addiction begins with legitimately prescribed opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. A study of 254 accidental opioid overdose deaths in Utah found that 92% of the decedents had been receiving prescriptions from health care providers for chronic pain. Sales to patients who doctor-shop (or visit multiple doctors to hide illicit or over-use) constitute approximately only 1% to 2% of opioid volume. This study is consistent with the observations of a Kentucky law enforcement officer, who perceived Endo's Percocet and heroin as among the most abused drugs in Franklin County. In his experience, which was confirmed by addiction treatment providers in Kentucky, prescription opioid abuse stemmed from overprescribing opioids, and almost all heroin abuse begins with prescription opioid abuse.

134. The escalating number of opioid prescriptions written by doctors who were deceived by Endo's deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout Kentucky.

135. Addiction has consumed the lives of countless Kentuckians 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.

136. The Commonwealth has incurred considerable costs in treating opioid addiction. At the beginning of 2014, the Medicaid program spent roughly $56 million on behavioral health and substance abuse treatment. By the end of 2016, Kentucky was spending about $117 million

in Medicaid money on those treatments. In addition, the Commonwealth is also providing funding to treat addiction among inmates in its corrections system.

137. In 2016, there were 1,404 reported fatal drug overdoses in Kentucky – 117 per month. This was a 7.4% increase from 2015, a year which, in turn, had seen in a 25% increase in fatalities from drug overdoses as compared to 2013. Altogether, between 2012 and 2016, drug overdoses claimed a total of 5,822 Kentuckians.

138. In the first month of 2017 alone, Louisville saw 695 overdoses (a figure which includes prescription drugs, illicit drugs, and alcohol). Louisville Metro Emergency Medical Services received 151 of these overdose calls within just four days.

139. The use and misuse of opioids have had an especially severe impact on veterans in Kentucky. Between 2010 and 2015, there were 452 fatal drug overdoses in Kentucky's military and veteran populations. That number has continued to rise – increasing from 46 in 2010 to 95 in 2015. The most frequently detected drug involved in these deaths was prescription opioids, which were found in 46.5%—nearly half—of all military and veteran fatal overdoses. The toll of overdoses and addiction is tied to the widespread prescribing of opioids to veterans in Kentucky. Between 2001 and 2012, there were 145.6 opioid prescriptions per 100 patients at the Lexington Veterans Affairs Medical Center.

140. Opana ER and its generic form, oxymorphone, were linked to many of the overdoses. In 2010, there was a spike in abuse and overdose from Opana ER across the United States, but particularly pronounced in Kentucky. The same year, toxicology reports showed that oxymorphone was involved in 2% of the state's overdoses, according to the Kentucky Office of Drug Control Policy. By 2011, oxymorphone was found in the blood of 23% of people who overdosed.

141. 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. [redacted] In the context of discussing generic versions of Opana, Endo recognized this phenomenon: "[a]n experienced drug abuser is omnipotent about what is available to abuse and is willing to migrate to the greatest value. . . They will seek to get the most for their money and for the least effort." In fact, some users migrate to heroin (sometimes with fentanyl) they buy on the street.

142. Nationally, roughly 80% of heroin users previously used prescription opioids. In Kentucky, toxicology reports showed that 34% of fatal overdoses in Kentucky in 2016 involved the use of heroin, while fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, is has made its way into Kentucky communities through trafficking, contributed to nearly half of the fatal overdoses with 623 lethal doses. One treatment provider confirmed that, in his experience, most heroin users started with prescription opioids.

143. 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. For example, Louisville Metro Police Major, Eric Johnson, said that the police force administered 123 doses of naloxone in one six-week period between January 1st and February 15th, 2017. One opioid addiction treatment center in Paducah, Kentucky doubled in size to meet the growing needs of the community. The center reports seeing as many 300 patients, of all ages and from all backgrounds, for addiction to prescription opioids, including Endo's Percocet, heroin, and

fentanyl. Law enforcement officers in Kentucky similarly observed opioid addiction and abuse affecting people across varying ages and demographics.

144. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a 2016 study by a Princeton economist, the increase in opioid prescriptions from 1999 to 2015 could account for roughly 20% 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.

145. Prescription drug abuse causes an increase in crimes such as domestic violence, burglaries, and thefts. An estimated 90% of defendants in Floyd County are prosecuted for crimes related to prescription drug abuse or diversion. A report from a 2012 Prescription Drug Abuse Summit in Kentucky noted that the "pill explosion" had increased armed robberies to 6 per month in areas of Kentucky when there were previously two to three per year in the same area. Domestic violence, burglaries, thefts, and driving under the influence are also now commonly linked to opioid use. One corrections officer estimated that nearly all of the inmates in a Woodford County jail as struggling with addiction, that almost all of the inmates with drug problems started with abusing opioids, and that 90% of the crimes for which they were convicted were drug related.

146. The abuse of opioids, especially Opana ER, have caused outbreaks of HIV, chronic Hepatitis C, and TTP. The increase is largely a result of intravenous drug use stemming from the opioid epidemic, particularly the greater ease of injecting reformulated Opana ER. A study of upstate New York intravenous drug users in 2012 found that nearly half injected Opana ER. This study further found that people injecting prescription opioids, of which Opana ER was

the most common, had higher rates of Hepatitis C than people who injected other drugs like heroin. Beyond the ease with which it can be made syringeable, Opana ER is particularly likely to be connected with the transmission of disease because of its high potency; withdrawal is more pronounced (there is a bigger crash), which causes intravenous users to use it more frequently to avoid withdrawal. Because Opana ER is both more expensive and requires greater frequency of use, users are more likely to share needles in order to share the drug.

147. In 2015, nearby Scott County, Indiana reported a cluster of 160 new cases of HIV (most of whom also had Hepatitis C). Most of those who were infected had shared needles to inject Opana ER. Prompted by this outbreak, in 2016 the CDC published a report which listed the top counties in the nation that are at risk of spreading HIV and Hepatitis C due to injecting drugs. Of the top 220 counties, 54 were located in Kentucky, and 18 counties were deemed more vulnerable than Scott County, including Wolfe County, which had the greatest risk in the United States. One researcher who has tracked 503 drug users since 2008 found that 70% of them have contracted Hepatitis C. St. Elizabeth Healthcare in Edgewood reports that it sees up to ten new cases of Hepatitis C daily.

148. In 2016, the Commonwealth spent $69.7 million on pharmacy claims to provide Hepatitis C drugs to 833 patients (which does not include the costs of testing for the infection or other treatment-related costs). The list price for a course of treatment ranges from $84,000 to close to $100,000. The total number of state Medicaid enrollees with a diagnosis of Hepatitis C increased from 8,000 in 2013 to 16,000 in 2014, though the CDC estimates that 90% of infections are unreported because the patients are still not symptomatic. If untreated, Hepatitis C continues to be transmitted (including in childbirth, which has become increasingly common in

Kentucky), ultimately can cause liver cancer, fibrosis, or cirrhosis, and is the leading cause of liver transplants in the country.

149. Children have not been spared by the opioid crisis. As of June 2017, there were over 8,000 children in foster care in Kentucky, compared to 6,000 in 2012, most commonly because of parent's abuse or drugs or alcohol. According to one foster-parent recruiter, the increasing number of children in foster care in Ashland, Kentucky has reached a "crisis point" as a result of the opioid epidemic.[32]

150. School districts also have seen a dramatic increase in suspensions of high school students found possessing, distributing, or under the influence of prescription drugs.

151. 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. In Kentucky, from August 1, 2014 until July 31, 2015, there were 1,234 cases of NAS reported to the Kentucky Department of Public Health. This translates to about 100 newborns per month.

[32] States hit hard by opioid crisis see increase in foster care kids, North Jefferson News, Jan. 19, 2017.

152. While the use of opioids has taken an enormous toll on the Commonwealth and its residents, Endo has realized billions of dollars in revenue from use of its opioids for chronic pain and its sales of reformulated "abuse-deterrent" Opana ER as a result of its deceptive, unfair, and unlawful conduct.

VI. CAUSES OF ACTION

COUNT I

Violations of Kentucky Consumer Protection Act

(KRS 367.110 *et seq.*)

153. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

154. Kentucky's Consumer Protection Act ("KCPA"), KRS 367.110 *et seq.* prohibits "unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." KRS 367.170.

155. Under KRS 367.190, "[w]henever the Attorney General has reason to believe that any person is using, has used, or is about to use any method, act or practice declared by KRS 367.170 to be unlawful, and that proceedings would be in the public interest," he may seek injunctive relief.

156. Under KRS 367.200, "[t]he court may make such additional orders or judgments as may be necessary to restore to any person in interest any moneys or property, real or personal, which may have been paid out as a result of any practice declared to be unlawful by KRS 367.130 to 367.300."

157. The Commonwealth is included among the persons in interest to whom the Court may order restoration of money or property under KRS 367.200.

158. At all times relevant to this Complaint, Endo, directly, through its control of third parties, and/or by aiding and abetting third parties, violated the KCPA by making or causing to be made, and by disseminating unfair, false, deceptive, and misleading statements and statements that were false and misleading by virtue of material omissions, to Kentucky prescribers and consumers to promote the sale and use of opioids to treat chronic pain. These unfair, false, deceptive, and misleading statements included, but were not limited to:

a. Mischaracterizing the risk of opioid addiction and abuse;

b. Claiming or implying that addiction can be avoided or successfully managed through the use of screening and other tools;

c. Promoting the misleading concept of pseudoaddiction, thus concealing the true risk of addiction;

d. Mischaracterizing the difficulty of discontinuing opioid therapy, including by mischaracterizing the prevalence and severity of withdrawal symptoms;

e. Claiming or implying that increased doses of opioids pose no significant additional risk;

f. Misleadingly depicting the safety profile of opioids prescribed by minimizing their risks and adverse effects while emphasizing or exaggerating the risks of competing products, including NSAIDs;

g. Creating a false sense of security by stating or implying that Opana ER was crush resistant and/or effective in deterring abuse;

h. Claiming or implying that opioids would improve patients' function and quality of life.

159. Endo knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions to be made or disseminated, that they were unfair, false, deceptive, and misleading and therefore likely to deceive the public. In addition, Endo knew or should have known that its marketing and promotional efforts created an unfair, false, deceptive, and misleading impression of the risks, benefits, and superiority of opioids generally and its opioids in particular.

160. Endo failed to disclose or misrepresented clinically significant risks of Opana, Opana ER, Percocet, Percodan, and opioid therapy to Kentucky consumers and their doctors. At all times relevant to this Complaint, Endo directly, through its control of third parties, and/or by aiding and abetting third parties, violated the KCPA by engaging in unfair acts or practices to promote the sale and use of opioids to treat chronic pain. These acts or practices are unfair in that they are unconscionable, offend public policy; are immoral, unethical, oppressive, or unscrupulous.

161. Endo's unfair acts or practices include, but are not limited to:

a. Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;

b. Engaging in untrue, false, unsubstantiated, and misleading marketing;

c. Deliberately using unbranded marketing to evade FDA oversight and rules prohibiting deceptive marketing; and

d. Deliberately using the funding and/or control of third parties to avoid regulatory scrutiny of its marketing and to mislead consumers into believing that claims being made by KOLs and front groups were those of objective, independent professionals untainted by financial interest in the success of Endo's drugs or the use opioids to treat chronic pain.

162. Endo's conduct also was oppressive to both patients and prescribers. Patients are laypersons and lack the medical expertise to independently assess pharmaceutical marketing. Physicians, in turn, are inclined to trust the advice of KOLs, front groups, and other seemingly independent sources of objective medical information. By engaging in the conduct described above, Endo co-opted the sources reasonable physicians relied upon to convince those physicians that the risks related to opioids were minimal, that the benefits were substantial, and—as a result—that opioids were medically necessary to treat their patients' chronic pain. Endo also deliberately targeted non-specialist physicians and non-physician prescribers, who lacked the

time and expertise to evaluate their deceptive claims. It also undermined even the ability of doctors to protect their patients, even once the toll of abuse and addiction become known, by falsely marketing Opana ER as safer and abuse-deterrent.

163. As a direct result of the foregoing acts and practices, Endo received, or will receive, income, profits, and other benefits, which it would not have received if they had not engaged in the violations of the KCPA described in this Complaint and which should rightfully the restored to the persons from which Endo obtained those funds.

164. Finally, Endo's conduct has caused substantial, indeed grievous, injury to Kentucky persons. The staggering rates of opioid use, abuse, and addiction resulting from Endo's marketing efforts have caused substantial injury to the Commonwealth, its residents, and to businesses including, but not limited to:

a. Upwards of 30% of all adults have used opioids, with the vast majority of the use stemming from prescribing for chronic pain conditions.

b. A substantial number of Kentucky residents prescribed opioids long-term for chronic pain have experienced the life-upending effects of addiction, abuse, misuse, overdose and death. For those who can stop taking narcotic opioids, there are years of struggling with the pull of the drugs and the fear of relapse (and often relapse itself), counseling sessions, or lining up each morning for daily maintenance drugs. And those who cannot overcome the need for opioids must deal with the compulsive use of and need for opioids, the haziness when they are on the drugs, and the nearly constant struggle to maintain their supplies of the drugs, whatever the cost. Both groups face a dramatically heightened risk of serious injury or death and sometimes an unrecoverable toll on their health, work, and family.

c. Elderly Kentuckians and Kentucky veterans are particularly vulnerable to serious adverse outcomes, including overdose, injury, and death;

d. Kentuckians, including thousands of infants and children, who have never taken opioids also have also been and continue to be injured. Infants have suffered NAS and painful withdrawal, children lost parents [and even grandparents] and/or been displaced from homes, and adults have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

e. Kentuckians have incurred health care costs due to the prescription of opioids for chronic pain and the treatment of opioids' adverse effects, including addiction and overdose.

f. Endo's success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. This increased demand also has created additional illicit markets in other opiates, particularly heroin. Patients addicted to opioids frequently migrate to lower-cost heroin, with the serious personal costs that accompany their use of unlawful drugs.

h. All of this has caused substantial injuries to the Commonwealth and its residents—in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken lives, families, and homes.

165. These profound injuries are not outweighed by any countervailing benefits to consumers or competition since there is no benefit from the deceptive marketing of these narcotic drugs. Moreover, no public policy justifies Endo's conduct in overstating the benefits, denying or downplaying the risks, and misrepresenting the superiority of opioids for chronic pain, which deprived patients and doctors of the honest and complete information they need to make informed choices about their treatment. In light of this campaign of misinformation (and especially given the addictive nature of these drugs), the injuries caused by Endo's misconduct could not reasonably have been avoided by those Endo harmed.

166. Endo's acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other Kentucky government functions, and caused significant actual harm.

167. For each of Endo's willful violations of KRS 367.170, the Commonwealth is entitled to recover a civil penalty of not more than two thousand dollars ($2,000) per violation, or a civil penalty of not more than ten thousand dollars ($10,000) per violation where Endo's conduct is directed at a person aged sixty (60) or older and Endo knew or should have known

that the person aged sixty (60) or older is substantially more vulnerable than other members of the public.

168. The Commonwealth is entitled, pursuant to KRS 367.200, to restoration of moneys paid out when the Commonwealth paid for prescription opioids as a direct result of Endo's violations of the KCPA and the ongoing expenditures for additional medical care and provision of other services that the Commonwealth has been required to make as a direct result of the violations alleged herein.

COUNT II

Violations of Kentucky Medicaid Fraud Statute

(KRS 205.8463; KRS 446.070; KRS 205.8469(1))

169. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

170. KRS 205.8463 is violated when any person "intentionally, knowingly, or wantonly make[s], present[s], or cause[s] to be made or presented to an employee or officer of the Cabinet for Health and Family Services any false, fictitious, or fraudulent statement, representation, or entry in any application, claim, report, or document used in determining rights to any benefit or payment." KRS 205.8463(2).

171. It is likewise a violation of KRS 205.8463 for any person to "in any matter within the jurisdiction of the Cabinet for Health and Family Services under this chapter, knowingly falsify, conceal, or cover up by any trick, scheme, or device a material fact, or make any false, fictitious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry." KRS § 205.8463(4).

172. Under KRS 205.8469(1), "[t]he Attorney General, on behalf of the Commonwealth, may commence proceedings to enforce KRS 205.8451 to 205.8483."

173. Additionally, KRS 446.070 provides that "[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation."

174. Endo's practices, as described in the Complaint, violated KRS § 205.8463(2) & (4). Endo, through its deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used a false statement, or statement which concealed or covered up a material fact, to get a false or fraudulent claim paid or approved by a program within the jurisdiction of the Cabinet for Health and Family Services.

175. The Cabinet for Health and Family Services administers the Medicaid program ("Medicaid") in Kentucky. Medicaid was created in 1965 and operates under Title XIX of the Social Security Act. Medicaid is a cooperative venture between the Federal and State governments to assist States in the provision of medical care to their poorest and most vulnerable citizens, including the poor, the disabled, the elderly, the blind, pregnant women, infants and dependent children. Medicaid is the largest program providing medical and health-related services to America's poorest people.

176. Within broad federal statutory and regulatory guidelines a State: (a) establishes its own eligibility standards; (b) determines the type, amount, duration, and scope of services; (c) sets the rate of payment for services; and (d) administers its own program. These statutes and regulations are set forth generally in the Grants to States for Medical Assistance Programs sections of the United States Code (42 U.S.C. § 1396 *et seq.*) and the Code of Federal

Regulations (42 C.F.R. § 430 *et seq.*). The Medicaid program is administered at the federal level by the United States Department for Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

177. The Medicaid program is administered at the State level by the Kentucky Department for Medicaid Services ("Kentucky Medicaid"). The Kentucky Department for Medicaid Services is a body politic created by the Kentucky Constitution and laws of the Commonwealth of Kentucky and, as such, is not a citizen of any State. The Department for Medicaid Services is an agency of the Executive Branch of Kentucky State Government and is the single state agency charged with administration of the Kentucky Medicaid program pursuant to Title XIX of the Federal Social Security Act, 42 U.S.C. § 1396a(a)(5), 42 C.F.R. § 431.10, 42 C.F.R. § 100, KRS 12.020(II)(8)(k), KRS 194A.030(2), Chapter 205 of the Kentucky Revised Statutes, Title 907 of the Kentucky Administrative Regulations and other applicable law.

178. Medicaid currently covers 1,394,761 Kentucky adults and children, over a third of the current population of approximately 4,436,000.

179. Endo knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting the Commonwealth's Medicaid program to pay for opioids for long-term treatment of chronic pain. In addition, Endo knew or should have known that its marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

180. Endo's misrepresentations and/or omissions were likely to deceive and confuse, and did actually deceive and confuse, Kentucky health-care providers into prescribing opioids that they would not otherwise have prescribed.

181. Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the Commonwealth's Medicaid program for payment.

182. The Commonwealth's Medicaid program only covers the costs of care that "meets professionally recognized standards," is not obtained through fraud, material misrepresentation, or material omission, or does not constitute "provider abuse." *See* 907 KAR 1:671(40) (defining "unacceptable practice[s]" prohibited by Kentucky's Medicaid regulations). Kentucky's Medicaid regulations expressly provide that it is an "unacceptable practice" to "[k]nowingly submit[], or caus[e] the submission of false claims." 907 KAR 1:671(40)(a). "[I]nducing, or seeking to induce, a person to submit false claims" is also an "unacceptable practice," as are "[k]nowingly making, or causing to be made, or inducing, or seeking to induce, a false, fictitious or fraudulent statement or misrepresentation of material fact in claiming a Medicaid payment, or for use in determining the right to payment" and "[h]aving knowledge of an event that affects the right of a provider to receive payment and concealing or failing to disclose the event or other material omission with the intention that a payment be made or the payment is made in a greater amount than otherwise owed." 907 KAR 1:671(40)(a)-(c). Further, Endo's deceptive marketing with and through KOLs and front groups constitutes conspiracy and complicity, in violation of 901 KAR 1:671(40)(j).

183. Endo's practices, as described in the Complaint, constitute fraud within the meaning of the statute and regulation. Fraud is "an intentional deception or misrepresentation made by a recipient or a provider with the knowledge that the deception could result in some

unauthorized benefit to the recipient or provider or to some other person" and includes any act that constitutes fraud under applicable federal or state law." KRS 205.8451(2)

184. Endo's practices, as described in the Complaint, constitute provider abuse within the meaning of the statute and regulation. Provider abuse captures practices that are "inconsistent with sound fiscal, business, or medical practices, and that result in unnecessary cost to the Medical Assistance Program established pursuant to this chapter, or that result in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care . . . and "includes practices that result in unnecessary cost to the Medical Assistance Program."

185. Doctors, pharmacists, other health care providers, and/or other agents of the Medicaid program expressly or impliedly certified to the Commonwealth that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements Endo disseminated about the risks, benefits, and superiority of opioids for chronic pain. Doctors, pharmacists, other health care providers, and/or other agents of the Medicaid program expressly or impliedly certified to the Commonwealth that it was not paying for "unacceptable practices."

186. As a direct and proximate result of Endo's misrepresentations and/or omissions, Kentucky health-care providers and Kentucky patients were deceived or mislead or were not provided with accurate information about the risks and benefits of using opioids to treat chronic pain.

187. Endo knew or should have known that, as a natural consequence of their actions, governments such as the Commonwealth would necessarily be paying for long-term

prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Endo's fraud. Indeed, Endo acted to maximize its reimbursements from these third party payors.

188. Endo's misrepresentations were material because if the Commonwealth had known of the false statements disseminated by Endo and its third-party allies and that doctors, pharmacists, other health care providers, and/or other agents of programs funded or administered through the Cabinet for Health and Family Services were certifying and/or determining that opioids were medically necessary and reasonably required, the Commonwealth would have refused to authorize payment for, or otherwise severely restricted the use of opioid prescriptions to treat chronic pain.

189. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the Commonwealth.

190. By virtue of the above-described acts, Endo knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Commonwealth to approve and pay such false and fraudulent claims.

191. To the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Endo's deceptive marketing.

192. The Commonwealth, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Endo, paid and continues to pay the claims that would not be paid but for Endo's illegal business practices.

193. By reason of Endo's unlawful acts, the Commonwealth has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Medicaid spending

accounts for more than 30% of all funds appropriated under the 2016-2018 biennium budget.[33] Historically, costs of prescription drugs have represented the largest component of Kentucky's Medicaid budget. These costs have increased over time. Costs of prescriptions written due to Endo's deceptive marketing scheme, and costs of addressing the public health crisis caused or substantially contributed to by that scheme, are direct and proximate results of Endo's violations as alleged herein and a significant financial burden on the Commonwealth. Since 2011, Kentucky has spent more than $33 million to pay for more than 1.2 million prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

194. As a direct and proximate result of Endo's misrepresentations and/or omissions, the rising number of persons addicted to prescription opioids have led to a dramatic increase in social problems, including drug abuse, criminal acts to obtain opioid drugs, including prescription opioids, heroin, and fentanyl, significantly and negatively impacting the public health and the resources provided for Medicaid, emergency, and other services.

195. Because Endo's unbranded marketing caused the doctors to prescribe and the Commonwealth to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Endo caused and are responsible for those costs and claims, as well.

[33] Commonwealth of Kentucky, 2016-2018 Executive Budget, Budget in Brief.

COUNT III

Violations of Kentucky Assistance Program Fraud Statute

(KRS § 194A.505(6); KRS § 194A.990)

196. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

197. KRS 194A.505(6) provides: "No person shall, with intent to defraud or deceive, devise a scheme or plan a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice."

198. Endo, by reason of the acts and/or omissions set forth herein, with the intent to defraud or deceive, devised a scheme or artifice to obtain benefits from the Kentucky Medicaid program that it was not entitled to receive, in violation of KRS 194A.505(6).

199. KRS 194A.505(8) provides: "The Attorney General on behalf of the Commonwealth of Kentucky may commence proceedings to enforce this section, and the Attorney General shall in undertaking these proceedings exercise all powers and perform all duties that a prosecuting attorney would otherwise perform or exercise."

200. KRS 194A.990(5) provides: "Any person who violates KRS 194A.505(1) to (6) shall, in addition to any other penalties provided by law, forfeit and pay a civil penalty of payment to the cabinet in the amount of all benefits and payments to which the person was not entitled."

201. KRS 194A.990(6) provides: "Any provider who violates KRS 194A.505(1) to (6) shall, in addition to any other penalties provided by law, including the penalty set forth in subsection (5) of this section, forfeit and pay civil penalties of: (a) Payment to the State

Treasury's general revenue fund in an amount equal to three (3) times the amount of the benefits and payments to which the person was not entitled; and (b) Payment to the State Treasury's general revenue fund of all reasonable expenses that the court determines have been necessarily incurred by the state in the enforcement of this section."

202. By engaging in the conduct set forth above, Endo violated KRS 194A.505(6), and the Kentucky Medicaid program, as a direct and proximate result, paid for opioid prescriptions that were not medically necessary and will be required to make payments for ongoing medical treatment and care on behalf of Kentucky Medicaid patients in the future.

203. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover damages from Endo in an amount to be proved at trial.

204. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Endo civil penalties in the amount of all benefits and payments to which Endo was not entitled in accordance with the provisions of KRS 194A.990(5).

205. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Endo civil penalties in an amount equal to three (3) times the amount of the benefits and payments to which Endo was not entitled in accordance with the provisions of KRS 194A.990(6)(a).

206. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Endo all reasonable expenses that the court determines have been necessarily incurred by the Commonwealth in the prosecution of this action in accordance with the provisions of KRS 194A.990(6).

COUNT IV

Fraudulent Insurance Acts

(KRS 304.47-020; KRS 446.070)

207. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

208. KRS 304.47-020(1)(a) provides that: "For the purposes of this subtitle, a person or entity commits a 'fraudulent insurance act' if he or she engages in any of the following, including but not limited to matters relating to workers' compensation: (a) Knowingly and with intent to defraud or deceive presents, causes to be presented, or prepares with knowledge or belief that it will be presented to an insurer, Kentucky Claims Commission, Special Fund, or any agent thereof, any written or oral statement as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy or from a 'self-insurer' as defined by KRS Chapter 342, knowing that the statement contains any false, incomplete, or misleading information concerning any fact or thing material to a claim."

209. KRS 446.070 provides that "[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation."

210. The Commonwealth is an employer required to provide workers compensation coverage under KRS 342.001 *et seq*.

211. Endo's practices, as described in the Complaint, violated KRS 304.47-020(1)(a). Endo, through its deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used a false statement, or statement which concealed or covered up a material fact, to get a false or fraudulent claim paid by the Commonwealth's workers compensation insurance.

212. Endo knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting the Commonwealth's workers compensation insurance to pay for opioids for long-term treatment of chronic pain. In addition, Endo knew or should have known that its marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

213. Endo's misrepresentations and/or omissions were likely to deceive and confuse, and did actually deceive and confuse, Kentucky health-care providers into prescribing opioids that they would not otherwise have prescribed.

214. Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the workers compensation program for payment. The Commonwealth's workers compensation program only covers the costs of care that is reasonable and necessary. Doctors, pharmacists, other health care providers, and/or other agents of the workers compensation program expressly or impliedly certified to the Commonwealth that opioids were reasonable and necessary to treat chronic pain because they were influenced by the false and misleading statements Endo disseminated about the risks, benefits, and superiority of opioids for chronic pain.

215. As a direct and proximate result of Endo's misrepresentations and/or omissions, Kentucky health-care providers and Kentucky patients were deceived or mislead or were not provided with accurate information about the risks and benefits of using opioids to treat chronic pain.

216. Endo knew or should have known that, as a natural consequence of their actions, governments such as the Commonwealth would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Endo's fraud. Indeed, Endo acted to maximize its reimbursements from these third party payors.

217. Endo's misrepresentations were material because if the Commonwealth had known of the false statements disseminated by Endo and its third-party allies and that doctors, pharmacists, other health care providers, and/or other agents of the workers compensation program were certifying and/or determining that opioids were medically necessary and reasonably required, the Commonwealth would have refused to authorize payment for, or otherwise severely restricted the use opioid prescriptions to treat chronic pain.

218. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the Commonwealth.

219. By virtue of the above-described acts, Endo knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Commonwealth to approve and pay such false and fraudulent claims.

220. To the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Endo's deceptive marketing.

221. The Commonwealth, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Endo, paid and continues to pay the claims that would not be paid but for Endo's illegal business practices.

222. By reason of Endo's unlawful acts, the Commonwealth has been damaged, and continues to be damaged, in a substantial amount to be determined at trial for spending related to opioids prescribed for chronic pain by its workers compensation program.

223. As a direct and proximate result of Endo's misrepresentations and/or omissions, the rising number of persons addicted to prescription opioids have led to a dramatic increase in social problems, including drug abuse, criminal acts to obtain opioid drugs, including prescription opioids, heroin, and fentanyl, significantly and negatively impacting the public health and the resources provided for other services.

224. Because Endo's unbranded marketing caused the doctors to prescribe and the Commonwealth to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Endo caused and are responsible for those costs and claims, as well.

COUNT V

Continuing Public Nuisance

225. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

226. A public nuisance is an unreasonable interference with a right common to the general public.

227. Circumstances that may sustain a holding that an interference with a public right is unreasonable include conduct that involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience.

228. A common or public nuisance has also been described as a condition of things which is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the

citizens at large, which may resulting either from an act not warranted by law, or from neglect of a duty imposed by law.

229. Through its deceptive marketing, Endo has created or assisted in the creation of a condition that significantly interferes with the public health, the public safety, the public peace, the public comfort or the public convenience and is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large.

230. The public nuisance was foreseeable to, and, in fact, foreseen by, Endo, which knew or should have known of the harm it would cause.

231. The public nuisance is substantial and unreasonable. Endo's actions were not only unreasonable, but unlawful and grievously harmful to the health and safety of Kentucky residents, and the harm from Endo's intentional misconduct outweighs any offsetting benefit.

232. This injury to the public includes, but is not limited to (a) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (b) high rates of opioid abuse and addiction, overdoses, and outbreaks of other serious diseases (like Hepatitis C), and fatalities; (c) children removed from their homes and newborns born addicted to opioids; (d) lost employee productivity due to opioid-related addiction and disability; (e) the creation and maintenance of a secondary, criminal market for opioids; (f) greater demand for emergency services, law enforcement, addiction treatment, and social services; and (g) increased health care costs for individuals, families, and the Commonwealth.

233. Endo's actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving prescribers and patients about the risks and benefits of opioids for the treatment of chronic pain, and in the public health crisis. Without

Endo's actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in Kentucky would have been averted or would be much less severe.

234. The public nuisance – i.e., the opioid epidemic – created and maintained by Endo can be abated.

235. The health and safety of Kentucky's citizens is a matter of great public importance and of legitimate concern to the Commonwealth and its residents.

236. The Commonwealth has been, and continues to be, injured by Endo's actions in creating a public nuisance. As a direct result of Endo's acts in creating the public nuisance, the Commonwealth has suffered economic harm, including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT VI

Fraud

237. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

238. Endo, itself and acting through third-party agents, fraudulently, intentionally, willfully, or recklessly made misrepresentations and omissions of facts material to the Commonwealth and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

239. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, Endo has engaged in misrepresentations and knowing omissions of material fact.

240. Endo's statements about opioids generally and its opioids in particular were false.

241. Further, Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead when taken in the context of the surrounding circumstances.

242. Endo fraudulently, intentionally, willfully, or recklessly made these misrepresentations and omissions, which were reasonably calculated to deceive and in fact did deceive the Commonwealth and its residents.

243. Endo intended that the Commonwealth and its residents would rely on its misrepresentations and omissions.

244. The Commonwealth and its residents reasonably relied upon Endo's misrepresentations and omissions.

245. As a direct and proximate result of Endo's misrepresentations and omissions of material fact, the Commonwealth suffered actual pecuniary damage.

COUNT VII

Unjust Enrichment

246. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

247. Many Kentucky citizens who could not otherwise afford medical care rely on the Commonwealth to provide medical care through programs such as Medicaid, and the Commonwealth also pays for opioids through, for instance, its workers compensation program.

248. By illegally and deceptively promoting opioids to treat chronic pain, Endo has unjustly enriched itself at the Commonwealth's expense. The Commonwealth has made payments for opioid prescriptions, and Endo benefited from those payments. Because of Endo's deceptive promotion of opioids, Endo obtained enrichment they would not otherwise have

obtained. The enrichment was without justification and the Commonwealth lacks a remedy provided by law.

249. Endo has unjustly retained a benefit to the Commonwealth's detriment, and its retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

250. While the Commonwealth and its institutions are struggling to pay for the services needed to combat the opioid crisis, and have expended funds in paying for prescription opioids that could otherwise have been used to serve Kentucky's residents, Endo has reaped millions of dollars in profits from its deceptive marketing campaign.

251. In equity and fairness, it is Endo, not the Commonwealth and its taxpayers, who should bear the costs occasioned by Endo's deceptive marketing campaign.

252. Accordingly, under principles of equity, Endo should be disgorged of money retained by reason of its deceptive and illegal acts that in equity and good conscience belong to the Commonwealth and its citizens.

COUNT VIII

Punitive Damages

(KRS 411.186)

253. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

254. By engaging in the conduct set forth above, Endo acted toward the Commonwealth with oppression, fraud, or malice, gross negligence, and/or reckless disregard for the lives and safety of others to a degree sufficient to warrant the imposition of punitive damages

pursuant to KRS 411.186 to deter such further conduct on behalf of the Defendants, or similarly situated parties.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the Commonwealth of Kentucky, *ex rel.* Attorney General Andy Beshear, respectfully requests the following:

A. Entry of judgment against Endo, finding that it committed repeated violations of KRS 367.170;

B. For an injunction, pursuant to KRS 367.190, prohibiting Endo from further marketing, sales, or distribution practices violating KRS 367.170;

C. An award of civil penalties in the amount of two thousand dollars ($2,000) for each violation of KRS 367.170, and ten thousand dollars ($10,000) for each violation targeted to consumers over the age of 65, pursuant to KRS 367.990;

D. Restoration to the Commonwealth of all moneys or property which it has paid out as a result of Endo's violations of the KCPA alleged in this Complaint, pursuant to KRS 367.200;

E. An order directing Endo to abate and pay damages for the public nuisance;

F. An order declaring pursuant to KRS 446.070 that Endo committed repeated violations of KRS 205.8463 and KRS 194A.505;

G. Civil penalties in the amount of all benefits and payments to which Endo was not entitled in accordance with the provisions of KRS 194A.990(5);

H. Civil penalties in an amount equal to three (3) times the amount of the benefits and payments to which Endo was not entitled in accordance with the provisions of KRS 194A.990(6)(a);

I. Compensatory damages for Endo's violations of the Kentucky Medicaid Fraud Statute, KRS § 205.8463 and the Kentucky Medicaid Fraud Statute, 194A.505(6), and for Endo's fraud;

J. Punitive damages against Endo pursuant to KRS 411.186;

K. Restitution or disgorgement of Endo's unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

L. An award of reasonable attorney's fees, interest, and costs to Plaintiff;

M. A trial by jury;

And any and all such other relief as this Honorable Court deems just and proper.

Respectfully submitted,

ANDY BESHEAR
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