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

COMMONWEALTH OF KENTUCKY, *ex rel.*, ANDY BESHEAR, ATTORNEY GENERAL,

Plaintiff.

v.

JOHNSON & JOHNSON;

Serve: Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICA, INC. n/k/a/ JANSSEN PHARMACUETICALS, INC.

Serve: CT Corporation System
4169 Westport Road
Louisville, KY 40207
REGISTERED AGENT

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

4. Janssen specifically marketed to doctors and patients in Kentucky and misrepresented that their opioid medications were safer than other alternatives, disseminated misleading statements about opioids, furthered the concept of pseudoaddiction, and misrepresented that opioids were "rarely addictive" when used for chronic pain. They targeted particularly vulnerable populations, such as the elderly, even though opioid use in this population carries a heightened risk of overdose, injury, and death.

5. 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

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

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

6. 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. Many of those victims were service members or veterans, who accounted for 452 drug overdoses between 2010 and 2015. As Kentucky citizens who become addicted to prescription opioids have predictably migrated to illicit, but less expensive, opioids, namely heroin and fentanyl, overdoses have dramatically increased.

7. 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 such addiction, which doubled in just two years—from $56 million in 2014 to $117 million in 2016.

8. 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 2017—representing three 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.

9. Children are 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 spend weeks in neonatal intensive care units while they painfully withdraw from the drugs—a process so painful that it later traps many adults in opioid addiction. Children also are injured when removed from their homes due to opioid abuse and addiction. *See infra* ¶ 103.

10. The Attorney General brings this lawsuit in the public interest to hold Janssen accountable for its violations of the Consumer Protection Act ("KCPA"), KRS 367.110 *et seq.*; the Kentucky Medicaid Fraud Statute, KRS 205.8463; and the Kentucky Assistance Program Fraud Statute, KRS 194A.505. 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 Medicaid, workers' compensation, and other spending on opioids, disgorgement of Janssen's unjust profits, civil penalties for its egregious violations of law, compensatory and punitive damages, injunctive relief, and abatement of the public nuisance Janssen has helped create.

II. PARTIES

11. 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 cases, including this one, 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 § 194A.505, 367.110 *et seq.*, and KRS 205.8451 through KRS 205.8483, 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.

12. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. These parties are collectively referred to as "Janssen."

13. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and in the Commonwealth of Kentucky, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen also developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. [redacted]

14. Janssen'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 Nucynta 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).

III. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over the Commonwealth's claims pursuant to KRS 23A.010, KRS 194A.505(8), KRS 205.8469, and 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.

16. 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.

17. 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.

18. 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.

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

IV. FACTUAL ALLEGATIONS

A. Janssen Falsely Trivialized, Mischaracterized, and Failed to Disclose the Known, Serious Risk of Addiction

20. Janssen spent millions of dollars on promotional activities and materials, including advertising, websites, and in-person sales calls, that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. It also relied upon seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that were unsupported and misleading, but seemed independent and therefore credible.

21. Janssen relies heavily on its sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. Not surprisingly, Janssen's sales representatives visited prescribers in Kentucky. Between the third quarter of 2013 and 2016, Janssen sales representatives visited Kentucky prescribers at least 379 times.

22. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report, which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal

manufacturer payments and physician prescribing practices."[2] The Report quotes findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty." On information and belief, Janssen understood the effectiveness of sales representatives' visits to doctors and used sales representatives to market its opioids because it knew that sales representatives influence prescribers to increase its sales.

23. To ensure that sales representatives deliver the desired messages to prescribers, Janssen directs and monitors them through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' notes (known as "call notes") from each visit. Janssen likewise required its sales representatives to use sales aids reviewed, approved, and supplied by the companies. It ensured marketing consistency nationwide through national and regional sales representative training. Thus, the company's sales forces in the Commonwealth carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

24. [redacted]

[2] Staff Report, Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.

[redacted]

25. Janssen also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from Janssen and other opioid manufacturers, who often sponsored the CMEs — giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but also helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do." [redacted]

26. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Society, that were also able to exert greater influence because of their seeming independence. Janssen exerted influence over these groups by providing major funding directly to them as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use

of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Janssen distributed these publications to prescribers or posted them on their websites.

27. Neither these unbranded third-party materials, nor the marketing messages and scripts relied on by Janssen's sales representatives, were reviewed or approved by the FDA.

28. Upon information and belief, all of the messages described below were disseminated to Kentucky prescribers and patients.

1. Minimizing or Mischaracterizing the Risk of Addiction

29. To convince prescribers and patients that opioids are safe, Janssen directly, through its control of third parties, and/or by aiding and abetting third parties, deceptively represented that the risk of abuse and addiction is modest, manageable, and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

30. [redacted] On information and belief, Janssen sales representatives also told doctors that Nucynta was less likely to be addictive than other opioids.

31. Janssen also undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to high-risk patients. Upon information and belief,[3] Janssen encouraged doctors in Kentucky to prescribe their opioids to the "right" patients or "appropriate" patients, which was meant, and understood, to mean patients who were not likely to

[3] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Kentucky in the same manner as elsewhere.

become addicted, notwithstanding the fact that a low-risk population did not exist or could not be ascertained.

32. [redacted] On information and belief, Janssen told Kentucky prescribers that patients were less likely to suffer from withdrawal, and that their drugs had less of a withdrawal effect than other opioids. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

33. Janssen also disseminated misleading information about opioids and addiction. Janssen was a sponsor of the Let's Talk Pain Coalition, which was founded by the American Pain Foundation ("APF") and other advocacy groups. The Coalition's *Let's Talk Pain* website stated, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." The website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management."

34. In addition, Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), as seen below, described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Until recently, this guide was still available online.

35. The American Geriatrics Society ("AGS"), a nonprofit organization which serves 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"). Janssen contracted with AGS to disseminate the 2009 AGS Guidelines and create CMEs based on them. Janssen was aware of the content of the 2009 AGS guidelines when it agreed to provide funding for these projects.

36. Treatment guidelines, like those produced by AGS, are especially influential with primary care physicians and family doctors to whom Janssen 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."[4]

37. 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

[4] 2016 CDC Guideline at 2.

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 have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.

38. Janssen currently runs a website, Prescriberesponsibly.com, which, until recently, claimed that concerns about opioid addiction are "overestimated."

39. Janssen's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk[] of . . . addiction"—"even at recommended doses"—of all opioids."[5] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[6] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[7]

[5] FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics, FDA (Sep. 10, 2013); see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[6] CDC Guideline at 2.

[7] *Id.* at 21.

2. Janssen Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids

40. Janssen, along with other opioid manufacturers, covered up the occurrence of addiction by attributing it to a made-up condition called "pseudoaddiction." Pseudoaddiction meant that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

41. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

42. Janssen, along with other opioid manufacturers, also promoted the concept of pseudoaddiction by its involvement and contracting with Dr. Russell Portenoy, a leading KOL for opioid manufacturers. He popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

43. The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[8] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use

[8] CDC Guideline at 13.

by discontinuing opioids" because the patient is "not receiving a clear benefit."[9]

3. Overstating the Efficacy of Screening Tools

44. Janssen falsely indicated to prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, Janssen advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else.

45. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients and patients more comfortable starting long-term opioid therapy for chronic pain. These misrepresentations were especially insidious when Janssen aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs.

46. On information and belief, Janssen conveyed these safe prescribing messages through their in-person sales calls to doctors. Upon information and belief, Janssen discussed screening tools and patient selection with Kentucky doctors as strategies for keeping patients safe and managing the risk of addiction, abuse, and diversion, and also described screening tools to Kentucky doctors as useful in helping to identify the "right" patients—meaning patients who can

[9] *Id.* at 25.

be identified as low risk for addiction. Janssen did not disclose the lack of evidence for efficacy of these tools.

47. Janssen also promoted screening tools as a means to manage addiction risk in CME programs and scientific conferences, which would have been attended by and were available online to Kentucky prescribers. Janssen sponsors the website prescriberesponsibly.com, which directly provides screening tools to prescribers for risk assessments. The website includes a "[f]our question screener" to purportedly help physicians identify possible opioid misuse.[10] The website also states that Janssen is "solely responsible for [the website' s] content."[11] The website is still available to both Kentucky prescribers and patients.

48. The CDC Guideline confirmed the falsity of Janssen's claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[12]

[10] http://www.prescriberesponsibly.com/risk-assessment-resources (last visited March 2, 2018).

[11] *Id*.

[12] CDC Guideline at 28 (emphasis added).

B. Janssen Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use

1. Mischaracterizing the Benefits of and Evidence for Long-Term Use

49. To convince prescribers and patients that opioids should be used to treat chronic pain, Janssen had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[13] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[14] The FDA, too, 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."[15] As a result, the CDC recommends that opioids not be used in the first instance and for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments.

50. On information and belief, Janssen touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. Upon information and belief, Janssen failed to disclose the lack of evidence for long-term opioid therapy in the treatment of chronic pain to Kentucky prescribers.

51. In addition, two prominent professional medical membership organizations, the

[13] *Id*. at 10.

[14] *Id.* at 9.

[15] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Janssen. Upon information and belief, Janssen exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, The Use of Opioids for the Treatment of Chronic Pain, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for an opioid manufacturer and later became its senior executive. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on the American Academy of Pain Medicine's ("AAPM") website until 2011 and was removed from AAPM's website only after a doctor complained.

52. A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for opioid manufacturers, stated that he would place the organization "at the forefront" of teaching that "*the risks of addiction* are there, but they are *small and can be managed*." (Emphasis added.)

53. AAPM and the American Pain Society ("APS") issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Janssen and the other opioid manufacturers in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Nine of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Janssen, and many of the other panel members received support from other opioid manufacturers.

54. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and

concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Janssen, made to the sponsoring organizations and committee members.

55. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

56. The AAPM/APS Guidelines are still available online, were reprinted in the Journal of Pain, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

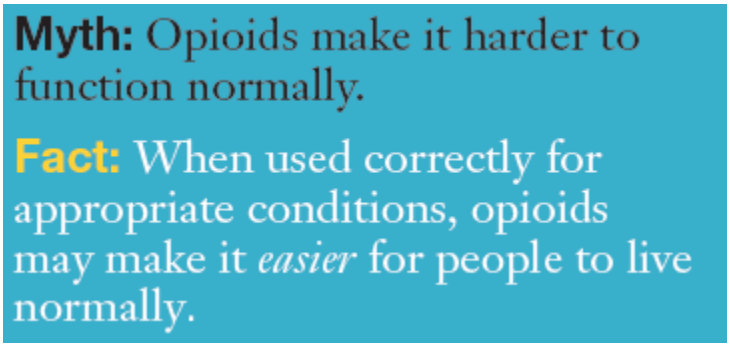
57. The use of third-party, unbranded marketing not only created the false impression that materials requested, reviewed, edited, and distributed by Janssen came from objective and disinterested sources, it allowed Janssen to avoid regulatory scrutiny, as such materials typically are not reviewed by the FDA.

2. Overstating Opioids' Positive Effect on Patients' Function and Quality of Life

58. Janssen also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Upon information and belief, Janssen sales representatives promoted the ability of opioids to improve patients' function and quality of life during visits in Kentucky.

59. Janssen's materials that were distributed or made available in Kentucky, reinforced

this message. Janssen's patient education guide, *Finding Relief: Pain Management for Older Adults* (2009), states as a "fact" that "opioids may make it easier for people to live normally."



The guide goes on to list expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

60. Janssen's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 12 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

61. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and

these patients are unable to function normally."[16] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

62. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[17] The CDC Guideline, following a "systematic review of the best available evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[18]

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[16] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

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

[18] CDC Guideline for Prescribing Opioids for Chronic Pain-United States, at 2, 18 (March 18, 2016).

According to the director of the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[19] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[20]

3. Omitting or Mischaracterizing Adverse Effects of Opioids

63. In materials Janssen produced, sponsored, or controlled, Janssen omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

64. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Janssen routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[21] in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

65. Janssen and other opioid manufacturers frequently contrasted the lack of a ceiling

[19] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

[20] *Id*.

[21] U.S. Senate Homeland Security & Governmental Affairs Committee, Minority Staff Report, Fueling and Epidemic, Report Two, at 4.

dosage for opioids with the risks of NSAIDs, and deceptively described the risks from NSAIDs while failing to disclose the risks from opioids. For example, *Finding Relief: Pain Management for Older Adults*, a Janssen-sponsored patient education guide, stated that NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, while opioids could cause temporary "upset stomach or sleepiness" and constipation.

66. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[22]

67. Again, Janssen's misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 19.3% to 29.1% of visits while NSAID and acetaminophen prescriptions fell from 36.9% to 24.5%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

C. Janssen Continued to Tell Doctors that Opioids Could be Taken in Ever-Higher Doses Without Disclosing their Greater Risks

68. Janssen falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Janssen needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

[22] Meredith Noble M, *et al*., *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

69. [redacted]

70. [redacted]

71. The Janssen sponsored patient education guide, *Finding Relief: Pain Management for Older Adults* (2009), was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. Until recently this guide was still available online.

72. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are approximately nine times more likely to suffer overdose from opioid-

related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

73. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[23] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[24]

74. Janssen 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.

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

75. Upon information and belief, the vast market for opioids was created and sustained in significant part by Janssen's deceptive marketing in establishing opioids as a first-line treatment

[23] CDC Guideline at 9 and 22. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[24] CDC Guideline at 16.

for chronic pain. Janssen'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.

76. Janssen's marketing, and especially its detailing to doctors, has been effective. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies. Janssen necessarily expected a return on its multi-million dollar investment in opioid marketing, and carefully calibrated its promotion efforts to serve that end.

77. Janssen marketed directly to patients to: (1) encourage them to ask doctors for opioids to relieve chronic non-cancer pain; and (2) allay their well-founded concerns that opioids were dangerous and addictive. [redacted] Unlike other direct-

to-consumer marketing, Janssen relied on unbranded advertising, knowing that the creation of a new, expansive market for opioids would benefit it. Janssen also targeted particularly vulnerable, but usually well-insured, groups of patients, such as the elderly. [redacted]

78. [redacted]

79. 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. In 2016, 97.2 opioid prescriptions were written for every 100 Kentucky residents.

80. 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.

81. 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."

82. 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.[25] 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."[26]

83. 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."[27] 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."

84. The FDA also has made clear that "most opioid drugs have 'high potential for abuse,'" and "the serious risks of misuse, abuse, neonatal opioid withdrawal syndrome (NOWS),

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[25]CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

[26] Id.

[27] 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).

addiction, overdose, and death [are] associated with the use of ER/LA opioids overall, and during pregnancy." (Emphasis added.) According to the FDA, because of the "known serious risks" associated with extended-release opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. (Emphasis added.)

85. Most opioid addiction begins with legitimately prescribed opioids. An estimated 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 prescription opioids and heroin as among the most abused drugs in his region of Kentucky. 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.

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

87. 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.

88. 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.

89. In 2016, there were 1,404 reported fatal drug overdoses in Kentucky—117 per month. This was a 12.4% increase from 2015, a year which, in turn, had seen in a 23.6% increase in fatalities from drug overdoses as compared to 2013. Altogether, between 2012 and 2016, drug overdoses claimed a total of 5,822 Kentuckians.

90. 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.

91. 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. During this time, the Lexington VA Center saw 387,355 veterans and prescribed 564,062 opioid prescriptions.

92. 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. Janssen also could have, and did, foresee that users who become addicted to a particular prescription opioid, such as Nucynta and Nucynta ER, would migrate to another drug (including heroin) if those drugs become less expensive or more readily available. In fact, some users migrate to heroin (sometimes with fentanyl) they buy on the street.

93. 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, 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.

94. 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 Janssen opioids, heroin, and fentanyl. Law enforcement officers in Kentucky similarly observed opioid addiction and abuse affecting people across varying ages and demographics.

95. 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.

96. 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 six 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 were 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.

97. The abuse of opioids, including Duragesic, Nucynta and Nucynta ER, and the resulting increase in heroin use and addiction have caused outbreaks of HIV, chronic Hepatitis C, and TTP.

98. 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, 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. Kentucky had the highest rate of new Hepatitis C infections in the nation from 2008 through 2015. St. Elizabeth Healthcare in Edgewood reports that it sees up to ten new

cases of Hepatitis C daily.

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

100. 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 of 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.[28]

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

102. 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 Neonatal Abstinence Syndrome ("NAS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience

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

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.

103. NAS as become a great source of concern within the Commonwealth. 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. As recently as March 2018, Madison County officials, including healthcare providers and social workers held a conference in order to solve the increasing problem of pregnant women being addicted to opioids. The goal of the conference was to create a plan that would provide support to mothers and families after giving birth, and the plan is currently in process.

104. While the use of opioids has taken an enormous toll on the Commonwealth and its residents, Janssen has realized billions of dollars in revenue from use of its opioids for chronic pain as a result of its deceptive, unfair, and unlawful conduct.

E. Janssen Fraudulently Concealed its Misconduct

105. Janssen made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain even though it knew that its marketing was 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. Janssen 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 that patients are suffering from addiction,

overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these misrepresentations.

106. Notwithstanding this knowledge, at all times relevant to this Complaint, Janssen took steps to avoid detection of and to fraudulently conceal its deceptive marketing and unlawful and fraudulent conduct. Janssen disguised its role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of its false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Janssen masked or did not disclose its role in shaping, editing, and approving the content of this information.

107. Janssen thus successfully concealed from the medical community, patients, and the Commonwealth of Kentucky facts sufficient to arouse suspicion of the claims that the Commonwealth now asserts. The Commonwealth did not know of the existence or scope of Janssen's fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

V. CAUSES OF ACTION

COUNT I

Deceptive Acts and Practices in Violation of Kentucky Consumer Protection Act

(KRS 367.110 *et seq.*)

108. 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.

109. 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.

110. 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.

111. 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."

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

113. At all times relevant to this Complaint, Janssen, 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; and

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

114. Janssen 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, Janssen 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.

115. Janssen failed to disclose or misrepresented clinically significant risks of Nucynta, Nucynta ER, and Duragesic, and opioid therapy to Kentucky consumers and their doctors. At all times relevant to this Complaint, Janssen directly, as well as 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, and are immoral, unethical, oppressive, or unscrupulous.

116. Janssen 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 Janssen's drugs or the use opioids to treat chronic pain.

117. For each of Janssen'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 Janssen conduct is directed at a person aged sixty (60) or older and Janssen knew or should have known that the person aged sixty (60) or older is substantially more vulnerable than other members of the public.

COUNT II

Restoration of Property due to Violations of Kentucky Consumer Protection Act

(KRS 367.110 *et seq.*)

118. Janssen's conduct also was deceptive 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, Janssen 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. Janssen also deliberately targeted non-specialist physicians and non-physician prescribers, who lacked the time and expertise to evaluate their deceptive claims.

119. Janssen's conduct has caused substantial, indeed grievous, injury to Kentucky persons. The staggering rates of opioid use, abuse, and addiction resulting from Janssen'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 have lost parents [and even grandparents] and/or have 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. Janssen'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.

120. 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 Janssen'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 Janssen's misconduct could not reasonably have been avoided by those Janssen harmed.

121. Janssen'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.

122. 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 Janssen'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 III

Violations of Kentucky Medicaid Fraud Statute

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

123. 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.

124. 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).

125. 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).

126. 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."

127. 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."

128. Janssen's practices, as described in the Complaint, violated KRS § 205.8463(2) & (4). Janssen, 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.

129. 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.

130. 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").

131. 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.

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

133. Janssen 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, Janssen 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.

134. Janssen'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.

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

136. 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, Janssen's deceptive marketing with and through KOLs and front groups constitutes conspiracy and complicity, in violation of 901 KAR 1:671(40)(j).

137. Janssen'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)

138. Janssen's practices, as described in the Complaint, constitute provider abuse within the meaning of the statute and regulation. KRS 205.8451(8). 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."

139. 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 Janssen 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."

140. As a direct and proximate result of Janssen'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.

141. Janssen 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 Janssen's fraud. Indeed, Janssen's acted to maximize its reimbursements from these third party payors.

142. Janssen's misrepresentations were material because if the Commonwealth had known of the false statements disseminated by Janssen 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.

143. 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.

144. By virtue of the above-described acts, Janssen 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.

145. 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

Janssen's deceptive marketing.

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

147. By reason of Janssen'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 approximately 30% of all funds appropriated under the 2016-2018 biennium budget. 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 Janssen'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 Janssen's violations as alleged herein and a significant financial burden on the Commonwealth. From 2013 to 2016, Kentucky's Medicaid spent over $400,000 on Janssen opioids. In 2016, Kentucky's Medicaid spending for medications to treat opioid addiction was $117 million, double the amount from only two years ago, which was $56 million in 2014.

148. As a direct and proximate result of Janssen'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 and criminal acts to obtain opioid drugs, including prescription opioids, heroin, and fentanyl. These social problems significantly and negatively impact the public health and the resources provided for Medicaid, emergency, and other services.

149. Because Janssen'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, Janssen caused and is responsible for those costs and claims, as well.

COUNT IV

Violations of Kentucky Assistance Program Fraud Statute

(KRS § 194A.505(6); KRS § 194A.990)

150. 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.

151. 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."

152. Janssen, 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).

153. 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."

154. 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."

155. 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."

156. By engaging in the conduct set forth above, Janssen 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.

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

158. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Janssen additional civil damages in accordance with the provisions of KRS 446.070.

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

160. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Janssen 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 V

Continuing Public Nuisance

161. 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.

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

163. 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.

164. 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.

165. Through its deceptive marketing, Janssen 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.

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

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

168. 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.

169. Janssen'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 Janssen'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.

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

171. 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.

172. The Commonwealth has been, and continues to be, injured by Janssen's actions in creating a public nuisance. As a direct result of Janssen'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

173. 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.

174. Janssen, 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.

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

176. Janssen's statements about opioids generally and its opioids in particular were false.

177. 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.

178. Janssen 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.

179. Janssen intended that the Commonwealth and its residents would rely on its misrepresentations and omissions.

180. The Commonwealth and its residents reasonably relied upon Janssen's misrepresentations and omissions.

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

COUNT VII

Unjust Enrichment

182. 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.

183. 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.

184. By illegally and deceptively promoting opioids to treat chronic pain, Janssen has unjustly enriched itself at the Commonwealth's expense. The Commonwealth has made payments for opioid prescriptions, and Janssen benefited from those payments. Janssen received, or will receive, income, profits, and other benefits, which it would not have received if it had not engaged in the deceptive and illegal conduct described in this Complaint. This enrichment was without justification, and the Commonwealth lacks a remedy provided by law.

185. Janssen 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.

186. 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, Janssen has reaped millions of dollars in profits from its deceptive marketing campaign.

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

188. Accordingly, under principles of equity, Janssen 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)

189. 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.

190. By engaging in the conduct set forth above, Janssen 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.

VI. PRAYER FOR RELIEF

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

a. Entry of judgment against Janssen, finding that it committed repeated violations of KRS 367.170;

b. For an injunction, pursuant to KRS 367.190, prohibiting Janssen 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 Janssen's violations of the KCPA alleged in this Complaint, pursuant to KRS 367.200;

e. An order directing Janssen to abate and pay damages for the public nuisance;

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

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

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

i. Civil damages not addressed by KRS 194A.990(5) in accordance with the provisions of KRS 446.070;

j. Punitive damages against Janssen pursuant to KRS 411.186;

k. Restitution or disgorgement of Janssen'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
ATTORNEY GENERAL

By: _s/LeeAnne Applegate____

LeeAnne Applegate
Elizabeth U. Natter
Charlie Rowland
Assistant Attorneys General
Office of Consumer Protection
OFFICE OF THE ATTORNEY GENERAL
1024 Capital Center Drive, Suite 200
Frankfort, Kentucky 40601
Elizabeth.Natter@ky.gov
LeeAnne.Applegate@ky.gov
Charlie.Rowland@ky.gov
Tel: (502) 696-5300
Fax: (502) 573-8317

Wesley W. Duke
Assistant Director
C. David Johnstone
Brian C. Thomas
Assistant Attorneys General
Office of Medicaid Fraud and Abuse
OFFICE OF THE ATTORNEY GENERAL
1024 Capital Center Drive, Suite 200
Frankfort, Kentucky 40601
David.Johnstone@ky.gov
Brian.Thomas@ky.gov
Tel: (502) 696-5300
Fax: (502) 573-8316

Linda Singer *
Elizabeth Smith*
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
lsinger@motleyrice.com
esmith@motleyrice.com

Tel: (202) 232-5504
Fax: (202) 386-9622

James D. Young*
Sarah A. Foster*
MORGAN & MORGAN COMPLEX LITIGATION GROUP
76 S. Laura St., Suite 1100
Jacksonville, FL 32202
jyoung@forthepeople.com
sarahfoster@forthepeople.com
Tel: (904) 398-2722

W. Mark Lanier*
Richard D. Meadow*
Evan Janush*
Reagan E. Bradford*
THE LANIER LAW FIRM
6810 FM 1960 West
Houston, Texas 77069
wml@LanierLawFirm.com
Richard.Meadow@LanierLawFirm.com
Reagan.Bradford@LanierLawFirm.com
evan.janush@LanierLawFirm.com
Tel: (713) 659-5200

(*denotes counsel who will seek pro hac vice admission)

Attorneys for Plaintiff the Commonwealth of Kentucky