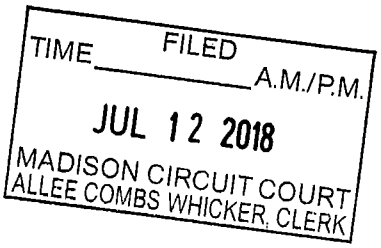

COMMONWEALTH OF KENTUCKY
MADISON COUNTY CIRCUIT COURT
DIVISION NO. II
CIVIL ACTION NO. 18-CI-381

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

Plaintiff.

v.

MALLINCKRODT PLC; MALLINCKRODT LLC, SPECGX LLC,

Defendants.

COMPLAINT

JURY TRIAL DEMANDED

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I. PRELIMINARY STATEMENT

1. The opioid epidemic is causing one of the deadliest drug crises in the history of the United States. Plaintiff, Commonwealth of Kentucky ("the Commonwealth" or "Kentucky"), is being hit especially hard, ranking sixth in the nation for opioid-related deaths in 2015. In 2016, 97.2 opioid prescriptions were written for every 100 Kentucky residents, 1.5 times the national average. The same year, there were 1,404 reported fatal drug overdoses in Kentucky—117 per month.

2. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can work to dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience often prolonged withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

3. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply restricted.

4. For opioid manufacturers like Mallinckrodt, this market was unacceptably small. 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.

5. To make that happen, opioid manufacturers had to persuade 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.

6. Mallinckrodt created and sponsored promotional materials that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. Mallinckrodt relayed their deceptive messages to prescribers through their marketing materials, websites, and in-person sales calls. Mallinckrodt also relied upon and sponsored professional associations and third party front groups who disseminated its misleading messages while appearing independent and therefore credible.

7. Through these efforts, Mallinckrodt was able to persuade prescribers that, even though opioids were addictive, that risk could be allayed if doctors carefully supervised their use by appropriate patients. Part of Mallinckrodt's message was that doctors should treat the right patients: legitimate patients who took the drugs as directed (orally) to treat their pain, rather than abusers seeking to snort or inject the drugs for recreation. By defining the class of individuals who should not receive opioids as only these abusers, Mallinckrodt gave doctors a false sense of security that they could safely prescribe opioids to patients they trusted without fear that these patients would become addicted.

8. Mallinckrodt knew or should have known that its representations regarding the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence.

9. In addition, Mallinckrodt deceptively and unfairly failed to put into place appropriate procedures to ensure suspicious orders would be reported to authorities and instead, continued to fill orders which supplied far more opioids than were justified. Each of Mallinckrodt's shipments of opioids into the stream of commerce in Kentucky without an adequate

system in place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious violated both its common law duties and its statutory duties under Kentucky law. Pursuant to Kentucky law, manufacturers must adhere to federal controlled substances laws in the sale of their products. *See* KRS 218A.170(1), (4). Thus, under Kentucky law, Mallinckrodt has a duty to report suspicious orders in order to prevent diversion. 21 C.F.R. § 1301.74(b). In 2017, Mallinckrodt paid a $35 million fine for its failure to put into place appropriate procedures to ensure suspicious orders would be reported, and its failure to report suspicious orders.[1]

10. Mallinckrodt's actions had a substantial effect on the Commonwealth's opioid epidemic. For example, Kentucky's Medicaid program spent $14,793,690 on Mallinckrodt's opioids from 2013 to 2016. [redacted]

11. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain[2]—has become a commonplace, and often first-line, treatment. Mallinckrodt's deceptive marketing was a substantial factor in causing prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, in 2012, prescribers wrote 259 million prescriptions for painkillers, which is enough for every American adult to have a bottle of pills. In 2015, there were 71 opioid prescriptions for every 100 people in the United States—the equivalent of enough prescriptions "for every American to be medicated around the clock for three weeks."[3]

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[1] *See* Press Release, U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

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

[3] How Opioid Prescriptions Have Changed Recently: New Report, https://www.livescience.com/59716-opioid-prescribing-cdc.html, last visited June 22, 2018.

12. Indeed, rather than compassionately helping patients, this explosion in opioid use has come at the expense of chronic pain patients. The CDC concluded in 2016 that "for the vast majority of [chronic pain] patients, the known, serious, and too-often-fatal risks [of opioids] far outweigh the unproven and transient benefits."[4] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[5]

13. As a direct result of Mallinckrodt's dangerously false marketing, the nation is now swept up in what the CDC called a "public health epidemic"[6] and what the U.S. President deemed a "public health emergency."[7] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

14. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. In 2017, overdose deaths that involved prescription opioids were five times higher than they were in 1999.

15. 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 overdose victims are service members or veterans, who accounted

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[4] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

[5] *Id.*

[6] The CDC, Prescription Painkiller Overdoses in the US, November 1, 2011, available at https://www.cdc.gov/vitalsigns/painkilleroverdoses/index.html.

[7] The New York Times, Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds, October 26, 2017, available at https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.

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.

16. 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.

17. 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.

18. Children are especially vulnerable to the opioid epidemic. In just one 12-month period, between August 1, 2014 and 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. Children also suffer when removed from their homes due to their parents' opioid abuse and addiction.

19. The burdens imposed on the Commonwealth of Kentucky are not the normal or typical burdens of government programs and services. Rather, these are extraordinary costs and losses that are related directly to Mallinckrodt's illegal actions. Mallinckrodt's conduct has created

a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

20. The Attorney General brings this lawsuit in the public interest to hold Mallinckrodt 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, unjust enrichment, and negligence. This action seeks repayment of the Commonwealth's Medicaid, workers' compensation, and other spending on opioids, disgorgement of Mallinckrodt's unjust profits, civil penalties for its egregious violations of law, compensatory and punitive damages, injunctive relief, and abatement of the public nuisance Mallinckrodt has helped create.

II. PARTIES

21. 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.

22. Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Mallinckrodt, LLC is licensed to conduct business in Kentucky. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc. SpecGX LLC, is a wholly owned subsidiary of Mallinckrodt plc and was incorporated in Delaware on November 14, 2016.[8] SpecGX, upon information and belief, currently manufactures and sells in the Commonwealth certain opioids which were previously manufactured by Mallinckrodt LLC. Mallinckrodt, plc Mallinckrodt, LLC and SpecGX LLC are referred to as "Mallinckrodt."

23. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Exalgo was designed with properties to make it harder to abuse, but it has not been approved by the FDA to make abuse-deterrent claims. Exalgo is still sold and marketed in the Commonwealth today. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt discontinued in August 2015. Mallinckrodt promoted its branded opioid

[8] The Commonwealth has listed SpecGX as a Defendant for the purpose of ensuring that the Commonwealth can obtain appropriate injunctive relief.

products with its own direct sales force.

24. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

25. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing specialty branded and generic opioid products, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

26. In 2017, Mallinckrodt entered into a settlement with the United States Drug Enforcement Administration ("DEA") after the DEA's investigation revealed that "Mallinckrodt knew about the diversion [of oxycodone] and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion." To settle these claims, Mallinckrodt paid a fine of $35 million.

III. JURISDICTION AND VENUE

27. 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.

28. This Court has personal jurisdiction over Mallinckrodt pursuant to KRS 454.210 because Mallinckrodt has 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.

29. The Complaint herein sets forth exclusively state law claims against Mallinckrodt. Nowhere does the Commonwealth plead, expressly or implicitly, any cause of action or request any remedy that arises under or is based on 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.

30. 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.

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

IV. FACTUAL ALLEGATIONS

A. Mallinckrodt Falsely Trivialized, Mischaracterized, and Failed to Disclose the Known, Serious Risk of Addiction and Overstated Opioids' Effect on Patients' Function and Quality of Life

32. Mallinckrodt promoted its branded opioids and opioids generally, in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement. Mallinckrodt conveyed these deceptive messages to Kentucky prescribers through

sales representatives, patient guides, and branded and unbranded websites and other marketing materials. It also disseminated deceptive messages through third party patient advocacy groups and professional associations who were financially tied to Mallinckrodt but seemed independent and, therefore, credible. Mallinckrodt distributed these messages, or facilitated their distribution, in Kentucky with the intent that Kentucky prescribers and/or consumers would rely on them in choosing to use opioids in general, and their opioids specifically, to treat chronic pain.

33. Mallinckrodt relies heavily on its sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. Not surprisingly, Mallinckrodt's sales representatives visited prescribers in Kentucky. Publicly available Open Payments Data[9] shows that between the third quarter of 2013 and 2016, Mallinckrodt sales representatives visited Kentucky prescribers at least 577 times, in visits that included some sort of payment[10] to the doctor. This number likely understates the amount of "detailing" by Mallinckrodt sales representatives, as it reflects only visits in which a payment was provided. [redacted]

34. Mallinckrodt's sales representatives misleadingly portrayed its opioids as being less addictive than others. For example, a prescriber in Kentucky was told that Exalgo had less "ups and downs" than other opioids, and provided "more stable levels." The sales representative also said that Exalgo was "less volatile" than other opioids for patients with metabolic issues. This

[9] Open Payments is a federal program that collects information regarding visits and payments to doctors from pharmaceutical and medical device companies. Pharmaceutical and medical device companies are required to disclose this information under the Physician Payments Sunshine Act in the 2010 Affordable Care Act.

[10] Payments include activities such as promotional speaking, consulting, travel, and meals.

would have created the misleading impression that Exalgo was less addictive or less likely to be abused.

35. Marketing materials also trivialized the risk of opioid addiction. Mallinckrodt's former parent Company, Covidien, published a "patient resource," called "Opioid Safe Use and Handling Guide," which stated that: "Addiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur;" and "Taking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."[11] The guide further explains that opioid tolerance is different from addiction, by explaining that tolerance may cause a patient to take more opioids in order to receive pain relief.

36. Until at least June 2007, Mallinckrodt sponsored pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."[12]

37. The FAQs section of pain-topics.org contained misleading information about a concept called "pseudoaddiction." Pseudoaddiction is a concept invented to foster the misconception 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. Specifically, the pain-topics.org website described pseudoaddiction as behavior that occurs in

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[11] CARES Alliance, "Opioid Safe Use and Handling Guide."

[12] https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php, (Last visited May 7, 2018.)

patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications, and may be erroneously perceived as 'drug seeking." [13]

38. The website also characterizes as "misinformation" the fact that patients who use opioids for long-term chronic pain become addicted, and questions why the daily administration of medications such as insulin and antidepressants is not considered addiction when the daily administration of opioids is. In addition, the website states that the constant media attention regarding opioid addiction, misuse and overdose creates a "false impression" that opioids should never be prescribed, and the number of "celebrities and street users" along with those who overdose from misuse is minimal in comparison to those who benefit from chronic opioid therapy.[14]

39. Furthermore, pain-topics.org implies that if a patient is diagnosed with a pain condition and non-opioids fail to provide relief, that patient is "right" for opioids.[15] The website also says that the practice of not using opioids for long-term pain is "nonsensical."[16] It claims that patients who do not legitimately need opioids "do not exhibit obvious causes of pain" or provide other information such as MRIs, medical records, or an event which caused the chronic pain.[17]

40. In addition, among its content, the website contained a handout titled *Oxycodone Safety for Patients,* which advised doctors that "[p]atients' fears of opioid addiction should be

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[13] https://web.archive.org/web/20071026152321/http://pain-topics.org/faqs/index1.php#tolerance (Last visited May 7, 2018.)

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

expelled."[18] The handout stated the following misleading information regarding the risk of addiction:

Will you become dependent on or addicted to oxycodone?

- ☐ After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- ☐ This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

41. The U.S. Food & Drug Administration ("FDA") does not regulate unbranded advertising or marketing funneled through third-parties. Thus, neither the third-party unbranded materials, such as the information found on pain-topics.org, nor the marketing messages or scripts relied on by Mallinckrodt's sales representatives, were reviewed or approved by the FDA .

42. Mallinckrodt'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."[19] 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

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[18] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

[19] *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.

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).[20] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[21]

43. Mallinckrodt also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Mallinckrodt's website, in a section on "responsible use" of opioids, claimed that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[22]

44. The Mallinckrodt-sponsored pain-topics.org website also claimed that long-term use of opioids for treatment of chronic pain conditions would improve patients' function. The website stated that the benefits of using opioids for chronic pain include improvement to functions such as eating, sleeping, socializing, sexual activity, driving, walking and working. The website also claims that chronic opioid administration improves "quality of life."[23] The website further states that people who do not take opioids for long-term pain are "unable to participate in a normal family, vocational or other desired pursuits."[24]

45. Mallinckrodt's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of

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[20] CDC Guideline at 2.

[21] *Id.* at 21.

[22] Mallinckrodt Pharmaceuticals, Responsible Use, www.mallinckrodt.com/corporate-responsibility/responsible-use.

[23] https://web.archive.org/web/20071025004137/http://pain-topics.org/pdf/OvercomingOpiophobia.pdf (Last visited June 25, 2018).

[24] *Id.*

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.

46. 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."[25] Studies of patients who suffer from chronic pain, 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.

47. 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.[26]

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

[26] 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

The CDC Guideline concludes 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."[27] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[28]

B. Mallinckrodt Made Misrepresentations Regarding Abuse-Deterrence

48. Mallinckrodt oversold its "abuse-deterrent" opioids as a reason that doctors could continue to prescribe their opioids. Mallinckrodt's false and misleading marketing of the benefits of its abuse-deterrent opioids influenced prescribers to discount evidence of opioid addiction and abuse and attribute it to other, "less safe" opioids—thereby prolonging the opioid epidemic.

49. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[29] One member of the FDA's Controlled

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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 Mallinckrodt on the FDA website.

[27] *Id* at 18.

[28] *See* n. 4, *supra*.

[29] Mallinckrodt Press Release, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe*

Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[30]

50. Mallinckrodt disseminated false messages regarding its abuse-deterrent formulations to Kentucky prescribers through its sales representatives. According to one Kentucky doctor, a Mallinckrodt representative told him that Exalgo was "crush resistant" and contained "tamper resistant properties," which made the drug difficult to inject or snort. Additionally, the representative stated that Exalgo would be a better drug than the generic alternatives for patients with Hepatitis-C, because it would be difficult for the patient to inject Exalgo.

51. In addition, with respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[31] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[32]

52. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting

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Chronic Pain (Aug. 27, 2012), available at http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159

[30] http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandanalgesicdrugproductsadvisorycommittee/ucm187490.pdf at 157-58.

[31] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014) at 14.

[32] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Business Journal (Dec. 30, 2013), available at http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/

that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[33] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [abuse deterrent opioids] actually reduce rates of addiction, overdoses, or death." [34]

53. Mallinckrodt promotes patented technology as the solution to opioid abuse and addiction, but none of its "technology" addresses oral ingestion, and its statements regarding abuse-deterrent formulations give the misleading impression that doctors need not worry about the abuse of these opioids. The above representations and resulting implications that Exalgo and Xartemis XR would prevent abuse and were, therefore, safer than other opioids were false and misleading.

C. Mallinckrodt Directed Front Groups to Promote Opioid Use and Combat Efforts to Restrict Opioid Prescribing

54. Patient advocacy groups and professional associations have been vehicles for Mallinckrodt to reach prescribers, patients, and policymakers. Mallinckrodt exerted influence and effective control over the messaging by these groups by providing funding directly to them. Mallinckrodt funded Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

55. "Patient advocacy organizations and professional societies like the Front Groups play a significant role in shaping health policy debates, setting national guidelines for patient

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[33] CDC Guideline at 22 (emphasis added).

[34] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), available at http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

treatment, raising disease awareness, and educating the public."[35] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[36]

56. The U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,[37] arose out of a 2017 Senate investigation and, drawing on disclosures from other opioid manufacturers, "provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy."[38] The Report found that Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[39] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[40]

57. Upon information and belief, by funding Front Groups, Mallinckrodt was able to exercise control over their false and deceptive messages. Mallinckrodt acted through the Front

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[35] *Id.* at p. 2.

[36] *Id.*

[37] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at 1.

[38] *Id.*

[39] *Id.* at 12-15.

[40] *Id.* at 12.

groups to deceptively promote the use of opioids for the treatment of chronic pain, and to press for policies and legislation that would advance its interests.

58. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[41] The organization is a Front Group. It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[42] As of January 2018, the APA listed 30 "Associate Members and Financial Supporters," which includes Mallinckrodt.[43]

59. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[44] Among other things, the white paper criticizes prescription monitoring programs,[45] purporting to express concern that they are

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[41] *About AfPA*, The Alliance for Patient Access, http://allianceforpatientaccess.org/ about-afpa/#membership (last visited May 8, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[42] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter "Jaklevic, *Non-profit Alliance for Patient Access*").

[43] APA's board members, including Dr. Robert A. Yapundich, Dr. Jack D. Schim, and Dr. Howard Hoffberg, have also directly received funding from pharmaceutical companies including Mallinckrodt. *See* ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/

[44] Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s. wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

[45] Prescription monitoring programs, such as the Kentucky All Schedule Prescription Electronic Reporting ("KASPER"), serve to curb diversion by providing physicians with access to information regarding prescriptions of controlled substances patients have received during a certain period of time.

burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
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> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[46]

60. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[47]

61. In addition, in an echo of earlier industry efforts to push back against what they

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[46] Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s. wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

[47] *Id.* at 5-6.

termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.[48]

62. In conclusion, the white paper advocates for the use of opioids for chronic pain, stating, "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[49]

63. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act").[50] An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "'could actually result in

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[48] *Id.* at 6.

[49] *Id.* at 7.

[50] Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015), http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_Access_Letter_of_Support_House_Bill.pdf.

increased diversion, abuse, and public health and safety consequences'"[51] and, according to DEA Chief Administrative Law Judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like Mallinckrodt here, in federal courts.[52] The law passed both houses of Congress and was signed into law in 2016. These efforts to prevent the implementation of programs and statutes that are designed to prevent diversion are in direct contravention of Mallinckrodt's public claims that it is committed to fighting opioid misuse and preventing diversion. *See* ¶¶ 91-92 *infra.*

64. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with Mallinckrodt. The USPF was one of the largest recipients of contributions from the Mallinckrodt and other opioid makers, collecting nearly $3 million from opioid makers in payments between 2012 and 2015 alone. The USPF was also a critical component of Mallinckrodt's lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to Mallinckrodt, listing opioid manufacturers like Mallinckrodt, as "Platinum," "Gold," and "Basic" corporate members.[53] Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

65. The USPF has made several misleading statements regarding opioids. For example,

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[51] Bill Whitaker, Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 2017), https://www.cbsnews.com/news/ ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").

[52] John J. Mulrooney, II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marquette L. Rev. (forthcoming Feb. 2018), https://www.documentcloud.org/ documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html.

[53] *Id.* at 12; Transparency, U.S. Pain Foundation, https://uspainfoundation.org/transparency/ (last accessed on March 9, 2018).

USPF claims that opioid treatment allows patients to function.[54] Additionally, Paul Gileno, the founder and president of the USPF, claimed that opioids allow people to "participate in daily life and be contributing members of society."[55] The USPF made further misleading statements, including statements that involve veterans. For example, the USPF website discusses recent opioid prescribing guidelines released by the Department of Veteran Affairs and Department of Defense. The USPF describe these guidelines as "problematic" due to their advice to prescribe 20-50 morphine milligram equivalents ("MME") per day with caution, and their warning against prescribing more than 90 MEEs per day. The group also suggests untreated chronic pain creates a risk of suicide, and therefore physicians should not necessarily be cautious in prescribing opioids to those with suicidal ideation.[56]

D. Mallinckrodt Told Doctors that Opioids Could be Taken in Ever Higher Doses without Disclosing their Greater Risks

66. Through third parties, Mallinckrodt 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. Mallinckrodt apparently 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.

67. Through its funding of the website pain-topics.org, Mallinckrodt claimed that there

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[54] U.S. Pain Foundation, New Coalition Calls for Balanced Approach to Opioids, available at https://uspainfoundation.org/news/new-coalition-calls-balanced-aproach-opioids/.

[55] *Id.*

[56] U.S. Pain Foundation, VA Restricts Opioids for Veterans and Military Service Members, available at https://uspainfoundation.org/news/va-restricts-opioids-veteran/.

is no ceiling dosage for opioids, and that dosage should be determined by starting on low dosages and titrating up until a patient finds relief. The website does not disclose the dangers associated with higher doses, but claims that risks associated with opioids, such as death, overdoses and accidents, occur when patients do not take opioids as prescribed, or when the patient is taking other drugs or substances unknown to the prescribing doctor.

68. 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.

69. 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."[57] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[58]

70. 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

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[57] 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."

[58] CDC Guideline at 16.

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.

E. Mallinckrodt Failed to Put into Place Proper Procedures to Report Suspicious Orders of Opioids

71. Through its misleading marketing, Mallinckrodt, on information and belief, created a larger market for opioids in Kentucky. Until at least 2007, Mallinckrodt deceptively promoted opioids through the website it funded, pain-topics.org. From 2008 until present, Mallinckrodt then compounded this harm by failing to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continuing to fill orders which supplied far more opioids than were justified. Each of Mallinckrodt's shipments of opioids into the stream of commerce in Kentucky that were fulfilled without an adequate system in place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious, violated both its common law duties and statutory duties under Kentucky law.

72. Under the common law, Mallinckrodt had a duty to exercise reasonable care in selling dangerous narcotic substances. Any time Mallinckrodt filled and failed to report orders that it knew or should have known were likely being diverted for illicit uses, Mallinckrodt breached that duty and created and failed to prevent a foreseeable risk of harm to the Commonwealth. In addition, Mallinckrodt had a duty, when speaking publicly about opioids and its efforts to combat diversion, to speak accurately and truthfully.

73. Mallinckrodt also had statutory duties pursuant to Kentucky law. Kentucky's Controlled Substance Act ("KYCSA") requires Mallinckrodt, as a manufacturer of controlled substances, to comply with the Commonwealth's licensing and permitting requirements, which incorporate the federal Controlled Substances Act. *See* Ky. Rev. Stat. Ann. §§ 218A.150(1)

(effective until July 14, 2018) ("No person shall manufacture . . . controlled substances, and no person as a wholesaler shall supply the same, without having first obtained a license to do so from the Cabinet for Health and Family Services."); 218A.160(1)(a) (effective until July 14, 2018) ("No manufacturer's or wholesaler's license shall be issued pursuant to this chapter unless the applicant therefor has furnished satisfactory proof: (a) That the applicant is in compliance with all applicable federal and state laws and regulations relating to controlled substances . . ."); 218A.170(1),(4) (effective until July 14, 2018) ("(1) A duly licensed manufacturer, distributor, or wholesaler may sell or distribute controlled substances . . . [and] (4) All sales and distributions shall be in accordance with KRS 218A.200 and the federal controlled substances laws"). *See also* 201 Ky. Admin. Regs. 2:320 §1(4)(d) (mandating that a manufacturer "continue. . . to demonstrate acceptable operational procedures, including . . . compl[iance] with all DEA regulations."); 902 Ky. Admin. Regs. 55:010, Section 4 ("(1) The cabinet shall consider the following factors in reviewing the qualifications of an applicant to engage in the manufacture . . . of controlled substances: . . . (c) An applicant's history with state or federal regulatory agencies as related to the manufacture or distribution of controlled substances.").

74. Thus, under Kentucky law, Mallinckrodt must register annually with the DEA to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a)(1). Any registration must be consistent with the public interest based on a consideration of, among other factors:

> (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.

Id.

75. In addition, Kentucky law, through its incorporation of federal law, requires Mallinckrodt to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

76. In sum, Mallinckrodt has several responsibilities with respect to suspicious orders of opioids. First, it must set up a system designed to detect such orders. That would include reviewing its own data, relying on its observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Second, it must refuse to fill suspicious orders and only fill orders flagged as potentially suspicious if, after conducting due diligence, it can determine that the order is not likely to be diverted into illegal channels. And, third, all suspicious orders must be reported to relevant enforcement authorities.

1. Mallinckrodt Understood the Importance of Its Reporting Obligations Yet Failed to Meet Them

77. The purpose of the reporting rules is to create a "closed" system intended to reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[59]

78. Mallinckrodt was well aware it had an important role to play in this system, and also knew or should have known that its failure to comply with its reporting obligations would

[59] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

have serious consequences.

79. In a letter to registrants, including Mallinckrodt, on December 27, 2007, the DEA reminded Mallinckrodt that, as a registered manufacturer of controlled substances, it shares, and must abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[60] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[61]

80. In 2011, the DEA began to investigate Mallinckrodt after DEA investigators noted large amounts of Mallinckrodt's oxycodone being sent to Florida. The investigation resulted in a fine of $35 million for Mallinckrodt's failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The Department of Justice and DEA determined that Mallinckrodt ignored its responsibility to report suspicious orders of as many as 500 million of its pills that were sent to Florida from 2008 to 2012, which was 66% of all oxycodone sold in the state. According to the *Washington Post*, an internal summary of the federal

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[60] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[61] *See* 2007 Rannazzisi Letter.

case against Mallinckrodt found that "Mallinckrodt's response was that 'everyone knew what was going on in Florida but they had no duty to report it.'"[62]

81. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . 'Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands' . . ."[63]

82. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[64]

83. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding

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[62] *The Government's Struggle to Hold Opioid Manufacturers Accountable: Sixty-Six Percent of All Oxycodone Sold in Florida Came From This Company. But the DEA's Case Against It Faltered,* Wash. Post, (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.256b39de1578.

[63] *See* Press Release, *U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[64] *Id.*

Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

i. conduct adequate due diligence of its customers;

ii. detect and report to the DEA orders of unusual size and frequency;

iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[65]

[65] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt,

84. In connection with the settlement, Mallinckrodt admitted that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[66] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product."[67] Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[68]

85. Mallinckrodt also acknowledged that at certain times prior to January 1, 2012, certain aspects of its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[69]

86. Mallinckrodt, through its internal sources, knew or should have known that some of the millions of pills it ignored its responsibility to report were being used to fill suspicious orders in Florida, and knew or should have known that those opioids were being diverted into Kentucky communities. In light of Kentucky's implementation of the KASPAR (Kentucky All Schedule Prescription Electronic Reporting System) system designed to detect diversion of in-state pill mills by Kentucky authorities, drug traffickers in Kentucky routed orders through Florida pharmacies

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LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA"), at 2-3.

[66] *Id.* at 1.

[67] *Id.* at 4.

[68] *Id.*

[69] *Id.*

or prescribers for diversion back into Kentucky communities, on a route that became known as the "Florida Pipeline" or "OxyContin Express."[70] Opioids that were diverted in this drug trafficking route included Roxicodone, an opioid manufactured by Mallinckrodt. In fact, the route was also known as the "Blue Highway," a reference to the color of the 30mg Roxicodone pills.[71] Law enforcement officials estimate that 90% of patients that used some Florida pill mills come from Kentucky. In addition, according to Kentucky law enforcement authorities and drug policy officials, 60% of Kentucky's illicit pills come from Florida.

87. The pipeline from Florida to Kentucky was well known. In another case, defendants who operated a pill mill in south Florida were prosecuted in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations.[72] As explained by the Sixth Circuit in its decision upholding the venue decision, "[d]uring its existence, the clinic generated over $10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the [Pain Center of Broward]'s customers came from Florida.. . . The [Pain Center of Broward] gained massive financial benefits by taking advantage of the demand for oxycodone by Kentucky residents."[73]

88. DOJ prosecutors found that Mallinckrodt knew of DEA enforcement actions against distributors for failing to report the disproportionately large amounts of painkillers they were shipping to retail customers in Florida and other states. Moreover, Mallinckrodt recognized

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[70] Decl. of DEA Diversion Investigator Christopher Kresnak, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9-2 ¶ 3 (S.D. Ohio June 30, 2011).

[71] John Temple, *American Pain* 171 (2016).

[72] *United States v. Elliott*, 876 F.3d 855, 858, 861 (6th Cir. 2017).

[73] *Id.* at 858.

in November 2010 that 68% of the purchases by one of its distributors, Cincinnati-based KeySource Medical, Inc., were for prescription opioids, and that 91% of this customer's purchasers were sent to Florida.[74]

89. Mallinckrodt also had other information that would have alerted it to potential diversion. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." As part of the settlement, Mallinckrodt agreed that, from this data, it could and would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[75] While the 2017 settlement arose out of Mallinckrodt's failure to report suspicious orders in Florida, upon information and belief, it is indicative of a systemic failure that continues to this day, not only in Florida, but in Kentucky as well.

90. [redacted]

[74] United States' Opposition to Plaintiff's Motion for a Preliminary Injunction, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9 at 6 (S.D. Ohio June 30, 2011).

[75] *Id.*

[redacted]

91. Mallinckrodt claims on its website to be "committed both to helping health care providers treat patients in pain and to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."[76]

92. These public statements create the false and misleading impression that Mallinckrodt has rigorously carried out its duty to report suspicious orders and to exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility. The truth, of course, is that Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill suspicious orders, which supplied far more opioids than were justified and led to diversion of opioids in Kentucky and other states. Furthermore, far from trying to address diversion, Mallinckrodt worked to defeat programs and laws designed to prevent diversion through its sponsorship of APA and USPF. *See* ¶¶58-65, *supra.*

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[76] Mallinckrodt website, Our Programs, http://www2.mallinckrodt.com/Responsibility/Responsible_Use/Our_Programs/

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

93. Upon information and belief, the vast market for opioids was created and sustained, in significant part, by Mallinckrodt's deceptive marketing in establishing opioids as a first-line treatment for chronic pain. Mallinckrodt'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. In addition, Mallinckrodt fueled the opioid epidemic in Kentucky by failing to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continuing to fill orders that it knew or should have known were suspicious, which supplied far more opioids than were justified. Each of Mallinckrodt's shipments of opioids into the stream of commerce in Kentucky without an adequate system in place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious, violated both its common law duties and its statutory duties under Kentucky law.

94. Mallinckrodt's marketing, and especially its detailing to doctors, have 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. Mallinckrodt necessarily expected a return on its investment in opioid marketing, and carefully calibrated its promotion efforts to serve that end.

95. Mallinckrodt devoted substantial resources to its marketing efforts. Publicly available data shows that Mallinckrodt sales representatives visited prescribers 577 times between the third quarter of 2013 and 2016. Furthermore, [redacted]

96. 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.

97. [redacted] Kentucky's Medicaid program spent $14,793,690 on Mallinckrodt's opioids from 2013 to 2016. [redacted]

98. 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.

99. 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."

100. 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.[77] 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."[78]

101. 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."[79] 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." Prescription opioids and heroin account for the majority of overdoses. For these reasons, the CDC concluded that efforts to improve the safer prescribing of opioids must be intensified "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

102. 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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[77] 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.

[78] Id.

[79] 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.)

103. 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.

104. Upon information and belief, the escalating number of opioid prescriptions written by doctors who were deceived by Mallinckrodt's deceptive marketing scheme, along with Mallinckrodt's failure to put in place appropriate procedures to ensure suspicious orders would be reported and instead, its continuing to fill orders which supplied far more opioids than were justified, caused a correspondingly dramatic increase in opioid addiction, overdose, and death throughout Kentucky.

105. 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. Opioids have had devastating effect on Kentucky's work force. According to one study, in 2015, nearly one-million eligible Kentucky employees were absent from the work force due to opioids.

106. Opioids have contributed to a significant labor shortage in Eastern Kentucky, as employment in the region dropped by 21% from 2006 to 2016 due, in part, to the high rate of opioid use in the region. For example, according to the Commonwealth's Energy and Environment Cabinet, in 2011, coal employment averaged 12,679 people, but decreased to 4,042 in 2017. Recent research has demonstrated that the Commonwealth's high rate of opioid usage has reduced the work force, created high turnover, increased employers' costs to train new employees, and caused an increase in employee thefts. Additionally, according to a study conducted by the Appalachian Regional Commission, small businesses and large manufacturing firms are having difficulties hiring employees who are able to pass drug screening tests. Convenience stores that are open 24 hours per day are having difficulties operating with fewer employees. The shortage in work force impacts customer service, and requires managers to work extra shifts, which increases overtime costs. According to a Commonwealth resident who owns convenience stores in London and Manchester, Kentucky, "[t]his is the hardest I've ever seen getting workers and keeping workers."[80]

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[80] Lexington Herald Leader, 'Nobody to pick from.' How opioids are devastating the workforce in Eastern Kentucky, available at https://www.kentucky.com/news/state/article213189309.html, last accessed June 28, 2018.

107. 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.

108. 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.

109. 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.

110. 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.

111. The increase in opioid-related deaths has created a shortage of forensic pathologists within the Commonwealth qualified to perform autopsies and post mortem toxicology tests.

Currently, the Commonwealth's medical examiner office only has nine doctors, and the demand for coroners has only increased due to growth in opioid-related deaths. The Kentucky Justice Cabinet recently announced a collaboration with the University of Kentucky to contract for forensic pathology services, which will increase training for medical students and strengthen salaries for doctors. The University of Kentucky will provide up to four pathologists and the University of Louisville will provide up to six in the Commonwealth's Medical Examiner Office in order to keep up with the surge in opioid-related deaths.

112. 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. Mallinckrodt also could have, and did, foresee that users who become addicted to a particular prescription opioid, such as Exalgo and Xartemis XR, 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.

113. 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.

114. 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, heroin, and fentanyl. A law enforcement officer in Kentucky similarly observed opioid addiction and abuse affecting people across varying ages and demographics.

115. 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.

116. 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.

117. The abuse of opioids, including opioids manufactured by Mallinckrodt, and the resulting increase in heroin use and addiction have caused outbreaks of HIV, chronic Hepatitis C, and TTP.

118. 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—more than six times the national average—from 2008 through 2015. St. Elizabeth Healthcare in Edgewood reports that it sees up to ten new cases of Hepatitis C daily.

119. 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. The CDC reports that nationwide from 2009 to 2014, hepatitis C present at the time of delivering a baby increased 89 percent, to 3.4 per 1,000 live births, according to the CDC, but in Kentucky, the rate was much higher at 15.1. Hepatitis C can ultimately cause liver cancer, fibrosis, or cirrhosis, and is the leading cause of liver transplants in the country.

120. 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.[81]

121. School districts also have seen a dramatic increase in suspensions of high school students found possessing, distributing, or under the influence of prescription drugs. According to a 2017 CDC study, one in seven high school students in the U.S. has misused opioids. In 2016, 90 Kentucky residents ages 15-24 years-old died of fatal drug overdoses. Drug use is also having an effect on local schools and playgrounds. In one school year, elementary schools in Boyd County found a total of 18 syringe needles in their playgrounds. To fight the epidemic, students from Ashland Middle school created a prototype to safely pick up and dispose of syringes and created a database enabling residents to see where the needles were found.

122. 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 convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

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

123. 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.

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

G. Mallinckrodt Fraudulently Concealed is Misconduct

125. Mallinckrodt 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. Mallinckrodt 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.

126. Notwithstanding this knowledge, at all times relevant to this Complaint, Mallinckrodt took steps to avoid detection of and to fraudulently conceal its deceptive marketing and unlawful and fraudulent conduct. Mallinckrodt disguised its role in the deceptive marketing

of chronic opioid therapy by funding and working through unbranded marketing, third party advocates, and professional associations.

127. In addition, Mallinckrodt affirmatively assured the public, and state and local governments, that it was working to prevent diversion and to curb opioid use and abuse. Yet, it failed to prevent diversion and worked in the shadows through Front Groups to undermine programs and statutes designed to combat the epidemic.

128. Mallinckrodt 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 Mallinckrodt'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.)

129. 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.

130. 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.

131. 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.

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

133. At all times relevant to this Complaint, Mallinckrodt, 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. Promoting the misleading concept of pseudoaddiction, thus concealing the true risk of addiction;

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

d. Misleadingly claiming that its abuse deterrent formulations were less likely to be abused than other opioids;

e. Misleadingly depicting the safety profile of opioids prescribed by minimizing their risks and adverse effects and

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

134. Mallinckrodt 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, Mallinckrodt 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.

135. At all times relevant to this Complaint, Mallinckrodt 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.

136. Mallinckrodt's unfair acts or practices include, but are not limited to::

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

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

c. Failing to maintain effective controls against diversion, including failing to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continuing to fill orders it knew or should have known were suspicious, which supplied far more opioids than were justified.

137. For each of Mallinckrodt'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 and ten thousand dollars ($10,000) for each violation targeted at consumers over the age of 60.

COUNT II

Restoration of Property due to Violations of Kentucky Consumer Protection Act

(KRS 367.110 et seq.)

138. Mallinckrodt'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 front groups, and other seemingly independent sources of objective medical information. By engaging in the conduct described above, Mallinckrodt 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.

Furthermore, Mallinckrodt's misleading and deceptive marketing increased the demand for opioids creating an environment ripe for diversion and abuse of opioids. Mallinckrodt also deliberately targeted non-specialist physicians who lacked the time and expertise to evaluate their deceptive claims.

139. Furthermore, Mallinckrodt failed to fulfill its duties to maintain effective controls against diversion. Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill orders which supplied far more opioids than were justified. Each of Mallinckrodt's shipments of opioids into the stream of commerce in Kentucky without an adequate system in place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious was an unfair practice under the KCPA.

140. Mallinckrodt's conduct has caused substantial, indeed grievous, injury to Kentucky persons. The staggering rates of opioid use, abuse, and addiction resulting from Mallinckrodt's marketing efforts and reporting failures 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. Mallinckrodt's success in extending the market for opioids to new patients and chronic conditions, and its failure to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continuing to fill orders which supplied far more opioids than were justified 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.

141. 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, or from the filling of suspicious orders of these drugs. Moreover, no public policy justifies Mallinckrodt's conduct in failing to put in place appropriate procedures to ensure suspicious orders would be reported, or in failing to detect and report suspicious orders. Further, no public policy justifies Mallinckrodt's conduct in overstating the benefits and denying or downplaying the risks of opioids, which deprived patients and doctors of the honest and complete information they need to make informed choices about their treatment. In light of Mallinckrodt's campaign of misinformation (and especially given the addictive nature of these drugs), the injuries caused by Mallinckrodt's misconduct could not reasonably have been avoided by those Mallinckrodt harmed.

142. Mallinckrodt'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.

143. 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 Mallinckrodt'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))

144. 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.

145. 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).

146. 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).

147. 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."

148. 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."

149. Mallinckrodt's practices, as described in the Complaint, violated KRS 205.8463(2) & (4). Mallinckrodt, 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.

150. 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.

151. 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").

152. The Medicaid program in Kentucky ("Kentucky Medicaid") is administered at the State level by the Kentucky Department for Medicaid Services ("DMS"). DMS 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. DMS is a governmental agency in the Executive Branch of the Commonwealth of Kentucky. Finally, DMS 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), KRS Chapter 205, KAR Title 907, and other applicable law.

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

154. Mallinckrodt engaged in a deceptive and misleading marketing scheme that was designed to, and successfully did, change the perception of opioids and cause their prescribing and sales to skyrocket in Kentucky. Mallinckrodt disseminated false and misleading information about the risks and benefits of opioids, which minimized the risks of addiction and overdose and exaggerated the purported benefits. At the same time, Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill orders that it knew or should have known were suspicious, which supplied far more opioids than were justified. Each of Mallinckrodt's shipments of opioids into the stream of commerce in Kentucky without an adequate system in place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious, violated both its common law duties and its statutory duties under Kentucky law.

155. Mallinckrodt 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, in part, for the purpose of getting the Kentucky Medicaid program to pay for opioids for long-term treatment of chronic pain. In addition, Mallinckrodt 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.

156. Mallinckrodt'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.

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

158. The Commonwealth's Medicaid program only covers the costs of care that "meets professionally recognized standards," are not obtained through fraud, material misrepresentation, or material omission, or do 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, Mallinckrodt's deceptive marketing with and through front groups constitutes conspiracy and complicity, in violation of 907 KAR 1:671(40)(j).

159. Mallinckrodt'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)

160. Mallinckrodt'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."

161. 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 Mallinckrodt 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."

162. As a direct and proximate result of Mallinckrodt'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.

163. Mallinckrodt 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, diverted and abused as a consequence of Mallinckrodt's fraud.

164. Mallinckrodt's misrepresentations were material because if the Commonwealth had known of the false statements disseminated by Mallinckrodt and its third-party allies and that doctors, pharmacists, and other health care providers, based upon those untrue, false, or misleading information, were certifying and/or determining that opioids were medically necessary, the Commonwealth would have refused to authorize payment for, or otherwise severely restricted, the use of opioid prescriptions to treat chronic pain.

165. 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.

166. By virtue of the above-described acts, Mallinckrodt 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.

167. 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 Mallinckrodt's deceptive marketing.

168. The Commonwealth, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Mallinckrodt, paid to pay the

claims that would not be paid but for Mallinckrodt's illegal business practices.

169. By reason of Mallinckrodt's unlawful acts, the Commonwealth has been damaged, in a substantial amount to be determined at trial. Medicaid spending accounts for nearly 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 Mallinckrodt'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 Mallinckrodt's violations as alleged herein and a significant financial burden on the Commonwealth. From 2013 to 2016, Kentucky's Medicaid spent $14,793,690 on Mallinckrodt 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.

170. As a direct and proximate result of Mallinckrodt'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.

171. Because Mallinckrodt'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, Mallinckrodt 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)

172. 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.

173. 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."

174. Mallinckrodt, 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).

175. 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."

176. 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."

177. 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."

178. By engaging in the conduct set forth above, Mallinckrodt 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.

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

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

181. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Mallinckrodt, in addition to any other penalties provided by law, forfeit and pay a civil penalty in the amount of all benefits and payments to which Mallinckrodt was not entitled in accordance with the provisions of KRS 194A.990(5).

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

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

184. 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.

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

186. 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.

187. 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.

188. Through its deceptive marketing and failure to maintain effective controls against diversion, Mallinckrodt 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.

189. The public nuisance was foreseeable to Mallinckrodt, which knew or should have known of the harm it would cause.

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

191. 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.

192. Mallinckrodt'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 Mallinckrodt'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.

193. The public nuisance—i.e., the opioid epidemic—created and maintained by Mallinckrodt can be abated.

194. 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.

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

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

197. Mallinckrodt, 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.

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

199. Mallinckrodt's statements about opioids generally and its opioids in particular were false.

200. Further, Mallinckrodt's 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.

201. Mallinckrodt 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.

202. Mallinckrodt intended that the Commonwealth and its residents would rely on its misrepresentations and omissions.

203. The Commonwealth and its residents reasonably relied upon Mallinckrodt's misrepresentations and omissions.

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

COUNT VII

Unjust Enrichment

205. 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.

206. 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.

207. By illegally and deceptively promoting opioids to treat chronic pain, Mallinckrodt has unjustly enriched itself at the Commonwealth's expense. The Commonwealth has made payments for opioid prescriptions, and Mallinckrodt benefited from those payments. Mallinckrodt 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.

208. Mallinckrodt also received a financial benefit from failing to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continuing to fill suspicious orders which supplied far more opioids than were justified. This enabled Mallinckrodt to maintain its highly profitable business practices without disruption at the expense of the Commonwealth.

209. Mallinckrodt 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.

210. 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, Mallinckrodt has reaped millions of dollars in profits from its deceptive marketing campaign.

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

212. Accordingly, under principles of equity, Mallinckrodt 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

Negligence

213. 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.

214. Mallinckrodt owed the Commonwealth a duty to not expose the citizens of the Commonwealth to an unreasonable risk of harm.

215. Mallinckrodt had a legal duty under Kentucky common law to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, marketing, and selling opioids.

216. Mallinckrodt also had a duty not to breach the standard of care established under Kentucky law to maintain effective controls against diversion of prescription opioids by having appropriate procedures in place to ensure suspicious orders would be reported, by reporting suspicious orders of opioids, and by not filling suspicious orders unless and until due diligence had eliminated the suspicion.

217. Each of Mallinckrodt's shipments of opioids into the stream of commerce in Kentucky without an adequate system in place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious violated both its common law duties and its statutory duties under Kentucky law.

218. Mallinckrodt has a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, Mallinckrodt, having engaged in conduct that created an unreasonable risk of harm to others, had, and still has, a duty to exercise reasonable care to prevent the threatened harm.

219. Mallinckrodt breached its duty to exercise the degree of care commensurate with the dangers involved in selling dangerous controlled substances.

220. Mallinckrodt breached its duty to the Commonwealth by aggressively marketing opioids in a way that minimized the risks of diversion, abuse, addiction, and overdose and exaggerated the purported benefits of long-term use of opioids for the treatment of chronic pain.

221. In addition, Mallinckrodt breached its duty to Commonwealth by, inter alia:

a. Selling opioids without maintaining effective controls against diversion, which facilitated and encouraged their flow into the illegal, secondary market;

b. Failing to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continuing to fill orders it knew or should have known were suspicious, which supplied far more opioids than were justified; and

c. Failing to report suspicious orders.

222. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

223. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the Commonwealth's communities.

224. Reasonably prudent manufacturers of prescription opioids would have anticipated

that the scourge of opioid addiction would wreak havoc on communities and the significant costs that would be imposed upon the governmental entities associated with those communities.

225. Reasonably prudent manufacturers of opioids would know that aggressively marketing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to Mallinckrodt. Reasonably prudent manufacturers would know that failing to put in place appropriate procedures to ensure suspicious orders would be reported, and failing to report suspicious orders, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

226. Mallinckrodt had control over its conduct in the Commonwealth. Mallinckrodt controlled its deceptive advertising and efforts to mislead the public, including its acts and omissions in detailing by its sales representatives, online communications, publications, and other means described in this Complaint. Mallinckrodt had control over its sale of opioids and over its reporting, or lack thereof, of suspicious orders. Mallinckrodt controlled the systems it developed to prevent diversion, including the criteria and process it used to identify suspicious orders, whether and to what extent it trained its employees to report and halt suspicious orders, and whether it filled orders it knew or should have known were likely to be diverted or fuel an illegal market.

227. Upon information and belief, Mallinckrodt's actions were a substantial factor in opioid use becoming so widespread, and the consequential enormous public health crisis of prescription opioid and heroin overuse, abuse, and addiction that now exists.

228. Upon information and belief, Mallinckrodt acted with actual malice and a wanton

and reckless disregard for the lives and safety of others, and said actions have a great probability of causing substantial harm.

229. The Commonwealth seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Mallinckrodt. It does not seek damages that may have been suffered by individual residents of the Commonwealth for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions Mallinckrodt.

230. The Commonwealth is not asserting a cause of action under the CSA or other federal controlled-substances laws cited above. Rather, it seeks to remedy harms caused to it by the breach of duty created by the statutory and common law of the Commonwealth of Kentucky.

231. Mallinckrodt's misconduct alleged in this case is ongoing and persistent.

232. As a direct and proximate result of Mallinckrodt's negligence, the Commonwealth has suffered actual pecuniary damage including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT IX

Negligence per se

233. 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.

234. Violation of a statute gives rise to a private right of action where the injured is within the class of persons the statute intended to be protected. This is true even where the statute is penal in nature and provides no civil remedy.

235. Mallinckrodt's conduct was negligence *per se* in that it violated the Kentucky laws discussed herein, including, but not limited to, KRS 194A.505, KRS 205.8463, KRS

218A.170(1),(4), and 201 Ky. Admin. Regs. 2:320 §2(4)(d).

236. The Commonwealth was a party intended to be protected by such laws and whose injuries said laws were designed to prevent. Mallinckrodt's violations of said laws proximately caused injury to the Commonwealth.

237. Mallinckrodt violated these laws, by, *inter alia*:

a. Disseminating unfair, false, deceptive, and misleading statements and statements that were false and misleading by virtue of material omissions in its promotion of opioids;

b. Presenting or causing to be presented false or fraudulent claims to the Commonwealth through its deceptive marketing of opioids;

c. Selling opioids without maintaining effective controls against diversion, which facilitated and encouraged their flow into the illegal, secondary market;

d. Failing to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continuing to fill orders it knew or should have known were suspicious, which supplied far more opioids than were justified; and

e. Failing to report suspicious orders.

238. Each of Mallinckrodt's shipments of opioids into the stream of commerce in Kentucky without an adequate system in place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious, violated both its common law duties and its statutory duties under Kentucky law.

239. As a direct and proximate result of Mallinckrodt's negligence *per se*, the Commonwealth has suffered actual pecuniary damage including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT X

Punitive Damages

(KRS 411.186)

240. 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.

241. By engaging in the conduct set forth above, Mallinckrodt 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 Mallinckrodt, or similarly situated parties.

PRAYER FOR RELIEF

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

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

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

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

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

g. Civil penalties in the amount of all benefits and payments to which Mallinckrodt 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 Mallinckrodt 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. Pecuniary damages for past and future losses and expenditures;

k. Punitive damages against Mallinckrodt pursuant to KRS 411.186;

l. Restitution or disgorgement of Mallinckrodt 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;

m. An award of reasonable attorney's fees, interest, and costs to Plaintiff for pre-judgement and post-judgement conduct;

n. A trial by jury;

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

Respectfully submitted,

ANDY BESHEAR
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