IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT IN ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. MALLINCKRODT PLC, MALLINCKRODT LLC, and SPECGX LLC Defendants.	)	Case No. _____

COMPLAINT

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I. PRELIMINARY STATEMENT

1. The State of Alaska brings this action in its persistent effort to protect the State and its citizens from the worst human-made epidemic in modern medical history—the over-use, misuse, and abuse of opioids. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control ("CDC"), "I don't think we've ever seen anything like this. Certainly not in modern times."

2. The CDC has reported that, in recent years, our nation has seen life expectancy decline. The increasing number of lives lost to overdoses, especially overdoses on opioids, represents the most significant factor in this alarming trend.

3. In Alaska, prescription opioids have created what the CDC called a "public health epidemic"[1] and what the President deemed a "public health emergency."[2] In 2011, Alaska saw 66 fatal opioid overdoses; by 2016, that number reached 96, and by 2017, 107—582 deaths over those seven years.

4. [redacted] Mallinckrodt is the largest manufacturer of opioids in the United States, and, on its own, accounts for 25% of the county's quota for controlled substances it manufactures. [redacted]

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

[2] 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.

[redacted][3]

5. 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.

6. 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

[3] [redacted]

(end-of-life) care. Consequently, the market for prescription opioids was sharply restricted and, for Mallinckrodt, unacceptably small.

7. For over a decade, Mallinckrodt engaged in a deceptive marketing campaign that minimized the risks of opioids, especially the serious risks of addiction, and sought to convince doctors that there was a significant upside to their use for chronic pain by exaggerating their purported benefits. These claims are unsupported by the scientific evidence and were, and remain, too often fatally false. Yet, Mallinckrodt relayed, and continues to relay, its deceptive messages to prescribers, which it has spread through marketing materials, websites, and in-person sales calls. It also relied upon and sponsored speakers' programs, professional associations, and third-party groups ("Front Groups") who disseminated its misleading messages while appearing independent and therefore credible.

8. This ongoing, fraudulent marketing played a significant role in transforming medical thinking about opioids, persuading doctors that the risk of addiction for legitimate pain patients is modest and manageable and outweighed by the benefits in reduced pain and improved quality of life for their patients. It also increased the comfort level of doctors and patients in converting opioids prescribed for acute pain—surgery or injuries, for example—to long-term use by patients who experienced or reported ongoing pain. Patients were subject to the same types of marketing messages and trusted that drugs prescribed by their doctors must be safe and useful.

9. Yet, roughly one in four patients who receive prescription opioids long-term for chronic pain in primary care settings will become addicted—a condition with which

they will struggle their entire lives. Addiction treatment professionals in Alaska confirm that opioid addictions in Alaska are steadily increasing.

10. Mallinckrodt knew or should have known that its representations regarding the risks and benefits of opioids, including the low risk of addiction, were not supported by or were directly contrary to the scientific evidence. [redacted]

11. Yet, instead of ceasing its untruthful marketing efforts, Mallinckrodt used addiction and abuse as a further opportunity to take advantage of a market others had substantially created. Mallinckrodt, which had long been a significant maker of generic opioids, launched its first branded (and more expensive) opioid Exalgo in 2010. Mallinckrodt promoted both Exalgo and later, Xartemis XR as having physical properties that made them less likely be addictive or abused, even though the drugs had never been approved by the Food and Drug Administration ("FDA") as abuse-deterrent.

12. Rather than compassionately helping patients, the explosion in opioid use has come at the expense of chronic pain patients. The CDC director 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

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

director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[5]

13. The increased volume of opioid prescribing correlates directly to increased addiction, overdose, and death; black markets for diverted prescription opioids; and, as noted above, an increase in heroin abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids. With the introduction of synthetic fentanyl, which can be added to heroin to increase the high, the transition from prescription pills to heroin has become even more deadly.

14. Compounding the harm it caused, Mallinckrodt also failed to control its supply of opioids into the state. Mallinckrodt promoted itself as a responsible manufacturer that went above and beyond what the law required by partnering with law-enforcement to address prescribing and diversion of opioids. In reality, however, Mallinckrodt shipped opioids into Alaska without an adequate system in place to prevent diversion of its opioids and to investigate, report, and refuse to fill orders that it knew or should have known were suspicious, breaching both its common law duties and its statutory duties under Alaska law. Despite its legal and ethical duty to report "suspicious orders" of its drugs, and, upon information and belief, ample red flags of potential diversion, Mallinckrodt has never once reported a single prescriber to state law enforcement or the Alaska State Medical Board.

[5] *Id*.

Instead, Mallinckrodt incentivized distributors to flood the State with opioids beyond even what the expanded market for chronic pain market could bear.[6]

15. Beyond fatal overdoses, the deceptive marketing, oversupply, and diversion of opioids have increased the need for addiction treatment; imposed a greater burden on first responders, hospitals and other health care providers dealing with opioid demand, overdoses, and other opioid-related injuries; created a generation of children with profound social service needs, either displaced by their parents' addiction or struggling with addiction themselves; and expanded the demands on law enforcement addressing diversion or other opioid-related crimes, among others. The State, and the services it provides its citizens, have been strained to the breaking point by this public health crisis.

16. While Mallinckrodt has profited enormously from its deceptive marketing, the State of Alaska and its residents have borne the costs in responding to opioid addiction and overdose, and opioid-related crime and dislocation. While many of those harms cannot be undone or ever adequately compensated, the Attorney General brings this action pursuant to his constitutional, statutory, and common law authority, alleging that Mallinckrodt has violated, and continues to violate, the Alaska Unfair Trade Practices and Consumer Protection Act ("UTPA"), AS 45.50.471 *et seq.* The Attorney General also alleges that Mallinckrodt's unlawful conduct has created a public nuisance, that Mallinckrodt has acted fraudulently and negligently, and that Mallinckrodt has been unjustly enriched through its actions. For these claims, the Attorney General seeks

[6] Alaska is suing the three largest wholesale distributors separately in *State of Alaska v. McKesson Corporation et al.*, No. 3AN-18-10023 CI (Alaska Super. Ct. Oct. 25, 2018).

injunctive relief, abatement of the public health epidemic that Mallinckrodt has helped create, the maximum civil penalties allowed by law for each violation of law, damages, and equitable relief within this Court's powers to redress and halt Mallinckrodt's unlawful practices.

II. PARTIES

A. PLAINTIFF

17. The State of Alaska brings this action, by and through its Attorney General, Kevin G. Clarkson, in its sovereign capacity in order to protect the interests of the State and its citizens. The Attorney General brings this action pursuant to his constitutional, statutory, and common law authority, including the authority granted to him by AS 44.23.020, and the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq*.

B. DEFENDANTS

18. 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, plc describes itself as "a global specialty pharmaceuticals company" that "develops, manufactures, markets and distributes both branded and generic specialty pharmaceutical products and medical imaging agents." Originally founded in 1867, Mallinckrodt Inc. was formerly a subsidiary of Covidien plc, which spun off its Mallinckrodt pharmaceuticals business into an independent, publicly traded company in June of 2013, in a transaction described by Mallinckrodt plc's President and CEO as having many benefits for the company's customers. [redacted]

[redacted]

19. Mallinckrodt plc has executive offices in the United States, and also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. The Mallinckrodt Pharmaceuticals logo appears on marketing and/or purportedly educational materials. Mallinckrodt Pharmaceuticals also has since responded to a letter from the FDA concerning the branded opioid Xartemis XR.

[redacted]

20. 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 has been a wholly owned subsidiary of Mallinckrodt, plc since June 28, 2013. It is licensed to conduct business in Alaska.

21. SpecGX LLC, is a wholly owned subsidiary of Mallinckrodt plc and was incorporated in Delaware on November 14, 2016.[7] SpecGX filed a Certificate of Registration with the State of Alaska on June 26, 2017 and has a registered agent in Juneau.

[redacted] Mallinckrodt, plc Mallinckrodt, LLC, and SpecGX LLC are referred to collectively as "Mallinckrodt."

[7] Alaska has listed SpecGX as a Defendant for the purpose of ensuring that the State can obtain appropriate injunctive relief.

22. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, and Roxicodone, which is oxycodone. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo, and launched it in the United States in 2010. Exalgo is still sold and marketed in Alaska today. Mallinckrodt expanded its branded opioid portfolio in 2012 by purchasing Roxicodone, an oxycodone, from Xanodyne Pharmaceuticals. Roxicodone was so widely known for diversion that a route between Florida "pill mills" and illicit markets in other states became known as the "Blue Highway" for the color of Mallinckrodt's 30 mg Roxicodone pills. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

23. While it has also 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 approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

24. 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.

III. JURISDICTION AND VENUE

25. Jurisdiction over the subject matter of this cause of action is proper based upon AS 22.10.020, 09.58.015, and 45.50.501. The State seeks damages in excess of $100,000.

26. This Court has personal jurisdiction over Mallinckrodt because it regularly conducts business in Alaska and/or has the requisite minimum contacts with Alaska necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being proper under Alaska's long-arm statute, as codified in AS 09.05/015.

27. Venue is appropriate in the Third Judicial District at Anchorage pursuant to Rule 3 of the Alaska Rules of Civil Procedure, in that many of the unlawful acts committed by Defendants were committed in Anchorage.

28. The Attorney General has determined that pursuit of this action is in the public interest, as required by AS 45.50.501(a).

IV. FACTUAL ALLEGATIONS

A. Mallincrodt Expanded And Sustained Its Opioid Market Through Fraud

29. 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. Though this scheme, Mallinckrodt helped ensure opioids were and remained entrenched as an appropriate—and often the first—treatment

for chronic pain conditions. Mallinckrodt has not only continued to make these deceptive claims, but has failed to acknowledge, retract, or correct its prior false and deceptive claims.

30. The long-term use of opioids for chronic pain is particularly dangerous because patients develop tolerance to the drugs over time, requiring higher doses to achieve their effect. At high doses, opioids depress the respiratory system, eventually causing the user to stop breathing, which is what makes opioid overdoses fatal. Patients also quickly become dependent on opioids and will experience often severe withdrawal symptoms if they stop using the drugs, making it very hard for patients to discontinue their use after even relatively short periods of time. The risk of addiction increases with the duration of use, and causes patients to use opioids at ever-higher doses, even when they are causing harm. It is this mix of tolerance, dependence, and addiction that has made the use of opioids for chronic pain so lethal. Contrary to Mallinckrodt's misrepresentations, as laid out below, pain patients who use opioids precisely as prescribed by a legitimate doctor can—and do—become addicted. Addiction is the result of using opioids, not just misusing or abusing them.

31. These misrepresentations were especially insidious because Mallinckrodt targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate both Mallinckrodt's marketing and patients' pain conditions. A district manager whose territory included Alaska observed that some offices in his territory had a high volume of patients and that it was physician's assistants or nurse practitioners who did most of the prescribing.

32. [redacted]

33. Mallinckrodt expected that a minority of high-prescribing doctors would be responsible for the vast majority of its sales, including in Alaska. Mallinckrodt's headquarters transmitted lists to sales representatives through company software on the representatives' laptops. [redacted]

34. Mallinckrodt encouraged prescribers and patients to start on its opioids through its use of copayment cards, which helped subsidize patients' out of pocket costs for new prescriptions. [redacted]

[redacted] Even today, www.exalgo.com enables patients or providers to print a card offering a chance to: "Save up to $60 every time you fill or refill your prescription" as long as patients pay the first $15. Of course, encouraging a patient to start on an addictive, Schedule II narcotic created a significant risk that the patient would remain on Mallinckrodt's opioids beyond that first prescription.

35. Mallinckrodt's sales messages and strategies paid off. By volume or weight, its sales in Alaska exceed those of any other opioid maker.

1. Through Aggressive and Deceptive Marketing, Mallinckrodt Falsely Trivialized, Mischaracterized, and Failed to Disclose the Known, Serious Risk of Addiction.

i. Mallinckrodt's publications and websites deceptively minimized the risk of addiction.

36. Mallinckrodt published materials, available to Alaska prescribers, trivializing the risk of opioid addiction. Mallinckrodt's former parent 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." 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.

37. 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." Mallinckrodt has never acknowledged, retracted, or corrected the misrepresentations on pain-topics.org.

38. The website 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. The also website seeks to calm fears about addiction and promote long-term opioid therapy as beneficial by describing media attention to fatal overdoses as overblown and creating a "false impression" about opioid prescribing. According to pain-topics.org, overdoses are limited to a "minimal" number of "celebrities and street users." The website even dismisses the practice of not using opioids for long-term pain as "nonsensical."

39. Among its content, the website also contained a handout titled *Oxycodone Safety Handout for Patients*, released in June 2007, which advised doctors that "[p]atients' fears of opioid addiction should be dispelled." The handout misleadingly stated that "[a]ddiction to oxycodone in persons without a recent history of alcohol or drug problems is rare." It also misleadingly characterized withdrawal symptoms as occurring only if medication is suddenly stopped and suggested that gradually lowering the dose as a way to "help prevent" withdrawal symptoms, which the handout characterized mildly as merely "uncomfortable" symptoms that may include "diarrhea, body aches, weakness,

restlessness, anxiety, loss of appetite, and other ill feelings." This handout is still available to prescribers and patients today.

40. In addition, Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt describes C.A.R.E.S as its own advocacy program, and promised "[t]hrough the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take."

41. The C.A.R.E.S. Alliance publicly describes itself as "[c]reated with leading pain experts through a scientific process" and offering "free resources" to "promote safe prescribing, dispensing, use, storage, and disposal" of opioid pain medications. It further described the "safe-use programs and voluntary tools" it developed as "grounded in science and research." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

42. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled Defeat Chronic Pain Now!. This book is still available online in Alaska and

elsewhere. The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "[I]n our experience, the issue of tolerance is overblown."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

43. Mallinckrodt also, upon information and belief, overstated the efficacy of screening tools in mitigating addiction.

44. Through the C.A.R.E.S. Alliance, Mallinckrodt offered a "Fact Sheet" with various "Physician Tools," including "risk assessment tools." These included the "Opioid Risk Tool," created by prominent opioid advocate Dr. Lynn Webster. It is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction. [redacted]

45. Mallinckrodt's messaging created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids. Mallinckrodt has never acknowledged, retracted, or corrected these misrepresentations.

46. Upon information and belief, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, Mallinckrodt omitted the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[8] hormonal dysfunction;[9] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[10] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.[11]

ii. Mallinckrodt's sales representatives spread and reinforced the message.

47. [redacted]

[8] Letter from Janet Woodcock, M.D., Dir. of Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. of Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[9] H.W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids,* 3(5) J. Pain 377, 377-84 (2001).

[10] Bernhard M. Kuschel, *The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People—A Swedish Case-Control Study*, 25(3) Eur. J. Pub. H. 527, 527-32 (July 31, 2014).

[11] Karen H. Seal *et al.*, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. of Am. Med. Assoc. 940, 940-47 (2012).

[redacted]

48. [redacted]

49. [redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]

50. [redacted]

iii. Mallinckrodt Used its Speakers Program and Purportedly Educational Outreach to Spread its Deceptive Messaging.

51. In addition to reliance on written materials and sales calls, Mallinckrodt used a speakers' program, paying doctors to make presentations to other prescribers. A former employee familiar with Mallinckrodt's sales and marketing efforts in Alaska recalled, for example, that Mallinckrodt sought to find "well-respected pain specialists" in who could be used to promote Exalgo to other doctors. Doctors recruited for Mallinckrodt's speakers program would then attend training provided by Mallinckrodt. These speakers ultimately would provide talks at dinner programs attended by other physicians. The slides they used for their presentations were provided by Mallinckrodt and the speakers were directed not to deviate from the slide deck.

52. [redacted]

2. Mallinckrodt Used Purportedly Independent Third Parties to Promote Opioid Use and Combat Efforts to Restrict Opioid Prescribing.

53. Upon information and belief, Mallinckrodt's strategy included courting prescribers and "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity— to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. A leading KOL, Dr. Perry Fine, provided an "update" on the management of chronic pain that "focused specifically on EXALGO" at the American Pain Society's Annual Scientific Meeting in 2010.

54. Mallinckrodt also used patient advocacy groups and professional associations as vehicles to reach prescribers, patients, and policymakers. Upon information and belief, by funding these "Front Groups," Mallinckrodt was able to exercise control over their false and deceptive messages. Mallinckrodt acted through the Front 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.

55. One such Front Group is the Alliance for Patient Access ("APA"). Founded in 2006, the 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."[12] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006. As of June 2017, the APA's list of "Associate Members and Financial Supporters" included Mallinckrodt.

56. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[13] Among other things, the white paper criticizes prescription monitoring programs,[14] purporting to express concern that they are burdensome, not user friendly, of questionable efficacy, and could lead physicians to stop prescribing pain medications, which the white paper described as threatening damaging or dangerous consequences. The white paper also purports to express concern about "well intentioned" policies that have been enacted in response to the prevalence of pill mills, claiming that they "have made it difficult for legitimate pain management centers to operate." In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication. In conclusion, the white paper advocates the

[12] *About AfPA*, The Alliance for Patient Access, http://allianceforpatientaccess.org/about-afpa/#membership (last visited January 23, 2019). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[13] 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.

[14] Prescription monitoring programs 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.

use of opioids for chronic pain, stating, "[p]rescription pain medications, and specifically the [sic] 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."[15]

57. 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"). An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"[16] 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, including Defendants, in federal courts.[17] 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* Section B, *infra*.

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[15] *Id.* at 7.

[16] 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").

[17] 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. (Feb. 2018), https://www.documentcloud.org/ documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html.

58. 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 Mallinckrodt and other opioid makers, collecting nearly $3 million from opioid makers in payments between 2012 and 2017 alone. The USPF was also a critical component of lobbying efforts to prevent limits on over-prescribing opioids. 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.

59. The USPF has made several misleading statements regarding opioids. For example, the USPF website discusses recent opioid prescribing guidelines released by the Department of Veteran Affairs and Department of Defense 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 MMEs 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.

60. The Front Groups put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. Upon information and belief, in many instances, Mallinckrodt distributed these publications to prescribers or posted them on websites.

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

61. Not only did Mallinckrodt minimize the occurrence of addiction, it also sought to cover up the occurrence of addiction by attributing it to a made-up condition called "pseudoaddiction." According to the fabricated concept of "pseudoaddiction," which Mallinckrodt encouraged, 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.

62. Despite there being no scientific support for pseudoaddiction, Mallinckrodt and its Front Groups were able to advance the concept because of their broad influence. For example, the Federation of State Medical Boards ("FSMB"), is a trade organization representing the 70 state medical and osteopathic boards, including the Alaska State Medical Board, that finances opioid- and pain-specific programs through grants from Mallinckrodt and other manufacturers. A 2004 version of the FSMB Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of pseudoaddiction.

63. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Mallinckrodt, through its C.A.R.E.S. Alliance, also promoted the book as a "physician tool." Based upon

information and belief, *Responsible Opioid Prescribing* was distributed nationally and in Alaska.

64. Mallinckrodt also promoted the idea of pseudoaddiction through other initiatives. For example, it promoted pseudoaddiction by sponsoring the website pain-topics.org, (described *supra* in ¶¶ 37-38). The FAQs section of pain-topics.org described pseudoaddiction as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications, and may be erroneously perceived as 'drug seeking."

65. The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts without conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[18] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[19]

[18] CDC Guideline at 13.
[19] *Id.* at 25.

4. Mallinckrodt Overstated Opioids' Effect on Patients' Function and Quality of Life While Failing to Disclose the Lack of Evidence Supporting Long-Term Use.

66. To convince prescribers and patients that opioids should be used to treat chronic pain, Mallinckrodt had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[20] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[21] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[22] As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

67. Nevertheless, Mallinckrodt touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence and failing to disclose potential risks.

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[20] *Id.* at 10.

[21] *Id.* at 9.

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

68. Mallinckrodt 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."[23] Mallinckrodt has never acknowledged, retracted, or corrected its misrepresentations, and continues to make them via its website.

69. 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." 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."

70. Mallinckrodt's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. On the contrary, the available evidence indicates opioids may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health

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

conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

71. 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."[24] 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.

72. 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.[25] The CDC Guideline concludes that "[w]hile benefits for pain relief,

[24] 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?

[25] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall

function 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."[26] According to the then CDC director, "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]."[27]

5. Mallinckrodt Made Misrepresentations Regarding Abuse-Deterrence.

73. Seeing abuse-deterrent products as a potential new business opportunity, 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."[28] One member of the FDA's Controlled 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."[29]

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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.

[26] CDC Guideline at 18.

[27] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, New Eng. J. of Med., at 1503 (Apr. 21, 2016).

[28] Mallinckrodt Press Release, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.

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

74. 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." [redacted]

75. These claims were part of the key messages that Mallinckrodt sought to deliver about Exalgo and Xartemis XR. Not only has the FDA not approved these drugs as abuse deterrent, however, none of the patented technology Mallinckrodt promotes as the solution to opioid abuse and addiction, addresses oral ingestion, the most common form of misuse. Mallinckrodt's false and misleading marketing of the benefits of its abuse-deterrent opioids would inspire misplaced confidence in the use of Mallinckrodt's opioids, particularly in the face of increased evidence of opioid addiction and abuse.

76. Even for opioids (unlike Mallinckrodt's) approved as abuse-deterrent, 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 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."[30] 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."[31] In this context, Mallinckrodt's claims regarding the abuse-deterrent features were especially unfounded. Once again, Mallinckrodt has never acknowledged, retracted, or corrected its misstatements.

6. Mallinckrodt Represented that Opioids Could Be Taken in Ever Higher Doses without Disclosing their Greater Risks.

77. [redacted] 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 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.

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

[30] CDC Guideline at 22.

[31] 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.

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.

79. 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.

80. [redacted]

81. [redacted]

[redacted]

82. [redacted]

[redacted]

83. 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."[32] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[33]

84. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health

[32] 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."

[33] CDC Guideline at 16.

Administration from 2004 to 2008 found the rate of overdose deaths directly related to maximum daily dose. Even so, Mallinckrodt has never acknowledged, retracted, or corrected its misstatements.

B. Mallinckrodt Was Required to and Failed to Maintain Effective Controls Against Diversion and to Report Suspicious Prescribers.

1. Mallinckrodt Had a Legal Duty to Maintain Effective Controls Against Diversion.

85. As both a manufacturer and as a distributor of opioids, Mallinckrodt had a duty to maintain effective controls against diversion. This includes a duty to put in place procedures to ensure potentially suspicious orders would be detected, reported, and not filled, instead of continuing to fill orders which supplied far more opioids than could have supplied a legitimate market.

86. Under the common law, Mallinckrodt had a duty to exercise reasonable care in selling dangerous narcotic substances.

87. In addition, Mallinckrodt had a duty, when speaking publicly about opioids and its efforts to combat diversion, to speak accurately and truthfully.

88. Mallinckrodt also had statutory duties under Alaska's Controlled Substance Act ("ACSA") and implementing regulations, which incorporate the requirements of the federal Controlled Substances Act, ("CSA"), 21 U.S.C. § 811 - 830. AS §17.30.020(a). Under Alaska 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, "maintenance of effective controls against diversion." *Id.* In addition,

Alaska 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.*

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

89. The purpose of the statutory and regulatory 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.[34]

90. 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 have serious consequences. In a letter to registrants, including Mallinckrodt, on December 27, 2007, the DEA reminded Mallinckrodt that, as a registered manufacturer of controlled substances (and as a registered distributor of the same), 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

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

substances."[35] 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."[36]

91. An investigation by the DEA that began in 2011 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.

92. 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

[35] *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 ("2007 Rannazzisi Letter").
[36] *See* 2007 Rannazzisi Letter.

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' . . ."[37]

93. 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."[38] 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."[39] Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[40]

94. 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

[37] *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.
[38] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA"), at 1.
[39] *Id.* at 4.
[40] *Id.*

the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[41]

95. Mallinckrodt also 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 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."[42]

96. In addition to chargeback data, upon information and belief, at all relevant times, Mallinckrodt was in possession of national, regional, state, and local prescriber- and patient-level data that allowed it to track prescribing patterns over time. As a routine practice, "[p]harmaceutical companies monitor the return on investment of detailing - and all promotional efforts - by prescription tracking."[43] Companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies, the majority of which sell these records.[44] Pharmaceutical companies are the primary customers for the prescribing data sold by these vendors. This

[41] *Id.* at 3-4.
[42] *Id.* at 5.
[43] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) *Following the Script: How Drug Reps Make Friends and Influence Doctors.* PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).
[44] *Id.* at 389.

information would have allowed Mallinckrodt to identify pill mills and red flags of abuse or diversion. In fact, one of the data vendor's experts previously testified that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product."[45] Upon information and belief, Mallinckrodt, instead of using information for this purpose, used this information to identify "high prescribers" for purposes of its marketing efforts, as described above.

97. Moreover, [redacted] The Alaska State Medical Board has received complaints about (from sources other than Mallinckrodt) and taken disciplinary action against doctors for improperly prescribing opioids, [redacted]

98. [redacted]

[45] *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, *467-471 (Feb. 22, 2011); *see also* Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

[redacted]

99. [redacted]

100. [redacted]

101. 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 Alaska as well. [redacted]

[redacted]

102. [redacted][46]

103. Mallinckrodt should have been particularly alert for suspicious orders of Roxicodone, a drug known to be widely abused and popular on the streets, especially in its 30 mg form. [redacted]

104. Moreover, the areas surrounding Anchorage, Fairbanks, and Juneau, Alaska in 2018 were designated a regional High Intensity Drug Trafficking Area ("HIDTA") by

[46] [redacted]

the U.S. Department of Justice National Drug Intelligence Center ("NDIC"). The designation requires, among other things, that an area be a "significant center of illegal drug production, manufacturing, importation, or distribution," that "State, local, and tribal law enforcement agencies have committed resources to respond to the drug trafficking problem in the area, thereby indicating a determination to respond aggressively to the problem," and that "Drug-related activities in the area are having a significant harmful impact in the area and in other areas of the country." Alaska's U.S. Senators requested the designation of a standalone HIDTA in Alaska given the incidence opioid addiction throughout the state.

105. [redacted]

106. [redacted]

107. [redacted]

[redacted]

108. [redacted] Yet, as reflected in its 2017 Settlement, its compliance failures continued.

3. Mallinckrodt Fraudulently Concealed its Misconduct.

109. 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 expose the known falsity of these misrepresentations.

110. Moreover, as described above, Mallinckrodt [redacted] Thus, not only was Mallinckrodt aware of the addictiveness of opioids, but also, it has turned a profit on both perpetuating and treating the opioid crisis.

111. 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.

112. 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, Mallinckrodt failed to prevent diversion and worked in the shadows through Front Groups to undermine programs and statutes designed to combat the epidemic.

113. For example, 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 . . ."

114. 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, and supplied far more opioids than were justified in Alaska. Furthermore, far from trying to address diversion, Mallinckrodt worked to defeat programs and laws designed to prevent diversion. *See, e.g.,* ¶¶ 57-58, *supra*.

115. Mallinckrodt thus successfully concealed from the medical community, patients, and the State of Alaska facts sufficient to arouse suspicion of the claims that the State now asserts. The State 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.

C. Mallinckrodt Fueled and Profited from a Public Health Epidemic That Has Significantly Harmed Alaska and Devastated Thousands of Its Citizens

116. Upon information and belief, the vast market for opioids was created and sustained, in significant part, by Mallinckrodt's deceptive marketing in establishing and maintaining 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 Alaska by failing to put in place appropriate procedures to prevent diversion and to detect and report suspicious orders, instead continuing to fill orders that it knew or should have known were suspicious, which supplied far more opioids than were justified.

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

118. Mallinckrodt devoted substantial resources to its marketing efforts. As described above, [redacted] it made

substantial contributions to third-party front groups and funded speaker's programs. In addition, upon information and belief, it devoted substantial resources to making the launch of its branded drugs a success. [redacted] In preparation for the launch of Xartemis XR, Mallinckrodt added 150 to 200 contracted sales representatives to promote the drug, which CEO Mark Trudeau anticipated could generate "hundreds of millions in revenue."[47]

119. [redacted]

120. As explained above, Mallinckrodt's deceptive and unfair practices paid off—for the company. Overall sales of prescription opioids in Alaska have dramatically increased. [redacted]

[47] 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/.

[redacted]

121. 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."

122. 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.[48] 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."[49]

123. 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."[50] 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."

[48] 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.
[49] *Id.*
[50] 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).

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." A Staff Report by the U.S. Senate Homeland Security & Governmental Affairs Committee Staff Report noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[51] The Report quotes findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

124. The U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,[52] which arose out of a 2017 Senate investigation, has also 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."[53] In addition, according to the report, "Patient advocacy organizations and professional societies like the Front Groups play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public."[54] "Even small organizations—with 'their large numbers and credibility with

[51] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*").
[52] *Fueling an Epidemic* at 1.
[53] *Id*. at 12-15.
[54] *Id.* at 2.

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.'"[55]

125. The FDA also has made clear that "most opioid drugs have 'high potential for abuse,'" and "the serious risks of misuse, abuse, neonatal opioid withdrawal syndrome (NOWS), addiction, overdose, and death [are] associated with the use of ER/LA opioids overall, and during pregnancy." (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.)

126. 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. [redacted]

[55] *Id*.

127. 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 Alaska.

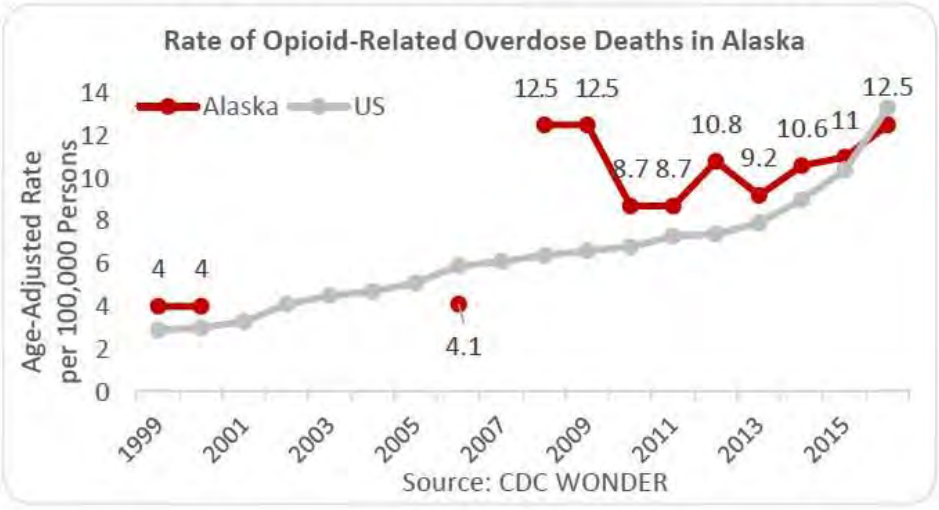
128. Research from the American Action Forum shows that as authorities went after pill mills and rogue doctors, sales of heroin and powerful synthetic opioids such as fentanyl filled the void. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. An individual who abuses opioid pain medication is 40 times more likely to develop a heroin addiction. Nationally, eighty percent of heroin users previously used prescription opioids; providers from addiction treatment programs across the state likewise report that more than half and up to 90% of their heroin-addicted patients were first exposed to opioids through a doctor's prescription. In Alaska, many of the patients in treatment programs seeking help with heroin addictions started with prescription opioids, but turned to heroin when pills were no longer available to them or too expensive. According to one Alaska emergency department doctor, every one of her patients who abuses heroin began with prescription opioids – theirs or someone else's. From 2009 to 2015, the number of heroin-associated deaths in Alaska more than quadrupled.

129. Beyond overdoses, Alaska hospitals have struggled to deal with other effects of the opioid epidemic. Dealing with these impacts has become a new normal for doctors

and administrators, who report dealing with patients who threaten violence or suicide if they are not given prescription opioids. One doctor described opioids as a daily part of practice from patients seeking refills, to patients with complications from injecting opioids, to patients in active withdrawal from opioids. Depending on the day, 15 to 30 of the patients in one emergency department will be there on issues related to opioids, and one doctor described it as surprising to see patients not affected by opioids.

130. Addiction has consumed the lives of countless Alaskans 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.

131. Alaska is on par with the national rate of opioid-related overdose deaths for 2016 and above the national rate for the preceding eight years. There were 94 opioid-related overdose deaths in Alaska in 2016, a rate of 12.5 deaths per 100,000 persons. From 2006 through 2016, the number of opioid-related deaths in Alaska tripled, though incomplete reporting likely understates the number of lives lost.



132. A recent, even more sinister problem stemming from the prescription opioid epidemic involves fentanyl, a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Alaska communities. Patients who traveled from prescription opioids to heroin may now find themselves graduated to heroin plus fentanyl. Fentanyl-related overdoses now far exceed those involving heroin alone. In Alaska, the rise in fentanyl-related deaths has been steep with 5 deaths in 2016 and 28 fentanyl-specific deaths in 2017. Fentanyl is 50 times more potent than heroin, and can quickly induce death in opioid-naïve users. And fentanyl abuse is often a game of Russian roulette, with users not knowing what mixture of fentanyl and heroin they are taking.

133. Preliminary data from 2017 shows that overdose deaths continued to rise, with one hundred people in 2017 alone losing their lives to unintentional overdoses on opioid drugs. Fifty of these deaths were linked to prescription painkillers, and lives lost to fentanyl and other synthetic opioids more than quadrupled.

134. Overdose deaths are only one consequence of the proliferation of opioid use. 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. Between 2016 and 2017, hospital visits in Alaska due to opioid overdoses cost more than $23 million. There were 375 opioid overdose emergency department visits between July 1, 2017 and June 30, 2018. In a similar one-year period, from June 1, 2017 and May 31, 2018, Emergency Medical Services and law enforcement administered 550 doses of Narcan and Project Hope, a state-wide program to get Narcan into the hands of heroin users, distributed 7,082 kits in Alaska. Between 2012 and 2017, Naloxone administrations by EMS more than doubled between, from 8.0 per 1,000 EMS calls in 2012 to 17.7 per 1,000 EMS calls in 2017.

135. As communities have worked to save lives, the opioid epidemic has continued to outpace their efforts. According to the National Survey on Drug Use and Health, an estimated 60,128 Alaskan adults, 11.5% of the state's population, need substance use disorder treatment. In 2016, Alaska funded programs provided substance use disorder treatment to 7,808 people. Yet, 88.2% of people in Alaska suffering from drug dependence or abuse go untreated.

136. Diseases connected to injecting drugs, particularly hepatitis C, are another side effect of opioid and heroin addiction. According to Dr. Jay Butler, Alaska's Chief Medical Officer and Division of Public Health Director, "[w]e talk mostly about opioid overdose deaths, but there's a lot more that happens related to opioid use than just deaths … The most concerning trend that we see is an increasing number of diagnoses [of hepatitis

C in people] age 18 to 29."[56] While there are new direct-acting antiviral drugs to treat hepatitis C, the cost of treatment, approximately $85,000 to $94,500 for two common medications, puts an enormous burden on the State's Medicaid program. In 2015, Alaska's Medicaid program spent $5.9 million on hepatitis C treatments, according to Erin Narus, the lead pharmacist for the state's Medicaid program. The next year, that more than doubled to $13.6 million. The McDowell Group, a research and consulting firm in Alaska, calculated that treating just the estimated 1,009 people in Alaska infected with hepatitis C from injecting drugs in 2015 would cost $90 million.

137. Perhaps the most profound effect of the opioid crisis has been on children and teenagers. Across the country there is a significant increase in children being abused, neglected, and eventually separated from their parents due to opioid addiction. Alaska is no exception. From 2012 to 2016, the number of children in foster care in Alaska increased from 1,860 to 2,802, more than 50%—five times the national rate. In 48% of Alaska's foster care placements, parental substance use was a factor. Grandparents have also been caring for children impacted by the opioid epidemic.

138. According to the Centers for Disease Control, from 2009 to 2015, while alcohol and marijuana use among Alaska youths declined, prescription drug use remained stable. A survey taken by the Alaska Youth Risk Behavior Surveillance of high school students ages 14 to 18, determined that prescription drugs are the most frequently used

[56] Zachariah Hughes, KTOO Public Media, *Wave of addiction costs is hitting Alaska's health care system*, June 29, 2017, https://www.ktoo.org/2017/06/29/wave-addiction-costs-hitting-alaskas-healthcare-system/.

drug category after alcohol and marijuana. More youth reported current prescription drug use than reported using cocaine, heroin, or methamphetamine. According to data from the National Survey on Drug Use and Health, one-third of all new prescription drug users in the past year were youth between the ages of 12 and 17. [redacted]

139. 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," also known as neonatal opioid withdrawal syndrome, or "NOWS"). 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.

140. A State of Alaska Epidemiology study of births between 2004 through 2015, found that there was a 566% increase in babies diagnosed with NAS during that time period, from 15 in 2004 to 100 in 2015—541 infants in total over the twelve-year period. According to an Alaskan maternal and child health epidemiologist and study author Abigail Newby-Kew, the study only looks at Medicaid-eligible births because that is the most

complete, long-term data set available, therefore these numbers do not represent the entire population. Moreover, because of difficulties in identifying symptoms, or delays in manifesting them, additional babies may not have been included in the statistics.

141. From 2014 to 2015, 97 babies admitted to Providence Alaska Medical Center's Neonatal Intensive Care Unit ("NICU") had NAS. Dr. Mary-Alice Johnson, the NICU medical director at Providence, stated: "Everybody is concerned about the fact that we're seeing more moms exposed and therefore more babies suffering from neonatal abstinence syndrome."[57]

142. The costs of this human tragedy cannot be calculated or adequately compensated. But the financial costs that are already known are staggering. The McDowell Group, a research and consulting firm in Alaska, estimated that the economic cost of substance abuse and addiction in Alaska amounted to $1.22 billion in 2015 alone. This estimate includes costs related to loss of productivity, traffic collisions, criminal justice and protective services, healthcare, public assistance and social services.

143. [redacted]

[57] Hope Miller, Anchorage Daily News, *How hospitals are treating babies caught in the crosshairs of Alaska's opioid crisis*, May 8, 2016, https://www.adn.com/alaska-news/article/how-hospitals-are-treating-babies-caught-crosshairs-alaska-s-opioid-epidemic/2016/05/09/.

[redacted]

144. While the use of opioids has taken an enormous toll on Alaska and its residents, Defendants have realized millions of dollars in revenue as a result of their deceptive, unfair, and unlawful conduct.

V. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF
(Violations of the Unfair Trade Practices and Consumer Protection Act)

145. The State incorporates the preceding paragraphs as if fully set forth herein.

146. Mallinckrodt is engaged in trade or commerce in the State of Alaska.

147. The Alaska Unfair Trade Practices and Consumer Protection Act (the "UTPA") states that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce are declared to be unlawful." AS 45.50.471(a).[58] The Alaska Supreme Court has determined if actions are unfair or deceptive by inquiring:

> (1) Whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is within at least the penumbra of some common-law, statutory or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers (or competitors or other businessmen).[59]

[58] In light of the exemption set forth in A.S. § 45.50.481(a)(1) and the statute's subsequent amendment in 2012, Plaintiff only asserts claims under the UTPA for Defendants' post-August 15, 2012 conduct.

[59] *State v. O'Niell Investigations, Inc.,* 609 P.2d 520, 528 (Alaska 1980).

148. Further, the UTPA lists fifty-seven different trade practices or acts that are expressly considered "unfair" or "deceptive" in violation of the Act, but does not limit violations of the Act to these enumerated practices. AS 45.50.471(b). At all times relevant to this Complaint, Mallinckrodt, directly, through the control of third parties, and/or by aiding and abetting third parties, violated the UTPA 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 Alaska prescribers and consumers to promote the sale and use of opioids to treat chronic pain.

149. Mallinckrodt violated the UTPA, as codified in AS 45.50.471, *et seq.*, by:

A. Representing that prescription opioids have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have, in violation of AS 45.50.471(b)(4);

B. Disparaging the goods, services, or business of another by false or misleading representation of fact, in violation of AS 45.50.471(7);

C. Engaging in other conduct creating a likelihood of confusion or of misunderstanding and which deceived or damaged a buyer or a competitor in connection with the sale or advertisement of goods or services, in violation of AS 45.50.471(b)(11).

D. Using or employing deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with the intent that others rely upon the concealment,

suppression, or omission in connection with the sale or advertisement of goods or services, in violation of AS 45.50.471(b)(12).

150. Mallinckrodt's violations include, but are not limited to, deceptively and misleadingly:

a. Claiming that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Omitting that opioids are highly addictive and may result in overdose or death;

c. Claiming that signs of addiction were "pseudoaddiction" reflecting undertreated pain and should be responded to with more opioids;

d. Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools and other strategies;

e. Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;

f. Claiming that opioids are an appropriate treatment for chronic pain and failing to disclose the lack of long-term evidence for their use;

g. Claiming chronic opioid therapy would improve patients' function and quality of life;

h. Claiming that its opioids had abuse deterrent features and deceptively suggesting these features would reduce addiction and abuse and make these drugs safer than other opioids;

i. Omitting other material facts that it had a duty to disclose by virtue of other representations to Alaska consumers, including other adverse effects from opioid use;

j. Using co-pay cards to promote highly addictive Schedule II controlled substances by making them appear more attractive and affordable than other options, without disclosing the difficulty patients would have to stop using the drugs; and

k. Promoting itself as committed to cooperating with law enforcement and dedicated to maintaining effective controls against opioid abuse and diversion while actually failing to maintain effective controls against diversion.

Mallinckrodt's acts and practices described in this Complaint had the capacity and tendency to deceive and were capable of being interpreted in a misleading way.

151. Mallinckrodt's acts and practices were also unfair under AS 45.50.471(a). These unfair and deceptive acts or practices include, but are not limited to, (a) deceptively promoting its highly addictive opioids, as described above, knowing that, once started, many patients would be unable to stop taking them; and (b) failing to maintain effective controls against opioid diversion by oversupplying opioids into Alaska failing to create, maintain, and use an adequate compliance program, failing to investigate, report, and halt suspicious orders, filling suspicious orders, and failing to exercise due diligence to ensure the customers to whom it sold and marketed could be trusted with prescription opioids.

152. In addition, Mallinckrodt's acts or practices were immoral, unethical, oppressive, or unscrupulous, caused substantial injury to consumers and businesses, and violated public policy, including:

A. The policy of "Harm reduction, Overdose prevention, and Education" being implemented by the Department of Health and Human Services;

B. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, which suggests a focus on "preventing the inappropriate transition from acute and subacute opioid use to chronic opioid use and to avoid [chronic opioid analgesic therapy] COAT altogether when other alternatives for treating pain may be equally effective and safer in the long-term;"

C. The policy, reflected in the Alaska Opioid Policy Task Force Final Recommendations (2017) of increasing public awareness and

understanding of appropriate opioid use and opioid abuse and addiction;

D. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, that continuing to prescribe opioids for chronic pain in the absence of clinically meaningful improvement in function, or after development of a severe adverse outcome, such as an overdose event, is not appropriate care;

E. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of prescribing the lowest possible effective dose;

F. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of ensuring informed consent regarding the risks and benefits of treating chronic pain with opioids;

G. The policies of preventing abuse and diversion of opioids and of education and awareness concerning risks, reflected in SB 174, which requires all prescribers to register with and use the State's prescription drug monitoring program and requires education on pain management and opioid use and addiction, and HB 159, which limited initial prescriptions of opioids and prescriptions for more than a 7-day supply;

H. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of reducing the risk to the community from diversion of opioids, which has been shown to correlate with the amount of opioids prescribed; and

I. The policy, reflected in ACSA and incorporated federal law, which requires the monitoring and reporting of suspicious orders of controlled substances and aims to reduce diversion.

153. Mallinckrodt's acts and practices also constitute unfair competition. At all times relevant to this Complaint, Mallinckrodt promoted Exalgo and Xartemis XR as having features that made them more difficult to abuse as means of maintaining a competitive advantage against other opioids.

154. As a direct result of the foregoing deceptive acts and practices, Mallinckrodt obtained income, profits, and other benefits that it would not otherwise have obtained.

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

156. Mallinckrodt's conduct has caused substantial injury to the State—in lives lost to drug overdoses, addictions endured, emergency room visits, the creation of an illicit drug market and all its concomitant crime and costs, and broken lives, families, and homes.

157. Mallinckrodt's acts and practices as alleged herein were motivated by a desire to retain and increase its market share and profits.

158. Mallinckrodt's use of acts or practices in violation of the UTPA warrant the maximum amount of civil penalties under AS 45.50.551.

159. As a result of Mallinckrodt's conduct as alleged herein, Alaska consumers, including the State and its agencies, suffered and continue to suffer injury.

160. In addition to penalties and restitution, Mallinckrodt is liable for attorneys' fees and costs, including costs of investigation, under AS 45.50.537(d).

SECOND CLAIM FOR RELIEF
(Public Nuisance)

161. The State incorporates the preceding paragraphs as if fully set forth herein.

162. A public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

163. Mallinckrodt's conduct, as described in the Complaint, involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, and unreasonably interferes with a public right by creating a public health epidemic in Alaska.

164. As the Restatement (Second) of Torts § 821B(2) (1979) explains, [c]ircumstances 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," that "is proscribed by a statute, ordinance or administrative regulation," or that "is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right." Mallinckrodt's conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of the State and its residents.

165. Mallinckrodt has created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, public comfort and public convenience, and offends the moral standards of communities throughout the State and significantly harmed any considerable number of the State's residents.

166. Here, Mallinckrodt's conduct is prescribed by statutes and regulations, including the Alaska UTPA, AS § 45.50.471, and the ACSA, AS §17.30 *et seq.*, and the federal CSA and regulations incorporated therein.

167. Mallinckrodt violated the standard of conduct set forth in the Alaska CSA by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report and reject suspicious orders of opioids, and violated the Alaska UTPA, AS 45.50.471 through its unfair and deceptive practices described in this Complaint.

168. Mallinckrodt knew and should have known that its promotion of opioids was false and misleading and that its deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

169. Mallinckrodt knew and should have known that their failure to comply with their statutory and common law duties to maintain effective controls against diversion, including by monitoring, reporting, and exercising due diligence not to fill suspicious orders, would create or assist in the creation or maintenance of a public nuisance.

170. Mallinckrodt's conduct is of a continuing nature and has produced a permanent or long-lasting effect on the public right that Mallinckrodt knew, or had reason to know, would occur.

171. Mallinckrodt's conduct created or increased an unreasonable risk of harm.

172. Mallinckrodt's conduct is unreasonable, intentional, reckless, and/or negligent, and unlawful.

173. The public nuisance is substantial and unreasonable. Mallinckrodt's actions caused and continue to cause the public health epidemic and state of emergency described in the Complaint.

174. It was reasonably foreseeable that Mallinckrodt's actions and omissions would result in the public nuisance and harm to the State described herein.

175. 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 that followed and has reached a state of emergency. Mallinckrodt controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without Mallinckrodt's actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists and the injury to the State would have been averted or much less severe.

176. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Mallinckrodt can be abated and further recurrence of such harm and inconvenience can be abated.

177. The State has been, and continues to be, injured by Mallinckrodt's actions in creating a public nuisance.

THIRD CLAIM FOR RELIEF
(Fraud and Negligence/Negligent Misrepresentation)

178. The State incorporates the preceding paragraphs as if fully set forth herein.

179. As alleged in this Complaint, Mallinckrodt has engaged in false representation and concealment of material facts about the use of opioids to treat chronic pain.

180. Mallinckrodt knew, deliberately ignored, or recklessly disregarded, that:

A. its statements about the risks and benefits of opioids to treat chronic pain were false or misleading;

B. it failed to correct prior misrepresentations and omissions about the risks and benefits of opioids;

C. its statements made to promote the use of opioids to treat chronic pain omitted or concealed material facts;

D. there is no evidence to support statements that the purportedly abuse-deterrent features of its opioids make the drugs less likely to be abused or diverted or less addictive, and the FDA has not approved those drugs as abuse-deterrent; and

E. it lacked the demonstrated commitment it professed to reducing or deterring abuse and to cooperating with law enforcement, as evidenced by its failure to prevent diversion, report suspicious prescribers, and to report and halt suspicious orders, as required by law and by its misrepresentations regarding the abuse-deterrent properties of is opioids.

181. The statements Mallinckrodt made, or caused to be made about the use of opioids to treat chronic pain and abuse-deterrent formulations of its opioids, were not supported by or were contrary to its own knowledge and studies and to the scientific evidence more generally, as confirmed by the CDC and FDA based on that evidence, and were false and fraudulent.

182. Mallinckrodt intended that healthcare providers and patients would rely on its misrepresentations and deceptive marketing regarding the use of opioids to treat chronic pain, the characteristics of Mallinckrodt's branded opioids, and Mallinckrodt's efforts to cooperate with law enforcement and assist in avoiding addiction, abuse, and overdose.

183. Mallinckrodt had a duty to the State to exercise due care in the advertising, marketing, promotion, and sale of opioid drugs.

184. Mallinckrodt had a duty to the State not to make false, misleading, or deceptive statements about opioids and treatment for chronic pain.

185. Mallinckrodt had a duty to the State to report suspicious prescribers and to refrain from providing opioids to providers and pharmacies it believed, or had reason to believe, were dispensing its opioids illegally, as well as a duty not to misrepresent its commitment to adhering to this obligation.

186. Mallinckrodt knew or should have known that it breached the duties described above.

187. Mallinckrodt's misrepresentations, omissions, and carelessness in this regard was done with the intention and effect of inducing the use of opioids to treat chronic pain, and with reckless disregard for the costs the State would incur as a proximate cause and legal result, including the costs of treating addiction and implementing programs to mitigate or reverse the public health epidemic.

188. Mallinckrodt knew, or should have known, that prescribers and patients would rely on its misrepresentations and deceptive statements, and would be misled by its material omissions.

189. Mallinckrodt failed to report prescribers engaged in suspicious prescribing of its opioids, as required by law. Mallinckrodt also knew, or should have known of diversion and of suspicious orders of Mallinckrodt opioids but failed to report its suspicions or halt these orders, as required by law, or even to have a legally-compliant system in place to investigate such orders.

190. Mallinckrodt knew, or should have known, that as an inevitable consequence of the conduct described herein, Alaska citizens would suffer opioid addiction, overdose, death, and associated economic loss, and the State would suffer economic loss. Further, Mallinckrodt knew, or should have known, that its failure to report prevent diversion and to suspicious prescribing has resulted in continued illicit prescribing and use of opioids.

191. In addition, Mallinckrodt's false representations and concealments were reasonably calculated to deceive the State, health care providers who prescribed opioids, and the patients who received the care.

192. Mallinckrodt's false representations and concealments also were designed to deceive the State and others concerning Mallinckrodt's role in the opioid epidemic.

193. Prescribers, patients, and the State relied to their determinant on Mallinckrodt's misrepresentations and concealment of material fact.

194. But for Mallinckrodt's misrepresentation and concealment of material facts, the State would not have incurred costs and damages in addressing the public health crisis that Mallinckrodt's actions have created.

195. As a proximate cause and legal result of Mallinckrodt's acts and omissions as alleged herein, the State has sustained and will sustain substantial expenses and damages, described in this Complaint.

FOURTH CLAIM FOR RELIEF
(Negligence/Negligence Per Se)

196. The State incorporates the preceding paragraphs as if fully set forth herein.

197. Mallinckrodt owed the State a duty not to expose the State to an unreasonable risk of harm.

198. Mallinckrodt had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in distributing highly dangerous opioid drugs in the state. This includes a duty not to cause foreseeable harm to others.

199. Mallinckrodt had a duty not to breach the standard of care established under Alaska law, which incorporates the federal CSA and its implementing regulations and which requires Mallinckrodt to maintain effective controls to prevent diversion and to report suspicious prescribing and orders, to stop such orders, and to maintain systems to detect and report such activity.

200. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Mallinckrodt's conduct in distributing and selling dangerously addictive drugs requires a high degree of care and places it in a position of great trust and responsibility vis a vis the State.

201. Mallinckrodt breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in distributing and selling dangerous controlled substances.

202. Mallinckrodt breached its duty to the State by, *inter alia*, oversupplying opioids into Alaska failing to create, maintain, and use an adequate compliance program, failing to investigate, report, and halt suspicious orders, filling suspicious orders, and failing to exercise due diligence to ensure the customers to whom it sold and marketed could be trusted with prescription opioids.

203. Mallinckrodt has engaged in affirmative acts of oversupplying opioids and facilitating an illegal, secondary opioid market by failing to exercise adequate control over the distribution and sale of their prescription opioids.

204. A reasonably prudent opioid manufacturer and/or distributor should have anticipated an injury to the State as a probable result of distributing and selling prescription opioids in this manner.

205. It was reasonably foreseeable that Mallinckrodt's actions and omissions would result in the harm to the State as described herein.

206. Mallinckrodt had control over its conduct in Alaska, including but not limited to its reporting, or lack thereof, of suspicious prescribers and orders, the systems it developed, or failed to develop and apply, to prevent diversion, and whether it filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

207. Because of Mallinckrodt's special position within the closed system of opioid distribution, without Mallinckrodt's actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

208. Mallinckrodt is in the business of selling and/or distributing prescription drugs, including opioids, which are specifically known to Mallinckrodt to be dangerous because, inter alia, these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

209. Reasonably prudent manufacturers and/or distributors of prescription opioids would have anticipated that opioid addiction would wreak havoc in the state, and that significant costs would be imposed upon the State.

210. Indeed, it is a violation of the ACSA, the federal CSA, and related regulations for Mallinckrodt not to set up a system to prevent diversion, detect and report suspicious orders and not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

211. Mallinckrodt's negligence and negligence per se were substantial factors in causing the State's damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services to address the opioid epidemic.

212. Mallinckrodt has engaged in a pattern of ongoing and persistent wrongful conduct, which caused the State to incur costs.

213. The State alleges wrongful acts that are neither discrete nor of the sort a State government can reasonably expect.

214. As a result of the harm inflicted by Mallinckrodt, the State incurred extraordinary and unpredictable costs for services it was forced to provide, over and above its ordinary public services.

215. The opioid epidemic is unprecedented in terms of its impact on the State of Alaska.

216. Mallinckrodt acted with a conscious disregard for the rights and safety of others, despite the great probability of causing substantial harm.

217. Alaska is without fault and the injuries to the State and its residents would not have occurred in the ordinary course of events had Mallinckrodt exercised the due care commensurate to the dangers involved in the distribution and sale of opioids.

218. As a proximate cause and legal result of Mallinckrodt's acts and omissions as alleged herein, the State has sustained and will sustain substantial expenses and damages, described in this Complaint.

FIFTH CLAIM FOR RELIEF
(Strict Products Liability – Design Defect and Failure to Warn)

219. The State incorporates the preceding paragraphs as if fully set forth herein.

220. Mallinckrodt's opioids failed to perform as safely as an ordinary consumer or an ordinary prescriber would expect when used in an intended or reasonably foreseeable manner because:

A. Mallinckrodt's opioids carried far greater risk and actual rate of addiction than the public was lead to believe, and,

B. Mallinckrodt's opioids failed to provide functional improvement for chronic pain patients and caused side effects, including addiction, that diminished their function and quality of life.

221. Under the circumstances, which include Mallinckrodt's unfair and deceptive marketing, Mallinckrodt failed to provide adequate warning that clearly indicated the scope of the risk or danger posed by its branded opioids, reasonably communicated the extent or seriousness of harm that could result from this risk or danger, and was conveyed in a manner that would alert a reasonably prudent person.

222. Mallinckrodt actually knew of the defective nature of its opioids, but continued to market and sell its branded opioids without proper warning, and with misrepresentations and omissions that contradicted and undermined its drug labels, in order to increase its sales and profits, in conscious disregard for the foreseeable harm caused by these drugs.

223. As a proximate cause and legal result of Mallinckrodt's failure to perform as reasonably expected and Mallinckrodt's failure to appropriately warn of known and reasonably knowable dangers associated with the use of its opioids, the State has suffered and will continue to suffer damages as outlined in this Complaint.

SIXTH CLAIM FOR RELIEF
(Unjust Enrichment)

224. The State incorporates the preceding paragraphs as if fully set forth herein.

225. Mallinckrodt has unjustly retained a benefit to the State's detriment, and Mallinckrodt's retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

226. The State has suffered, and continues to cope with, a crisis of opioid addiction, overdose, injury, and death that Mallinckrodt helped create.

227. Further, as an expected and intended result of its conscious wrongdoing as set forth in this Complaint, Mallinckrodt has profited and benefited from the increase in the distribution and purchase of opioids within the state, including from opioids foreseeably and deliberately diverted within Alaska. The State has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Mallinckrodt's

conduct. These expenditures include the provision of healthcare services and treatment services to people who use opioids. These expenditures have helped sustain Mallinckrodt's businesses.

228. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

229. Mallinckrodt has reaped revenues and profits from the State's payments for opioid prescriptions, enriching itself at the State's expense. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

230. In addition, the State has conferred a benefit upon Mallinckrodt by paying for Mallinckrodt's externalities: the cost of the harms caused by Mallinckrodt's improper marketing and distribution practices. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

231. 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 State and its citizens.

PRAYER FOR RELIEF

WHEREFORE, the State prays for judgment against Mallinckrodt as permitted by Alaska law, as follows:

a. For a declaration that Mallinckrodt has violated the UTPA;

b. For an injunction pursuant to AS 45.50.501 enjoining Mallinckrodt from engaging in any acts that violate the UTPA, including, but not limited to, the unfair

and deceptive acts and practices, and unfair methods of competition alleged in this Complaint;

c. For restoration of money Mallinckrodt obtained from consumers under AS 45.50.501(b);

d. For civil penalties in the amount of $25,000 for each and every violation of the UTPA under AS 45.50.551;

e. For an injunction permanently enjoining Mallinckrodt from engaging the acts and practices that caused the public nuisance;

f. For an order directing Mallinckrodt to abate and pay damages for the public nuisance;

g. For compensatory damages for Mallinckrodt's fraud, negligence, negligent misrepresentation, and strict liability for design defect and failure to warn;

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

i. For punitive damages;

j. For costs, interest, and attorney's fees; and

k. For all other relief deemed just by the Court.

DATED: January ___, 2019.

KEVIN G. CLARKSON
ATTORNEY GENERAL

By:_____

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