October 22, 2019

ATTORNEY GENERAL RAOUL TAKES ACTION AGAINST OPIOID MANUFACTURER

Chicago — Attorney General Kwame Raoul filed a motion to take action against Mallinckrodt plc, Mallinckrodt LLC, and Specgx LLC (Mallinckrodt) for its role in the opioid epidemic. The filing seeks to expand the Attorney General's lawsuit against opioid manufacturers and distributors for creating and contributing to the nation's opioid epidemic.

The Attorney General's office filed a motion Monday in Cook County Circuit Court seeking to add the Irish pharmaceutical manufacturer, Mallinckrodt, to a lawsuit currently pending against opioid manufacturers alleging that the companies carried out unfair and deceptive marketing campaigns that prioritized profits over public health. According to Raoul, actions by Mallinckrodt and other pharmaceutical companies resulted in unprecedented levels of opioid prescribing, while the distributors irresponsibly flooded Illinois with opioids, failing in their role as gatekeepers in preventing the diversion of opioids.

Subject to court approval, the motion adds Mallinckrodt to the lawsuit Raoul's office filed in September against Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Teva Pharmaceutical Industries Limited; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Allergan Finance, LLC; Actavis Pharma, Inc.; Actavis LLC; Watson Laboratories, Inc.; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation.

"Countless lives were ruined or lost as a result of the ruthless pursuit of profits by opioid manufacturers and distributors," Raoul said. "I will continue fighting to ensure that the companies that created the crisis are held accountable for the immeasurable damage opioid addiction has caused in our communities."

Raoul alleged Mallinckrodt engaged in an unfair and deceptive campaign to shift public perception of opioids, resulting in an increase in opioid prescriptions. According to Raoul, it pushed for the use of more opioids at higher doses and for longer periods of time under the guise of what it characterized as the widespread and problematic under-treatment of pain. The manufacturer also allegedly sought to convince health care providers and patients that opioids were a safe and effective treatment, by minimizing the risk of addiction, touting deceptive concepts like "pseudo addiction," and making false and unsubstantiated claims about the drugs' benefits.

Raoul also alleged that Mallinckrodt failed in its responsibility to identify, report and stop suspicious orders. According to Raoul, the actions by Mallinckrodt and other defendants flooded Illinois with hundreds of millions of dosage units of opioids with little oversight, fueling the diversion of these drugs towards illegal and harmful uses.

Opioids are often prescribed to treat severe pain, as they reduce the intensity of pain signals reaching the brain; however, they can have serious side effects and are highly addictive. Opioids – such as morphine, hydrocodone, oxycodone, oxymorphone, and methadone – are a class of narcotic drugs that include heroin, some prescription pain relievers, and fentanyl.

According to the Centers for Disease Control (CDC), more than 130 Americans die each day from an opioid overdose. According to the Illinois Department of Public Health (IDPH), more than 2,000 Illinoisans were killed by opioid overdoses in 2017. IDPH's data also shows that between 2011 and 2017, instances of babies born with neonatal abstinence syndrome (NAS), which can occur when a newborn is prenatally exposed to

opiates, increased by 64 percent. Babies born with NAS experience a variety of medical complications, including withdrawal symptoms, and often require longer hospital stays after being born.

Raoul's lawsuit seeks to abate and remedy the statewide public nuisance caused by these companies. Raoul also asks the court to prohibit the manufacturers' and distributors' deceptive and unfair conduct in order to ensure it does not happen again in the future, and to hold the companies accountable for the devastation they have caused in Illinois and nationwide.

The lawsuit is part of Attorney General Raoul's ongoing efforts to combat the opioid epidemic and hold accountable companies whose deceptive practices have increased opioid prescriptions at the expense of public health. In April, Raoul's office filed a lawsuit against opioid manufacturer Purdue Pharma for carrying out an aggressive and misleading marketing campaign to increase prescriptions of opioid painkillers as communities throughout Illinois and across the country faced an opioid addiction epidemic. In August, Raoul's office expanded the lawsuit to include several members of the Sackler family, which founded and owns Purdue Pharma, for their roles in directing and approving the company's misleading marketing efforts. Attorney General Raoul has vowed to oppose any settlement with Purdue Pharma that does not address the Sackler family's participation in creating the opioid crisis.

Raoul urges anyone who believes they or a loved one may be addicted to opioids to seek help by calling the Illinois Helpline for Opioids and Other Substances at 833-2FINDHELP, which operates 24 hours a day, seven days a week.

Assistant Chief Deputy Attorney General Thomas Verticchio; Division Chief Susan Ellis; Deputy Bureau Chief Judith Parker; Assistant Attorneys General Lauren Barksi, Jennifer Crespo, Darren Kinkead, Andrea Law, and Vivian Sapthavee are handing the case for Raoul's Consumer Protection Division.

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT – CHANCERY DIVISION

THE PEOPLE OF THE STATE OF ILLINOIS Plaintiff, v. JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, WATSON LABORATORIES, INC., MCKESSON CORPORATION, CARDINAL HEALTH, INC., and AMERISOURCEBERGEN DRUG CORPORATION, Defendants.	)	No. 2019-CH-10481 The Hon. Caroline Kate Moreland (Calendar 10)

PLAINTIFF'S MOTION FOR LEAVE TO FILE ADDITIONAL COUNTS TO ITS COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF, *INSTANTER* (PROPOSED COUNTS FIFTEEN AND SIXTEEN)

Plaintiff, The People of the State of Illinois, for its Motion for Leave to File Additional Counts to its Complaint for Injunctive and Other Relief, *Instanter*, pursuant to §2-616 of the Illinois Code of Civil Procedure (735 ILCS 5/2-616), states as follows:

1. The State filed its Complaint for Injunctive and Other Relief on September 10, 2019.

2. Illinois law provides that amendments adding new defendants and causes of action to complaints should be liberally permitted as is just and reasonable:

> (a) At any time before final judgment amendments may be allowed on just and reasonable terms, introducing any party who ought to have been joined as ...[a] defendant...adding new causes of action...which may enable the plaintiff to sustain the claim for which it was intended to be brought....

735 ILCS 5/2-616(a); *see also, e.g.*, *Sigma Co. v. Regas*, 255 Ill. App. 3d 857, 863 (1st Dist. 1993) (amendments to pleadings should be freely exercised so that litigants may fully present their alleged claims).

3. The proposed additional counts to the State's complaint name Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC as additional defendants. The proposed additional counts to the Complaint are filed with this motion and attached as Exhibit A.[1]

WHEREFORE, plaintiff, the State, respectfully requests the Court enter an order granting it leave to name Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC as additional defendants and file Counts Fifteen and Sixteen to its Complaint for Injunctive and Other Relief, *Instanter*, and that the Court enter such other and further orders as it deems just and appropriate.

Attorney No. 99000

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Respectfully submitted,

The People of the State of Illinois

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[1] Because some of the information contained in the proposed additional counts was obtained pursuant to confidentiality agreements entered into as part of plaintiff's investigation into the defendants' conduct, several paragraphs of the proposed additional counts are redacted. If the Court grants the motion for leave to add additional counts to its complaint, the plaintiff will file a motion seeking the Court's ruling on whether the redacted portions of the proposed additional counts should be filed under seal or whether the publicly filed complaint should be filed in an unredacted form.

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CERTIFICATE OF SERVICE

I, Lauren Barski, an attorney, hereby certify that on October 21, 2019, I caused a true and correct copy of the foregoing document to be served electronically on the counsel of record listed on the attached Service List.

Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certifies that the statements set forth in this instrument are true and correct, except as to matters therein stated to be on information and belief and as to such matters the undersigned certifies as aforesaid that she verily believes the same to be true.

/s/Lauren Barski

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EXHIBIT A

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT – CHANCERY DIVISION

THE PEOPLE OF THE STATE OF ILLINOIS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 19 CH 10481
	)	
JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., TEVA PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, WATSON LABORATORIES, INC., MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN DRUG CORPORATION, MALLINCKRODT PLC, MALLINCKRODT LLC, and SPECGX LLC,	)	
	)	
Defendants.	)	

ADDITIONAL COUNTS TO COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Plaintiff, THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, for Counts XV and XVI of its Complaint for Injunctive and Other Relief against defendants, MALLINCKRODT PLC, MALLINCKRODT LLC, and SPECGX LLC, states as follows:

932. The State repeats and realleges the allegations set forth in Paragraphs 1-762 of its Complaint for Injunctive and other Relief, as if the same were fully set forth herein.

PARTIES

933. Defendant MALLINCKRODT PLC is an Irish public limited company headquartered in the United Kingdom. Mallinckrodt plc operates in the United States under the business name "Mallinckrodt Pharmaceuticals" and maintains its U.S. headquarters in St. Louis, Missouri. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June 2013. As part of Mallinckrodt plc's separation from Covidien, Mallinckrodt plc assumed Covidien's historical liabilities related to the manufacture and sale of opioid drugs.

934. Defendant MALLINCKRODT LLC, formerly Mallinckrodt, Inc., is a Delaware corporation headquartered in St. Louis, Missouri and registered to do business in the State of Illinois. Prior to June 2013, Mallinckrodt LLC was a wholly owned subsidiary of Covidien plc. Since June 2013, Mallinckrodt LLC has been a wholly owned subsidiary of Mallinckrodt plc.

935. Defendant SPECGX LLC is a Delaware limited liability company with a principal place of business in St. Louis, Missouri and registered to do business in the State of Illinois. SpecGx LLC was formed in November 2016 and is a wholly owned subsidiary of Mallinckrodt LLC. In 2017, Mallinckrodt LLC transferred its assets, operations, and patents to SpecGx LLC.

936. Mallinckrodt plc is the parent company of Mallinckrodt LLC and SpecGx LLC, which have sold billions of dollars in opioids in the United States, including in Illinois. The companies share many common employees and corporate officers; engage in the same business enterprise of manufacturing and supplying pharmaceutical products; and make use of each other's cash flows and assets. Mallinckrodt plc exerts significant dominion, authority, and control over the daily business affairs of it agents Mallinckrodt LLC and SpecGx LLC such that it directed, approved,

and oversaw deceptive conduct that was purposefully directed at Illinois and which gives rise to the claims alleged herein.

937. For purposes of this Complaint, any references to the acts and practices of Defendants Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC (collectively, "Mallinckrodt") shall mean that such acts and practices are by and through the acts of Defendants' members, owners, directors, employees, salespersons, representatives, and/or other agents.

938. Defendants Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC acted together as part of a common enterprise to carry out the conduct described in this Complaint.

939. Defendants Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC are included in the term "Manufacturer Defendants."

DEFENDANTS' DECEPTIVE AND UNFAIR ACTS AND PRACTICES

Mallinckrodt

940. Mallinckrodt has marketed and sold its opioid products under several brands. These products include Exalgo, Xartemis XR, Roxicodone, and Methadose.

941. Mallinckrodt has a significant generic opioids portfolio as well. For instance, in fiscal year 2017, Mallinckrodt had $654.1 million in net U.S. sales of its specialty generics, including $83.5 million for hydrocodone products and $78.8 million for oxycodone products.

942. Between 2006 and 2012, Mallinckrodt was the single largest supplier of prescriptions opioids in the U.S.

943. In 2014, Mallinckrodt's five-year plan categorized the company's position as [redacted]

944. Mallinckrodt unfairly and deceptively promoted its branded and generic opioids, as well as opioids generally. Mallinckrodt disseminated false and misleading claims about opioids, promoted opioid use, minimized the risk of addiction, and fought efforts to restrict opioid prescribing. Mallinckrodt did so through various websites, front groups and materials, as well as through unbranded communications, including those distributed through the "C.A.R.E.S. Alliance" it created and led.

Mallinckrodt misled providers and patients about the risk of opioid addiction

945. Mallinckrodt misled Illinois health care providers and patients about the adverse effects of opioids, particularly the risk of addiction.

946. Mallinckrodt downplayed the risk of addiction including by deceptively using terms like "pseudoaddiction."

947. Mallinckrodt disseminated its false and misleading statements regarding opioid addiction in its branded advertisements throughout Illinois.

948. For instance, Mallinckrodt downplayed the risks of addiction from Exalgo in its "Patient Guide." [redacted]

949. Mallinckrodt knew that consumers would be persuaded by the messaging in its "Patient Guide" because it conducted extensive consumer surveys in August 2012. [redacted]

[redacted]

950. Mallinckrodt's market research even showed this messaging caused confusion in consumers, [redacted]

951. Mallinckrodt similarly trained its sales representatives to disseminate these misleading concepts. [redacted]

952. Mallinckrodt frequently disseminated its misleading marketing through its website.

953. In a 2013 "*Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*" (the "Policy Statement"), Mallinckrodt stated that "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

954. The Policy Statement also highlights Mallinckrodt's significant investment in prescriber education programs, stating that one of its goals is to increase prescriber understanding of pain terminology, including the concept of "pseudoaddiction."

955. Mallinckrodt also funded, influenced, and distributed third-party publications of doctor and patient "educational" materials, as well as created and disseminated unbranded materials, which misled their target audiences about the danger of prescription opioids. These publications downplayed the true risk of addiction, asserted that patients should be persistent in getting opioids for their pain, and assured doctors that they were following the appropriate approach by prescribing opioids long-term with manageable risk.

C.A.R.E.S. Alliance

956. In 2010, Mallinckrodt created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it described 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." At least between 2012 and 2019, the "C.A.R.E.S. Alliance" was a service mark of Mallinckrodt LLC (previously Mallinckrodt, Inc.) and copyrighted by Covidien, its former parent company.

957. Mallinckrodt instructed its sales reps to [redacted] including the "Opioid Safe Use and Handling Guide," which was available for download or order through www.caresalliance.org, and which told patients that "[a]ddiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur." The guide, which referenced specific opioid drugs such as Exalgo, also stated that "[t]aking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."

958. [redacted]

959. [redacted]

960. [redacted]

961. By 2012, Mallinckrodt was using the C.A.R.E.S. Alliance to promote another book titled *Defeat Chronic Pain Now!* This book is still available online. 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."
- "[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."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "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."
- "[I]n our opinion," the book's authors explained, "many of these folks on TV [shows about opioid addiction] appeared not to be addicted, but rather had developed a physical dependence, which is a normal bodily reaction that happens with lots of different types of medication, including medications not used for pain, and is easily remedied."

962. The statements in *Defeat Chronic Pain Now!* had the effect of downplaying the difficult and painful effects that many patients experience when opioid dosages are lowered or discontinued, which decrease the likelihood that patients will be able to stop using opioids. These statements also downplayed the prevalence and risk of opioid addiction.

963. [redacted] The book was available for order through the C.A.R.E.S. Alliance catalog, which was sponsored by Mallinckrodt.

964. In September 2013, [redacted]

www.pain-topics.org

965. Mallinckrodt was the founding sponsor of www.pain-topics.org, a website that launched in 2006. The website was funded through an unrestricted educational grant provided by Mallinckrodt.

966. Pain-topics.org consistently downplayed the risk of addiction from opioids. For example, the article "*Opioid Pain-Relief Benefits Outweigh Risks of Abuse*" highlighted a press release and presentation from the front group American Pain Society concluding that "research shows that

less than 3% of patients without prior history of drug abuse who are prescribed opioids for chronic pain will show signs of possible drug abuse or addiction.

967. Pain-topics.org prominently featured an article titled "*Opioid-Analgesic Abuse & Addiction Prevalence Still Uncertain*," that gave extensive coverage to a study review performed by opioid industry key opinion leader ("KOL") Dr. Fishbain, which found that, across studies, the abuse/addiction rate for patients taking opioids long-term for chronic noncancer pain was 3.27%, but that for those without a previous or current history of substance-use problems, the rate was only 0.19%.

968. The article concluded that "all indications are that these problems [of addiction in opioid patients] may not be as common as many practitioners, regulators, and the public seem to believe" and that the chance of "abuse/addiction development is probably quite rare in patients not having a prior history of substance-use disorders."

969. Pain-topics.org also contained an "Oxycodone Safety Handout for Patients" brochure which stated that: "[p]atients' fears of opioid addiction should be dispelled. Along with that, they must be cautioned against reducing oxycodone dosing on their own."

970. Another section of the brochure titled "Patient Instructions: Safely Taking Oxycodone" posed the question "[w]ill you become dependent on or addicted to oxycodone?" And, in response, reassured patients that "[a]ddiction to oxycodone in persons without a recent history of alcohol or drug problems is rare."

971. This brochure is still available today on the website[1] of the opioid industry front group The Pain Community, whose board includes the former Director of Communications and Advocacy of the American Pain Foundation.

[1]http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf _(Last accessed Oct. 21, 2019).

972. Pain-topics.org also included misleading information about "pseudoaddiction." The website told doctors and patients that "[m]any of the concerns regarding opioid use originate from misconceptions or confusion regarding the terminology describing the risks of addiction, tolerance, and dependence." The website went on to promote the concept of "pseudoaddiction" which it acknowledged was "not supported by rigorous investigation." It stated that it has been "widely observed" that patients with "undertreated" pain "may become very focused on obtaining opioid medications, and may be erroneously perceived as 'drug seeking'" and advised that, in such cases, such behaviors will resolve after the pain is effectively treated.

973. The website stated that "[p]atient anxieties" relating to undertreated pain can "result[] in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief."

974. Mallinckrodt's understating of the risk of addiction was misleading and was done with the intent that providers and patients would rely on it so providers would be more comfortable with prescribing opioids and patients more comfortable with taking them.

Mallinckrodt made deceptive claims about the extent to which addiction risk can be managed and addiction prevented

975. Mallinckrodt sought to reassure doctors that they could effectively manage risks and prevent addiction in their patients by using tools that Mallinckrodt and its third-party groups provided.

976. Mallinckrodt's claims that screening patients could effectively manage addiction risk were deceptive.

977. For example, Mallinckrodt stated: "Through 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."

978. [redacted]

979. According to a January 2012 [redacted]

980. [redacted]

981. As part of its strategy to increase opioid prescribing, Mallinckrodt sought to reassure doctors that they could effectively manage any addiction risk in their patients by using abuse and diversion mitigation tools, even though there was not adequate evidence to support the effectiveness of such strategies.

982. A 2014 Evidence Report by the Agency for Healthcare Research and Quality identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring

intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[2]

983. Indeed, the 2016 CDC Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient agreements, urine drug testing or pill counts "for improving outcomes related to overdose, addiction, abuse or misuse."[3]

Mallinckrodt deceptively claimed that the abuse-deterrent formulations of its drugs could lower opioid abuse and addiction risk

984. Mallinckrodt made misrepresentations regarding the so-called "abuse-deterrent" properties of Exalgo and Xartemis, both long-acting opioids.

985. Mallinckrodt promoted Exalgo and Xartemis as having physical properties that made them less likely to be addictive or abused, even though the drugs had never been approved by the FDA as abuse-deterrent. Not only had the FDA rejected Mallinckrodt's request for abuse-deterrent labeling for these two drugs, it had concluded that each drug was dangerous.

Exalgo

986. In March 2010, The FDA approved the 8, 12 and 16 mg tablets of Exalgo.

987. The FDA's Controlled Substance Staff had concluded in November 2009 that "it is expected that, once on the market, Exalgo tablets [] will be associated with higher levels of misuse and abuse than OxyContin" and that "[i]n the spectrum of abuse, [Exalgo] is towards the top of the spectrum of the drugs that are currently in the market. It is reasonable to predict that the abuse of Exalgo will parallel its availability, much like OxyContin."

988. The FDA had also concluded, as part of the approval process, that:

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[2] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain,* Agency for Healthcare Res. & Quality, Sept. 19, 2014.

[3] Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016,* 65 Morbidity and Mortality Weekly Report 1, 8 (2016) (2016 CDC Guideline).

> "The human bite force is great enough to crush an OROS hydromorphone tablet [Exalgo]. Since crushing the tablet defeats the controlled release mechanism and results in immediate release characteristics, hydromorphone HCl ER Tablets will increase the potential risks for overdose or abuse in those seeking to defeat the extended-release system.
> ...
>
> The PK profile of crushed OROS hydromorphone 8 mg was similar to that of hydromorphone 8 mg IR. Thus, the advantages of the OROS dosage form can be defeated by simply crushing the tablet and ingesting the powder. This raises safety and abuse liability issues for the higher strength OROS tablets."

989. In August 2012, the FDA approved a 32mg Exalgo tablet, but did not permit Mallinckrodt to make statements about any alleged abuse-deterrent properties of the drug.

990. Nevertheless, in a widely disseminated press release on August 27, 2012, Mallinckrodt made the following "abuse-deterrent" claims about Exalgo:

> ... 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.

991. Mallinckrodt also misleadingly marketed Exalgo as a substitute for reformulated Opana ER, an opioid that Endo was itself falsely marketing as "abuse deterrent." [redacted]

Xartemis

992. By late 2013, Mallinckrodt was banking on Xartemis XR to hit the market in 2014 and, according to CEO Mark Trudeau, earn "hundreds of millions in revenue." [redacted]

993. [redacted]

994. In 2013, months before FDA approval of Xartemis, Mallinckrodt began publicizing the alleged "abuse-deterrent" features of the drug, in particular through KOL Lynn Webster, who was being investigated by the DEA at the time and to whom Mallinckrodt paid more than $3 million for research and consulting expenses from 2013 through 2016. Webster, appearing to be an independent pain management physician, played a key role in Mallinckrodt's campaign to concoct a myth – debunked in early 2014 by the FDA – that Xartemis had "abuse-deterrent" properties.

995. In an interview published online, Dr. Webster stated that Xartemis "has abuse deterrent properties which mean that the new design and technology within this formulation may prevent people who try to manipulate, alter or convert the extended release into an immediate release in order to achieve a greater high." Dr. Webster failed to disclose that he had been paid millions of dollars by Mallinckrodt.

996. After extensively reviewing scientific data provided by Mallinckrodt, the FDA rejected Mallinckrodt's request for abuse-deterrent labeling for Xartemis, concluding on February 24, 2014, that "[Mallinckrodt] has failed to adequately demonstrate [abuse-deterrent] properties that

warrant inclusion of the findings in the label." This conclusion aligned with the FDA's finding, as part of its Final Risk Evaluation and Mitigation Strategy (REMS) Review in January 2014, that "Xartemis XR is an extended-release Schedule II opioid analgesic with no abuse-deterrent properties."

997. In March 2014, shortly after the FDA's publication of its detailed explanation of why it rejected abuse-deterrent labeling for Xartemis, [redacted]

998. [redacted]

999. Mallinckrodt also touted Xartemis XR's "abuse-deterrent" properties to health care providers to position its drug as comparatively safer than competitors' products, so that health care providers would feel more comfortable prescribing it.

1000. [redacted]

i. [redacted]

ii. [redacted]

iii. [redacted]

iv. [redacted]

Mallinckrodt misrepresented opioids' ability to improve function and quality of life

1001. Mallinckrodt made deceptive and unsubstantiated claims regarding the improved quality of life and function resulting from opioids in general and its own drugs in particular.

1002. Despite the lack of evidence of improved function long term, Mallinckrodt deceptively promoted opioids as improving function and quality of life without disclosing the lack of evidence for this claim.

1003. Mallinckrodt's website claims, without citing any clinical evidence, that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."

1004. [redacted]

[redacted]

This Xartemis advertisement photo is similar to a photo in a Purdue Pharma advertisement for OxyContin that the FDA had found illegal in 2003:

1005. Mallinckrodt also misled consumers by disseminating advertisements suggesting that people in physically demanding jobs could return to work after taking Xartemis XR. [redacted]

1006. [redacted]

1007. The Mallinckrodt-founded website *pain-topics.org* also included misrepresentations regarding opioids' ability to provide improved function and quality of life.

1008. An article posted to the website titled *Overcoming Opiophobia & Doing Opioids Right* stated that opioid treatment for chronic pain leads to "enhanced biologic functions, including eating, sleeping, socializing, and sexual relations" and that "[p]hysical functions, including the ability to walk, drive, and work usually improve. Patients and clinicians commonly refer to the benefits of chronic opioid administration as improving 'quality of life.'"

1009. The Mallinckrodt-funded article went on to warn health care providers that without opioids, a chronic pain patient may be in and out of the "hospital or sickbed and be unable to participate in normal family, vocational, and other desired pursuits."

1010. These claims were made without adequate substantiation to support them. In fact, the available evidence indicates opioids do not improve function or quality of life when taken long-term—indeed, they may harm patients' health.

Mallinckrodt deceptively pushed prescribers to increase opioid doses

1011. The ability to escalate doses was critical to Mallinckrodt's efforts to market opioids for long-term use to treat chronic pain. Health care providers may not have chosen to initiate opioid therapy at all if they did not feel comfortable prescribing increasingly higher doses of opioids to counter their patients' building tolerance to the drugs' effects and if patients did not feel comfortable taking high doses of opioids.

1012. One 32mg tablet of Exalgo contains 128 MME, which means that it is 128 times as strong as a milligram of morphine, and well above the CDC-recommended daily threshold of 90 MMEs.[4]

[4]Dowell, *supra* note 3, at 15-16.

1013. Mallinckrodt disseminated false and misleading claims about the safety of high opioid dosages via unbranded advertising. For example, *Overcoming Opiophobia & Doing Opioids Right*, an article funded by Mallinckrodt and posted to *pain-topics.org* stated that "[t]here is no ceiling or maximal level of opioid dose in chronic [pain]."

1014. Mallinckrodt's branded advertising also promoted more opioid prescribing to more patients at higher doses. [redacted]

1015. [redacted]

1016. In a presentation Mallinckrodt developed for sales representatives to use directly with health care providers, Mallinckrodt similarly emphasized the safety and downplayed the risks of prescribing Exalgo at high dosages. [redacted]

1017. By instructing physicians that opioid doses can be safely increased, and encouraging them to dramatically increase patients' dosages, Mallinckrodt misrepresented the risks associated with taking increasingly high doses of opioids – risks that include addiction and fatal overdose.

1018. Data show that patients prescribed higher opioid dosages are at higher risk of overdose death. In a national sample of Veterans Health Administration patients receiving opioids from 2004–2009, patients who died of opioid overdose were prescribed an average of 98 MME/day, compared to those who received half that amount who did not experience fatal overdose.[5]

Mallinckrodt used branded and unbranded marketing targeted at Illinois health care providers and patients to disseminate its misleading messages

1019. Mallinckrodt disseminated these deceptive and unfair messages directly to consumers and health care providers and indirectly through third-parties and speakers programs.

1020. Through its sales representatives, Mallinckrodt provided the following services to induce health care providers to prescribe and consumers to take Mallinckrodt opioids:

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

1021. [redacted]

1022. Between 2010 and 2014, Mallinckrodt's sales representatives promoted Exalgo by calling on physicians and pharmacies in Illinois [redacted] Between 2014 and 2015 alone, Mallinckrodt's sales representatives also detailed Xartemis to health care providers in Illinois [redacted]

[5] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf (Last accessed Oct. 21, 2019).

1023. Mallinckrodt created its own front organizations and worked closely with established front groups and KOLs to disseminate pro-opioid messages to prescribers, patients, and policymakers, from seemingly neutral and credible third parties.

1024. Mallinckrodt provided funding to various established front groups, including the American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine.

1025. [redacted]

1026. The C.A.R.E.S. Alliance included opioid industry front groups and addiction treatment organizations. Mallinckrodt held out the C.A.R.E.S. Alliance as an independent, unbiased organization that "aims to improve pain management outcomes for people with pain and society through education that is both innovative and science-based."

1027. However, Mallinckrodt sought to use the C.A.R.E.S. Alliance to [redacted]

1028. [redacted]

1029. Similarly, pain-topics.org, of which Mallinckrodt was the founding sponsor, billed itself as "independent," but actually conveyed [redacted] Some of its content remains online today.

1030. Mallinckrodt also repeatedly detailed physicians who were ultimately arrested, convicted or received professional discipline for conduct related to their prescribing of controlled substances.

1031. As one example, Mallinckrodt sales representatives called on one Illinois pain specialist, [redacted] In January 2017, this pain specialist's license was placed on indefinite probation by IDFPR based on allegations that the doctor prescribed controlled substances for non-therapeutic purposes.

Mallinckrodt's unfair and deceptive marketing increased the sales of its generic opioid products

1032. Mallinckrodt had a significant generic opioids portfolio, which included generic versions of, among other drugs, OxyContin, MS Contin, Duragesic and Opana.

1033. [redacted]

1034. [redacted]

1035. Mallinckrodt's efforts in support of its branded drugs, as well as Mallinckrodt's unbranded marketing, inevitably impacted sales of generic opioids which Mallinckrodt knew health care providers would frequently prescribe or dispense in place of branded products.

1036. Through its unfair and misleading marketing, Mallinckrodt sought to expand overall demand for these dangerous drugs, fueling abnormally high levels of opioid prescribing and unprecedented levels of diversion, addiction, and death.

Mallinckrodt failed to implement effective procedures to monitor and report suspicious orders

1037. As an entity registered with the State of Illinois and the DEA as both a manufacturer and distributor, Mallinckrodt had a duty to maintain effective controls against diversion, including by putting in place policies and procedures to detect, halt and report suspicious orders.

1038. [redacted]

1039. By 2008, Mallinckrodt was well aware of the growing opioid epidemic and the role that prescription opioids played. In 2006 and 2007 the DEA sent letters to registrants regarding suspicious order monitoring, discussing reporting obligations and "the responsibilities of controlled substance manufacturers and distributors." The DEA's 2006 letter stated, "[a]s each of

you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country."

1040. The DEA's 2007 letter warned against the use of "rigid formulas" to define whether an order was "suspicious" and the filling of suspicious orders, even if they had been reported, before first determining that the order is not being diverted.

1041. At some point prior to 2008, Mallinckrodt established a suspicious order monitoring program ("SOMP").

1042.

1043.

1044.

[redacted]

1045. [redacted]

1046. In July 2010, [redacted]

1047. [redacted]

[redacted]

1048. Nevertheless, throughout this time period, Mallinckrodt continued to apply rigid formulas to determine whether an order may be suspicious, shipped questionable orders before making a determination as to whether they in fact were or were not suspicious, and failed to report suspicious orders to the DEA.

1049. In April 2010, [redacted]

1050. In May 2010, [redacted]

1051. In June 2010, [redacted]

1052. [redacted]

1053. At least between October 2008 and October 2010, [redacted]

1054. [redacted]

[redacted]

1055. In August 2011, [redacted]

1056. In July 2013, [redacted]

1057. Even in 2016, [redacted]

1058. In 2017, Mallinckrodt entered into a settlement with the United States Drug Enforcement Administration ("DEA") after the DEA's investigation revealed that "Mallinckrodt knew about the diversion [of oxycodone] and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion." The settlement also alleged that Mallinckrodt failed to conduct adequate due diligence of its customers and failed to detect and report suspicious orders, including orders of

unusual size or frequency or that deviated substantially from normal patterns, to the DEA. To settle these claims, Mallinckrodt paid a fine of $35 million.

FIFTEENTH CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, *et seq.* (MALLINCKRODT)

1059. The State incorporates Paragraphs 932 through 1058 herein as if set forth in their entirety.

1060. While engaged in trade or commerce, Mallinckrodt committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risk of opioid addiction;

b. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the extent to which addiction risk can be managed and addiction prevented;

c. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the ability of abuse-deterrent formulations of Mallinckrodt's drugs to lower opioid abuse and addiction risk;

d. Misrepresenting, with the intent that prescribers and patients rely on its misrepresentations, the true risk of addiction of Mallinckrodt's drugs by deceptively using the terms addiction, dependence, tolerance, physical dependence, and "pseudoaddiction";

e. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about opioids' generally and Mallinckrodt's products' ability to improve function and quality of life long-term;

f. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, that increased doses of opioids do not pose significant health risks;

g. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, regarding the risks and benefits of its opioid products compared to those of other opioid products;

h. Unfairly using a marketing and sales scheme intended to overcome prescriber and patient concerns regarding opioid addiction;

i. Unfairly using a marketing and sales scheme intended to increase the doses of its dangerous drugs taken by patients;

j. Unfairly targeting and encouraging health care providers with high rates of opioid prescription through in-person detailing, dissemination of educational materials and programs, and third-party materials containing misleading statements about the efficacy and risks of opioids. This targeted marketing sought to cause high volume prescribers to continue prescribing at those rates and encouraging additional prescriptions, even in some cases where Mallinckrodt recognized or should have recognized that the health care provider was not meeting the standard of care, and/or that opioids were being diverted or abused, thereby harming the public health;

k. Unfairly failing to detect, investigate, halt, and report suspicious orders of opioid drugs;

l. Unfairly facility to create, maintain, and use an adequate suspicious order monitoring system; and

m. Engaging in a deceptive and unfair scheme to increase sales of its opioid drugs by ignoring its duty and/or using inadequate measures to identify and prevent the shipment of suspicious and illegal orders of opioid drugs.

SIXTEENTH CAUSE OF ACTION

PUBLIC NUISANCE (MALLINCKRODT)

1061. The State incorporates Paragraphs 932 through 1058 herein as if set forth in their entirety.

1062. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

1063. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

1064. Mallinckrodt is required to abide by the federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, as well as, the Illinois Controlled Substances Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

1065. Mallinckrodt also has a duty under the Consumer Fraud Act to refrain from disseminating deceptive or misleading promotional material and a duty under the Consumer Fraud Act to disclose material facts. Mallinckrodt violated these duties.

1066. As described in detail above, Mallinckrodt's unlawful practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of Mallinckrodt's conduct:

a. Opioid use, abuse, and overdose deaths have significantly increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers who were profitable to Mallinckrodt but harmful to the public continued prescribing increasing numbers of opioids throughout the State in light of Mallinckrodt's failure to report suspicions of illicit prescribing to the State or law enforcement.

1067. Mallinckrodt controlled and controls the "instrumentality" of the nuisance – its marketing of opioid medications, including the deceptive and misleading representations regarding particular opioid medications, and the deceptive and misleading marketing schemes Mallinckrodt used to disseminate messages about opioids in general, and failing to appropriately monitor and report the potential abuse and diversion of opioids, including by failing to identify, report and refuse to fill suspicious orders of opioid pharmaceuticals.

1068. McKesson's failure to maintain an appropriate system to detect, investigate, halt, and report orders that it knew or should have known were suspicious was also a substantial factor in opioids becoming widely available and widely used and misused.

1069. Mallinckrodt's deceptive and unfair conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. Mallinckrodt's actions proximately caused prescribers' and patients' inability to assess and weigh the risks and benefits of opioids, resulting in pervasive overprescribing and abuse of these drugs. No third party broke the causal chain between Mallinckrodt's wrongful conduct and the resulting harm.

1070. But for Mallinckrodt's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Mallinckrodt's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

1071. The intent of Mallinckrodt's promotion of opioids was to sell more of them. Mallinckrodt intended for health care providers to prescribe more opioids, for patients to fill those prescriptions, and then for that prescription pattern to continue, often at higher and higher doses.

1072. The public nuisance and associated financial and economic losses resulting from Mallinckrodt's deceptive and unfair conduct were foreseeable to Mallinckrodt, which knew or should have known that its conduct would create a public health crisis. As alleged herein, Mallinckrodt engaged in widespread deceptive and unfair promotion and oversupply of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death. In addition to being unlawful, Mallinckrodt's conduct was also unreasonable and negligent in light of the lack of scientific support for Mallinckrodt's claims, and reckless and/or intentional in light of the known risks associated with opioids.

1073. A reasonable pharmaceutical manufacturer in Mallinckrodt's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result of Mallinckrodt's conduct – the widespread problems of opioid addiction and abuse. In fact, Mallinckrodt was on notice and aware of signs that pharmacies were dispensing, and health care providers were prescribing unreasonably higher numbers of opioids and that the broader use of opioids was causing just the kinds of injuries described in this Complaint, but it continued to make deceptive and misleading statements to promote opioids.

1074. Mallinckrodt's unlawful business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

1075. The injuries resulting from Mallinckrodt's deceptive and unfair conduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

1076. Mallinckrodt acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

1077. Mallinckrodt's conduct was not insubstantial or fleeting; to the contrary, Mallinckrodt substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. Mallinckrodt's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

1078. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by Mallinckrodt can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) ceasing any further marketing of Mallinckrodt's opioid products; (b) ceasing the further dissemination of any misleading information about opioids in general; (c) educating prescribers (especially primary care physicians, nurse practitioners, physician assistants and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction; (d) educating young people in particular about the risks of addiction; (e) educating women in particular about the risks of opioid use during pregnancy, including neonatal abstinence syndrome; (f) creating a publicly-accessible repository for independent, peer-reviewed studies on the risks and benefits of opioids; (g) providing and expanding access to addiction treatment to patients who are already addicted to opioids; and (h) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

1079. The State seeks an order that provides for abatement of the public nuisance Mallinckrodt has created, enjoins Mallinckrodt from further deceptive and unfair conduct, and awards the

State the costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

PRAYER FOR RELIEF (COUNTS FIFTEEN AND SIXTEEN)

Wherefore, the State prays for the following relief:

A. Finding that Mallinckrodt violated Section 2 of the Consumer Fraud Act, 815 ILCS 505/2, by engaging in unlawful acts and practices including, but not limited to, the unlawful acts and practices alleged herein;

B. Permanently enjoining Mallinckrodt from engaging in the unfair and/or deceptive acts or practices described herein;

C. Ordering Mallinckrodt to pay a civil penalty of $50,000 per deceptive or unfair act or practice, and an additional amount of $50,000 for each act or practice found to have been committed with the intent to defraud, all as provided in Section 7 of the Consumer Fraud Act, 815 ILCS 505/7;

D. Assessing an additional civil penalty in the amount of $10,000 per violation found by the Court to have been committed by Mallinckrodt against a person 65 years of age and older as provided in Section 7(c) of the Consumer Fraud Act, 815 ILCS 505/7(c);

E. Disgorging all revenues, profits, and gains achieved in whole or in part through the deceptive and unfair acts or practices complained of herein;

F. Requiring full restitution be made to consumers who were harmed by Mallinckrodt's deceptive and unfair acts or practices;

G. Requiring the Defendants to pay all costs for the prosecution and investigation of this action, as provided by Section 10 of the Consumer Fraud Act, 815 ILCS 505/10;

H. An order requiring Mallinckrodt to abate the public nuisance that they created and compensate the State for costs associated with its abatement efforts; and

I. Providing such other and further relief as justice and equity may require.

THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL ATTORNEY GENERAL OF ILLINOIS

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