



NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES
ONE STATE STREET
NEW YORK, NEW YORK 10004

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In the Matter of: :

MALLINCKRODT PLC, :
MALLINCKRODT LLC, and :
SPECGX LLC, :

No. 2020-0012-C

Respondents. :

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STATEMENT OF CHARGES AND NOTICE OF HEARING

TO THE ABOVE-NAMED RESPONDENTS:

PLEASE TAKE NOTICE that a hearing will be held at the office of the New York State Department of Financial Services, One State Street, New York, New York 10004, 6th Floor, on the 24th day of August, 2020, at 10:00 a.m., and continuing thereafter day to day, as determined by the Department, before a Hearing Officer to be appointed by the Superintendent of Financial Services, to determine whether RESPONDENTS have violated Section 403 of the New York Insurance Law and/or Section 408(a)(1)(A) of the New York Financial Services Law and whether civil monetary penalties shall be imposed and other appropriate relief granted as a result of such violation(s).

I.

OVERVIEW

1. The opioid epidemic has caused a devastating public health crisis in the United States. The human cost of that crisis has been profound, with more than 400,000 deaths linked to opioid-related drug abuse since 1997. The financial cost has been debilitating, with costs to the U.S. economy estimated in the hundreds of billions of dollars.

2. The crisis was created and fueled, in part, by greed. Entities and individuals at multiple levels of the opioid supply chain enjoyed huge profits as the drugs they sold both destroyed lives and dramatically increased the cost of health care in America.

3. These entities and individuals were well aware that opioids were highly addictive and subject to abuse, and, as a result, were generally appropriate only for cancer pain, short-term pain relief (such as immediately after surgery or trauma) or palliative (end of life) care.

4. Despite knowing that the long-term use of opioids for chronic pain treatment could lead to addiction and abuse, these entities and individuals took steps to expand the market for their pills into areas of treatment that they knew to be unsafe.

5. To do so, among many other things, the entities and individuals misrepresented the safety and efficacy of their drugs in marketing materials and in communications to healthcare professionals. They downplayed the addictive nature of their products and actively promoted a discredited theory of “pseudoaddiction.” They paid prominent doctors, advocacy groups, and professional associations vast sums of money to promote the use of opioids in areas that were not medically responsible. Moreover, they chose to look the other way when faced with blatant signs of over-prescription, abuse, and illegal diversion.

6. These efforts to expand the opioid market were fabulously successful. Despite the fact that there were no material changes in the circumstances under which opioids were medically indicated, the sales of opioids increased dramatically.

7. The consequences of this explosion of opioids on the market were as predictable as they were tragic. In every community, in every walk of life, Americans became addicted to these powerful drugs. When they could no longer obtain “legitimate” prescriptions from their doctors, they often turned to illicit sources, including “pill mills” where unscrupulous healthcare providers would hand out opioid prescriptions, for cash, on demand. When the opioid medications themselves became too expensive or too difficult to obtain, many victims turned to street-level drugs to feed their habit, including heroin and fentanyl-laced narcotics.

8. This addiction cycle has not only destroyed countless families and lives, but it has also resulted in a tremendous increase in healthcare costs, including claims paid by commercial health insurers. In addition to billions of dollars in unnecessary opioid prescriptions, healthcare costs related to treatment of opioid addiction and abuse has skyrocketed. From 2007 to 2014, for example, private insurance claims related to opioid dependence diagnoses rose more than 3000% nationally, and nearly 500% in New York State. It is estimated that, just in the past 10 years, commercial health insurance companies in the State of New York (and ultimately the consumers who pay insurance premiums) have paid \$1.8 billion in additional claims as a direct result of the opioid crisis.

9. One study has estimated that opioid overdose patients add approximately \$11.3 billion to the U.S. healthcare system each year — or approximately 1% of all expenditures. In 2015, the Centers for Disease Control and Prevention (“CDC”) estimated that healthcare costs directly related to opioid abuse on the whole totaled \$28 billion in that year alone. That year, the

average cost for private payors for a patient with an opioid abuse or dependence diagnosis was more than 550% higher — an increase of almost \$16,000 — than the average per-patient cost based on all patients’ claims.

10. These costs ultimately have been handed down to consumers who have been made to pay higher premiums for health insurance products.

11. Indeed, New Yorkers spend more on average than the rest of the country on health insurance. Per-person spending on health care was about 3% higher than the national average in 2013. By 2017 that gap increased to approximately 12%. The average annual rate of growth in per-person spending from 2013 to 2017 was 6.2% in New York, compared with a 3.9% national rate. A large degree of this increase in spending has been due to prescription drugs, whose costs constitute a high proportion of this growth. Indeed, compared with other categories of healthcare costs, prescription drugs have experienced the largest spending growth in New York as well as nationally, with rates of 40% and 29% respectively.

12. This enforcement action seeks to make Mallinckrodt accountable for the harm caused by the opioid crisis and incurred by the New York insurance industry and consumers of private commercial health insurance policies.

II.

THE ROLE AND JURISDICTION OF THE DEPARTMENT OF FINANCIAL SERVICES

13. The New York State Department of Financial Services (the “Department”) is the sole insurance regulator in the State of New York, including with respect to commercial health insurance plans through which more than five million New Yorkers obtain their vital health insurance coverage. As such, among other things, the Department licenses health insurance companies, conducts examinations thereof, and reviews and approves insurance rates.

14. The Superintendent of the Department also bears the responsibility of ensuring the safety and soundness of New York’s insurance industry and to promote the reduction and elimination of fraud, criminal abuse, and unethical conduct with respect to insurance institutions and their customers.

15. The Superintendent has the authority to conduct investigations, to bring enforcement proceedings, and to levy monetary penalties against parties who have engaged in wrongdoing in violation of the relevant laws and regulations.

16. In particular, pursuant to Section 403 of the New York Insurance Law, the Superintendent has the authority to levy civil penalties upon any person who has committed a fraudulent insurance act, as defined in Section 176.05 of the New York Penal Law, up to \$5,000 and the amount of the claim — per fraudulent claim.

17. Under New York Penal Law Section 176.05, a fraudulent insurance act is an act “committed by any person who, knowingly and with intent to defraud presents [or] causes to be presented . . . to or by an insurer . . . or any agent thereof: . . . a claim for payment, services or other benefit pursuant to [a health insurance] policy, contract or plan that he or she knows to: (a) contain materially false information concerning any material fact thereto; or (b) conceal, for the purpose of misleading, information concerning any fact material thereto”

18. In addition, under Sections 404 and 408(a)(1)(A) of the New York Financial Services Law, the Superintendent has the authority to levy civil penalties upon any person who has committed any intentional fraud or intentional misrepresentation of a material fact with respect to a financial product or service or involving any person offering to provide or providing financial products or services, up to \$5,000 per offense. “Financial product or service” includes, among other things, any financial product or service provided by a person regulated by the

Superintendent under the New York Insurance Law. This includes commercial health insurance plans.

III.

RESPONDENTS

19. Respondent Mallinckrodt plc is an Irish public limited company. In the United States, Mallinckrodt plc operates under the name Mallinckrodt Pharmaceuticals and maintains its U.S. headquarters in Hazelwood, Missouri.

20. Respondent Mallinckrodt LLC is a Delaware corporation with a principal place of business in Hazelwood, Missouri. Since in or around June 2013, Mallinckrodt LLC has been a wholly-owned subsidiary of Mallinckrodt, plc.

21. Between 2000 and 2007, Tyco International Ltd. owned Mallinckrodt Inc. In 2007, Tyco Healthcare, including Mallinckrodt Inc., was spun-off into an independent company called Covidien. In June 2013, Mallinckrodt plc spun-off from Covidien.

22. Respondent SpecGx LLC is a Delaware limited liability company with its principal place of business in Clayton, Missouri. SpecGx was formed in or around November 2016 as a wholly-owned subsidiary of Mallinckrodt LLC.

23. Respondents Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC are referred to herein collectively as “Mallinckrodt” or the “Mallinckrodt Respondents.”

24. Mallinckrodt has manufactured its own name-brand opioids, Exalgo (hydromorphone hydrochloride, extended release), Xartemis XR (oxycodone hydrochloride and acetaminophen (extended release)), and Roxicodone (oxycodone hydrochloride), and numerous generic formulations, including generic versions of OxyContin, Percocet, and Vicodin. Mallinckrodt discontinued Xartemis XR in December 2016.

25. Mallinckrodt was the most prolific manufacturer of opioid pills in the United States, including in New York, from at least 2006 to 2014. Indeed, according to data from the Automation of Reports and Consolidated Orders System (“ARCOS”), a database maintained by the U.S. Drug Enforcement Administration (“DEA”) that tracks the movement of controlled substances around the nation, Mallinckrodt manufactured approximately 39% of the opioid pills that flooded New York from 2006 to 2014 — a percentage significantly higher than that for any other opioid manufacturer. These pills accounted for approximately 36% of the total morphine milligram equivalents (“MME”) in New York during this period. Mallinckrodt’s heavy footprint extended also to the New York private commercial healthcare insurance industry. From 2009 to 2019, Mallinckrodt supplied New York policyholders of private commercial healthcare insurance, a population that has included approximately five million New Yorkers, with over one *billion* opioid pills — equivalent to over five billion MME and significantly more pills than the number manufactured by any other opioid manufacturer.

IV.

FACTUAL ALLEGATIONS

A. Introduction

26. Opioids are a class of drugs that includes narcotic painkillers derived from opium or that mimic opium’s effects. Older opium-derived drugs such as morphine, codeine, and heroin, are often referred to as “opiates”; newer, mostly synthetic drugs like oxycodone, hydrocodone, and fentanyl are distinguished from opiates and will be referred to herein as “opioids.”

27. Like heroin and morphine, prescription opioids work by binding to receptors in the brain and on the spinal cord, thereby dampening the perception of pain. At sufficient doses, opioids slow the user's breathing and can cause respiratory depression and death.

28. Prior to the mid- to late-1990s, medical professionals generally viewed opioids as dangerous and therefore limited their use. As a result, opioids were primarily prescribed only to treat short-term pain in controlled settings (such as immediate post-surgical or trauma pain in hospitals), and for acute cancer pain and palliative (end of life) care.

29. At the same time, there were no long-term studies demonstrating the safety and efficacy of opioids for long-term treatment of chronic pain. Indeed, no studies examined the use of opioids beyond 16 weeks, and there was no evidence that opioids improved patients' pain management or function in the long term. To the contrary, studies demonstrated that opioids were less effective than non-addictive analgesic alternatives and often resulted in the poor outcomes of opioid tolerance (*i.e.*, requiring ever-greater doses to get the same pain-relieving effect), diminished function, increased side effects, and addiction and abuse.

30. With the creation of powerful synthetic opioids in the mid-to late-1990s, however, opioid manufacturers, including the Mallinckrodt Respondents herein, and others embarked upon a deliberately false and misleading marketing and promotional campaign to change the perception of the danger and addictive quality of opioids. The goal of this campaign was to convince healthcare professionals to embrace opioids as safe and proper treatments for a much larger group of chronic pain sufferers, such as patients suffering from chronic back pain, arthritis, and migraine headaches, to name a few.

31. To accomplish this shift, opioid manufacturers, including the Mallinckrodt Respondents, spent vast sums of money on a variety of false and misleading marketing and

promotional activities. For example, among other things, the activities included developing and disseminating seemingly truthful scientific and educational and marketing materials that misrepresented the safety and efficacy of long-term use of opioids; paying sales representatives to deliver misleading messages about opioids to healthcare professionals; recruiting and funding healthcare providers to draft misleading studies and present deceptive and misleading continuing medical education programs; and helping develop and fund seemingly independent, objective advocacy groups, herein called front groups, that themselves developed false and misleading educational materials and treatment guidelines that promoted long-term opioid use.

32. These efforts were designed to convince healthcare professionals and patients, falsely, that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be safely used by most patients. Such efforts featured numerous material misrepresentations about opioids. Among other things, these efforts repeatedly overstated the benefits of long-term opioid treatment and failed to disclose the lack of evidence supporting such use; downplayed the risks of negative outcomes for patients, including the risk of addiction and abuse and the difficulty of withdrawal; falsely masked the signs of addiction by calling them “pseudoaddiction”; and overstated opioids’ success versus other, less dangerous pain relief alternatives.

33. These false and misleading marketing efforts were both ubiquitous and highly successful. The deception tainted nearly every source that healthcare professionals could rely upon for information about the safety and efficacy of opioids for chronic pain relief, and the institutional and public perception of the standard of care for treating patients with chronic pain changed.

34. As a result, the prescription of opioid medications dramatically increased over time. Opioid prescriptions doubled between 1980 and 2000 and just kept rising thereafter. A study of 7.8 million doctor visits found that prescriptions for pain increased by 73% between 2000 and 2010, for example, even though the number of office visits in which patients complained of pain did not change and the prescribing of non-opioid pain medications actually decreased during that period. Opioid prescriptions peaked in or around 2012, when more than 280 million prescriptions were issued (roughly a one-month supply for every American adult), and opioid prescription levels have remained far higher than historical norms through the present.

35. But for the misleading information disseminated by the opioid manufacturers, including the Mallinckrodt Respondents, doctors would not have, in most instances, prescribed opioids as medically necessary or reasonably required to treat chronic pain.

36. It is well known that a strong correlation exists between opioid use and abuse, and the sharp increase in opioid use caused by the opioid manufacturers' actions, including those of the Mallinckrodt Respondents, predictably, led directly to a dramatic increase in opioid abuse, addiction, overdoses, and death. The CDC estimates that more than 400,000 deaths in the United States can be attributed to opioid-related drug abuse since 1997. Moreover, mortality statistics are just a small part of the picture: according to data from 2009, for every overdose death, there were nine abuse treatment admissions, 30 emergency room visits, and 118 people with addiction or abuse problems.

37. Moreover, opioid abuse can rapidly evolve from prescribed opioid pain management to street-level heroin and fentanyl abuse. For many, the cycle begins with a "legitimate" opioid prescription for chronic pain management. Some patients become addicted

and request more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and, when those sources run out, they turn to the streets for illicit opioids and other narcotics, including heroin and street-level fentanyl. It is estimated that a majority of heroin users began by using prescription opioids.

38. In sum, the causal chain is straightforward. The intentional falsehoods of the opioid manufacturers, including the Mallinckrodt Respondents, about the safety and efficacy of opioids were successful in creating over-prescription of opioids on a massive scale. Then, that massive over-prescription resulted in an epidemic of abuse and addiction of opioids that itself has caused devastation in human and financial terms.

39. This chain of events caused tremendous financial harm to New York's health insurance companies and the consumers who pay their premiums. It is estimated that, just in the past 10 years, New York health plans have incurred as much as \$1.8 billion in claims for opioid prescriptions that were not medically necessary and to cover treatment for opioid-related abuse such as overdose, addiction counseling, emergency room visits, and anti-overdose medication that resulted from the opioid epidemic.

B. Specific Allegations Concerning Mallinckrodt Respondents

40. Mallinckrodt promoted its branded opioids, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about patients' functional improvement. By doing so, Mallinckrodt helped ensure opioids were and remained viewed, wrongly, as an appropriate treatment for chronic pain.

41. On its website and through other marketing channels, Mallinckrodt disseminated misleading messages about the risks and benefits of opioids. For example, its 2013 "Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of

Opioid Abuse” (the “Policy Statement”), stated that “sadly, even today, pain frequently remains undiagnosed and either untreated or undertreated,” and cited 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.” The Policy Statement also highlighted Mallinckrodt’s significant investment in prescriber education programs, stating that one of its goals was to increase prescriber understanding of pain terminology, including the concept of “pseudoaddiction.”

42. Mallinckrodt was also the founding sponsor of www.pain-topics.org, a website that launched in 2006. Articles on [pain-topics.org](http://www.pain-topics.org) consistently downplayed the risk of addiction from opioids.

43. For example, the website published a brochure entitled “Commonsense Oxycodone Prescribing & Safety” that stated “[p]sychological dependence, or addiction, cannot always be predicted. Very few patients taking opioids continuously for pain will exhibit addictive behavior; however, patients with a history of substance addiction or active addiction to other drugs or alcohol are at risk for addiction with oxycodone as well.”

44. [Pain-topics.org](http://www.pain-topics.org) also prominently featured an article entitled, “Opioid-Analgesic Abuse & Addiction Prevalence Still Uncertain,” that 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.”

45. The website also featured a brochure entitled “Oxycodone Safety Handout for Patients” that stated: “Patients’ fears of opioid addiction should be dispelled. Along with that, they must be cautioned against reducing oxycodone dosing on their own.” Another section of the

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

46. 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.” Although the website acknowledged that pseudoaddiction was “not supported by rigorous investigation,” it nonetheless went on to promote the concept, stating 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 advising that, in such cases, such behaviors will resolve after the pain is effectively treated.

47. 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.”

48. The website also included misrepresentations regarding opioids’ ability to provide improved function and quality of life. An article posted to the website entitled “Overcoming Opiophobia & Doing Opioids Right,” for example, 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.’”

49. The article went on to warn healthcare 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.”

50. All of 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.

51. In 2010, Mallinckrodt published “Opioid Safe Use and Handling Guide; A Resource for Patients” that stated: “[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 also defined pseudoaddiction as “[d]rug-seeking behavior that appears similar to addiction but is due to a need for more medication to control pain rather than addiction.”

52. Mallinckrodt also disseminated false and misleading claims about the safety of high opioid dosages via unbranded advertising. For example, the pain-topics.org article “Overcoming Opiophobia & Doing Opioids Right,” discussed above, stated: “There is no ceiling or maximal level of opioid dose in chronic [pain].”

53. Mallinckrodt’s marketing strategy also included the creation and/or support of front groups — supposedly independent advocacy groups that were in fact funded by and beholden to Mallinckrodt and other opioid companies — to amplify Mallinckrodt’s messaging. Mallinckrodt acted through these 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.

54. 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.” A C.A.R.E.S. Alliance fact sheet from 2011 explained that C.A.R.E.S. offers free resources to “promote safe prescribing, dispensing, use, storage, and disposal of [pain] medication.” At least between 2011 and 2019, the “C.A.R.E.S. Alliance” was a service mark of Mallinckrodt LLC (previously Mallinckrodt, Inc.).

55. A C.A.R.E.S. Alliance brochure entitled “Opioid Clinical Management Guide: A Resource for Responsible Opioid Prescribing and Use” offered the following definition of pseudoaddiction: “Some patients may exhibit aberrant behaviors, including inappropriate drug seeking behaviors when pain is undertreated. Unlike true addiction, however, these behaviors resolve and function and quality of life increase when pain is effectively treated.”

56. By 2012, Mallinckrodt was using the C.A.R.E.S. Alliance to promote a book entitled *Defeat Chronic Pain Now!*. The false claims and misrepresentations in this book include the following:

- a) “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.”
- b) “[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.”
- c) “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- d) “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- e) “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.”

- f) “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.”
- g) “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.”
- h) “[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.”

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

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

59. Upon information and belief, the C.A.R.E.S. Alliance catalog also offered the book *Responsible Opioid Prescribing: A Physician’s Guide* by Scott Fishman, M.D. *Responsible Opioid Prescribing* instructed healthcare providers to:

Be aware of the distinction between pseudoaddiction and addiction. Patients who are receiving an inadequate dose of opioid medication often ‘seek’ more pain medications to obtain pain relief. This is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction . . . Some common signs of pseudoaddiction resulting from inadequate analgesia are:

- Requesting analgesics by name,
- Demanding or manipulative behavior,
- Clock watching,
- Taking opioid drugs for an extended period,
- Obtaining opioid drugs from more than one physician, and
- Hoarding opioids.

60. Mallinckrodt’s website pain-topics.org also featured materials from the front group American Pain Foundation, relentlessly overstated the benefits and minimized the risks of opioids, gave extensive coverage to the unproven phenomena “pseudoaddiction” and “opiophobia,” and made blatantly false statements such as, “the clinical benefits of opioid treatment dwarf the clinical risks.”

61. Mallinckrodt also compensated doctors directly. For example, Mallinckrodt paid a New York pain management doctor — one of the top Exalgo prescribers from 2011 to 2013 — between \$15,000 and \$20,000 in honoraria from speaking engagements.

62. Mallinckrodt employees showed callous disregard for the problem that Mallinckrodt had helped foment. In January 2008, for example, as the opioid epidemic was raging in America, a Mallinckrodt national account manager sent an email to the vice president of sales for a wholesale drug distributor in Ohio. The Mallinckrodt account manager said that 1,200 bottles of oxycodone 30 mg tablets had been shipped. The distributor employee replied: “Keep ‘em comin’!” and “Flyin’ out of there. It’s like people are addicted to these things or something. Oh, wait, people are. . .” The Mallinckrodt account manager countered: “Just like Doritos keep eating. We’ll make more.”

63. In an August 2013 email, a Mallinckrodt Senior District Sales Manager in Kansas City told sales representatives: “You only have 1 responsibility, SELL BABY SELL!”

64. Mallinckrodt’s misrepresentations also extended to statements about how abuse-resistant its products were. Though Mallinckrodt advertised Exalgo and Xartemis XR as abuse-resistant, Mallinckrodt knew, and had known for years, that its opioids were at high risk of being abused and that abuse-resistant formulas did not make opioids less addictive. In fact, the U.S.

Food and Drug Administration (“FDA”) specifically barred Mallinckrodt from making such claims because they lacked any scientific basis.

65. In rejecting Mallinckrodt’s request for permission to market Exalgo as “abuse deterrent,” for example, the FDA stated that the tablets “will increase the potential risks for overdose or abuse in those seeking to defeat the extended-release system” and that “we predict that Exalgo will have high levels of abuse and diversion.”

66. Despite the FDA’s findings, Mallinckrodt began marketing Exalgo as abuse-deterrent as early as May 2011, stating: “Although once-daily hydromorphone ER can still be misused or abused, these studies indicate that the pharmacological and physical properties of this formulation are performing as designed to make it less susceptible to blood plasma level peaks and troughs and potentially difficult to manipulate.” In 2012, Mallinckrodt misleadingly 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.”

67. Mallinckrodt also made false abuse-deterrent claims about 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.” Mallinckrodt’s main selling point for Xartemis (a claim that was rejected by the FDA) was that Xartemis is less likely to be abused than other opioids.

68. Notwithstanding the FDA’s findings, in March 2014 Mallinckrodt posted a document on its public website falsely stating that Xartemis “is more resistant to simple spoon crushing compared to Percocet” and 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.”

69. As an entity registered with the New York Bureau of Narcotics Enforcement (“BNE”) and the DEA as both a manufacturer and distributor, Mallinckrodt knew that it was required to: (a) set up a system designed to detect and investigate suspicious orders of opioids; (b) refuse to fill suspicious orders and fill orders flagged as potentially suspicious only if, after conducting due diligence, it could determine that such orders were not likely to be diverted; and (c) report all suspicious orders to DEA and BNE. These duties include monitoring the downstream flow of opioid products to detect potential diversion. These duties applied to both Mallinckrodt’s branded and generic opioids.

70. At all relevant times, Mallinckrodt possessed ample sources of data that allowed it to identify suspicious orders of opioids. For example, Mallinckrodt had prescribing data that allowed it to track healthcare providers’ prescribing patterns over time, which, upon information and belief, it used to identify candidates to target for marketing and to monitor its own and competitors’ sales.

71. Mallinckrodt also obtained detailed data showing drug orders delivered to specific pharmacies that allowed it to precisely monitor the flow of its opioids. Distributors provide manufacturers such as Mallinckrodt with this data to receive “chargebacks,” which are payments from a drug manufacturer to a distributor in which the manufacturer reimburses the distributor for the difference between the full price paid by the distributor for the drug and the price received by the distributor from a pharmacy for the drug. Through this data, among other sources, Mallinckrodt knew that its opioids were widely diverted across the United States by 2010 at the latest.

72. Mallinckrodt purported to discharge its anti-diversion duties through its suspicious order monitoring program (“SOMP”), which was touted on its website as state-of-the-art and “exceeding” DEA requirements. However, the company’s SOMP was egregiously deficient.

73. A high-level Mallinckrodt employee has testified that Mallinckrodt knew its drugs were being diverted. Upon information and belief, so much of its 30mg generic oxycodone pill — which is blue — was being diverted in Florida that Interstate 75 was dubbed by users as the “Blue Highway.”

74. Key employees of Mallinckrodt knew of SOMP deficiencies. For example, Mallinckrodt’s director of controlled substance compliance stated in a deposition in January 2019 that as early as 2008 she was aware that Mallinckrodt’s SOMP was not detecting suspicious orders.

75. Mallinckrodt employees demonstrated a preoccupation with profit at the expense of the suspicious order monitoring requirements. For example, in July 2011, a national account manager for Mallinckrodt, sent an e-mail to a customer service representative, stating “[I]et’s not let suspicious order monitoring limit or restrict shipments because this is only a swapping of business between wholesalers.”

76. Mallinckrodt not only failed to cut off supply from customers most likely to be serving suspicious healthcare providers, it actually aggressively targeted those over prescribers in New York, including a number of whom were later indicted or convicted. Because Mallinckrodt carefully tracked their prescribing patterns using detailed pharmacy-level data, at a minimum the company knew that these healthcare providers were potentially engaged in diversion.

77. 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. Such prescribing data would have allowed Mallinckrodt to identify pill mills and note red flags of abuse or diversion. Upon information and belief, instead of using the information for this purpose, Mallinckrodt actually used it to identify “high prescribers” for purposes of its marketing efforts.

78. In January 2020, a New York pain doctor pled guilty to conspiracy to distribute controlled substances and healthcare fraud. The doctor issued more prescriptions for controlled substances annually than any other prescriber or prescribing entity in New York State, including hospitals. The doctor admitted writing prescriptions without a legitimate medical purpose and that the conspiracy began in 2006. In 2010, Mallinckrodt’s eastern Regional Sales Director described this doctor as “the number one potential prescriber in the Northeast Region. [...] By working together to make [the doctor] a product advocate the entire nation will benefit.” Mallinckrodt assigned seven people to work on the doctor’s account. Upon information and belief, Mallinckrodt-manufactured opioid pills made up approximately one-third of the doctor’s opioid prescriptions. Upon information and belief, Mallinckrodt sales representatives visited the doctor over 100 times to promote Exalgo and Xartemis.

79. The deficiencies in Mallinckrodt’s suspicious order monitoring program were confirmed in a July 2017 Memorandum of Agreement (“MOA”) between Mallinckrodt and DEA, in which Mallinckrodt agreed to pay fines of \$35 million. In the MOA, Mallinckrodt agreed that at certain times prior to January 1, 2012, certain aspects of Mallinckrodt’s system to monitor and detect suspicious orders did not meet DEA standards and that “at certain times during the Covered Time Period, at Mallinckrodt’s Hobart plant, certain of Mallinckrodt’s

recordkeeping and physical security practices at that facility were, in some respects, not consistent with DEA regulation.”

V.

SPECIFICATION OF VIOLATIONS

COUNT ONE

New York Insurance Law § 403
(Against Each Respondent)

80. The Department realleges and incorporates by reference the assertions contained in paragraphs 1-79 above as if set forth fully herein.

81. Pursuant to Section 403 of the New York Insurance Law, the Superintendent has the authority to levy civil penalties upon any person who has committed a fraudulent insurance act, as defined in Section 176.05 of the New York Penal Law.

82. Under New York Penal Law Section 176.05, a fraudulent insurance act is an act “committed by any person who, knowingly and with intent to defraud presents [or] causes to be presented . . . to . . . an insurer . . . or any agent thereof: . . . a claim for payment, services or other benefit pursuant to [a health insurance] policy, contract or plan that he or she knows to: (a) contain materially false information concerning any material fact thereto; or (b) conceal, for the purpose of misleading, information concerning any fact material thereto”

83. Since the mid- to late-1990s, the Mallinckrodt Respondents and their predecessors in interest have knowingly and with intent to defraud caused to be presented to an insurer or any agent thereof written statements or other physical evidence as part of or in support of claims for payment, services or other benefit pursuant to a health insurance policy or private or public health plan that they knew to (a) contain materially false information concerning any material

fact thereto; or (b) conceal, for the purpose of misleading, information concerning any factor material thereto.

84. Specifically, Respondents knowingly and with intent to defraud made numerous misrepresentations, directly or through third parties, concerning the safety and efficacy of opioids.

85. Those misrepresentations caused healthcare providers to present false claims for payment to insurers regulated by DFS on multiple and continuous occasions over the past decades in the form of written prescriptions for opioid medications and related documentation.

86. Such prescriptions carried with them express and/or implied representations that the opioid drugs being prescribed were medically necessary. Respondents were aware that such representations were, for the majority of the opioid prescriptions written during the relevant time period, false. The falsity of these representations was material to the successful claims for payment.

87. In the alternative, to the extent that third parties engaged in conduct that violated New York Penal Law §176.05, including without limitation prescribing doctors who wrote fraudulent prescriptions and patients who sought and obtained such fraudulent prescriptions, Respondents are liable for such conduct because they, knowingly and with an intent to defraud, solicited, requested, commanded, importuned and/or intentionally aided such third parties in such conduct.

88. Accordingly, Respondents have committed a fraudulent insurance act as that term is defined in New York Insurance Law §403. As a result, the Department is entitled to levy a civil penalty not to exceed five thousand dollars (\$5,000) plus the amount of each claim paid, for each violation. In this case, each fraudulent prescription constitutes an independent violation.

COUNT TWO
New York Financial Services Law § 408
(Against Each Respondent)

89. Petitioner realleges and incorporates by reference the assertions contained in paragraphs 1-88 above as if set forth fully herein.

90. Pursuant to Section 408(a)(1)(A) of the New York Financial Services Law, the Superintendent has the authority to levy civil penalties upon any person who has committed any intentional fraud or intentional misrepresentation of a material fact with respect to a financial product or service or involving any person offering to provide or providing financial products or services. “Financial product or service” includes, among other things, any financial product or service provided by person regulated by the Superintendent under the New York Insurance Law. This includes commercial health insurance plans.

91. Respondents, through their marketing, promotion, manufacture, and supply of opioids to patients for whom such drugs were not medically necessary, legitimate, and appropriate, committed acts of intentional fraud or intentional misrepresentation of material facts with respect to claims for insurance products or services or involving any person offering to provide or providing financial products or services.

92. Respondents, with the intent to defraud, made knowingly false representations about the safety and efficacy of opioid drugs.

93. These misrepresentations were made with the intent of increasing the demand for opioids into areas of treatment that were not medically necessary, legitimate, and appropriate.

94. Respondents were aware that the increase in demand would cause fraudulent claims to be made to insurance companies.

95. According, Respondents committed intentional fraud and/or made intentional misrepresentations of material facts with respect to a financial product or service and are thus liable to pay a civil penalty of up to five thousand dollars (\$5,000) per offense. In this case, each fraudulent prescription constitutes an independent offense.

PLEASE TAKE NOTICE THAT, as a result of these charged violations, the Department is seeking the following relief:

- a) The imposition of civil monetary penalties against Respondents;
- b) An order directing Respondents to cease and desist all activity that constitutes the violations of law enumerated herein; and
- c) Such other relief as is deemed just and appropriate.

PLEASE TAKE FURTHER NOTICE THAT:

(A) This Notice of Hearing and Statement of Charges is issued to Respondents pursuant to § 403 of the Insurance Law and §§ 305 and 306 of the Financial Services Law, and notice of the hearing is given to Respondents in accordance with § 304 of the Financial Services Law.

(B) Your attention is directed to a statement in plain language, attached hereto as Appendix A, summarizing the provisions of 23 NYCRR Part 2. **This statement contains important information concerning your rights and the Department's hearing procedures and should be read carefully.** A copy of 23 NYCRR Part 2 will be furnished upon request.

(C) Interpreter services shall be made available to deaf persons, at no charge.

(D) Should you fail to appear at the time and place set forth above, or at any subsequent date fixed for the hearing, the hearing will proceed as scheduled and may result in the following:

- i. The issuance of a report by the Superintendent finding violations of Section 403 of the Insurance Law and Section 408 of the Financial Services Law and the issuance of an order upon the Respondent requiring it to cease and desist from engaging in such violations; and
- ii. The assessment of monetary fines against the Respondents pursuant to Insurance Law § 403(c) and Financial Services Law § 408.

Dated: New York, New York
April 16, 2020

NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES

By:  _____
KEVIN R. PUVALOWSKI
Senior Deputy Superintendent
Consumer Protection and Financial Enforcement

 _____
KATHERINE A. LEMIRE
Executive Deputy Superintendent
Consumer Protection and Financial Enforcement

JOHN NICOSIA
LINDA DONAHUE
JANET LIPINSKI
NICOLAS KELLER
SAMANTHA JACOBSON
Of Counsel

One State Street
New York, New York 10004
(212) 709-5578

APPENDIX A



NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES
ONE STATE STREET
NEW YORK, NEW YORK 10004

SUMMARY OF HEARING PROCEDURES

Summary of Hearing Procedures for Adjudicatory Proceedings as Set Forth in 23 NYCRR 2, as Required by section 301.3 of the State Administrative Procedure Act.

1. The Hearing will be conducted and administered in compliance with the State Administrative Procedure Act and the Financial Services Law and regulations promulgated thereunder and will be held before an impartial hearing officer who will make a Report of findings and recommendations to the Superintendent.
2. You must be ready and prepared with your evidence to present your case on the hearing date.
3. You may be represented by an attorney at the hearing. In the event you do not have an attorney, you may appear on your own behalf, a member of the partnership may appear on behalf of the partnership, or an authorized officer of an entity may represent that entity.
4. You may file a written answer to notice of action or proposed action. If you do so, it should be delivered at least two (2) days before the hearing date to the New York State Department of Financial Services (“Department”) official who signed the notice of action or proposed action.
5. You may present evidence and have witnesses testify at the hearing. If you believe a witness will not appear voluntarily and you do not have an attorney representing you, you may request the Superintendent, a Deputy Superintendent, the hearing officer assigned to hear the matter, or any employee of the department authorized by the Superintendent to furnish you with a subpoena to compel the witness’ attendance. If the subpoena is issued to you, the service of the subpoena upon the witness and payment of all required fees is your responsibility.
6. All parties are entitled to discovery of the evidence intended to be introduced at the hearing.
7. All witness will be sworn or give an affirmation.

8. The rules of evidence are not the same as those in a court of law. Evidentiary and burden of proof issues are governed by Financial Services Law section 305(e) and State Administrative Procedure Act section 306.
9. The burden of proof is substantial evidence.
10. Prior to the commencement, a hearing may be postponed upon your written request if there is a good reason why the hearing should not begin on the scheduled date. To request a postponement you should contact the Department official who signed the notice of action or proposed action.
11. A hearing in progress may be adjourned by the hearing officer at your request if you can give a good reason and support your request with written evidence as the hearing officer deems appropriate.
12. If you do not appear or are not represented at the hearing, the hearing will take place as scheduled and a decision on the charges will be made. The decision may result in the revocation or suspension of your license(s) and the denial of any pending applications, and such other action as may be permitted by law, including the imposition of monetary fines.
13. If you do not appear at a hearing and a decision against you is issued, the hearing may be reopened upon a written application, if you satisfy the hearing officer that there are valid reasons for your failure to appear or your failure to request an adjournment or postponement and you have a meritorious case. If you do appear at the hearing and the decision is made against you, the hearing may be reopened on written request to the hearing officer if you can show newly discovered evidence or a compelling reason for such reopening. The application to reopen must be made within one-hundred and twenty (120) days from the date of the Superintendent's decision.
14. You may request a copy of the hearing officer's report and an opportunity to comment on it in writing before the Superintendent acts on the report. The request must be made to the hearing officer on the record prior to the close of the hearing.
15. Once a decision is made against you, you may, if you wish, take an appeal to the courts. This appeal must be made within one-hundred and twenty (120) from the date the decision was effective. It should be emphasized that your right to take an appeal is not connected in any way with your right to reopen the hearing as described in section 13, and an application to reopen does not extend your time to take an appeal to the courts.