REDACTED PUBLIC VERSION OF ADV. DOCKET NO. 205

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	Chapter 11
MALLINCKRODT PLC,	Case No. 20-12522 (JTD)
Reorganized Debtor.[1]	
OPIOID MASTER DISBURSEMENT TRUST II,	
Plaintiff,	Adv. No. 22-50435 (JTD)
v.	
BARCLAYS CAPITAL INC.; BEC CAPITAL LLC; BLACKROCK FINANCIAL MANAGEMENT INC.; BLACKROCK INC.; BLACKROCK INSTITUTIONAL TRUST COMPANY, N.A. (UK BRANCH); BLACKROCK INTERNATIONAL LIMITED; BLACKROCK INVESTMENT MANAGEMENT LLC; BLUE RIDGE CAPITAL HOLDINGS LLC; BLUE RIDGE CAPITAL LLC; BNP PARIBAS ARBITRAGE SNC, CAPITAL FUND MANAGEMENT SA; CAPITAL GROWTH MANAGEMENT LIMITED PARTNERSHIP CGM MUTUAL FUND; CGM FOCUS FUND; CARLSON CAPITAL LP; CHIMERA SECURITIES LLC; CITADEL SECURITIES LLC; CUBIST CORE INVESTMENTS, L.P.; CUBIST SHORT HORIZON INVESTMENTS I, L.P.; CUBIST SYSTEMATIC INVESTMENTS II, L.P.; CUBIST SYSTEMATIC INVESTMENTS L.P.; D.E. SHAW ASYMPTOTE PORTFOLIOS LLC; D.E. SHAW VALENCE PORTFOLIOS LLC; DEUTSCHE BANK AG; EG MARKET TECHNOLOGIES LLC; ENGINEERS GATE MANAGER LP; EVERPOINT ASSOCIATES LLC; G1 EXECUTION SERVICES LLC; GF TRADING LLC, GOLDMAN SACHS & CO. LLC; GOLDMAN SACHS INVESTMENT PARTNERS – GSAM A/K/A GOLDMAN	

[1] The Reorganized Debtor in this chapter 11 case is Mallinckrodt plc. On May 3, 2023, the Court entered an order closing the chapter 11 cases of the Reorganized Debtor's debtor affiliates. A complete list of the debtor affiliates in these Chapter 11 cases may be obtained on the website of the Reorganized Debtor's claims and noticing agent at http://restructuring.ra.kroll.com/Mallinckrodt. The Reorganized Debtor's mailing address is 675 McDonnell Blvd., Hazelwood, Missouri 63042.

SACHS ASSET MANAGEMENT, L.P.; GTS SECURITIES LLC; HEALTHCOR MANAGEMENT LP; HRT EXECUTION SERVICES LLC; HRT EXECUTION SERVICES LLC A/K/A SUN TRADING LLC; HRT FINANCIAL LLC; HRT FINANCIAL LP; INTEGRATED ASSETS II LLC; INTEGRATED ASSETS LTD.; INTEGRATED CORE STRATEGIES (US) LLC; JANE STREET CAPITAL LLC; JUMP TRADING LLC; KCG AMERICAS LLC; LATOUR TRADING LLC, LION CAVE CAPITAL LLC; LION CAVE MANAGEMENT LLC; MORGAN STANLEY; MORGAN STANLEY CAPITAL SERVICES LLC; PALOMINO LIMITED; PARTNER FUND MANAGEMENT LP; PAULSON & CO., INC.; PDT PARTNERS PORTFOLIO I, LLC; PDT PARTNERS PORTFOLIO II, LLC; PDT PARTNERS, LLC; PFM HEALTH SCIENCES L.P. A/K/A PARTNER FUND MANAGEMENT LP; PFM HEALTHCARE EMERGING GROWTH MASTER FUND, L.P.; PFM HEALTHCARE OPPORTUNITIES MASTER FUND, L.P.; PFM THEMATIC GROWTH INSTITUTIONAL MASTER FUND, L.P.; PFM THEMATIC GROWTH MASTER FUND, L.P.; PFM THERAPEUTICS MASTER FUND, L.P. F/K/A ONCOLOGY OPPORTUNITIES MASTER FUND, L.P.; PFM THEMATIC GROWTH PRINCIPALS FUND, L.P.; PFM HEALTHCARE MASTER FUND L.P.; PFM LIQUIDATING SIDEPOCKET FUND, L.P., POINT72 ASSOCIATES, LLC; POINT72 SELECT INVESTMENTS; QUANTBOT MANAGEMENT MASTER FUND SPC LTD; QUANTLAB TRADING PARTNERS U.S., L.P. A/K/A QUANTLAB SECURITIES, LP A/K/A QUANTLAB TRADING PARTNERS, L.P.; RESILIENT CAPITAL LLP, RGM SECURITIES LLC; RIEF RMP LLC; RIEF TRADING LLC; ROCK CREEK MB LLC; SG AMERICAS SECURITIES; SIMPLEX TRADING LLC; SPIREX TRADING LLC; SQUAREPOINT OPS LLC; SUSQUEHANNA SECURITIES LLC; T. ROWE PRICE ASSOCIATES, INC.; T. ROWE PRICE ALL-CAP OPPORTUNITIES FUND, INC.; T. ROWE BALANCED FUND, INC.; T. ROWE PRICE ALL-CAP OPPORTUNITIES PORTFOLIO, AS SERIES OF T. ROWE EQUITY SERIES, INC.; T. ROWE PRICE HEALTH SCIENCES PORTFOLIO, A SERIES OF T. ROWE PRICE EQUITY SERIES, INC.; T. ROWE PRICE EQUITY INDEX 500 PORTFOLIO, A SERIES OF T. ROWE PRICE EQUITY SERIES, INC.; T. ROWE PRICE

MODERATE ALLOCATION PORTFOLIO, A SERIES OF T. ROWE PRICE EQUITY SERIES, INC.; T ROWE PRICE GLOBAL ALLOCATION FUND, INC.; T. ROWE PRICE HEALTH SCIENCES FUND, INC.; T. ROWE PRICE HEALTH SCIENCES PORTFOLIO; T. ROWE PRICE SPECTRUM CONSERVATIVE ALLOCATION FUND, A SERIES OF T. ROWE PRICE SPECTRUM FUNDS II, INC.; T. ROWE PRICE SPECTRUM MODERATE ALLOCATION FUND; T. ROWE PRICE SPECTRUM MODERATE GROWTH ALLOCATION FUND, A SERIES OF T. ROWE PRICE SPECTRUM FUNDS II, INC.; T. ROWE PRICE U.S. VALUE EQUITY TRUST; T. ROWE PRICE VALUE FUND, INC.; TEWKSBURY INVESTMENT FUND LTD; THESYS TECHNOLOGIES LLC, TOWER RESEARCH CAPITAL LLC, TRADEBOT SYSTEMS, INC.; TWO SIGMA INVESTMENTS LP; TWO SIGMA SECURITIES; VIRTU AMERICAS LLC A/K/A VIRTU FINANCIAL BD; XTX MARKETS LLC; AND JOHN DOE DEFENDANTS,

Defendants.

AMENDED COMPLAINT

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Plaintiff the Opioid Master Disbursement Trust II, also known as the Opioid MDT II ("**Trust**"), is a statutory trust created by the confirmed plan of reorganization ("**Plan**")[2] of the debtors and debtors-in-possession in the above-captioned chapter 11 cases (collectively, "**Debtors**" and, together with certain non-debtor affiliates, "**Mallinckrodt**"). Under the Plan, the Trust received, among other assets, certain claims and causes of action of the Debtors, *see* Plan art. IV.W.6 at 97, including "any claims or Causes of Action against any current or former shareholders of Mallinckrodt plc, other than any Released Party, from whom Mallinckrodt plc purchased, repurchased, cancelled, or redeemed its own ordinary shares in connection with its share repurchase program(s) during the years 2015-2018," defined in the Plan as "Share Repurchase Claims." Plan art. I.A.400 at 45. The Trust has sole authority to pursue the Share Repurchase Claims,[3] *see* Plan art. IV.W.2(d) at 95, and the claims and causes of action that it asserts in this proceeding are Share Repurchase Claims. Accordingly, the Trust files this Amended Complaint against the Defendants named herein, alleging as follows:

NATURE OF THE ACTION

1. This action seeks to recover, for the benefit of opioid crisis victims and other Mallinckrodt creditors, funds that Mallinckrodt wrongfully transferred to its shareholders in exchange for no value, at a time when Mallinckrodt was deeply insolvent. Between 2015 and 2018, Mallinckrodt transferred close to $1.6 billion to its shareholders to buy back its own worthless shares. At that time, Mallinckrodt's vast accrued liability for its role in creating and

[2] As used herein, "Plan" refers to the Modified Fourth Amended Joint Plan of Reorganization (with Technical Modifications), the materials referred to and incorporated therein, and its implementing documents (D.I. 7670). Capitalized terms not otherwise defined shall have the meaning ascribed to them in the Plan. The Plan was confirmed by this Court's order of March 2, 2022 ("**Confirmation Order**") (D.I. 6660). Pleadings filed in *In re Mallinckrodt plc*, No. 20-bk-12522 (JTD) (Bankr. D. Del.) are referred to with the citation "**D.I. __**").

[3] Under the Plan, the Trust receives 50% of the proceeds of the Share Repurchase Claims, and the General Unsecured Claims Trust receives the other 50% of the proceeds. Plan art. I.A.179, 299 at 20, 32.

fueling the nationwide opioid crisis—the worst manmade public health crisis in American history—dwarfed the value of its assets and capital and far outstripped Mallinckrodt's ability to pay. The transfers that Mallinckrodt made to its shareholders therefore were textbook fraudulent conveyances, and must be avoided and recovered for the benefit of Mallinckrodt's creditors. These creditors include, among others, the countless individual victims whose lives were devastated by Mallinckrodt's opioid products and opioid-related conduct, as well as the state and local governments and Native American tribes that have incurred massive costs from the destruction that Mallinckrodt's opioid products wrought on the American public.

2. Mallinckrodt is a global pharmaceutical enterprise, which, among other things, is the largest producer and seller of opioid medications in the United States, and one of the largest in the world. [redacted] It, along with other pharmaceutical companies, engaged in an extensive unbranded opioid promotional campaign that changed the medical consensus regarding the proper uses of opioid drugs and the risks of addiction when opioids were used to treat chronic pain. This caused a dramatic increase in opioid prescriptions and addiction to opioid drugs. Indeed, the Drug Enforcement Administration ("**DEA**") called Mallinckrodt "the kingpin within the drug cartel" of companies driving the opioid epidemic.

3. Mallinckrodt's opioid-related liability arising from its products and from its role in creating and perpetuating the opioid crisis, including through its unbranded opioid promotional campaign, ultimately led to the filing of more than 3,000 lawsuits against Mallinckrodt around the

country seeking massive damages based on allegations that Mallinckrodt's opioid products and, because of Mallinckrodt's unbranded promotional campaign, the opioid products of other pharmaceutical companies and illicit opioid drugs, caused bodily injuries and death. The tidal wave of litigation and the liability it faced as a result led Mallinckrodt to file for bankruptcy in 2020. Many of the allegations included in this Amended Complaint also were made by claimants in the opioid litigation and throughout Mallinckrodt's bankruptcy proceedings. Those allegations cover periods preceding and during the fraudulent transfers described in this Amended Complaint. Mallinckrodt's role in creating and perpetuating the opioid crisis gave rise to enormous opioid liability that dwarfed the company's assets, and Mallinckrodt ultimately recognized this fact in filing for bankruptcy protection.

4. The consequences of flooding communities with opioids and altering the medical consensus through the unbranded marketing campaign were devastating. Opioids are highly addictive and can be fatal. According to the Centers for Disease Control and Prevention ("**CDC**"), between 1999 and 2020, more than 564,000 Americans have died from an overdose involving opioids. Countless more have become addicted or suffered other problems as a direct result of opioid use. Families have lost loved ones. Children exposed in utero have been born with neonatal abstinence syndrome ("**NAS**"), which means they suffered from withdrawal symptoms from opioids when they were born. Communities have been ravaged. Americans became addicted to their prescribed drugs and then were forced to turn to pill mills and street drugs to feed those addictions. In addition to its tragic human costs, the opioid crisis has also resulted in staggering financial costs, which have been estimated in the trillions of dollars.

5. Mallinckrodt played a substantial role in the opioid crisis. Given its outsized market share, Mallinckrodt's opioids comprised a large percentage of the opioids that were

diverted and abused throughout the nation. In addition, through aggressive, deceptive marketing and promotional activities, sales strategies and efforts to encourage the increased prescription of opioids generally, and failure to satisfy its duty to report and block suspicious orders, Mallinckrodt encouraged widespread overprescribing of opioid products and failed to prevent the diversion of its opioids into the black market where they could be sold "on the street" and abused.

6. Mallinckrodt faced crushing liability as a result of its conduct. It was subject to government investigations and beset by an admitted "all-consuming tidal wave of litigation concerning the production and sales of its opioid products."[4] This litigation included claims by diverse groups of plaintiffs, including, among others, individuals who suffered addiction, illness, bodily injury, and death as a result of Mallinckrodt's opioids; hospitals and insurance companies burdened with increased expenses associated with opioid-related health problems; and state, municipal, and tribal governments, that have incurred, and continue to incur, astronomical costs to address and alleviate the social and public health problems that Mallinckrodt's conduct caused. This "tidal wave of litigation" rendered Mallinckrodt hopelessly insolvent and ultimately drove the Debtors into bankruptcy.

7. At the same time that Mallinckrodt was manufacturing and selling opioids, promoting a false and dangerous narrative to change the medical consensus regarding the proper uses and risks of opioid drugs, and incurring crushing opioid-related liability, it also implemented a program by which it transferred close to ***$1.6 billion*** to its shareholders. Specifically, from 2015 through 2018, Mallinckrodt announced and implemented a program by which it repurchased its own shares from various shareholders on the open market ("**Share Repurchase Program**").

[4] Decl. of Stephen A. Welch, Chief Transformation Officer, in Support of Chapter 11 Pets. and First Day Mots. ("**Welch Decl.**"), D.I. 128 ¶ 76.

Altogether, Mallinckrodt repurchased approximately 36 million shares, for close to $1.6 billion, and received no value in return for those repurchases ("**Share Repurchase Transfers**").

8. The Share Repurchase Transfers enriched Mallinckrodt's equity owners at the expense of those most harmed by Mallinckrodt's products and conduct. Properly accounting for Mallinckrodt's crushing opioid liabilities makes clear that Mallinckrodt was deeply insolvent throughout the entire time period during which it conducted the Share Repurchase Program. Yet Mallinckrodt nonetheless transferred cash to its equity holders through the Share Repurchase Program and, in doing so, deprived its creditors—including individuals who suffered addiction and overdose, babies born with NAS, and states and communities that incurred massive costs due to Mallinckrodt's opioids—of close to $1.6 billion in value that rightfully should have been available to satisfy their claims.

9. Under the Plan, the Trust received the sole authority to pursue claims to recover the value that was transferred away in connection with the Share Repurchase Program. Accordingly, by this Amended Complaint, the Trust seeks to recover the funds Mallinckrodt unlawfully transferred to shareholders through the Share Repurchase Transfers, so that those funds may be rightfully distributed to Mallinckrodt's opioid claimants (including individual opioid victims, state and local governments, and others with opioid-related claims) and other unsecured creditors.

JURISDICTION AND VENUE

10. In accordance with Federal Rule of Bankruptcy Procedure 7008(a), this proceeding relates to the cases that the Debtors commenced on October 12, 2020 ("**Petition Date**") under chapter 11 of the Bankruptcy Code, which were jointly administered under the caption *In re Mallinckrodt plc*, Case No. 20-12522 (JTD) (collectively the **"Bankruptcy Case"**).

11. The United States District Court for the District of Delaware (**"District Court"**) has jurisdiction over this proceeding in accordance with 28 U.S.C. § 1334(b), and this proceeding arises under the Bankruptcy Code or arises in or is related to the Bankruptcy Case. This Court exercises such jurisdiction in accordance with 28 U.S.C. § 157(a) and the standing order of the District Court referring bankruptcy cases and proceedings to bankruptcy judges in this district.

12. This is a "core" proceeding as defined in 28 U.S.C. § 157(b)(2)(A), (H), and (O).

13. This Court has personal jurisdiction over each of the Defendants located within the United States under Rules 7004(d) and (f) of the Federal Rules of Bankruptcy Procedure. This Court has personal jurisdiction over the defendants located outside of the United States under Rule 7004(f) of the Federal Rules of Bankruptcy Procedure and Rule 4(f) of the Federal Rule of Civil Procedure, as incorporated by Federal Rule of Bankruptcy Procedure 7004(a)(1). Moreover, this Court may exercise jurisdiction over each of the Defendants located within and outside of the United States consistent with the Due Process Clause of the Fifth Amendment to the United States Constitution. The officers and employees who oversaw and implemented the Share Repurchase Program were located in the United States, and the parties Mallinckrodt contracted with to buy shares on its behalf are U.S.-based companies. Each of the Defendants purposefully sold Mallinckrodt stock, which was traded on U.S.-based exchanges, and received non-equivalent transfers of cash denominated in U.S. dollars from Mallinckrodt in exchange. Accordingly, each of the Defendants has sufficient minimum contacts with the forum and the exercise of personal jurisdiction over the Defendants does not offend traditional notions of fair play and substantial justice.

14. Venue in this district is proper under 28 U.S.C. § 1409(a) because this adversary proceeding arises under the Bankruptcy Code or arises in or is related to the Bankruptcy Case.

THE PARTIES

I. THE PLAINTIFF

15. The Trust is a Delaware statutory trust formed under the Plan and created pursuant to the provisions of the Delaware Statutory Trust Act, 12 Del. C. § 3801, *et seq*., and is a "qualified settlement fund" within the meaning of the Treasury regulations issued under section 468B of the Internal Revenue Code. *See* 26 U.S.C. § 468B.

16. The Trust was formed under the Plan for the benefit of the individuals and entities that hold claims against Mallinckrodt based, in whole or in part, on its role in creating, perpetuating, and exacerbating the opioid crisis (each, as defined in the Plan, "**Opioid Claims**" and the holders of such claims, "**Opioid Claimants**").[5] The Opioid Claimants comprise the individuals, entities, and communities that Mallinckrodt harmed through the widespread distribution and aggressive marketing of its opioid products and promotion of opioids generally. They include individuals who suffered bodily injuries, including addiction, overdose, other sickness or disease, and death due to Mallinckrodt's opioid products and related marketing, and non-Mallinckrodt opioid drugs, licit and illicit, that were used as a result of Mallinckrodt's unbranded promotional campaign. They include personal injury claims for babies born with NAS. They include emergency room physicians and hospitals that bore costs to care for those harmed

[5] The Plan defines "Opioid Claim" as "a Claim or Cause of Action (other than Claims or Causes of Action arising from violations of the Voluntary Injunction or Opioid Operating Injunction), whether existing now or arising in the future, based in whole or in part on any conduct or circumstance occurring or existing on or before the Effective Date and arising out of, relating to, or in connection with any opioid product or substance, and any and all Opioid Demands related thereto, including, for the avoidance of doubt, claims for indemnification, contribution, or reimbursement on account of payments or losses in any way arising out of, relating to, or in connection with any such conduct or circumstances and Co-Defendant Claims. For the avoidance of doubt, Opioid Claims do not include (i) any liability solely to the extent premised on allegations regarding conduct undertaken by the Reorganized Debtors after the Effective Date, (ii) any Generics Price Fixing Claims, or (iii) any claims arising under section 502(h) of the Bankruptcy Code." Plan ¶ 274. The Plan defines "Opioid Claimant" as "a Holder of an Opioid Claim, including Governmental Opioid Claimants and Other Opioid Claimants." Plan ¶ 275. Descriptions of the Plan herein are subject in all respects to the actual terms of the Plan

by opioids, and other claimants with claims arising out of the opioid crisis. They also include all states and territories, their political subdivisions, Native American tribes, hospitals, emergency room physicians, insurance ratepayers, and third-party payors.[6] Mallinckrodt's liability is a result of the claims against it by individuals who suffered bodily injuries because of their use of opioid drugs, and by governmental and other claimants that incurred costs because of those bodily injuries. The Opioid Claimants have claims in the aggregate trillions of dollars yet will receive on account of their claims only a fraction of their value. The vast majority of funds that the Trust collects and distributes to governmental units and other entities are to be used for abatement purposes per the Plan.

II. THE DEFENDANTS

17. Mallinckrodt plc transferred funds to hundreds of entities and individuals in connection with the Share Repurchase Program. The named Defendants are among the recipients of those transfers. The Defendants and the amounts Mallinckrodt transferred to each as part of the Share Repurchase Transfers are set forth below and in the attached Exhibit A. The details of the dates and amounts transferred are set forth in the attached Exhibit B.

18. Defendant Barclays Capital Inc. is a corporation with its principal place of business located at 745 Seventh Avenue, New York, NY 10019. [redacted]

19. Defendant BEC Capital LLC is a limited liability company with its principal place of business located at 3422 Old Capitol Trail #438, Wilmington, DE 19808. [redacted]

[6] The specific beneficiaries of the Trust include seven operating opioid trusts, created pursuant to the Plan, to which the Trust is obligated to distribute proceeds obtained through this litigation, and the Opioid Claimants who will receive the distributions from those seven operating opioid trusts.

20. Defendant BlackRock Financial Management Inc. is a Delaware corporation with its principal place of business located at 55 E 52nd Street, New York, NY 10022. [redacted]

21. Defendant BlackRock Inc. is a corporation with its principal place of business located at 55 E 52nd Street, New York, NY 10022. [redacted]

22. Defendant BlackRock Institutional Trust Company, N.A. (UK Branch) is a company with its principal place of business located at 400 Howard Street, San Francisco, CA 94105. [redacted]

23. Defendant BlackRock International Limited is a public limited company with its principal place of business located at 55 E 52nd Street, New York, NY 10022. [redacted]

24. Defendant BlackRock Investment Management LLC is a Delaware limited liability company with its principal place of business located at 1 University Square Drive, Princeton, NJ 08540. [redacted]

25. Defendant Blue Ridge Capital Holdings LLC is a limited liability company with its principal place of business located at 660 Madison Avenue, Suite 2025, New York, NY 10065. [redacted]

26. Defendant Blue Ridge Capital LLC is a limited liability company with its principal place of business located at 660 Madison Avenue, Suite 2025, New York, NY 10065. [redacted]

27. Defendant BNP Paribas Arbitrage SNC is a société en nom collectif (general partnership) with its principal place of business located at 1 Rue Laffitte Paris 9 FR-75C 75009 France. [redacted]

28. Defendant Capital Fund Management SA is a public limited company with its principal place of business located at 23 Rue de l'Université, 75007 Paris, France. [redacted]

29. Defendant Capital Growth Management Limited Partnership is a limited partnership with its principal place of business located at 1 International Place, Floor 45, Boston, MA 02110. Capital Growth Management Limited Partnership manages CGM Mutual Fund and CGM Focus Fund (collectively, the "**CGM Funds**"), which are funds that received proceeds as part of the Share Repurchase Transfers. [redacted]

30. Defendant Carlson Capital LP is a limited partnership with its principal place of business located at 2100 McKinney Avenue, Suite 1900, Dallas, Texas 75201. [redacted]

31. Defendant Chimera Securities LLC is a limited liability company with its principal place of business located at 27 Union Square W, Floor 4, New York, NY 10003. [redacted]

32. Defendant Citadel Securities LLC is a limited liability company with its principal place of business located at 131 S Dearborn Street, Floor 32, Chicago, IL 60603. [redacted]

33. Defendant Cubist Core Investments, L.P. is a limited partnership with its principal place of business located at 72 Cummings Point Road, Stamford, CT 06902. [redacted]

34. Defendant Cubist Short Horizon Investments I, L.P. is a limited partnership with its principal place of business located at 72 Cummings Point Road, Stamford, CT 06902. [redacted]

35. Defendant Cubist Systematic Investments II, L.P. is a limited partnership with its principal place of business located at 72 Cummings Point Road, Stamford, CT 06902. [redacted]

36. Defendant Cubist Systematic Investments L.P. is a limited partnership with its principal place of business located at 72 Cummings Point Road, Stamford, CT 06902.

[redacted]

37. Defendant D.E. Shaw Asymptote Portfolios LLC is a limited liability company with its principal place of business located at 1166 Avenue of the Americas, Floor 9, New York, NY 10036. [redacted]

38. Defendant D.E. Shaw Valence Portfolios LLC is a limited liability company with its principal place of business located at 1166 Avenue of the Americas, Floor 9, New York, NY 10036. [redacted]

39. Defendant Deutsche Bank AG is a public limited company with its principal place of business located at 60 Wall Street New York, NY 10005. [redacted]

40. Defendant EG Market Technologies LLC is a limited liability company with its principal place of business located at 640 5th Avenue, 19th Floor, New York, NY 10019. [redacted]

41. Defendant Engineers Gate Manager LP is a limited partnership with its principal place of business located at 230 Park Avenue, Suite 835, New York, NY 10169. [redacted]

42. Defendant Everpoint Associates LLC is a limited liability company with its principal place of business located at 72 Cummings Point Road, Stamford, CT 06902.

[redacted]

43. Defendant G1 Execution Services LLC is a limited liability company with its principal place of business located at 175 W Jackson Boulevard, Suite 1700, Chicago, IL 60604. [redacted]

44. Defendant GF Trading LLC is a limited liability company with its principal place of business located at 800 Third Avenue, New York, NY 10022. [redacted]

45. Defendant Goldman Sachs & Co. LLC is a limited liability company with its principal place of business located at 200 West Street, New York, NY 10282. [redacted]

46. Defendant Goldman Sachs Investment Partners – GSAM a/k/a Goldman Sachs Asset Management, L.P. is a limited partnership with its principal place of business located at 200 West Street, New York, NY 10282. [redacted]

47. Defendant GTS Securities LLC is a limited liability company with its principal place of business located at 545 Madison Avenue, Floor 15, New York, NY 10022. [redacted]

48. Defendant Healthcor Management LP is a limited partnership with its principal place of business located at 55 Hudson Yards, Floor 28, New York, NY 10001. [redacted]

49. Defendant HRT Execution Services LLC is a limited liability company with its principal place of business located at 3 World Trade Center, 175 Greenwich Street, Floor 76, New York, NY 10007. [redacted]

50. Defendant HRT Execution Services LLC a/k/a Sun Trading LLC is a limited liability company with its principal place of business located at 100 S Wacker Street, Suite 300, Chicago, IL 60606. [redacted]

51. Defendant HRT Financial LLC is a limited liability company with its principal place of business located at 3 World Trade Center, 175 Greenwich Street, Floor 76, New York, NY 10007. [redacted]

52. Defendant HRT Financial LP is a limited partnership with its principal place of business located at 3 World Trade Center, 175 Greenwich Street, Floor 76, New York, NY 10007. [redacted]

53. Defendant Integrated Assets II LLC is a limited liability company with its principal place of business located at 666 5th Avenue, 8th Floor New York, NY 10103. [redacted]

[redacted]

54. Defendant Integrated Assets Ltd. is a limited company with its principal place of business located at 666 5th Avenue, 8th Floor New York, NY 10103. [redacted]

55. Defendant Integrated Core Strategies (US) LLC is a limited liability company with its principal place of business located at 666 5th Avenue, 8th Floor New York, NY 10103. [redacted]

56. Defendant Jane Street Capital LLC is a limited liability company with its principal place of business located at 250 Vesey Street, Floor 5, New York, NY 10281. [redacted]

57. Defendant Jump Trading LLC is a limited liability company with its principal place of business located at 600 W Chicago Avenue, Suite 600, Chicago, IL 60654. [redacted]

58. Defendant KCG Americas LLC is a limited liability company with its principal place of business located at 200 Vesey Street, New York, NY 10282. [redacted]

59. Defendant Latour Trading LLC is a limited liability company with its principal place of business located at 148 Lafayette Street, Floor 10, New York, NY 10013. [redacted]

[redacted]

60. Defendant Lion Cave Capital LLC is a limited liability company with its principal place of business located at 295 Main Street, Chatham, NJ 07928. [redacted]

61. Defendant Lion Cave Management LLC is a limited liability company with its principal place of business located at 295 Main Street, Chatham, NJ 07928. [redacted]

62. Defendant Morgan Stanley is a Delaware corporation with its principal place of business located at 1585 Broadway Avenue, New York, NY 10036. [redacted]

63. Defendant Morgan Stanley Capital Services LLC is a limited liability company with its principal place of business located at 1585 Broadway Avenue, New York, NY 10036. [redacted]

64. Defendant Palomino Limited is a public limited company with its principal place of business located at 745 Seventh Avenue, New York, NY 10019. [redacted]

65. Defendant Partner Fund Management LP is a limited partnership with its principal place of business located at 475 Sansome Street, Suite 1720, San Francisco, CA 94111. [redacted]

66. Defendant Paulson & Co., Inc. is a corporation with its principal place of business located at 1133 Avenue of the Americas, Floor 33, New York, NY 10036. [redacted]

67. Defendant PDT Partners Portfolio I, LLC is a Delaware limited liability company with its principal place of business located at 1745 Broadway, 25th Floor New York, NY 10019. [redacted]

68. Defendant PDT Partners Portfolio II, LLC is a Delaware limited liability company with its principal place of business located at 1745 Broadway, 25th Floor New York, NY 10019. [redacted]

69. Defendant PDT Partners, LLC is a Delaware limited liability company with its principal place of business located at 1745 Broadway, 25th Floor New York, NY 10019. [redacted]

70. Defendant PFM Health Sciences L.P. a/k/a Partner Fund Management LP is a limited partnership with its principal place of business located at 475 Sansome Street, Suite 1720, San Francisco, CA 94111. PFM Health Sciences LP manages PFM Healthcare Emerging Growth Master Fund, L.P.; PFM Healthcare Opportunities Master Fund, L.P.; PFM Thematic Growth Institutional Master Fund, L.P.; PFM Thematic Growth Master Fund, L.P.; PFM Therapeutics Master Fund, L.P. f/k/a Oncology Opportunities Master Fund, L.P.; PFM Thematic Growth Principals Fund, L.P.; PFM Healthcare Master Fund L.P.; and PFM Liquidating Sidepocket Fund, L.P. (collectively, the "**PFM Funds**"), which are funds that received proceeds as part of the Share

Repurchase Transfers. [redacted]

71. Defendant Point72 Associates, LLC is a limited liability company with its principal place of business located at 72 Cummings Point Road, Stamford, CT 06902. [redacted]

72. Defendant Point72 Select Investments, LLC is a limited liability company with its principal place of business located at 72 Cummings Point Road, Stamford, CT 06902. [redacted]

73. Defendant Quantbot Management Master Fund SPC LTD is a limited segregated portfolio company with its principal place of business located at 369 Lexington Avenue, Floor 9, New York, NY 10017. [redacted]

74. Defendants Quantlab Trading Partners U.S., L.P. a/k/a Quantlab Securities, LP a/k/a Quantlab Trading Partners, L.P. is a limited partnership with its principal places of business located at 3 Greenway Plaza, Suite 200, Houston, TX 77046. [redacted]

75. Defendant Resilient Capital LLP is a limited liability partnership with its principal place of business located at 245 Hammersmith Road, suite 220, London, England W6 8PW. [redacted]

76. Defendant RGM Securities LLC is a limited liability company with its principal place of business located at 221 W 6th Street, Suite 1510, Austin, TX 78701. [redacted]

77. Defendant Rief RMP LLC is a limited liability company with its principal place of business located at 800 Third Avenue, New York, NY 10022. [redacted]

78. Defendant Rief Trading LLC is a limited liability company with its principal place of business located at 800 Third Avenue, New York, NY 10022. [redacted]

79. Defendant Rock Creek MB LLC is a limited liability company with its principal place of business located at 800 Third Avenue, New York, NY 10022. [redacted]

80. Defendant SG Americas Securities, LLC is a Delaware limited liability company with its principal place of business located at 245 Park Avenue, New York, NY 10167. [redacted]

81. Defendant Simplex Trading LLC is a limited liability company with its principal place of business located at 230 S Lasalle Street, Suite 08-500, Chicago, IL 60604. [redacted]

82. Defendant SpireX Trading LLC is a limited liability company with its principal place of business located at 377 Broadway, Floor 11, New York, NY 10013. [redacted]

[redacted]

83. Defendant Squarepoint OPS LLC is a limited liability company with its principal place of business located at 250 W 55th Street, Floor 32, New York, NY 10019. [redacted]

84. Defendant Susquehanna Securities LLC is a limited liability company with its principal place of business located at 401 City Avenue, Suite 220, Bala Cynwyd, PA 19004. [redacted]

85. Defendant T. Rowe Price Associates, Inc. is an investment management corporation with its principal place of business located at 100 E Pratt Street, Baltimore, MD 21289. T. Rowe Price Associates, Inc. manages T. Rowe Price All-Cap Opportunities Fund, Inc.; T. Rowe Balanced Fund, Inc.; T. Rowe Price All-Cap Opportunities Portfolio, as series of T. Rowe Equity Series, Inc.; T. Rowe Price Health Sciences Portfolio, a series of T. Rowe Price Equity Series, Inc.; T. Rowe Price Equity Index 500 Portfolio, a series of T. Rowe Price Equity Series, Inc.; T. Rowe Price Moderate Allocation Portfolio, a series of T. Rowe Price Equity Series, Inc.; T Rowe Price Global Allocation Fund, Inc.; T. Rowe Price Health Sciences Fund, Inc.; T. Rowe Price Health Sciences Portfolio; T. Rowe Price Spectrum Conservative Allocation Fund, a series of T. Rowe Price Spectrum Funds II, Inc.; T. Rowe Price Spectrum Moderate Allocation Fund; T. Rowe Price Spectrum Moderate Growth Allocation Fund, a series of T. Rowe Price Spectrum Funds II, Inc.; T. Rowe Price U.S. Value Equity Trust; and T. Rowe Price Value Fund, Inc. (collectively, the "**T. Rowe Price Funds**"), which are funds that received proceeds as part of the Share Repurchase

Transfers. [redacted]

86. Defendant Tewksbury Investment Fund LTD is a limited company with its principal place of business located at 73 Front Street, Floor 3, Hamilton HM 12, Bermuda. [redacted]

87. Defendant Thesys Technologies LLC is a limited liability company with its principal place of business located at 1325 Avenue of the Americas, Floor 28, New York, NY 10019. [redacted]

88. Defendant Tower Research Capital LLC is a limited liability company with its principal place of business located at 377 Broadway, New York, NY 10013. [redacted]

89. Defendant Tradebot Systems, Inc. is a corporation with its principal place of business located at 1251 NW Briarcliff Parkway, Suite 700, Kansas City, MO 64116. [redacted]

90. Defendant Two Sigma Investments LP is a Delaware limited partnership with its principal place of business located at 100 Avenue of the Americas, 16th Floor, New York, NY 10013. [redacted]

91. Defendant Two Sigma Securities LLC is a Delaware limited liability company with its principal place of business located at 100 Avenue of the Americas, 16th Floor, New York, NY 10013. [redacted]

92. Defendant Virtu Americas LLC a/k/a Virtu Financial BD LLC is a limited liability company with its principal place of business located at 1633 Broadway, Floor 41, New York, NY 10019. [redacted]

93. Defendant XTX Markets LLC is a limited liability company with its principal place of business located at 50 Hudson Yards, 64th Floor, New York, NY 10001. [redacted]

94. In addition, certain other as-yet unidentified parties received Share Repurchase Transfers on the dates set forth in the attached Exhibit C. The Trust sues each shareholder that sold Mallinckrodt shares on the dates set forth in Exhibit C as part of the Share Repurchase Transfers (the "**John Doe Defendants**").

FACTS COMMON TO ALL COUNTS

I. THE OPIOID EPIDEMIC

95. Beginning in the mid-1990s, manufacturers actively engaged in aggressive and deceptive marketing and promotional campaigns, which resulted in health care providers going against previously established practice and prescribing opioids in mass quantities. The widespread over-prescription, diversion, and abuse of opioid drugs, and the associated addiction, other injury, and death that followed, has devastated lives and communities across the country.

96. Overdose fatalities are one measure of the human toll that the opioid epidemic took. In a 2016 report, the CDC reported that "[o]pioid pain reliever prescribing has quadrupled since

1999 and has increased in parallel with [opioid] overdoses."[7] More recently, the CDC reported that "[o]verdoses involving opioids killed nearly 69,000 people in 2020, and over 82% of those deaths involved synthetic opioids."[8] In total, between 2000 and 2020, more than 270,000 people died of prescription opioid overdoses in the United States. When looking at deaths involving any opioid, including illicit and prescription opioids, the number increases dramatically to approximately 650,000 deaths from 2000 to 2020.

97. Prescription opioids also have a causal relationship to overdoses from illicit substances. Studies have shown that patients who can no longer obtain prescription opioids turn to illicit substances such as fentanyl-laced narcotics and heroin, which are molecularly similar to opioids. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade began with prescription opioids.[9] Based on data—including findings that people addicted to prescription opioids are 40 times more likely to become addicted to heroin—the CDC identified prescription opioid addiction as the strongest risk factor for heroin addiction.

98. The opioid crisis in the United States has also caused devastating socio-economic fallout. The CDC concluded that in 2017, when more than 47,000 people died of an opioid overdose and 2.1 million people over the age of 12 suffered from opioid use disorder, the opioid crisis cost the United States as a whole $1.02 trillion: $480.7 billion in the value of lives lost; $471 billion in the costs of opioid use disorder; almost $35 billion in health care and opioid use disorder

[7] Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000-20014*, CDC, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm (Jan. 1, 2016).

[8] *The Drug Overdose Epidemic: Behind the Numbers*, CDC, https://www.cdc.gov/opioids/data/index.html#:~:text=Overdose%20deaths%20involving%20opioids%2C%20including,than%20eight%20times%20since%201999.&text=Overdoses%20involving%20opioids%20killed%20nearly,those%20deaths%20involved%20synthetic%20opioids (June 1, 2022).

[9] *Opioid Addiction 2016 Facts & Figures*, Am. Soc'y of Addiction Med., https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

treatment; and $14.8 billion in criminal justice spending.[10] The CDC had previously calculated that prescription opioid misuse alone imposed total economic costs of $78.5 billion each year.[11] In 2018, the Altarum Institute, a nonprofit healthcare research and consulting firm, released a study underscoring the cost of the opioid crisis through 2016 and estimating its growth beyond.[12] The burden of the opioid crisis comes in many forms: lost wages and productivity; increased health care costs; lost tax revenue at the local, state, and federal levels; and higher spending on social services, education, and criminal justice. The Altarum study estimated the socio-economic impact of the opioid crisis between 2001 and 2016 to be $1 trillion.[13]

99. The Altarum study also highlighted how the cost of the opioid crisis has increased exponentially over time. In 2001, the annual cost was $29.1 billion. By 2006, the annual cost rose to $48.7 billion.[14] By 2007, it was $60.9 billion, and then in 2016, when the study was conducted, it was $95.8 billion.[15] Based on the rapidly escalating costs observed from 2011 to 2016, Altarum estimated that, between 2017 and 2020, the opioid crisis would cause an additional $500 billion in economic harm.[16]

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[10] *The Economics of Injury and Violence Prevention*, CDC, https://www.cdc.gov/injury/features/health-econ-cost-of-injury/index.html (Dec. 6, 2021).

[11] Curtis Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States, 2013*, at 1 (Wolters Kluwer Health, Inc. 2016), https://stacks.cdc.gov/view/cdc/55377/cdc_55377_DS1.pdf.

[12] *Economic Toll of Opioid Crisis in U.S. Exceeded $1 Trillion Since 2001*, Altarum, https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001 (Feb. 13, 2018); *see also* Corwin N. Rhyan, *The Potential Societal Benefit of Eliminating Opioid Overdoses, Deaths, and Substance Use Disorders Exceeds $95 Billion per Year*, Altarum (Nov. 16, 2017), http://altarum.org/sites/default/files/uploaded-publication-files/Research-Brief_Opioid-Epidemic-Economic-Burden.pdf.

[13] *Economic Toll of Opioid Crisis in U.S. Exceeded $1 Trillion Since 2001*, Altarum, https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001 (Feb. 13, 2018).

[14] *Id.*

[15] *Id.*

[16] *Id.*

100. Moreover, one study estimated that the overall economic burden of opioid use disorder and fatal opioid overdoses for just the year 2017 was $1.02 trillion.[17] And a study prepared by the Society of Actuaries estimated "that the total economic burden of the opioid crisis in the United States from 2015 to 2018 was at least $631 billion," with projections for 2019 ranging from $172 to $214 billion.[18]

II. THE DEBTORS

101. The Debtors comprise a global pharmaceutical enterprise that, among other things, is the largest supplier of opioid medications in the United States, and one of the largest in the world.

102. The original Mallinckrodt entity (G. Mallinckrodt & Co.) was formed in St. Louis, Missouri in 1867, and developed, manufactured, and sold pharmaceutical products and active pharmaceutical ingredients ("**APIs**"). APIs are the main ingredient in medicine that cause the desired effect of the medicine. Since that time, Mallinckrodt has undergone a series of corporate transactions, sales, and restructurings. Nevertheless, Mallinckrodt has always continued in the pharmaceuticals business and has always maintained a continuous and significant corporate presence in Missouri. Mallinckrodt's U.S. headquarters, principal operations, and principal place of business remain in Hazelwood, Missouri.

103. Mallinckrodt has manufactured, developed, marketed, promoted, and/or sold opioid pharmaceutical products and/or opioid APIs since at least 1898 and through today. Mallinckrodt's opioid portfolio included branded opioid products Magnacet, Exalgo, and Xartemis XR, which it

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[17] Curtis Florence, et al., *The Economic Burden of Opioid Use Disorder and Fatal Opioid Overdose in the U.S., 2017*, Drug Alcohol Depend., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8091480/ (Jan. 1, 2021).

[18] Stoddard Davenport, et. al., *Economic Impact of Non-Medical Opioid Use in the U.S., Annual Estimates and Projections for 2015 through 2019*, Society of Actuaries, https://www.soa.org/49bd58/globalassets/assets/files/resources/research-report/2019/econ-impact-non-medical-opioid-use.pdf (2019).

manufactured, marketed, and promoted at various times between 2007 and at least 2015—and the branded opioid product, Roxicodone, which it continues to sell today. Mallinckrodt also engaged in an extensive unbranded promotional campaign that promoted the use of opioid pharmaceuticals generally, overstating the benefits and downplaying the risks involved with opioid products to encourage more use. Mallinckrodt's generic opioid portfolio includes both APIs and finished dosage products, including generic versions of oxycodone, hydrocodone, and other well-known opioids. Mallinckrodt's finished dosage opioid products have included the following:

Branded/Generic (Branded Name)	**Chemical Name**
Branded (Exalgo)	Hydromorphone hydrochloride, extended release
Branded Generic (Roxicodone)	Oxycodone hydrochloride
Branded (Xartemis XR)	Oxycodone hydrochloride and acetaminophen
Branded (Magnacet)	Oxycodone and acetaminophen
Branded (Methadose)	Methadone hydrochloride
Generic	Morphine sulfate, extended release
Generic	Morphine sulfate oral solution
Generic	Fentanyl transdermal system
Generic	Oral transmucosal fentanyl citrate
Generic	Oxycodone and acetaminophen
Generic	Hydrocodone bitartrate and acetaminophen
Generic	Hydromorphone hydrochloride
Generic	Hydromorphone hydrochloride, extended release
Generic	Naltrexone hydrochloride
Generic	Oxymorphone hydrochloride
Generic	Methadone hydrochloride
Generic	Oxycodone hydrochloride
Generic	Buprenorphine and naloxone

104. Mallinckrodt's opioid business was substantial. Indeed, Mallinckrodt became the most significant manufacturer, marketer, and producer of opioid products in the United States.

105. The Share Repurchase Program began approximately two years after a spinoff transaction that Mallinckrodt's former parent, Covidien plc ("**Covidien**"), undertook in 2013. Specifically, Covidien owned and controlled Mallinckrodt's business from 2007 to 2013. In June 2013, Covidien completed a separation and spinoff ("**Spinoff**") of its pharmaceuticals and imaging business into Mallinckrodt plc, a newly created Irish public limited company. Covidien plc and Mallinckrodt plc effected the Spinoff through a series of agreements, including a separation and distribution agreement ("**Separation Agreement**") dated June 28, 2013.

106. Under the Separation Agreement executed at the time of the Spinoff, Mallinckrodt plc was to assume liabilities that Covidien's pharmaceuticals and imaging businesses incurred at any time, including the liabilities associated with the operation and ownership of Mallinckrodt plc's subsidiaries before the Spinoff. As such, the Spinoff purported to saddle Mallinckrodt plc with liability for claims relating to Mallinckrodt's opioid business regardless of whether the underlying conduct took place before or after the Spinoff.

107. Since the Spinoff, Mallinckrodt plc has been the ultimate parent in the Mallinckrodt enterprise. Mallinckrodt plc is an Irish public limited company, with its legal headquarters in Dublin, Ireland and principal offices in the United Kingdom, Missouri, and New Jersey. Mallinckrodt plc is a holding company with subsidiaries that include all of the other Debtors and certain non-debtor affiliates. Most of the subsidiaries have their principal place of business at Mallinckrodt's U.S. headquarters in Missouri. Certain other subsidiaries have their principal place of business in New Jersey, and the enterprise has production facilities throughout the United States.

108. Mallinckrodt's business grew, and its structure evolved, between the Spinoff and the Debtors' filing for bankruptcy on the Petition Date. Mallinckrodt eventually organized its businesses into two lines—Specialty Brands and Specialty Generics—but continued to operate as

a fully integrated enterprise. It maintained an organizational structure that consolidated the design, manufacturing, marketing, sales, supply, reporting, compliance, administration, and cash management functions of the entire Mallinckrodt enterprise into a single, unified economic entity.

109. Mallinckrodt plc directs and controls the other Mallinckrodt entities and develops sales, marketing, and business strategies for the entire Mallinckrodt enterprise. Mallinckrodt plc's Memorandum and Articles of Association under the Irish Companies Act make clear that Mallinckrodt plc's role is to direct, control, and manage the entire enterprise as one united business, specifying that Mallinckrodt plc's purpose is to "design, manufacture, produce, supply and provide generic and branded pharmaceuticals," "co-ordinate the administration, finances and activities of any subsidiary companies," and to "act as managers and to direct or co-ordinate the management of other companies or of the business[.]"

110. Since the Spinoff, a board of directors ("**Board**") consisting of nine directors none of whom are employees, has managed Mallinckrodt plc. The Board exercised control over the day-to-day affairs of the businesses, including Specialty Generics, and all of the subsidiaries' finances, revenues, transfer, sale and assignment of assets, assumption of debt, strategy, vision, policy, business practices, marketing, reporting, budgets, management compensation, and equity awards. The Board also exercised control over the enterprise's pharmaceutical sales and marketing and promotional strategies, including by implementing programs to review and approve product-specific materials, presentations, and external communications. Mallinckrodt provided the Board with reports regarding the foregoing, specifically updates about the marketing of opioid products, such as Xartemis XR, and updates on Mallinckrodt's aggressive actions to promote messaging to targeted prescribers. The Board also exercised ultimate control over the financing of the entire Mallinckrodt enterprise and the use of earnings from the operations of subsidiaries.

111. Mallinckrodt plc acknowledged its responsibility for monitoring and managing the risks the entire Mallinckrodt enterprise faced as a result of opioid liability. The Board explicitly communicated this to Mallinckrodt plc's shareholders and issued the Opioid Risk Oversight Shareholder Report in March 2020 regarding the "governance measures [Mallinckrodt plc] and SpecGx have implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the United States[.]" In the report, the Board confirmed that it "oversees an enterprise-wide approach to risk management[,]" that "[t]he involvement of the full Board in approving our overall business strategy is a key part of its assessment of management's appetite for risk and the determination of what constitutes an appropriate level of risk for the Company[,]" and that "the full Board has oversight responsibility for the enterprise-wide risk management process," while "various committees of the Board also have targeted responsibility for risk management[.]"

112. With respect to its opioid business, the Board wrote that it "and its committees . . . [are] actively engaged in monitoring the financial and reputational risks to the Company related to its subsidiaries' opioid business," that it "regularly receives detailed, privileged updates on the status of all material litigation . . . including opioid-related litigation," and that its Governance and Compliance Committee "has oversight of regulatory, healthcare compliance, public policy and corporate social responsibility matters – including legal and compliance matters related to prescription opioids [.]" The Board further explained that it "has complete access to contact and meet with any [Mallinckrodt] employee," that "directors are encouraged to visit [Mallinckrodt] operations and facilities and meet with local management[,]" that "members of senior management and other key employees are invited to attend meetings and make presentations to the Board," and that "a number of senior executives have regular communications with directors outside of formal

meetings as well." The report by the Board went on to provide a detailed explanation of various initiatives that, "[u]nder the Board's oversight," Mallinckrodt plc has taken "both directly and through its subsidiaries" regarding Mallinckrodt's opioid-related business.

113. Mallinckrodt plc and its various subsidiaries, at all times, acted as a single, unified enterprise in all other respects as well. Mallinckrodt conducts its business under a single trademark name—Mallinckrodt—and refers to itself as "us," "we," "the Company," or "our" in public filings and communications. For example, when Mallinckrodt disclosed issues regarding opioid-related lawsuits and liability in its public filings, it has historically referred to lawsuits against "the Company," defined as "Mallinckrodt plc, an Irish public limited company, and its consolidated subsidiaries." Mallinckrodt also files its financial results on a consolidated basis, reporting net sales by business segment—not by subsidiary—and offsetting its losses against its gains as a single economic entity. Moreover, Mallinckrodt regularly pooled cash and freely upstreamed money from subsidiaries to Mallinckrodt plc to pay for needs as they arose, such as debt payments and the Share Repurchase Program.

114. Mallinckrodt plc and its subsidiaries also share common officers and employees, many of whom execute documents on behalf of multiple entities. The Missouri headquarters provides shared corporate services for Mallinckrodt plc and many of its U.S.-based subsidiaries, which share assets used to manage the enterprise as a whole, including information technology, finance, human resources, corporate compliance, communications, and government affairs functions. Most of Mallinckrodt's employees, operations, and primary business activities are conducted in the United States, and the vast majority of its revenues come from the U.S. market.[19]

[19] Mallinckrodt's opioid businesses are nominally consolidated in the Specialty Generics side, which has included subsidiaries Mallinckrodt LLC, Mallinckrodt Equinox Finance Inc., Mallinckrodt Enterprises LLC, SpecGx Holdings LLC, SpecGx LLC, Mallinckrodt Enterprises Holdings, Inc., WebsterGx Holdco LLC, Mallinckrodt ARD Finance LLC, and Mallinckrodt APAP LLC. At all times relevant to this action and on the Petition Date, the principal location

115. Despite the fact that the various Mallinckrodt entities always shared numerous assets and services related to information technology, finance, human resources, corporate compliance, communications, and government affairs functions, the enterprise was so unified and well-integrated that there was no need for a formal shared services agreement, and one did not exist until as late as 2020. Indeed, the Mallinckrodt enterprise is so well-integrated that, during their depositions in litigations involving Mallinckrodt, several Mallinckrodt officers could not name which specific Mallinckrodt entity they worked for.

116. Through these mechanisms and others, the Debtors and the other Mallinckrodt entities act as a single, unified pharmaceutical business.

III. MALLINCKRODT DOMINATED THE OPIOID MARKET SPACE

117. Mallinckrodt's opioid business includes both generic and branded opioid products, including both opioid APIs and finished dosage products, and generic formulations of oxycodone, hydrocodone, methadone, and fentanyl. Mallinckrodt entered the opioid business decades ago, and has obtained a dominant market share. From 2007 until at least 2015, Mallinckrodt also actively manufactured, marketed, and promoted branded opioid products Magnacet (between 2007 and 2009), Exalgo (between 2010 and 2014), and Xartemis XR (between 2014 and at least 2015). Through today, Mallinckrodt continues to sell the branded opioid product Roxicodone.

118. Including its generic products, Mallinckrodt's opioid products dominated the opioid market space. [redacted]

of the Specialty Generics business was in Missouri, Specialty Generics' Research and Development operations were located in Missouri, and one of Specialty Generics' four production facilities was located in Missouri, with the others spread across North Carolina, Illinois, and New York.

119. Mallinckrodt itself estimated contemporaneously that, in 2015, it was allocated approximately 25% of the DEA's entire annual quota for controlled substances.

120. In some locations, Mallinckrodt had an even larger presence. For instance, at times, Mallinckrodt's pills accounted for 66% of the oxycodone in Florida. As such, by any measure, Mallinckrodt's products accounted for an outsized share of opioids sold in the United States.

IV. MALLINCKRODT'S WRONGFUL OPIOID PRACTICES

121. Mallinckrodt's success was driven by concerted efforts by it and others in the pharmaceutical industry to persuade prescribers and patients (incorrectly) that opioids—which, due to concerns about addiction, had traditionally been reserved for patients with the most serious conditions such as cancer—were in fact safe, effective, and appropriate for individuals experiencing virtually any type of chronic pain (when in truth, they were anything but). These efforts caused opioid sales to skyrocket, and corporate profits to soar along with those sales, leading one Mallinckrodt vice president of sales to refer to Mallinckrodt's oxycodone business as a "new economy" in 2008.

122. Lured by the promise of increased profits, Mallinckrodt, both directly and indirectly through groups that it and its parent, Covidien, sponsored, overstated the benefits of opioid products, particularly for long term use, while understating associated risks of addiction and abuse. Mallinckrodt did so notwithstanding its awareness of the wealth of scientific studies, articles, and other resources since the early 2000s that linked opioids (including Mallinckrodt opioids) with addiction and abuse. Moreover, Mallinckrodt did so despite its awareness of the diversion of opioids to the black market.

123. Furthermore, Mallinckrodt failed to implement the necessary and required systems to detect and prevent abuse and diversion. It had the prescriber-level data necessary to identify orders that were likely to be diverted, stop those orders before they were shipped, and report

suspicious customers to the DEA. Nonetheless, Mallinckrodt failed for years to design and implement an effective system for doing so, in contravention of its obligations under federal and state law. As a result of its decisions that prioritized corporate profits, Mallinckrodt gravely exacerbated the deadly and costly consequences of the opioid crisis.

A. Mallinckrodt's False and Deceptive Marketing of Opioids

1. Mallinckrodt Employed a Vast Network of Sales Representatives, and Pressured and Incentivized Them to Aggressively Sell Opioids

124. Mallinckrodt commissioned an army of sales representatives, on whom it placed intense pressure to sell opioids. [redacted]

125. Mallinckrodt encouraged its sales representatives to relay false and misleading claims about opioids' benefits to prescribers while downplaying risks of abuse and addiction. The business gave its sales employees "pain cards" that instructed them to use messages like, "start dose low, go slow, but go!!" and to falsely tell prescribers that "[m]ost opioid agonists have no analgesic ceiling dose[.]" As the regulatory and legal environment around opioid sales became more stringent, Mallinckrodt sales representatives "spent a great deal of time practicing how to be more 'edgy' in our selling style while reinforcing how to sell in this more challenging access environment."

126. Mallinckrodt sales representatives who succeeded in overcoming physicians' concerns and selling large amounts of opioids won high praise, while those who did not had their jobs threatened. For example, in January 2011, a representative shared that she had convinced a prescriber concerned about Exalgo's addictive qualities, who had been "very adamant . . . that Exalgo was something he would never write[,]" to begin prescribing Exalgo by "overc[oming] his fear of" hydromorphone, leading her district manager to encourage other representatives to follow her example and "[k]eep pushing!" Similarly, in February 2011, a district sales manager emailed his team to encourage aggressive Exalgo sales: "All I am asking is to find 1 patient a week to get Exalgo. They see 100% pain patients a day all week long . . . . There will be prizes for those that achieve this goal on a consistent weekly basis!"

127. Mallinckrodt pressured its sales representatives to increase Exalgo prescriptions. In December 2010, a district sales manager for specialty pharmaceuticals, Alex Panzardi, encouraged aggressive Exalgo sales, stating in a weekly email to twenty-one members of his sales team that "[w]e are losing some momentum and need to follow up with our providers that have committed to prescribing Exalgo. Let's not forget to focus on the OxyContin failures or patients that are complaining of the adverse events, especially in light of the fact that the scripts for OxyContin grew by roughly 1400 from the previous week." In September 2011, another district sales manager referenced a $60 rebate for Exalgo and urged his team that "[e]xcuse time with Exalgo is over. We need to turn on the spigot. You have all the clinical evidence to support the effectiveness of Exalgo and now you have the economic support. Go get 'em!!"

128. In fact, one of Mallinckrodt's main tactics to drive Exalgo growth focused on switching patients from OxyContin to high dosage Exalgo. Mallinckrodt told its sales representatives to focus on the 87% of OxyContin patients who received large "opioid tolerant"

doses. The goal was to get patients who were already taking large doses of opioids, and switch them to Exalgo, which had "a more restrictive indication" (*i.e.*, only for opioid-tolerant patients).

129. In August 2012, a regional sales director wrote that Exalgo was Mallinckrodt's "number 1 priority[,]" that performance evaluations would be based "almost exclusively [on] Exalgo performance" and that representatives need to "[m]ake sure [they] are driving Exalgo every day" and on "every single sales call[.]" [redacted] As one strategy to encourage prescribers to adopt Exalgo, Mallinckrodt developed a program by which prescribers could obtain a 14-day free trial voucher, with the goal of "accelerat[ing] EXALGO growth trends by allowing physicians to secure real-life experience with EXALGO at no cost to patients[.]"

130. To meet these quotas, Mallinckrodt encouraged its sales representatives to be bold in asking prescribers to increase their number of patients who were prescribed its drugs. For instance, in 2010, a sales representative reported on the success of the sales team's relentlessness and high-pressure sales tactics, relaying that a prescriber told him "he is using [Exalgo] because I am constantly in his office." Another sales representative wrote to his supervisor in December 2010: "I am getting more aggressive with asking for the business . . . there should be no excuse not to write Exalgo . . . I am feeling confident with my messaging and hungry for scripts, so I am asking for the business more aggressively." In 2012, still another sales representative commented that, as part of her action steps to get prescribers to prescribe Exalgo to more of their patients, she would explicitly ask "for 5 new Exalgo patients[.]" [redacted]

131. Mallinckrodt put intense and constant pressure on sales representatives. Underperforming sales representatives felt the threat of termination. For example, in an April 2013 email, a regional sales director wrote to his sales representatives that "expectations are escalating. We can't afford to carry unprofitable weight, and the organization won't let us." That same year, regarding the Exalgo free trial program referenced above, a Mallinckrodt regional sales director emphasized to his colleagues that, "We have to hit home with the representatives that they have NO CHANCE for success if the program fails . . . This is not a free product giveaway that everybody wants. This program has to be sold, and sold aggressively." Sales representatives who failed to sell aggressively enough were met with threats and hostility. For example, when his sales representatives failed to secure a sufficiently high number of Exalgo free trial redemptions, a district manager wrote, "YOU ARE MAKING ME LOOK BAD. Why can't we get our speakers to use them? Why won't our current customer's [*sic*] use them or simply do you a favor? You can find a way to get them to use them or pick up the phone and tell me what the f[—]ck is going on because I'm lost."

132. Mallinckrodt incentivized its sales representatives to maximize sales of opioids with the promise of large bonuses, lavish vacations, and other incentive compensation. Mallinckrodt's management applauded and encouraged such efforts to tie sales representatives' pay to their success in selling opioids. This led sales representatives to use a number of tactics to try to increase prescriptions, ensure those prescriptions would be filled, and meet their high sales quotas. In the face of pharmacies' reluctance to accept new pain patients due to concerns about opioid misuse, sales representatives would work directly with these pharmacies and/or direct pain patients to specific pharmacies to ensure their prescriptions would get filled, a process that in January 2012 Mallinckrodt called "protecting the script." In 2014, Mallinckrodt instructed sales

representatives on the importance of making sure pharmacies were stocked with Mallinckrodt's opioids at all times, and encouraged them to use a "Girl Scout cookie approach" of asking a prescriber to buy a large amount of opioids so that the physician would feel guilty and make at least a modest purchase. When faced with difficulties meeting sales quotas, some sales representatives sought alternatives to get prescriptions filled, with one representative expressing in 2014 that she "can't afford to have another physician stop writing or tell [her] they need to stop until the 1st of the month."

133. When the advent of generic competitors shifted market conditions, Mallinckrodt put additional efforts behind its next branded opioid, Xartemis, which it pushed with equally aggressive tactics. A 2014 memo to sales representatives emphasized that "it is vital to present Xartemis XR to ALL targets" and that "[w]ide adoption is vital to the success" of Xartemis. The memo encouraged representatives to call prescribers multiple times to increase the likelihood that they would prescribe Xartemis. [redacted] In 2014, a district sales manager wrote to his sales representatives: "10 surgeon's [*sic*] prescribing, 5XXR [Xartemis] per week over a 13 week period pays $36,000 . . . I could use $36,000. Could you?" In another email, a regional sales manager explained that "the district goal is to have everyone achieve 110% of their XXR [Xartemis] sales projection for the 3rd quarter. What's in it for all of us – more bonus dollar$." Another senior district manager, in a July 2014 email to his team expressing disappointment about

Xartemis XR sales, wrote: "I need everyone to start posting increasing scripts week after week. If you are sighing a bit of relief because you have 1-2 Rx each week, that's not a reason to sigh relief . . . You are paid on every script you get dependent on the number of writers you have. The more writers you have, the greater amount the script is worth."

134. Like with Exalgo, Mallinckrodt had a single-minded focus to meet the sales quotas for Xartemis. For instance, in one email, sales representatives received instructions to "average a min[imum] of 10 XARTEMIS XR TRxs [per week] by the last week of September [2014]." Those that achieved that aggressive goal advanced to the "next milestone," which was over 25 prescriptions per week. In another October 2014 email, a regional sales manager directed sales representatives to "choose 6 targeted XXR [Xartemis] physicians . . . where he was confident he could get them to prescribe XXR [Xartemis] to [at] least 1 patient per week."

2. Mallinckrodt Trained Its Sales Representatives to Use False and Misleading Messages to Sell Opioids

135. As part of its marketing efforts, Mallinckrodt encouraged its sales representatives to relay misleading claims about opioids' benefits to prescribers, while downplaying risks of abuse and addiction.

136. As far back as the early 2000s, Mallinckrodt understood opioids carried high potential for abuse, addiction, and overdose. Indeed, initial reports of abuse and diversion of OxyContin, Purdue Pharma's extended-release opioid product, began to circulate at least as early as 2000, and Mallinckrodt's internal presentations included surveys and analyses of the abuse potential of various opioid products. With respect to its own products, Mallinckrodt's employees routinely monitored and circulated media coverage regarding addiction and abuse of its opioids. One such 2010 email mentioned a study finding that "people who take high doses of opioid painkillers, even for legitimate medical reasons, are at risk of overdosing." Mallinckrodt was also

aware that these high risks came with little tradeoff in terms of improved patient outcomes. For example, a 2014 email summary of a National Institutes of Health panel that was circulated among Mallinckrodt employees acknowledged the panel's conclusion that there "isn't any consistency in prescribing chronic opioids[,]" and that there "isn't any data supporting their use long term in most disease states."

137. [redacted]

Common objections that sales representatives received concerning Exalgo were that it was too powerful, that it was "just as addicting as Dilaudid," that it was perceived as a desirable street drug, that healthcare providers were "very concerned with abuse potential," and that there were concerns about "abuse, overdosing, pricing[.]" Similarly, a Mallinckrodt senior district sales manager told other sales managers that certain pharmacies had flagged "Xartemis XR [a]s higher in abuse potential" and that "the State of New York advises against using this product!"

138. Nonetheless, Mallinckrodt trained its sales representatives to use misleading reassurances to prescribers about the purported benefits and low addiction risk of its products to overcome prescribers' concerns. It encouraged its sales representatives to draw false and misleading distinctions between drugs that Mallinckrodt made and sold and other addictive opioids, and to push back on the belief by some healthcare professionals that "hydromorphone [the active ingredient in Exalgo] was more addictive than other ER opioids." Mallinckrodt instructed its sales representatives to encourage providers to 'mov[e] . . . [Exalgo] up in the treatment algorithm' by convincing the providers that "Exalgo is NOT a big gun and should be used sooner" in a patient's treatment process.

3. Mallinckrodt Used Tactics Designed to Keep Patients on Opioids at Higher Doses for Longer Periods of Time

139. Mallinckrodt encouraged its sales representatives to work with prescribers to ensure that, once patients had been prescribed opioids, they stayed on the drugs for long periods of time and continued to take increasingly higher doses. For example, in January 2012, one district sales manager insisted that sales representatives "MUST ensure that patients stay on Exalgo once prescribed through proper dose initiation and titration." In July 2012, Mallinckrodt told its sales representatives that "each dose of Exalgo accounts for a third of your business" and to "drive home proper dosing and conversion" so that prescribers would prescribe "less 8mg and more 16mg." As such, "titration[,]" the process of consistently increasing a patient's dosage of opioids over time, was a focus of sales representatives' conversations with prescribers. As one sales representative noted in September 2012, the stronger 32 milligram dose was "the biggest thing we have going for us right now. For the next 4 weeks, every 32 MG script [counts] double!!!" towards the sales representatives' weekly sales goal. [redacted]

140. Mallinckrodt pushed dosing higher than what was consistent with the FDA-approved labels. For example, although FDA-approved labels for Exalgo permitted once-a-day use, a 2010 meeting summary regarding Exalgo noted: "Doctors complaining that patients having withdrawals and problems when only using once a day, so doctors are using 2x a day, and patients loved it."

141. This strategy ensured steady business and profits for Mallinckrodt, but had devastating consequences for patients, whose risk of addiction skyrocketed as they took opioids for longer periods of time at stronger doses.

4. Mallinckrodt Marketed Its Branded Opioids as "Abuse-Deterrent" Despite Knowing That These Products Carried High Risks of Abuse

142. Mallinckrodt specifically marketed its branded opioids, Exalgo and Xartemis XR, as having abuse-deterrent qualities, despite knowing for years that they did not actually deter abuse.

143. Mallinckrodt promoted Exalgo as abuse-deterrent, stating that the "pharmacological and physical properties of [Exalgo's] formulation are performing as designed to make it less susceptible to blood plasma level peaks and troughs and potentially difficult to manipulate." When attempting to overcome wholesalers' caution about shipping Exalgo to pharmacies "due to recent DEA actions[,]" a key talking point Mallinckrodt used was that the drug was not subject to the same level of abuse as oxycodone. Mallinckrodt further stated in marketing materials 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." Training materials for sales representatives also described Exalgo as "Specifically Designed for Gradual Release over 24 Hours . . . which contributes to steady plasma levels" and having a "barrier to crushing, chewing."

144. Mallinckrodt was acutely aware that its "abuse deterrent" claims were invalid. [redacted]

[redacted] Indeed, the FDA explicitly rejected Mallinckrodt's abuse deterrent claims, stating that a human bite was enough to break open a tablet of Exalgo.

145. In September 2009, Karen Harper, a senior manager of the controlled substances compliance group at Mallinckrodt, circulated an article from Reuters that highlighted opinions from a panel of medical experts on Exalgo's high abuse potential. The article quoted the panel chairman stating that "Exalgo was 'highly efficacious' but very prone to crushing and other methods of abuse compared to other opioid painkillers. 'On the spectrum of abuse, I think it's toward the top[.]'"

146. In December 2009, Mallinckrodt held a meeting of the Exalgo executive advisory board. The meeting notes indicated that "Exalgo is not intended to resist abuse." Further, "[t]he advisors recommended not overstating the abuse-resistant characteristics of Exalgo, since addicts will find ways to abuse Exalgo. Methods for extracting hydromorphone from Exalgo will likely become common knowledge among addicts within months after launch and be available via internet forums . . . ."

147. Mallinckrodt knew physicians were skeptical of the abuse-deterrent claims. In March 2010, a pharmaceutical consultant that Mallinckrodt retained indicated common objections to Exalgo from prescribers that Mallinckrodt should address, including: "it can be tampered with, and potentially fatal?" and "it is not tamper-resistant, when newer medications have tamper resistant features?" And in May 2010, a regional sales director for Covidien specialty pharmaceuticals forwarded an email from a Mallinckrodt sales representative to Mike Wessler, who served as the product director for Exalgo, stating that physicians "were surprised and

disappointed that Exalgo did not have any kind of tamper proof properties to the product. They felt like the FDA as well as Covidien would have made that a requirement with this product."

148. Mallinckrodt published abuse-deterrent claims for Exalgo even after the FDA concluded in 2010 that Exalgo "will increase the potential risks for overdose or abuse in those seeking to defeat the extended-release system" and predicted that "Exalgo will have high levels of abuse and diversion." Indeed, in subsequent emails, employees of Mallinckrodt acknowledged that the "FDA was originally reluctant to approve this 'strong' of an extended release [EXALGO] hydromorphone (the first ER hydromorphone product) . . . FDA was concerned that abuse could go the way of OxyContin. They actually disallowed approval for the strongest dosage strength we wanted to launch, but approved 4 strengths of 5[.]" [redacted]

149. Despite the FDA's warning and the other clear evidence of Exalgo's abuse potential, Mallinckrodt considered clever ways to send the message that its products were abuse-deterrent while evading legal restrictions on its ability to explicitly do so. For instance, one Mallinckrodt employee noted that "I noticed many of the competitor's data reference their respective products 'performing as designed[.]' This seems a particularly elegant way to discuss specific attributes without invoking the phrase abuse deterrent. Have we considered discussing Exalgo or OROS as performing as designed?" [redacted]

150. Mallinckrodt praised its sales representatives for convincing health care providers that the product was not addictive or prone to abuse and applauded them for making sales by describing it as abuse-resistant. For instance, in 2011, after the FDA had concluded that Exalgo presented a high risk for abuse, a regional sales director praised a sales representative for

overcoming a prescriber's reluctance to prescribe Exalgo due to the prescriber's "belief . . . that hydromorphone was more addictive than other ER opioids"—the representatives' "persistence" was held up as an example to others at Mallinckrodt, who received instructions to "[u]se the peaks and troughs graph" and to "Keep pushing!!!"

151. [redacted]

152. [redacted] In 2014, after the FDA declined to approve a label that would permit Mallinckrodt to market Xartemis as abuse-deterrent, Mallinckrodt still promoted the message 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 considered promoting Xartemis with slogans that included "[e]ngineered to discourage a common form of abuse" and "[d]emonstrated to be less liked for oral abuse vs Percocet[.]"

5. To Sell More Opioids, Mallinckrodt Employees Used Strategies to Evade Insurers' Restrictions on Opioid Coverage

153. Due to opioids' risk of addiction and abuse, insurance policies often included restrictions designed to limit the amount that a patient could access. These restrictions included

coverage and reimbursement limits, as well as "utilization management" strategies such as step therapy, quantity limits, and prior authorization requirements. Mallinckrodt employees routinely worked to bypass those restrictions, often working with healthcare providers to do so, to sell more pills.

154. In a September 2012 email, a Mallinckrodt key account director emailed a number of sales personnel with detailed instructions on how to work with prescribers to appeal and push back on insurers' denials of prescriptions due to quantity limits. The email noted that "physician pushback is vital to our initiative and will support other tactics that we are applying to effect change." Another Mallinckrodt employee followed up, noting that "our team saved a bunch of scripts [] as a result" of their efforts to combat these denials. In another email from that same period, that same key account director explained her efforts to persuade her contact at Anthem to ease its quantity restrictions on Exalgo, stating that she "may have an opportunity soon to present Exalgo to Anthem's Clinical and Health Outcomes departments and appreciate your patience while I work to lessen the current restrictions that Anthem has placed on Exalgo."

155. In 2013, Mallinckrodt employees worked with CoverMyMeds, a company owned by drug distributor McKesson that developed online software to streamline the process of seeking prior authorization. The employees worked to develop standard language that patients and prescribers could use to seek exceptions to quantity limits, such as "current available strengths do not allow the patient to get to the therapeutic dose, therefore multiple tablets are a medical necessity for the patient."

156. In 2014, insurance companies like Aetna and WellPoint/Anthem imposed prior authorization requirements for Xartemis. Calling these requirements "unacceptable," Mallinckrodt employees prepared strategies to lobby insurance companies to change their

processes to make it easier for patients to access Xartemis (and, thus, for Mallinckrodt to sell more pills). Mallinckrodt instructed sales representatives to discuss the restrictions with prescribers, give the prescribers contact information for Anthem's medical director, and encourage them to lobby directly to secure prior authorization. To avoid creating a written record of its attempts to influence prescribers to evade prior authorization requirements, Mallinckrodt emphasized to its sales representatives that their communications with prescribers regarding this issue should be done only orally, never in writing.

6. Mallinckrodt Targeted Physicians Who It Knew Were High Opioid Prescribers

157. As part of its efforts to maximize opioid sales, Mallinckrodt specifically targeted healthcare providers who it knew prescribed opioids in unusually large quantities. Mallinckrodt categorized prescribers based on "deciles" and focused its marketing efforts on healthcare providers who prescribed the largest amounts of opioids, without due regard for whether those healthcare providers were prescribing opioids responsibly. When launching new opioids, Mallinckrodt developed target lists of the top 25 "biggest opioid writers" in particular territories on whom to focus its marketing efforts. Mallinckrodt gave its sales representatives lists of "targets" and "hyper targets" on whom to focus their energies, as determined by those healthcare providers' likelihood of prescribing large amounts of opioids.

158. Mallinckrodt told its sales representatives to grow their business by focusing on "top volume prescribers" and "large accounts" that had potential to prescribe significant amounts of opioids. Rather than focus on the kinds of practices where opioid use would arguably be most appropriate—such as cancer pain practices—Mallinckrodt told its sales representatives to target large practices where uptake of Mallinckrodt branded opioids was the fastest, including such diverse practices as podiatry, plastic surgery, and orthopedics. For example, Mallinckrodt

encouraged sales representatives promoting Xartemis to target surgeons because they did not "accumulate patients[,]" but instead saw "5-12 NEW patients per week or 20-50 potential patients per month," meaning that "4 or 5 surgeons would be able to knock out about 50-100 XXR [Xartemis] patients per month!"

159. Mallinckrodt also instructed its sales representatives to target their efforts by focusing on prescribers who had been high prescribers of other branded opioids in the past. For example, internal training materials instructed sales representatives marketing Exalgo to focus on high prescribers of Dilaudid and other branded extended-release opioids. Similarly, Mallinckrodt told sales representatives marketing Xartemis to encourage doctors to "identify patients for [Xartemis]" on the day of the sale and to "adopt [Xartemis] for all their commercial patients who normally would receive Percocet, Nucynta or possible [*sic*] OxyContin."

160. The depth of Mallinckrodt's misconduct went well beyond targeting large practices or inappropriate specialties. As a way to focus sales efforts on high decile prescribers, Mallinckrodt produced quarterly playbooks for sales representatives to help them plan their work in their sales territories. These playbooks included lists of clinicians within the territory, ranked by the number of opioid prescriptions they sold, so that sales representatives could target their effort at the highest prescribers. Many of the healthcare providers identified in these playbooks as the highest prescribers—and, thus, Mallinckrodt's most important targets— were later indicted, lost licenses, or were otherwise penalized for questionable practices. To list just a few examples:

- Quarterly playbook, FY2013Q2, Territory 50101-New Hampshire: In 2019 former physician assistant Christopher Clough was sentenced to 48 months for participating in a kickback scheme in which he prescribed fentanyl spray to patients in violation of federal law.

- Quarterly playbook, FY2013Q2, Territory 50102-Boston: Dr. Fathallah Mashali was sentenced in 2018 to eight years in prison for healthcare fraud and money laundering.

- Quarterly playbook, FY2013Q2, Territory 50109-Hartford: Heather Alfonso, APRN, was sentenced in 2019 to three years of probation for engaging in a kickback scheme related to fentanyl spray prescriptions.

- Quarterly playbook, FY2013Q2, Territory 50202-Manhattan: Dr. Ricardo Cruciani was charged in 2021 with the sexual abuse of numerous pain management patients over the course of more than 15 years. Dr. Todd Schlifstein was sentenced in 2020 to nearly five years in prison for his involvement with a kickback scheme.

- Quarterly playbook, FY2013Q2, Territory 50302-New Brunswick: Dr. Kenneth Sun, who practiced in New Jersey and Pennsylvania, pled guilty in 2020 to participating in a kickback scheme relating to a fast-acting fentanyl narcotic.

- Quarterly playbook, FY2013Q2, Territory 50306-South Jersey: Dr. Louis Spagnoletti was barred in 2018 from treating patients and prescribing drugs under a consent order filed with the state Board of Medical Examiners, after being accused of "indiscriminately" prescribing painkillers.

- Quarterly playbook, FY2013Q2, Territory 50408-Richmond East: The Virginia Board of Medicine revoked Dr. Roger Phillips's license in 2014 due to infractions such as failure to obtain patient records and coordinate care, lack of considering alternative treatments to narcotics, and liberal prescription of narcotics.

- Quarterly playbook, FY2013Q2, Territory 60607-McAllen Laredo: The Texas Medical Board revoked Dr. Judson Somerville's medical license in 2017, citing his operation of unlicensed pain management clinics, violation of state law by pre-signing prescription forms, and not meeting the standard of care in treatment of patients with chronic pain. Separately, a federal jury convicted Dr. Jorge Zamora-Quezada in 2020 for his role in a $325 million healthcare fraud scheme in which he falsely diagnosed patients with lifelong diseases and treated them with toxic medications on the basis of that false diagnosis.

- Quarterly playbook, FY2013Q2, Territory 70306-Tucson: Dr. Sheldon Gingerich reached a settlement with the Arizona Attorney General's Office in 2021 regarding his involvement in a kickback scheme. In addition, Dr. Gingerich was permanently barred from prescribing controlled substances, taking money from pharmaceutical companies, or keeping compensation received for practicing medicine.

- Quarterly playbook, FY2013Q3, Territory 60506-Huntsville: Dr. Mark Murphy, along with six co-conspirators, was charged in September 2020 with a $41 million healthcare fraud, drug distribution, and kickback conspiracy run out of his pain clinic.

- Quarterly playbook, FY2013Q3, Territory 70108-Memphis: Dr. Christine Kasser's license to practice in New York was temporarily suspended in 2018, when she also was disciplined by the Tennessee Department of Health for prescribing large doses of narcotics and other controlled substances without documenting sufficient justification and treatment plans.

161. In all, Mallinckrodt ranked 239 medical professionals as top prescribers of opioids while the opioid crisis was raging.[20] Ultimately, more than 25% of those prescribers were convicted of crimes related to their medical practices, had their medical licenses suspended or revoked, or paid state or federal fines after being accused of wrongdoing.[21] In many instances, Mallinckrodt continued working with certain prescribers even after they were suspected of diverting narcotics to the black market.

162. As just one example, in 2010, Mallinckrodt's eastern regional sales director described a New York pain doctor as "the largest C2 [Schedule II] prescriber in NY and one of the biggest in the nation," but added that the doctor was "under a bit of scrutiny." At this time, Mallinckrodt assigned seven people to work on the doctor's account. Despite knowing that the doctor was under scrutiny for his prescribing practices, Mallinckrodt worked hard to convince him to prescribe its opioids, assigning nine people to work on the doctor's account. The doctor issued more prescriptions for controlled substances annually than any other prescriber or prescribing entity in New York State, including hospitals. Then, in 2016, the doctor was indicted on 114 counts of conspiracy to distribute controlled substances and healthcare fraud. In January 2020, he pled guilty and was sentenced to 70 months in prison. In his guilty plea, the doctor admitted to writing prescriptions without a legitimate medical purpose, and admitted that the conspiracy began in 2006—and thus lasted the entire period that Mallinckrodt promoted its products to the doctor and worked to make him an "advocate" for opioids.

163. As another example, in January 2011, a Mallinckrodt sales representative identified a pain management specialist who operated four busy clinics in Massachusetts and Rhode Island

[20] Meryl Kornfield et al., Inside the Sales Machine of the 'Kingpin' of Opioid Makers, Wash. Post (May 10, 2022), https://www.washingtonpost.com/investigations/interactive/2022/mallinckrodt-documentsdoctors-sales/.

[21] *Id.*

as a potential top prescriber. In September 2013—the same month the specialist lost his DEA license, necessary to prescribe controlled substances such as narcotics—a field contact report praised the Mallinckrodt sales representative for winning the doctor's business. The specialist was ultimately arrested in 2014, and later pled guilty to healthcare fraud, conspiracy to commit mail fraud, and money laundering. His arrest caused consternation among Mallinckrodt employees—but tellingly, their worry was on how to re-capture those (clearly medically unnecessary) high sales targets, rather than patient safety. One sales representative wrote that the arrest "hurts to say the least. Not only did he literally produce half my Exalgo scripts but his opioid market output was incomparable to any other practice in my territory . . . A large portion of my time was spent w [*sic*] him so I've been trying to use that time to increase my number of writers even more to try to make up for his production." Another sales manager wrote that the arrest "had a significant negative impact on this territory, the Boston District and likely the Northeast Region." In 2018, the specialist was sentenced to eight years in prison.

164. In 2010, a district manager identified a doctor in Laredo, Texas as someone worth meeting because he believed that "pain medications do not create addicts—they may help to identify them but do not cause patients to become one." Throughout 2010 and 2011, sales representatives met with the doctor and persuaded him to prescribe the painkiller Exalgo. He became one of Mallinckrodt's top opioid prescribers. In 2017, his Texas medical license was revoked for improper prescribing practices.

165. In yet another instance, until his 2021 conviction for accepting kickbacks in exchange for prescribing opioids, a doctor in Baltimore was a top Exalgo prescriber. He believed in "the benefit of chronic usage of long acting formulations of opioids" and worked closely with

sales representatives in speaking engagements and efforts to promote Mallinckrodt drugs to other healthcare providers.

166. Mallinckrodt was well aware of the dubious prescribing practices of the healthcare providers it was targeting. In February 2012, a district business manager noted Mallinckrodt's low market share in areas with significant numbers of "Opana ER [a competitor to opioid] Pill Mills[,]" but stated that he "heard the pill mills are switching patients to Oxycodone," which Mallinckrodt sold, and expressed that "we have to find some business with the current opportunity." In May 2012, a clinic that represented a Mallinckrodt sales representative's largest extended-release volume was shut down because of "state allegations of being a pill mill clinic[,]" in part based on its involvement with a pharmacy that was "missing 400,000 hydrocodone pills over a 4 yr period[.]" In March 2013, a Mallinckrodt sales representative described a success story promoting Exalgo to the largest pain clinic in Knox County, Tennessee—which represented 80% of all OxyContin prescriptions in Knox County—that another employee described as a "big glorified pill mill."

167. [redacted] After a manager shared a success story in March 2012 about a Mallinckrodt sales representative successfully switching a prescriber whose patients "come in bi-weekly for Lortab® refills" to Exalgo, another sales representative commented, "[t]hey come in bi-weekly for Loratab [*sic*] refills? . . . Can you say Pill Mill?? I am not sure I would have published this[.]" In one December 2013 email, upon being provided with a list of the top 25 targets in her district, a Mallinckrodt

employee pointed out that one of those targets had been "[k]icked out of workers comp in the past for questionable practices[,]" operated an "all cash clinic" seeing "multiple patients at once in his living room[,]" and had been identified by other area doctors as operating a "pill mill[.]" [redacted] Yet another Mallinckrodt sales representative noted that, after a nurse practitioner at a particular pain clinic was fired for 'not following protocol[,]' the representative continued to sell to the pain clinic, which was "utilizing the Oxy problem" to prescribe more Exalgo. [redacted]

168. These unusually high prescribers drove sales, and profits, for Mallinckrodt. When one Mallinckrodt sales representative informed his district manager that his "#1 target for OxyContin is a [family nurse practitioner] who was recently arrested and office was shut down due to improper prescribing habits[,]" the district manager commented that Mallinckrodt was "running into many issues in the field where Reps don't have viable targets" due to opioid prescribers losing their licenses, and expressed concern about the impact on sales representatives' ability to meet their quotas. [redacted]

[redacted]

169. Even when Mallinckrodt's sales representatives raised concerns about physicians suspected of inappropriate prescribing, those prescribers would remain on the sales representatives' target lists or would be removed temporarily only to be added back later. This practice led one district manager to complain that "we consistently need to remove suspicious targets who are regularly added back onto our list." [redacted]

7. Mallinckrodt Used Its Website and Other Media to Disseminate False and Misleading Information Regarding Appropriate Uses of, and Dangers from, Opioid Pharmaceuticals

170. In addition to its aggressive and targeted marketing to prescribers, Mallinckrodt used websites and other media to promote false and misleading information about the efficacy of both its opioid products and opioids generally while downplaying the attendant risks of addiction and abuse.

171. Mallinckrodt used promotional videos, websites, pamphlets, and other materials to encourage physicians to prescribe more opioids. In one particularly notorious example, Mallinckrodt released a video in April 2012 with a reggae-style song encouraging physicians to prescribe ever-higher amounts of opioids, with the lyrics, "You can start at the middle / You can start at the top / You can start with very little / But that's not where you should stop / Cause your patient needs relief, mon."

172. Between 2006 and 2007, Mallinckrodt sponsored a now-defunct website called "pain-topics.org," which characterized reports of addiction in patients who were prescribed opioids for chronic pain as misinformation and promoted the concept of "pseudoaddiction"—an unproven and false theory that the pharma industry championed, positing that signs of addiction actually reflect undertreated pain and should be addressed with more opioids.[22]

173. On behalf of Mallinckrodt, pain-topics.org published articles for prescribers and patients that, among other things, overstated the benefits of opioids while downplaying risks of addiction, including through statements that:

(a) "the clinical benefits of opioid treatment dwarf the clinical risks";

(b) "[a]ddiction to oxycodone in person without a recent history of alcohol or drug problems is rare";[23]

(c) "all indications are these problems [of addiction in opioid patients] may not be as many practitioners, regulators and the public seems to believe";

[22] Press Release, Pain-Topics.org Addresses Oxycodone Safety Concerns (June 12, 2007), https://www.pr.com/press-release/41743.

[23] *See* Lee A. Kral & Stewart B. Leavitt, Oxycodone Safety Handout for Patients, at 4 (June 2007), https://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

(d) opioid overdoses are limited to a "minimal" number of "celebrities and street users";

(e) "[v]ery few patients taking opioids continuously for pain will exhibit addictive behavior";

(f) "[p]atients' fears of opioid addiction should be dispelled . . . they must be cautioned against reducing oxycodone dosing on their own";[24] and

(g) "there is no ceiling or maximum level of opioid dose in chronic [pain]."

174. Pain-topics.org did not tie these assertions specifically to Mallinckrodt's opioid products, but rather stated them as to opioid pharmaceuticals generally, in an effort to change the medical consensus and public perceptions regarding the proper use of opioids, and to minimize the consensus and perceptions regarding the risks attendant to opioid use.

175. In 2010, Mallinckrodt published its *Opioid Safe Use and Handling Guide: A Resource for Patients*, which, among other false and misleading claims, stated 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 same guide 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."

176. These false statements, that Mallinckrodt directly or indirectly disseminated, stand in sharp contrast to the scientific evidence and data regarding drug overdoses, including numerous studies that found that opioid medications carry a high risk of addiction regardless of patient history or potential misuse. Indeed, the CDC's guidelines for prescribing opioids for chronic pain reject the concept of pseudoaddiction.

[24] *Id.* at 2.

177. Likewise, Mallinckrodt's promotion of the "patient function" and "quality of life" benefits of its opioid products was deceptive and deliberately ignored public health guidance. Mallinckrodt claimed on its website, for instance, 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." But this statement directly contradicts positions that the FDA and the CDC took, which, following a review of scientific studies, issued guidelines concluding that "there is not good evidence that . . . [opioids] improve pain or function with long term use."

178. Ultimately, Mallinckrodt and its industry peers succeeded in persuading prescribers, regulators, and patients that opioids were a safe and effective treatment for chronic pain. By the mid-2000s, nearly every source of information on which healthcare providers relied had been tainted by misinformation sourced from Mallinckrodt and its industry peers. As such, addictive opioids that were once reserved for patients in the most dire need of chronic pain relief—primarily, those with cancer-related pain—became a common treatment for virtually any type of pain, and prescriptions for opioids skyrocketed. At the same time, Mallinckrodt's failure to detect, stop, and report suspicious orders, despite having both a legal obligation and ample opportunities to do so, caused widespread diversion of its opioid products to illicit drug markets around the country. As explained below, this combination of overprescribing and widespread diversion led to a crisis of abuse, addiction, and death of historic proportions.

8. Mallinckrodt Paid "Key Opinion Leaders" to Disseminate False and Misleading Information

179. Mallinckrodt also recruited and compensated top opioid prescribers, known as "Key Opinion Leaders," to promote its opioid products (and opioids generally) by speaking at or attending events to promote opioid prescription and use; delivering scripted talks and drafting

misleading studies that promoted opioids; presenting deceptive continuing medical education programs; and serving in leadership positions in professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy.

180. Mallinckrodt actively promoted the purported benefits of opioid drugs to and through its "Key Opinion Leaders." It selected and paid physicians for these programs, and they attended trainings it hosted and delivered presentations to medical community peers at expensive restaurants and resorts. These payments were vital to Mallinckrodt's ability to win Key Opinion Leaders to its cause; in March 2010, after Mallinckrodt's speaker program had been active for two years, the medical affairs division of Covidien, Mallinckrodt's parent company at the time, expressed concern when new Senate legislation was proposed that would require pharmaceutical companies to disclose payments to doctors in promotional speaking roles.

181. Mallinckrodt was careful to select speakers who would extol the benefits of its products and spread its preferred messaging about opioids. In April 2011, a sales representative described one common speaker as "frequently instruct[ing] his audiences that there is no ceiling for pain medications" and as someone who "believes in Exalgo." To ensure favorable messaging, Mallinckrodt instructed Key Opinion Leaders to use—and not deviate from—slide decks that the company prepared.

182. Mallinckrodt's sales representatives, moreover, played a major role in organizing Key Opinion Leader events. Mallinckrodt encouraged its sales representatives to organize speaker programs that "[t]arget[ed] physicians who are receptive to using" its opioid products. It encouraged representatives to schedule as many speaker programs as they could. For instance, in a 2012 email, a field manager from Mallinckrodt reminded his colleagues that "we are contractually obligated to complete $400,000 worth of [speaker] programs in the first 6 months of

[Exalgo] promotion," which, "[b]ased on an average program cost of $5,000," equated to "roughly 80 programs" within a mere six-month period. In a June 2013 email, a Mallinckrodt district manager expressed disappointment that his district had "only 10 [speaker] programs on the books for" the latter half of the fiscal year, and instructed sales representatives that if they were "not tracking ABOVE 100% for Exalgo," they should be "scheduling as many of these teleconferences and lunch speaker programs as you possibly can[,]" and noted that their efforts were "being watched and tracked not only by me but those much higher than me."

183. Unsurprisingly, doctors whom Mallinckrodt targeted as Key Opinion Leaders were also high prescribers of its products. These programs undoubtedly achieved Mallinckrodt's goal of winning business and increasing prescriptions. Mallinckrodt praised one sales representative for being able to "tie 18 scripts and 2 new writers" to an Exalgo speaker program she held. In another instance, a sales representative described a "success story" in which a speaker series that Mallinckrodt developed convinced a prescriber that he "had under dosed the patient" and that he should "bump[] up his dose[,]" noting that "[w]ithout the program, we probably would have lost this patient . . . and the physician might have lost confidence in the drug." Similarly, another Exalgo representative shared a story about meeting with two doctors who felt guilty for even prescribing opioids due to concerns about "pill mills[,]" but whom a Key Opinion Leader assured that Exalgo had "minimal abuse potential."

9. Even in the Face of the Ongoing Opioid Epidemic, Covidien and Mallinckrodt Lobbied Against State and Federal Restrictions on Opioids and Opposed Oversight from Legislators

184. As state and federal governments sought to crack down on easy access to opioids to stem the rapidly escalating opioid crisis, Mallinckrodt sought to avoid increased regulations on its opioid business.

185. Mallinckrodt and its parent company, Covidien, opposed new legislation in various states that would have encouraged the use of abuse-resistant drugs, which are drugs manufactured with measures intended to reduce the likelihood of abuse. For instance, Mallinckrodt took an active role in opposing the rescheduling of hydrocodone at the federal level.

10. Mallinckrodt Used and Provided Funding to Front Groups to Encourage Doctors to Prescribe Opioids for All Kinds of Chronic Pain

186. In addition to sales and marketing efforts for Mallinckrodt's products, Mallinckrodt, together with Covidien, sought to "change the culture" around opioid-prescribing more generally to position opioids as a safe, effective solution for all types of everyday chronic pain. The prospect of an increase in API sales to other opioid manufacturers incentivized Mallinckrodt to increase the overall opioid market even if competitors would capture some of the increase. Mallinckrodt accomplished this by funding "front groups" that developed educational materials and treatment guidelines encouraging doctors to prescribe, and patients to use, opioids long-term to treat chronic pain for a wide variety of conditions. These front groups presented themselves as neutral and credible professional societies and patient advocacy groups. However, their true purpose was to encourage the widespread over-prescription of opioids and to convince lawmakers to loosen or forego restrictions on opioid prescribing, manufacturing, and distribution.

187. For example, in 2010, Mallinckrodt's parent, Covidien, founded and funded the C.A.R.E.S. Alliance,[25] an advocacy organization whose stated goal was to "promote safe prescribing, dispensing, use, storage, and disposal" of opioid medication. In fact, as emails among Mallinckrodt employees made clear, the true purpose of the C.A.R.E.S. Alliance, which was one of Mallinckrodt's and Covidien's earliest efforts at advocacy, was to promote messaging that

[25] C.A.R.E.S. stood for Collaborating and Acting Responsibly to Ensure Safety.

served Mallinckrodt's commercial interests, and serve as a "vehicle in which to position Mallinckrodt as a leader in the pain space[.]" The C.A.R.E.S. Alliance distributed free books and fact sheets for healthcare providers that contained misleading information regarding opioid use and addiction. Mallinckrodt sales managers provided sales representatives with information on the C.A.R.E.S. Alliance to use as a resource with healthcare providers, to help assuage physician discomfort with opioids and increase their total prescriptions. In monthly pharmaceutical reports, Covidien carefully monitored the actions that the C.A.R.E.S. Alliance was taking in furtherance of these goals.

188. In 2012, the C.A.R.E.S. Alliance published and promoted the book *Defeat Chronic Pain Now!* which was aimed at chronic pain patients. The book was available for sale and promoted online at the now defunct www.defeatchronicpainnow.com. The book included numerous false claims and representations, including:

(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."[26]

(b) "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."[27]

[26] Defeat Chronic Pain Now! at 177, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804-DAP (N.D. Ohio Aug. 13, 2019), D.I. 2251-25.

[27] *Id.* at 172.

(c) "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."[28]

(d) "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medication, including medications not used for pain, and is easily remedied."[29]

(e) "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."[30]

(f) "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."[31]

(g) "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."[32]

(h) "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."[33]

189. These books and fact sheets that the advocacy organization that Mallinckrodt's parent founded published brushed aside the difficult and painful effects that many patients

[28] *Id.* at 174

[29] *Id.* at 175

[30] *Id.* at 176

[31] *Id.* at 177

[32] Defeat Chronic Pain Now! at 26, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804-DAP (N.D. Ohio Aug. 13, 2019), D.I. 2251-25.

[33] *Id.*

experience when opioid dosages are lowered and downplayed the relevance and risk of opioid addiction, instead promoting concepts like "pseudoaddiction."

190. Another front group that Mallinckrodt's parent and other opioid manufacturers sponsored was the Alliance for Patient Access ("**APA**"). In 2013, the APA published a paper titled *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse* that criticized prescription-monitoring systems as overly burdensome. The APA's paper also claimed that policies enacted to police increasingly prevalent pill mills cause "[l]egitimate pain management centers [to] close." Later, in 2015, the APA lobbied Congress to limit the DEA's ability to enforce the "suspicious orders" provision in the Controlled Substances Act. The APA's board members received substantial payments from pharmaceutical companies, including Mallinckrodt.

191. Another front group connected to Mallinckrodt, the U.S. Pain Foundation ("**USPF**"), made misleading claims regarding risks associated with opioid use, including through false statements published on the group's website. One article the USPF published criticized as "problematic" opioid guidelines that the Department of Veteran Affairs and the Department of Defense released that, among other things, warned prescribers to exercise caution when prescribing opioids with higher MMEs.[34] Materials that the USPF published also stated that untreated chronic pain creates a risk of suicide and therefore prescribers should not be overly cautious in prescribing opioids to patients experiencing suicidal ideations.[35]

192. Mallinckrodt used these front groups to make available and disseminate promotional materials at medical conferences, forums, and meetings.

[34] *VA Restricts Opioids for Veterans and Military Service Members*, U.S. Pain Foundation, https://uspainfoundation.org/news/va-restricts-opioids-veteran/ (Feb. 27, 2017).

[35] *Id.*

B. Mallinckrodt's Failure to Properly Identify and Monitor Suspicious Orders

193. In addition to its deceptive marketing practices, Mallinckrodt failed to meet its legal obligations to design and implement an effective system to detect, report, and prevent suspicious opioid orders, *i.e.*, those most likely to lead to diversion of the products to the black market for recreational use and abuse. As explained below, Mallinckrodt had legal obligations to detect, monitor, refuse to fill, and report orders with telltale signs of diversion. It also had access to the detailed, prescriber-level data necessary to fulfill those obligations. Yet it consistently prioritized profits and high sales over compliance with its legal obligations. Mallinckrodt's enabling of the widespread diversion of its products only exacerbated the growing opioid crisis, while exposing Mallinckrodt to significant legal liability.

1. Mallinckrodt Was Aware of Its Legal Obligations to Detect, Prevent, and Report Suspicious Orders

194. Under the Controlled Substances Act and analogous state laws, Mallinckrodt was required to (a) set up a system designed to detect and investigate suspicious orders of opioids, meaning "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency"; (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 the DEA and analogous state agencies.

195. Mallinckrodt was well aware of these obligations. On December 27, 2007, the DEA sent a letter to Mallinckrodt and other companies highlighting that, as a registered manufacturer of controlled substances, it must abide by statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and reiterating the company's obligations to detect, report, and not fill suspicious orders.

196. Mallinckrodt employees discussed and otherwise acknowledged their awareness of these legal obligations. [redacted]

197. [redacted]

198. The DEA also provided Mallinckrodt with compliance training and materials to assist it in meeting its legal obligations. In 2008 emails, Mallinckrodt employees discussed the DEA's expectations that a controlled substance manufacturer must "know [their] customer," *i.e.*, that manufacturers were responsible for scrutinizing their customers' orders to ensure they were

for legitimate purposes. Later that same year, a Mallinckrodt employee's notes from a DEA conference acknowledged that "know your customer is not enough anymore; you must now know your customer's customers as well." A Mallinckrodt report from an April 2011 DEA seminar repeats this mantra: "Again, 'know your customer's customer' was mentioned extensively[.] DEA is working their way back up the supply chain as part of their investigations[.]" Mallinckrodt advertised on its own website that it "address[ed] diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances."[36]

199. Despite all this, Mallinckrodt failed to put in place appropriate procedures to ensure that its employees reported suspicious orders, and they instead continued to fill suspicious orders and supplied more opioids than were justified, leading to widespread diversion and abuse.

2. Mallinckrodt Was Aware That Diversion of Its Opioid Products Was a Major Problem

200. From the early 2000s, Mallinckrodt was aware of the widespread diversion and abuse of opioid products. Mallinckrodt regularly tracked and monitored media reports regarding diversion and abuse of opioids, and circulated these reports among employees. Despite its awareness that its opioid products were being diverted and abused, and that there was a significant risk of government enforcement actions as a result, Mallinckrodt continued to adopt a cavalier attitude toward its suspicious order monitoring obligations.

201. Even a cursory review of the data available to Mallinckrodt should have alerted it that a high portion of its products was being diverted. Mallinckrodt's products accounted for noticeably high percentages of sales of opioids in certain states known for significant rates of

[36] *Mallinckrodt plc Receives FDA Approval for XARTEMIS XR (oxycodone hydrochloride and acetaminophen) Extended-Release Tablets (CII)*, Mallinckrodt, https://www.mallinckrodt.com/about/news-and-media/news-detail/?id=7176 (Mar. 12, 2014).

opioid diversion and abuse. For example, between 2008 and 2012, 500 million of Mallinckrodt's pills ended up in Florida—where 66% of all oxycodone nationwide was sold. In November 2009, reacting to an article regarding the prevalence of pill mills in Florida, a Mallinckrodt accounts director observed that "[o]ur biggest customers like McKesson, Cardinal, Optisource, HD Smith, Masters etc. . . . all ship to Florida." [redacted]

202. Indeed, Mallinckrodt was aware that its products, specifically, were a key contributor to the epidemic of diversion and abuse. [redacted]

203. Moreover, Mallinckrodt was aware that certain customers, which included wholesalers and distributors, purchased disproportionately large amounts of its most commonly abused opioids—such as its 30mg oxycodone dose—and sent a large percentage of those drugs to Florida. [redacted]

204. Communications among Mallinckrodt's sales and marketing personnel highlight their awareness that Mallinckrodt's opioids carried a high risk of abuse and addiction, and were, in fact, being widely abused. Indeed, this was such common knowledge among Mallinckrodt employees that they sometimes made morbid jokes about the devastation their drugs were causing. In one especially telling email from as early as January 2009, a Mallinckrodt vice president of purchasing wrote to a national account manager, joking "it's like people are addicted to these things or something. Oh wait, people are." The account manager responded, "just like Doritos, keep eating, we'll make more." In other emails, sales personnel made comments like, "Have we thought about a snortable form? Could appeal to substance abusers" and quipped about using "a hammer, coffee grinder, blender, stand mixer, agent other than water to dissolve it . . . Or a blow torch." In another display of disdain for the victims harmed by their products, a senior manager of controlled substance compliance forwarded a director of security an article about a woman who was found dead in a car that was "travelling from Florida pill mills," making a joke about the similarity to the movie "[W]eekend at Bernie's"; that director responded, "It just gets better and better. They must have known her pretty well or they would have dumped her along the way[.]" Most tellingly, they acknowledged that the drug that caused the woman's death was "probably [Mallinckrodt's] Oxy[,]" demonstrating awareness that, by that point, Mallinckrodt's opioids had become a major fuel of the opioid crisis—and a major liability for Mallinckrodt.

205. In another email, Mallinckrodt employees discussed an online chatroom in which abusers discussed obtaining and abusing Exalgo, leading one employee to remark, "This is an indication of what is going on out there[.]" In November 2011, a Mallinckrodt compliance coordinator shared an online blog with several other compliance employees, noting that the blog "states that the 'mallies' [Mallinckrodt's opioids] are better than [other opioids] to blow."

206. One of Mallinckrodt's drugs that became particularly popular for diversion and abuse was its 30mg oxycodone tablet. Demand for the 30mg tablet skyrocketed after Purdue introduced a new formulation of its own opioid, OxyContin, in 2010, purportedly to make it more difficult to abuse. This led addicts and abusers to seek out other, easier-to-abuse opioids—and Mallinckrodt's 30mg pill was one of their prime targets. This issue was widely known and discussed within Mallinckrodt. For instance, in 2011, a Mallinckrodt employee circulated an article describing this issue, and commented, "I think it supports our suspicions in regard to the increased usage of the Oxy 30mg." These "suspicions" were that abusers and addicts who could no longer access easy-to-abuse OxyContin were driving an increasing demand for Mallinckrodt's generic oxycodone products. Mallinckrodt further confirmed these "suspicions" that same year, when the Department of Justice ("**DOJ**") informed Mallinckrodt that 30mg oxycodone tablets had replaced the old formulation of OxyContin 80mg tablets as the main illicit drugs on the streets in New England and had "gained wide acceptance by New England Rx opiate abusers who refer to them as 'perc 30s'"; this led one controlled substance compliance manager to tastelessly joke that he would soon be out of a job. In April 2012, one suspicious order monitoring report from AmerisourceBergen in Mallinckrodt's possession showed that 81% of sales to one of its pharmacies were 30mg tablets. Similarly, in January 2013, a Mallinckrodt compliance coordinator received a call from a law enforcement agent stating that "there has been an explosion in Oxy 30's on their streets and everything has gone from the OC30's [Purdue's 30mg OxyContin] to the M30's [Mallinckrodt's 30mg oxycodone]."

207. The high demand for Mallinckrodt's various opioids on the black market was public knowledge. At one point, Mallinckrodt-manufactured drugs were so popular on the street that a pharmacist at a trade show suggested Mallinckrodt remove the "M" from the tablets to make them

less recognizable. In Florida, a hotbed of opioid diversion, so much of Mallinckrodt's 30mg generic oxycodone pill—which is blue—was being diverted that the Interstate 75 corridor from Florida to Ohio was colloquially referred to as the "Blue Highway."

208. Not only did Mallinckrodt have the data necessary to understand that its products were being diverted, it actually gathered, reviewed, and analyzed this data. [redacted]

209. Mallinckrodt had additional data that allowed it to detect and report suspicious opioid orders, though it failed to do so consistent with its obligations. [redacted]

[redacted]

Mallinckrodt also maintained national, regional, state, and local prescriber- and patient-level data that allowed the company to track patterns over time.

3. Mallinckrodt Failed to Meet Its Obligation to Establish an Adequate System for Detecting and Investigating Suspicious Orders

210. Despite the available data, Mallinckrodt's suspicious order monitoring system was ineffective, and Mallinckrodt's managers knew that it was such. As early as 2008, Karen Harper, senior manager of the controlled substances compliance group at Mallinckrodt, alerted her superiors that the business was not capable of detecting suspicious orders and that its suspicious order monitoring system required updating.[37] In a later deposition, Karen Harper testified that she did not believe that Mallinckrodt took adequate measures to correct the issues she identified and reported. She stated that one of the reasons behind the need to upgrade the system was letters from the DEA that Mallinckrodt received in 2007 and 2008, which provided guidance for effective implementation of a suspicious order monitoring system.

211. Among other problems, Mallinckrodt's suspicious order monitoring protocols, at various times, (i) relied on a simple numerical formula (based on an order's size relative to the customer's average order) to identify potentially suspicious orders, despite the DEA's clear warnings that reliance on such "rigid formulas" fell short of meeting Mallinckrodt's legal obligations, (ii) unjustifiably exempted Mallinckrodt's largest customers, (iii) required sales personnel to make the initial determination of whether an unusually large order was peculiar enough to warrant further review—an obvious conflict of interest given their conflicting

[37] Sari Horwitz et al., *Newly Unsealed Exhibits in Opioid Case Reveal Inner Workings of the Drug Industry*, Wash. Post (July 23, 2019), https://www.washingtonpost.com/investigations/newly-unsealedexhibits-in-opioid-case-reveal-inner-workings-of-the-drug-industry/2019/07/23/acf3bf64-abe5-11e9-8e77-03b30bc29f64_story.html.

incentives,[38] (iv) failed to track customers whom other pharma companies identified as suspicious, (v) failed to follow suspicious customers if they changed their addresses, (vi) measured "suspicious orders" by product family, rather than by specific product, which masked increases in orders of particular products that were likely to be abused, (vii) failed to inquire about their customers' own suspicious order monitoring systems, which violated their obligation to "know their customers' customers[,]" (viii) changed their algorithm for identifying suspicious orders to allow Mallinckrodt to send orders up to three times as large as a customer's average order out the door without investigation, (ix) required Mallinckrodt employees to make judgment calls that they were not comfortable with, (x) did not conduct reviews to develop a detailed understanding of pharmacy purchases or to identify Mallinckrodt customers whose DEA license had been suspended or revoked, despite its legal obligations to "know [its] customers' customers" and halt shipments to customers whose DEA license had been suspended, and (xi) occasionally shipped opioids to customers even *after* putting shipping restrictions on them, revealing a "clear gap" in the suspicious order monitoring process.

212. The problems with Mallinckrodt's faulty suspicious order monitoring system reflected, and were compounded by, the company's culture. In fact, in a September 30, 2010 email to Karen Harper, Bill Ratliff, Mallinckrodt's director of security, admitted: "[Before 2010] [t]here was an existing program, but it did little to truly monitor suspicious orders," and employees would take shortcuts when DEA regulations were "inconvenient."

213. In a November 2010 memorandum, an outside consultant criticized Mallinckrodt's suspicious order monitoring system—which, up to that point, had been based simply on a

[38] Notably, sales personnel's role in the process remained significant, and only increased, as Mallinckrodt updated its suspicious order monitoring policies throughout 2009 and 2010.

numerical algorithm—as "problematic," including because "should an occasion arise where an order is three times over the historical average for that customer and item or in a situation where the order meets but does not exceed the '3 X' criteria, it would theoretically be filled through normal processing without further question[,]" in which case "Mallinckrodt would be unnecessarily exposing itself to potential liability." The consultant wrote that "numeric formulas do not identify circumstances [aside from unusually high orders] that might be indicative of diversion[,]" and observed that the DEA requires manufacturers to 'know your customer' and "consider the totality of the circumstances when evaluating an order prior to it being filled[.]" The consultant "recommended the immediate revision" of Mallinckrodt's suspicious order monitoring system "to include additional definitive criteria . . . such that a more vigilant determination can be made whether the order is suspicious and/or excessive prior to filling any order[.]" Notably, Mallinckrodt continued to regularly ship to customers who had been flagged for suspicious orders under its system.

214. Also in 2010, a Mallinckrodt employee asked if the suspicious order monitoring system was up and running and wrote, "I know that I should not submit [a suspicious order monitoring report] to DEA because it includes Distributors and such." And a year after that, Mallinckrodt's vice president of retail sales was not even aware of the suspicious order monitoring checklist process, although it had purportedly been in place for two years. Additionally, in 2010, in response to an unusually large order of oxycodone for a distributor that had gone through Mallinckrodt's system, Ginger Collier, senior director of marketing for specialty generics, replied to Karen Harper, "YIKES! I guess this is why you have a team pulled together to improve our process."

215. As a result of having such a faulty suspicious order monitoring system, Mallinckrodt shipped massive quantities of opioids that it knew, or should have known, would be diverted and abused. Just a few examples of the numerous failures of Mallinckrodt's suspicious order monitoring system include:

- In 2009, when a private shipment of opioids was sent to a former employee's aunt; one employee questioned the shipment, "this equates to 50 tablets per day. Is that even possible?"

- Also in 2009, after American Pharmacy Solutions placed a suspicious order, a Mallinckrodt employee emailed that "it makes it difficult to not ship when Nick [the global director of bulk narcotics] told them we would."

- [redacted]

- [redacted]

- In October 2010, a Mallinckrodt senior manager of controlled substance compliance wrote that neither Harvard nor Sunrise (another customer whose license had been suspended by the DEA) triggered Mallinckrodt's algorithms for detecting suspicious orders because Mallinckrodt was "looking at overall purchase trends for each distributor, not reviewing where the distributors were sending [the] product[.]" Even more shockingly, the manager wrote that, "during the last two years, all Peculiar Orders that were on [Mallinckrodt's daily suspicious order monitoring reports] were . . . deemed to be ok and NONE rose to the level of Peculiar." She further wrote that "it was not feasible to forward the Peculiar Order Report to DEA due to lengthiness[.]"

4. Mallinckrodt Was Aware That Legal Liability for Failure to Monitor Suspicious Orders Was a Significant Risk

216. Just as it knew about the widespread diversion of its own drugs and the insufficiencies of its suspicious order monitoring procedures, Mallinckrodt was aware that other opioid manufacturers, distributers, and pharmacies were facing significant liability and penalties as a result of their failure to prevent diversion.

217. As early as the early 2000s, Mallinckrodt knew of enforcement actions against manufacturers and distributors regarding suspicious order monitoring issues, yet it adopted a cavalier attitude towards its own obligations. As one stark illustration of this, in April 2007, in connection with circulating an article about the DEA's halting of AmerisourceBergen shipments to Florida, a Mallinckrodt compliance manager noted that "sometimes we are met with internal pushback and the attitude that we are 'such big players' that DEA would never suspend our license."

218. Nevertheless, investigations into violations continued. In 2008, Mallinckrodt compliance employees circulated information about recent DEA enforcement actions taken against Cardinal and McKesson, including an article that explained how "drug manufacturers are violating the Controlled Substances Act by failing to report to the DEA any suspicious sales . . . drug manufacturers are not only violating the Controlled Substances Act they are also contributing to the growing epidemic of prescription drug abuse." In 2009, Mallinckrodt sales representatives learned of numerous violations, including a $5 million DEA penalty against Rite Aid for opioid misconduct, a $13 million settlement by McKesson for failing to report suspicious sales, and additional multi-million dollar fines levied against Cardinal Health. In 2010, Mallinckrodt sales personnel discussed the fact that the DEA was making visits to distributors, that the visits were seen as "warnings," and that Mallinckrodt could not "afford to be on the wrong side of the DEA."

By 2011, Mallinckrodt also knew that the DEA suspended the licenses of several large customers due to opioid abuse and diversion. In 2012, Mallinckrodt knew of government enforcement actions against CVS and AmerisourceBergen arising from opioid misconduct, as well as of DEA raids on pharmacies.

219. Mallinckrodt understood that these were serious issues that carried serious penalties and fines. In 2011, Mallinckrodt knew that "the sale of controlled substances to dispensers by distributors has come under great debate and concern from the DEA. Many wholesale drug distributors have already had significant fines and had to add to their existing protocols." A Mallinckrodt director of security admitted that "[w]e are very aware of the multi-million dollar fines levied against Cardinal Health and McKesson for not being diligent with regard to sales." In 2011, McKesson asked Mallinckrodt to manufacture a 500-count bottle of oxycodone, but Mallinckrodt noted that "the DEA may not look kindly" on "a lot of pills for a very powerful (and abused) drug." Similarly, in 2012, Mallinckrodt employees discussed how Walgreens was "burning thru their Florida DC inventory" but it may repurchase in smaller quantities for Florida, "just in case the DEA comes in to lock it up."

220. Nonetheless, Mallinckrodt maintained its cavalier attitude toward its compliance obligations, in part because it benefitted financially from the high black market demand for its opioids. As one illustration of this, in July 2010, a Mallinckrodt product manager expressed "concern about the sheer volume [of opioids] going through the state of Florida[,]" observing that "[w]e are doing roughly 45% of our sales on Oxycodone IR in the state of Florida," and warning that "if the state of Florida were to right-size [*i.e.*, correct], *this has huge financial implications*." (emphasis added). The manager was promptly warned to limit email discussion of the topic,

presumably to avoid putting these incriminating facts—that widespread, illegal diversion of its products was generating massive profits for Mallinckrodt—in writing.

5. Mallinckrodt Failed to Meet Its Obligation to Refuse to Fill Suspicious Orders and Report Them to the DEA

221. Even where Mallinckrodt was aware, or had reason to believe, that a particular order was problematic, or a particular customer was engaged in misconduct, Mallinckrodt often shipped these orders anyway—in direct violation of its legal obligations to halt these orders, fully investigate them, and report them to the DEA.

222. [redacted]

223. Tellingly, in October 2012, after Mallinckrodt questioned an order from a customer that was flagged by its suspicious order monitoring algorithm, a national accounts director asked, "Would we be questioning the big 3?," referring to major opioid distributors.

224. The example of Sunrise Wholesalers illustrates Mallinckrodt's attitude towards its suspicious order monitoring obligations. In May 2008, a Mallinckrodt employee noticed that one of Mallinckrodt's customers, Sunrise Wholesalers, was placing unusually large orders, such as an order for 2,520 bottles of oxycodone 30mg tablets. At the time, Mallinckrodt employees

commented that Victor Borelli, the national account manager with the Sunrise relationship, would "tell [Sunrise] anything they want to hear just so he can get the sale." Later that year, Borelli wrote that Sunrise has been "growing in sales each and every month" and has a new sales manager who "is extremely tied into the Florida market and has been the cause of most of the growth[.]" Borelli requested projections for Sunrise to be *increased*, to 3,000 bottles of immediate-release 15mg oxycodone per month and 12,000 bottles of immediate-release 30mg oxycodone per month.

225. In early July 2009, a police officer in Tennessee advised Bill Ratliff, a director of security for Mallinckrodt, that oxycodone made by Mallinckrodt and shipped from Florida was found during the course of an investigation in his jurisdiction. Upon investigation, Ratliff traced this product back to Sunrise, and concluded that Sunrise had not reported any lost product to Mallinckrodt, which could mean that Sunrise was actively involved in the diversion of the oxycodone product. [redacted]

226. [redacted]

[redacted]

227. [redacted]

228. The parade of red flags continued. In an internal 2010 report on one of its customers, distributor Masters Pharmaceutical, Mallinckrodt noted that Tru Value Drugs, one of Masters' pharmacy customers, had signs indicating "cash only sales" to purchase Mallinckrodt's oxycodone. After receiving a letter from Mallinckrodt in November 2010, Masters cut off its sales to Tru Value. Mallinckrodt wrote that "Masters may not be acting upon the information obtained about customers from on-site pharmacy inspection reports or documentation gathered such as a 'Drug Dispensed' listing." [redacted]

[redacted]

229. [redacted]

230. Despite the growing problems caused by the failures of Mallinckrodt's suspicious order monitoring system, Mallinckrodt avoided proactively addressing this issue with its customers during the sales process, preferring to focus on aggressively selling opioids rather than ensuring compliance with legal requirements.

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

Mallinckrodt found that "Mallinckrodt's response was that 'everyone knew what was going on in Florida but they had no duty to report it.'"[39]

232. The DOJ and Mallinckrodt reached a settlement in 2017. At the time of the settlement, the DOJ stated in a press release that Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . 'Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands' . . ."[40]

233. Among the allegations resolved by the settlement, the federal government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances - orders that are unusual in their frequency, size, or other patterns. . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[41]

234. The federal government claimed that Mallinckrodt "sold excessive amounts of the most highly abused forms of oxycodone, 30mg and 15mg tablets, placing them into a stream of commerce that would result in diversion . . . even though Mallinckrodt knew of the pattern of

[39] Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/deamallinckrodt/?utm_term=.256b39de1578.

[40] *See* Press Release, *Mallinckrodt Agrees to Pay Record $35 Million Settlement, Failed to Report Suspicious Orders of Pharmaceutical Drugs and Recordkeeping Violations*, U.S. Dep't of Justice (July 11, 2017), https://www.dea.gov/press-releases/2017/07/11/mallinckrodt-agrees-pay-35-million-settlement.

[41] *Id.*

excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious sales," and "never notified the DEA of suspicious orders in violation of the CSA [Controlled Substances Act]."[42]

235. In connection with the settlement, Mallinckrodt admitted that "[a]s a registrant under the . . . CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[43] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product."[44] Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[45]

236. Ultimately, Mallinckrodt and its industry peers succeeded in persuading doctors, regulators, and patients that opioids are a safe and effective treatment for chronic pain. By the mid-2000s, nearly every source of information on which healthcare professionals relied had been tainted by misinformation sourced from Mallinckrodt and its industry peers. As such, addictive opioids that were once reserved for patients in the most dire need of chronic pain relief—primarily, those with cancer-related pain—became a common treatment for many common types of pain, and prescriptions for opioids skyrocketed. A study of 7.8 million doctor visits found that prescriptions

[42] Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the DEA, and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC, at 1 (July 10, 2017), https://www.justice.gov/usaoedmi/press-release/file/986026/download.

[43] *Id.* at 1

[44] *Id.* at 4.

[45] *Id.*

for pain increased by 73% between 2000 and 2010, 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. More than 280 million opioid prescriptions were issued in 2012 alone. At the same time, Mallinckrodt's failure to detect, stop, and report suspicious orders, despite having both a legal obligation and ample opportunities to do so, caused widespread diversion of its opioid products to illicit drug markets around the country. As explained below, this combination of overprescribing and widespread diversion led to a crisis of abuse, addiction, and death of historic proportions.

V. INVESTIGATIONS AND LITIGATIONS FROM THE OPIOID CRISIS

A. Public Information on the Opioid Crisis and Liabilities

237. Evidence of the abuse and diversion of opioid pharmaceutical products became public at least in the early 2000s, and evidence of the liability related to marketing such opioids followed shortly thereafter. In October 2003, New York Times reporter Barry Meier published *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death*, which was an outgrowth of previous reporting on OxyContin. The book detailed the lethal nature of opioids and how misleading marketing about the addictive properties of OxyContin led to over-prescription and abuse.[46]

238. In August 2004, doctors from the University of Wisconsin-Madison presented a study that showed the trends in the medical use and abuse of frequently prescribed opioid analgesics including oxycodone from 1997-2002.[47] The study showed that oxycodone usage

[46] David F. Musto, *Books of the Times; Boon for Pain Suffers, and Thrill Seekers.*, (Dec. 17, 2023), https://www.nytimes.com/2003/12/17/books/books-of-the-times-boon-for-pain-sufferers-and-thrill-seekers.html.

[47] *See* James Zacny et al., *College on Problems of Drug Dependence Taskforce on Prescription Opioid Non-Medical Use and Abuse: Position Statement*, 69 Drug and Alcohol Dependence 215, 215-232 (2003).

increased by over 400% and abuse increased by over 346% between 1997 and 2002.[48] The College on Problems of Drug Dependence noted that, as of April 1, 2003, "the prevalence of prescription opioid abuse appears to be similar to that of heroin and cocaine."[49]

239. In 2006, Howard Birnbaum and his coauthors published an economic study in the Clinical Journal of Pain estimating $8.6 billion of quantifiable societal harm from prescription opioid dependence for the year 2001.[50] The study found that prescription opioid dependence generated substantial health care costs ($2.6 billion), criminal justice costs ($1.4 billion), and workplace costs ($4.6 billion).[51]

240. In 2007, 26 states and the District of Columbia settled certain investigations into Purdue Pharma's aggressive and deceptive marketing of its opioid pain relievers, most notably OxyContin, for $19.5 million.[52] The investigations found, *inter alia*, that Purdue pushed prescribers to advise patients to take OxyContin every 8 hours instead of the 12-hour doses that the FDA approved.[53] The settlement required Purdue to implement further internal controls and to stop basing bonuses solely on the volume of OxyContin prescribed.[54] Reporting at the time noted that OxyContin "can be highly addictive," and "can produce a heroinlike high if crushed and then swallowed, inhaled or injected."[55]

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[48] *See id.*

[49] *Id.* at 215.

[50] Howard G. Birnbaum et al., *Estimated Costs of Prescription Opioid Analgesic Abuse in the United States in 2001: A Societal Perspective*, 22 Clinical J. Pain 667, 667-676 (2006).

[51] *Id.*

[52] Associated Press, *Painkiller's Maker Settles Complaint*, N.Y. Times (May 9, 2007), https://www.nytimes.com/2007/05/09/business/09purdue.html.

[53] *Id.*

[54] *Id.*

[55] *Id.*

241. Also in 2007, Purdue Frederick Company, an affiliate of Purdue Pharma, pled guilty to one felony count of misbranding OxyContin, with the intent to defraud or mislead.[56] Three corporate officers also pled guilty to a misdemeanor charge of misbranding, solely in their capacity as responsible corporate officers.[57] Among other things, Purdue Fredrick admitted that from 1995 to 2001 it "marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications," despite knowing that these claims were untrue.[58] As part of the plea agreement, Purdue Frederick agreed to pay over $600 million in fines and various other payments to settle related civil claims, one of the largest monetary sanctions imposed in the history of the pharmaceutical industry at that time.[59] The Purdue guilty pleas and settlements were national news and other companies in the opioid industry followed them closely.

242. In 2011, Ryan Hansen and his coauthors published an economic study in the Clinical Journal of Pain that estimated $53.4 billion of quantifiable societal harm from prescription opioid dependence for the year 2006.[60] Among other things, the study estimated that $2.2 billion went to substance abuse treatment, including for hospitals, physician services, and substance treatment facilities.[61] Deaths from opioid poisoning resulted in $12.4 billion in lost productivity, and unemployment and sub-employment that resulted from opioid abuse generated $14.7 billion

[56] Opinion & Order at 1, *United States v. Purdue Frederick Co.*, No. 1:07-CR-00029-JPJ (W.D. Va. July 23, 2007), D.I. 77

[57] *Id.* at 2.

[58] *Id.*

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

[60] Ryan N. Hansen et al., *Economic Costs of Nonmedical Use of Prescription Opioids*, 27 Clinical J. Pain 185, 194-202 (2011).

[61] *Id.* at 197.

in costs.[62] Incarceration accounted for $14.8 billion of the total, while other criminal justice costs accounted for $8.8 billion of the total.[63] This study cited the 2006 Birnbaum study and noted that its increased estimate was largely "attributable to inflation and to the considerable increase in the prevalence of nonmedical use of prescription opioids during the period 2001 to 2006."[64]

243. In 2011, Howard Birnbaum and his coauthors published another economic study that estimated $55.7 billion of quantifiable societal harm from prescription opioid dependence for the year 2007.[65] The study concluded that in 2007 alone, lost workplace productivity accounted for $25.6 billion, health care costs accounted for $25.0 billion, and criminal justice costs accounted for $5.1 billion.[66] Included in lost workplace productivity were the costs of premature death ($11.2 billion) and lost wages or employment ($7.9 billion), among other costs. The study noted that, in 2007, "12.5 million Americans had used prescription pain relievers for nonmedical purposes" and "that the number of patients admitted to substance abuse treatment facilities due to non-heroin opiate/opioid abuse nearly quadrupled from 23,000 to more than 90,000 from 1999 to 2007."[67] However, the study focused only "on costs of patients diagnosed with opioid abuse" and did "not account for undiagnosed opioid abuse."[68] The study concluded that "it is clear that the costs of opioid abuse have increased substantially due to changes in the prevalence of opioid abuse and associated costs."[69] Both of these studies were well known in the opioid industry.

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[62] *Id.*

[63] *Id.* at 198.

[64] *Id.* at 198, 200.

[65] Howard G. Birnbaum et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 Pain Med. 535, 661 (2011).

[66] *Id.*

[67] *Id.* at 657

[68] *Id.* at 658.

[69] *Id.* at 662.

244. Moreover, in November 2011, the CDC declared an "opioid epidemic" and introduced guidelines to reduce the number of opioid prescriptions and the supply of opioids.[70] The CDC noted that "[t]he death toll from overdoses of prescription painkillers has more than tripled in the past decade."[71] The CDC director stated that "[o]verdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined."[72] Mallinckrodt was aware of the CDC's proclamation and circulated it internally.

B. Investigations and Lawsuits Against Mallinckrodt Lead to Bankruptcy

245. [redacted]

246. [redacted]

247. Approximately two weeks after receiving the 2011 subpoena, Mallinckrodt's former parent company, Covidien, announced its plan to spin off Mallinckrodt as a stand-alone company.

248. [redacted]

[70] *Prescription painkillers overdoses at epidemic levels kill more Americans that heroin and cocaine combined*, CDC Online Newsroom - Press Release (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

[71] *Id.*

[72] *Id.*

[redacted]

249. In May 2013, the City of Chicago issued a subpoena to Mallinckrodt for information relating to Mallinckrodt's opioid misconduct.[73]

250. After receiving the foregoing subpoenas, in 2013, Covidien effectuated Mallinckrodt's Spinoff from its enterprise, which specifically ensured that Mallinckrodt plc assumed all past and future liabilities arising from its opioid-related business, including those related to the recently launched investigations. [redacted]

251. By Spring 2014, the first government lawsuit against an opioid manufacturer (Purdue Pharma) had been filed seeking substantial damages related to the opioid crisis, including claims for public nuisance. Similar lawsuits against other manufacturers, as well as distributors, some of whom were customers of Mallinckrodt, piled up.

252. [redacted]

[73] *City of Chicago v. Purdue Pharma L.P. et al.* . 1:2014cv04361 (N.D. Ill. Sept. 3, 2021) Dkt. No. 1130-4.

[redacted]

253. By June 2017, in a storm of opioid litigation, victims of the opioid epidemic had named Mallinckrodt as a defendant in thousands of cases, and by December 2017, so many lawsuits had been filed that a multidistrict opioid litigation had been consolidated in the Northern District of Ohio ("**MDL**"). These lawsuits alleged that Mallinckrodt was liable for opioid-related misconduct that spanned over a decade.

254. In 2017, Mallinckrodt disclosed in its 10-K that it was named in various lawsuits, subpoenas, and Civil Investigative Demands, including:

(a) Multiple state court lawsuits filed in California, Florida, Louisiana, Maryland, New Jersey, Ohio, Pennsylvania, Tennessee, and West Virginia, including a suit by the State of New Mexico and suits by local governmental entities, Medicaid managed care organizations, Native American tribes, and an addiction recovery corporation;

(b) A subpoena from the DOJ, sent on July 26, 2017;

(c) Civil Investigative Demands from the Missouri, Kentucky, and Washington attorneys general;

(d) Subpoenas from the New Hampshire and Alaska attorneys general and the USAO for the Southern District of Florida; and

(e) An investigation by a coalition of State Attorneys General regarding Mallinckrodt's role in contributing to the increased use of opioids in the United States.

255. [redacted]

256. In July 2017, following a multi-year probe by the DEA, Mallinckrodt agreed to pay millions to settle allegations by the DOJ that Mallinckrodt had violated the Controlled Substances Act, and failed to implement a proper suspicious order monitoring system. It was a landmark settlement. In a press release accompanying the settlement, the DOJ stated that Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic." Mallinckrodt, for its part, acknowledged that, prior to 2012, certain aspects of its "system to monitor and detect suspicious orders did not meet the standard outlined in letters from the DEA . . . ."

257. As of the time of its bankruptcy filing in 2020, Mallinckrodt had been sued in more than 3,000 opioid-related cases.[74] This "enterprise-threatening litigation" forced Mallinckrodt into bankruptcy in October 2020. The Debtors described these lawsuits as an "all-consuming tidal wave of litigation concerning the production and sales of [their] opioid products."[75] The facts and

[74] Welch Decl. ¶ 12.

[75] *Id.* ¶ 76.

liability underlying these lawsuits rendered Mallinckrodt insolvent throughout the entire period it engaged in the Share Repurchase Program. While the "tidal wave of litigation" drove Mallinckrodt into bankruptcy in late 2020, the Opioid Claims underlying it arose well before then.

258. These Opioid Claims span a wide range of conduct and causes of action. They include claims by (a) states and territories, municipalities, and tribes that have incurred damages along with the harm that their citizens suffered for bodily injuries that the opioid epidemic caused, and that seek recovery based on, *inter alia*, public nuisance and false or deceptive marketing theories; (b) personal injury victims, who have suffered a variety of debilitating injuries including opioid dependence, addiction, overdose, other bodily injuries, death, and associated lost wages, loss of earning capacity, loss of consortium, and treatment and rehabilitation costs; (c) children suffering from NAS caused by opioid use by pregnant mothers; (d) hospitals that have borne the costs of providing uncompensated and undercompensated treatment to patients with opioid-related conditions and other costs because of bodily injuries resulting from the opioid epidemic; (e) independent emergency room physicians who have incurred operational and other costs because of bodily injuries to their patients resulting from the opioid epidemic; and (f) third-party payors and insurance ratepayers, who incurred higher medical benefits costs and/or insurance costs because of bodily injuries resulting from the opioid epidemic. The specific causes of action asserted against Mallinckrodt in the complaints included, *inter alia*: fraud, fraudulent and negligent misrepresentation, common law public nuisance, statutory public nuisance, absolute public nuisance, negligence, civil conspiracy, violation of various deceptive and unfair trade practice acts, unjust enrichment, violation of the federal RICO provisions, and numerous violations of various other state laws relevant to Mallinckrodt's conduct.

259. The complaints filed sought a wide range of damages and sanctions against Mallinckrodt. The claims for relief included abatement of nuisance, disgorgement of unjust enrichment, civil penalties, interest, actual damages, treble damages, exemplary damages, punitive damages, and equitable and injunctive relief. Because some plaintiffs asserted claims for civil conspiracy, those complaints sought damages both for the harms that Mallinckrodt caused as well as the harms that other opioid manufacturers and distributors caused who also were part of the conspiracy. Collectively, Opioid Claimants alleged trillions of dollars in damages and penalties.

260. Although the plaintiffs and claims varied across lawsuits, two common theories ran through the majority of the complaints.[76] First, plaintiffs alleged that Mallinckrodt engaged in misleading marketing that overstated the benefits of opioid products and understated their risks. Plaintiffs claimed that Mallinckrodt's misleading marketing caused health care providers to prescribe opioids inappropriately, increasing addiction, misuse, and abuse.[77] Second, plaintiffs alleged that Mallinckrodt did not comply with suspicious order monitoring obligations under federal and state law. As a result, Mallinckrodt flooded the market with opioids, increasing diversion of opioid products and thus increasing addiction, misuse, and abuse.[78]

261. Faced with enterprise-crippling liabilities, and having exhausted all other options, the Debtors were forced to seek protection under chapter 11 to contain the opioid lawsuits. Stephen A. Welch, the Debtors' chief transformation officer, admitted as much in response to a question about "what generally caused Mallinckrodt to file for Chapter 11."[79] Welch answered, without qualification, that the "debtors filed . . . to resolve enterprise-threatening litigation in the face of

[76] *Id.* ¶ 77.

[77] *Id.*

[78] *Id.*

[79] Hr'g Tr. 57:18-19, Dec. 6, 2021.

near-term debt maturities."[80] This enterprise-threatening litigation included "nationwide opioid litigation against the Debtors."[81] Randall S. Eisenberg, a restructuring specialist whom the Debtors retained in connection with their bankruptcy, confirmed the same, stating in an expert report that "[t]he primary objective of these Chapter 11 proceedings is to resolve the 3,000-plus litigation cases against the Debtors."[82]

262. Even under conservative estimates, the magnitude of the Debtors' opioid liabilities rendered the Mallinckrodt enterprise insolvent years before its bankruptcy. On information and belief, in relation to Mallinckrodt's reported assets, the Opioid Claims arising against the Debtors, including disputed and contingent claims, rendered the Mallinckrodt enterprise insolvent, on a balance sheet basis, no later than by 2010.

263. The Debtors' admissions in their chapter 11 proceedings underscored Mallinckrodt's insolvency as a result of its opioid liabilities. Welch acknowledged "potentially trillions of dollars of damages" that Opioid Claimants alleged—which no company, let alone Mallinckrodt, could satisfy, even if judgments were a fraction of that amount—and the Debtors' opinion that opioid litigation posed a threat to the viability of Mallinckrodt's business.[83] Welch further admitted that Opioid Claims may have arisen in excess of the Debtors' ability to pay them as far back as 2013, noting there were "questions as to whether Mallinckrodt was even insolvent when it spun off from Covidien due to the opioid litigation."[84]

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[80] *Id.* at 57:20-22

[81] Welch Decl. ¶ 11.

[82] Expert Report of Randall S. Eisenberg ¶ 37, In re Mallinckrodt plc, et al., No. 20-12522 (JTD) (Bankr. D. Del. Aug. 13, 2021).

[83] Hr'g Tr. 61:25-62:2, Dec. 6, 2021.

[84] *Id.* at 62:2-5

264. Mallinckrodt's insolvency during the years 2010-2018 (and beyond) is evident in the Debtors' own estimates of their potential liabilities for Opioid Claims. Welch, who relied on commonly utilized methodologies for valuing litigation claims—primarily, by extrapolating settlement amounts that Mallinckrodt paid in 2019—estimated that the Debtors potentially faced more than $30 billion of liabilities on Opioid Claims.[85] According to Welch, "if even a fraction of plaintiffs . . . [were] successful in winning all the damages they seek," judgments on those claims "could quickly aggregate into the billions or tens of billions of dollars."[86]

265. The Debtors' estimates of historical opioid liabilities exceed, by far, the total value of their assets at any point in time, including during the years 2015-2018. Houlihan Lokey, Inc., an investment banking company that Covidien hired to prepare a solvency analysis of Mallinckrodt in 2013 in connection with the Spinoff, placed a value of approximately $3.1 billion on the Mallinckrodt assets. Mallinckrodt's opioid liabilities were far in excess of this value at the time of the Spinoff and the Share Repurchase Transfers. This point was not lost on the Court, which, after reviewing the expert reports submitted in connection with this Bankruptcy Case, determined that the Debtors were "hopelessly insolvent."[87]

266. Mallinckrodt's total opioid liabilities might greatly exceed even what the Debtors estimated them to be. Using reasonable extrapolation methods from settlements that other opioid manufacturer defendants reached also confirm that Mallinckrodt faced many billions of dollars in liability. For example, during 2019, three opioid manufacturers, Endo International plc, Johnson & Johnson, and Teva Pharmaceutical Industries Limited, reached settlements with the two Ohio bellwether counties in the MDL, the cumulative value of which was approximately $76

[85] *Id.* at 62:21-63:5.

[86] Welch Decl. ¶ 91.

[87] Hr'g Tr. 76:16-17, June 16, 2021.

million. Extrapolating from those settlements indicates that these manufacturers (who collectively had an MME[88] market share that was less than Mallinckrodt's) have a cumulative state and political subdivision opioid liability of approximately $67 billion. In addition, Johnson & Johnson reached a national settlement of $5 billion to resolve all outstanding claims of state and local governments. Applying Johnson & Johnson's settlement per MME ratio to Mallinckrodt's sales metrics results in an estimated 2020 Mallinckrodt opioid liability to state and local governments only, of approximately $72 billion. For both of these examples, the liability estimate is understated because it does not include claims of the federal government, Native American tribes, personal injury victims, NAS victims, hospitals, emergency room physicians, or many other creditor groups.

267. Various economic studies and other data regarding the societal cost of the opioid epidemic collectively indicate that the total cost of the opioid epidemic is at least $3.7 trillion, which would mean that Mallinckrodt's proportionate share of the societal costs was more than $700 billion as of 2020 (based on the company's market share).

268. Thus, no matter how one measures Mallinckrodt's opioid liabilities during 2015-2018, the liabilities dwarf any plausible estimation of Mallinckrodt's enterprise value, which irrefutably demonstrates the substantial degree of Mallinckrodt's insolvency.

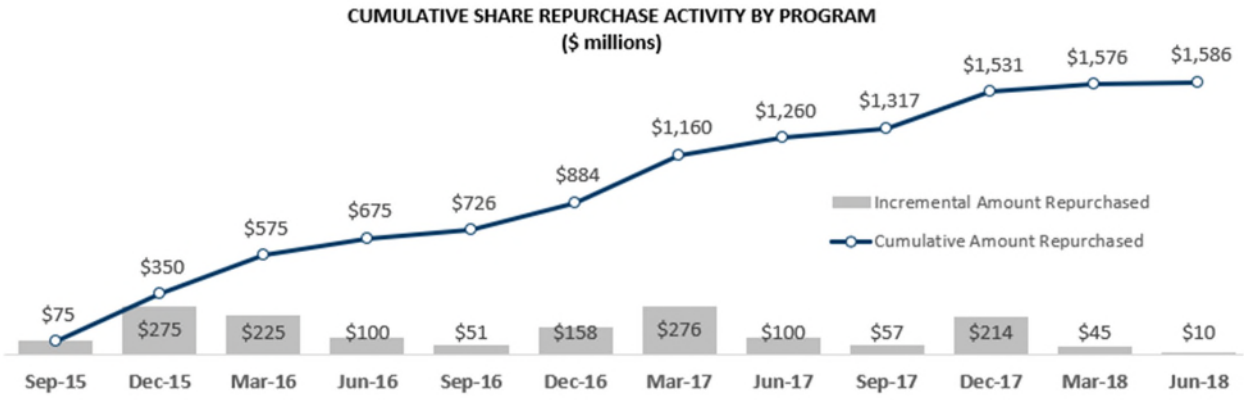
269. Although at the start of 2015 Mallinckrodt was already insolvent from the weight of overwhelming opioid liability, it dove further into insolvency throughout the period of the Share Repurchase Program, under which it paid $1.6 billion in exchange for 35.57 million of its own shares that had no value given its insolvency.

[88] "MME" refers to morphine milligram equivalent, a measure of potency in prescription opioids.

VI. THE SHARE REPURCHASE PROGRAM

270. The Board authorized the Share Repurchase Program on four separate occasions: (1) on January 22, 2015, the Board authorized a $300 million Share Repurchase Program; (2) on November 19, 2015, the Board authorized an additional $500 million in share repurchases; (3) on March 16, 2016, the Board authorized an additional $350 million in share repurchases; and (4) on March 1, 2017, the Board authorized an additional $1 billion in share repurchases.

271. Mallinckrodt's first Share Repurchase Transfer occurred on August 4, 2015, and the final Share Repurchase Transfer occurred on April 23, 2018. The details about the date, amount, and shareholder recipient involved in each Share Repurchase Transfer subject to this Amended Complaint is set forth in Exhibits B and C. As the following table shows, altogether Mallinckrodt repurchased approximately 35.57 million shares, for approximately $1.6 billion.



272. Mallinckrodt routinely reported to the Board, and to the audit committee of the Board, regarding the status of repurchases under the Share Repurchase Program.

273. Mallinckrodt authorized the Share Repurchase Program to artificially inflate the market price of its shares during a period of consistent, dramatic decline in Mallinckrodt's enterprise value. This decline was affected by the risks, liabilities, and other problems associated with Mallinckrodt's opioid business. During this period of decline, Mallinckrodt attempted to

manipulate its stock price upwards by announcing to the public that it was buying back shares, and by spending more than a billion dollars on those share repurchases, rather than conserving those funds for the operation of its business and the benefit of those harmed by its opioid-related conduct. The scheme failed. Mallinckrodt's stock continued to plummet. The business continued to erode. The opioid liabilities continued to mount. The Share Repurchase Program fell on "deaf ears" and simply transferred value away for no value in return.

274. Mallinckrodt entered into a series of contracts ("**Purchase Agreements**") with two brokers in connection with the share repurchases. Mallinckrodt contracted with Goldman Sachs & Co. through a series of Purchase Agreements from May 2015 until February or March 2017, and with Morgan Stanley & Co. through a series of Purchase Agreements from March 2017 until May 2018. Mallinckrodt entered into Purchase Agreements with the brokers,[89] under which the brokers agreed to purchase outstanding ordinary shares, at a par value of $0.20 per share, for Mallinckrodt.

275. Under the Purchase Agreements, Mallinckrodt authorized the brokers to repurchase shares in the open market or through privately negotiated transactions, in accordance with certain price, quantity, and timing terms set forth in the Purchase Agreements. The Purchase Agreements further required that any purchases made thereunder comply with the requirements of Rule 10b5-1(c)(1)(i) and, to the extent applicable, Rule 10b-18, of the Securities Exchange Act of 1934. Consistent with the Purchase Agreements, the Board retained no control over the brokers' actual purchasing decisions and merely authorized the brokers to perform contractual services and serve as conduits for the Share Repurchase Transfers. This approach was specifically and carefully

[89] While Mallinckrodt plc and the brokers entered into multiple Purchase Agreements throughout the course of the Share Repurchase Program, each of the Purchase Agreements has materially the same terms.

designed to create distance between the Board and the Share Repurchase Transfers, in an attempt to shield Mallinckrodt from potential liability that might arise from the timing of specific purchases.

276. The Share Repurchase Transfers effectuated through the Share Repurchase Program took place over U.S.-based exchanges.

A. The Board Authorized the Share Repurchase Program Despite Crushing Opioid Liability

277. [redacted]

278. [redacted]

279. Even while it faced these potential liabilities (and others that were certain to materialize as a result of Mallinckrodt's conduct), certain shareholders pressured Mallinckrodt to provide them with the opportunity to sell back their shares in exchange for cash. [redacted]

280. [redacted]

281. [redacted]

282. [redacted]

[redacted]

283. [redacted]

284. [redacted]

285. [redacted]

[redacted]

286. At the same time, Mallinckrodt's business continued to decline sharply largely due to problems with its opioid business, including increased regulatory scrutiny. Yet the Board continued to expand the Share Repurchase Program in an attempt to shovel value to equity and prop up share value temporarily.

287. [redacted]

288. [redacted]

289. [redacted]

[redacted]

290. [redacted]

[redacted]

291. [redacted]

[redacted] In other words, at a time Mallinckrodt was already insolvent, it wanted to increase the amount of debt it could take on to enable more share repurchases.

292. [redacted]

[redacted]

[redacted]

293. [redacted]

294. [redacted]

295. [redacted]

[90] The Board delegated to the audit committee the full power and authority of the Board to approve $1 billion in share repurchases.

[redacted]

296. [redacted]

297. [redacted]

298. [redacted]

299. On October 20, 2016, a Specialty Generics presentation alerted the Board that SpecGx was facing "significant headwinds" in 2017, that strategic pricing initiatives from 2014 and 2015 were eroding quickly, and that sales would further decrease.

300. [redacted]

[redacted]

301. [redacted]

302. [redacted]

303. [redacted]

304. [redacted]

305. [redacted]

[redacted]

306. [redacted]

307. [redacted]

308. [redacted]

309. [redacted]

310. [redacted]

311. [redacted]

312. [redacted]

313. [redacted]

[redacted]

314. [redacted]

315. [redacted]

316. [redacted]

[redacted]

317. Mallinckrodt conducted the Share Repurchase Program in violation of Irish law. [redacted]

318. [redacted]

319. [redacted]

320. [redacted]

Period (CY)	Shares (000s)	Purchase Price	Cost ($millions)
2015-Q3	824	$91.11	$75
2015-Q4	3,903	$70.39	$275
2016-Q1	3,424	$65.77	$225
2016-Q2	1,703	$58.88	$100
2016-Q3	680	$74.21	$50
2016-Q4 (stub)	2,565	$61.79	$158
2017-Q1	5,587	$49.31	$276
2017-Q2	2,374	$42.39	$101
2017-Q3	1,517	$37.36	$57
2017-Q4	9,605	$22.78	$219
Total	**32,182**	**$47.72**	**$1,536**

321. [redacted]

322. [redacted]

323. [redacted]

324. Mallinckrodt's final Share Repurchase Transfer occurred on April 23, 2018, after Mallinckrodt had spent close to $1.6 billion on share repurchases over the tenure of the program.

325. [redacted]

326. [redacted]

B. Mallinckrodt Engaged in the Share Repurchase Program Despite Having Insufficient Cash

327. Because Mallinckrodt did not have sufficient cash on hand to fund its ever more aggressive Share Repurchase Program, Mallinckrodt had to draw on intercompany loans to do so.

328. [redacted]

329. [redacted]

330. [redacted]

331. [redacted]

332. [redacted]

[redacted]

333. [redacted]

334. [redacted]

335. [redacted]

336. [redacted]

[redacted]

337. [redacted]

338. [redacted]

339. [redacted]

340. [redacted]

341. [redacted]

342. [redacted]

VII. AUTHORITY TO PROSECUTE CAUSES OF ACTION FOR THE BENEFIT OF THE MALLINCKRODT ESTATES AND CREDITORS

343. The Trust has standing and authority to prosecute and enforce all claims and causes of action arising from the matters set forth in this Amended Complaint that (a)(i) belonged to the Debtors' bankruptcy estates under 11 U.S.C. § 541, or (ii) are exercisable by a bankruptcy trustee in accordance with 11 U.S.C. §§ 544(b) and 550 or other provisions of the Bankruptcy Code; and (b) were transferred to the Trust under the Plan as "Share Repurchase Claims."

344. Under § 544(b)(1) of the Bankruptcy Code, the Trust "may avoid any transfer of an interest of the debtor in property or any obligation incurred by the debtor that is voidable under applicable law by a creditor holding an unsecured claim that is allowable under section 502 of [the Bankruptcy Code]." There exist one or more unsecured creditors, including Opioid Claimants, who, on the Petition Date, held allowable unsecured claims and timely rights to avoid and recover

the Share Repurchase Transfers under applicable nonbankruptcy law, including, without limitation, the Uniform Voidable Transactions Act, as in force in several states, and the Uniform Fraudulent Transfer Act ("**UFTA**"), as in force in numerous states including Delaware, Missouri, and New Jersey (together, "**Fraudulent Transfer Claims**").

345. Mallinckrodt's unsecured creditors iinclude children who were born within one year prior to the Petition Date with NAS as a result of being exposed to opioids during their mother's pregnancy and individuals injured by direct exposure to opioids within one year prior to the Petition Date. Until these children were born and diagnosed with NAS, or until those individuals became injured as a result of direct opioid exposure, they and their family members did not know, and could not have reasonably discovered, that their recourse against Mallinckrodt had been impaired by the Share Repurchase Transfers. In accordance with the Confirmation Order and the Plan, the Trust wields all avoidance rights derived from these NAS children and opioid personal-injury victims under § 544(b)(1) of the Bankruptcy Code. Such rights include the right to avoid the Share Repurchase Transfers under section 4(a)(1) of the UFTA within one year after the same "was or could reasonably have been discovered" by these recent creditors. *See* UFTA § 9(a).

346. The Debtors' unsecured creditors also include individuals with asbestos-related claims against the Debtors. Claims have been filed against one or more of the Debtors for personal injury or wrongful death arising from exposure to asbestos or asbestos-containing products. The Trust believes that at least some of these asbestos claims pertain to individuals who were diagnosed with an asbestos-related disease within one year prior to the Petition Date. Until those diseases manifested themselves and were diagnosed, those individuals did not know, and could not reasonably discover, that they had suffered an asbestos-related injury. By the same token, until

those diseases manifested themselves and were diagnosed, those individuals did not know, and could not reasonably discover, that their recourse against Mallinckrodt for their asbestos-related injuries had been impaired by the Share Repurchase Transfers. In accordance with the Confirmation Order and the Plan, the Trust wields all avoidance rights derived from those recently diagnosed individuals, their heirs, or their estates. Such rights include the right to avoid the Share Repurchase Transfers under section 4(a)(1) of the UFTA within one year after the same "was or could reasonably have been discovered" by these recent creditors. *See* UFTA § 9(a).

347. The Debtors' creditors also include various state and federal taxing authorities, such as the U.S. Internal Revenue Service ("**IRS**"), which filed several claims in the Bankruptcy Case. In accordance with the Confirmation Order and the Plan, the Trust wields all avoidance rights derived from the IRS as of the Petition Date, including, without limitation, the right to seek avoidance of the Share Repurchase Transfers by way of the Fraudulent Transfer Claims, under the doctrine *nullum tempus occurrit regi* with respect to otherwise applicable statutes of limitations or statutes of repose.

348. Moreover, on April 6, 2021, the New Jersey Division of Medical Assistance and Health Services (**"NJ Division of Health Services"**) filed a proof of claim against Mallinckrodt plc, asserting a nonpriority unsecured claim of $47,851,026.49 arising from the alleged underpayment of certain Medicaid rebates during the period of January 2013 through June 2020 (Claim No. 48640). Accordingly, on the Petition Date, the NJ Division of Health Services was a creditor holding an allowable unsecured claim against Mallinckrodt plc and a timely right to avoid the Share Repurchase Transfers. In accordance with the Confirmation Order and the Plan, the Trust wields all avoidance rights derived from the NJ Division of Health Services as of the Petition

Date, including the right to pursue avoidance rights and collection remedies by way of the Fraudulent Transfer Claims.

349. In addition to the IRS and the NJ Division of Health Services, on information and belief, one or more other governmental units, including certain political subdivisions in New Jersey, held allowable unsecured claims against one or more of the Debtors as of the Petition Date, together with timely rights to avoid the Share Repurchase Transfers by way of the Fraudulent Transfer Claims. These governmental units include those holding Opioid Claims. In accordance with the Confirmation Order, the Plan, and 11 U.S.C. § 544(b)(1), the Trust wields all rights derived from these governmental units.

350. Pursuant to the Plan, any net proceeds recovered on account of the Share Repurchase Claims are to be shared between the Opioid Claimants and the Debtors' other unsecured creditors, with 50% distributed to the Trust for the Opioid Claimants and 50% distributed to the General Unsecured Claims Trust (as defined in the Plan). Proceeds distributed to Opioid Claimants under the Plan must be used solely for programs to abate the opioid crisis, to compensate individual personal injury victims directly, and to cover related fees and administrative costs.

CLAIMS FOR RELIEF

COUNT I
Avoidance of the Share Repurchase Transfers Based on Intent to Hinder, Delay, or Defraud Creditors – UFTA or Other Applicable State Law

351. The Trust repeats and realleges the preceding allegations as if more fully set forth herein.

352. In connection with the Share Repurchase Transfers, Mallinckrodt plc transferred close to $1.6 billion to shareholders between August 2015 and April 2018.

353. Specifically, Mallinckrodt plc made Share Repurchase Transfers to the Defendants, in the total amounts set forth in this Amended Complaint and in more detail in the attached Exhibit B. Each of the Defendants sold Mallinckrodt shares to Mallinckrodt in the amounts set forth herein and in Exhibit B. Each of the Defendants owned the relevant shares that were sold to Mallinckrodt. Each of the Defendants received proceeds from Mallinckrodt in the amounts set forth herein and in Exhibit B.

354. Through the Share Repurchase Transfers, Mallinckrodt plc transferred property in which it held interests with actual intent to hinder, delay, or defraud present and future Opioid Claimants or other entities to which Mallinckrodt plc was or became indebted, on or after the date that such transfers were made.

355. The intent to hinder, delay, or defraud the Debtors' creditors, including present and future Opioid Claimants, is apparent from, *inter alia*, the direct and natural consequence of the Share Repurchase Transfers prejudicing the rights of Opioid Claimants by depriving the Debtors and their bankruptcy estates of the value of the nearly $1.6 billion that was transferred to the Defendants.

356. Such intent is also apparent from abundant "badges of fraud," including the following:

(a) Multiple insiders sold Mallinckrodt stock throughout the share repurchase period. The Share Repurchase Transfers were intended to buoy the price of Mallinckrodt stock in the marketplace. As such, the Share Repurchase Transfers were for the benefit of insiders who held and sold Mallinckrodt stock.

(b) The consideration received in exchange for the transfers was woefully inadequate. In exchange for the Share Repurchase Transfers, Mallinckrodt plc received only shares of stock in a deeply insolvent company, which had no value.

(c) The transfers were made at a time when the Board and Mallinckrodt were aware of spiraling opioid litigation against opioid manufacturers and Mallinckrodt's largest distributor customers. The Board and Mallinckrodt were also aware of Mallinckrodt's conduct that caused it to accrue crushing opioid-related liability throughout the entire period of 2015-2018 when the Share Repurchase Transfers were approved and were ultimately implemented. As discussed in detail in this Amended Complaint, by January 22, 2015, when the Board approved the first round of share repurchases, Mallinckrodt was already aware that it was under investigation for opioid-related conduct and aware that litigations and enforcement actions had been commenced against other opioid manufacturers. By June 2017, Mallinckrodt had been added as a named defendant in the storm of opioid litigation, but Mallinckrodt nevertheless continued to transfer more than $340 million in Share Repurchase Transfers even after having been directly named in the opioid litigation.

(d) The Debtors were insolvent at the time of each of the Share Repurchase Transfers, including due to their liabilities for present and future Opioid Claims that exceeded their ability to pay.

357. The Share Repurchase Transfers should be avoided in their entirety and recovered for the benefit of the Debtors' estates.

358. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), the UFTA, and/or other applicable state law, the Trust is entitled to (a) avoid the transfers of assets or property made in connection with the Share Repurchase Transfers; and (b) recover the value of assets or property

transferred to the Defendants in connection with, or as a result of, the Share Repurchase Transfers, with interest.

COUNT II
Avoidance of the Share Repurchase Transfers Based on Intent to Hinder, Delay, or Defraud Creditors – 28 U.S.C. § 3304(b)(1)(A) or Other Applicable Law

359. The Trust repeats and re-alleges the preceding allegations as if more fully set forth herein.

360. In connection with the Share Repurchase Transfers, Mallinckrodt plc transferred close to $1.6 billion to shareholders between August 2015 and April 2018.

361. Specifically, Mallinckrodt plc made Share Repurchase Transfers to the Defendants, in the total amounts set forth in this Amended Complaint and in more detail in the attached Exhibit B. Each of the Defendants sold Mallinckrodt shares to Mallinckrodt in the amounts set forth herein and in Exhibit B. Each of the Defendants owned the relevant shares that were sold to Mallinckrodt. Each of the Defendants received proceeds from Mallinckrodt in the amounts set forth herein and in Exhibit B.

362. Through the Share Repurchase Transfers, Mallinckrodt plc transferred property in which it held interests with actual intent to hinder, delay, or defraud present and future Opioid Claimants or other entities to which Mallinckrodt plc was or became indebted, on or after the date that such transfers were made.

363. The intent to hinder, delay, or defraud the Debtors' creditors, including present and future Opioid Claimants, is apparent from, *inter alia*, the direct and natural consequence of the Share Repurchase Transfers prejudicing the rights of Opioid Claimants by depriving the Debtors and their bankruptcy estates of the value of the nearly $1.6 billion that was transferred to the Defendants.

364. Such intent is also apparent from abundant "badges of fraud," including the following:

(a) Multiple insiders sold Mallinckrodt stock throughout the share repurchase period. The Share Repurchase Transfers were intended to buoy the price of Mallinckrodt stock in the marketplace. As such, the Share Repurchase Transfers were for the benefit of insiders who held and sold Mallinckrodt stock.

(b) The consideration received in exchange for the transfers was woefully inadequate. In exchange for the Share Repurchase Transfers, Mallinckrodt plc received only shares of stock in a deeply insolvent company, which had no value.

(c) The transfers were made at a time when the Board and Mallinckrodt were aware of spiraling opioid litigation against opioid manufacturers and Mallinckrodt's largest distributor customers. The Board and Mallinckrodt were also aware of Mallinckrodt's conduct that caused it to accrue crushing opioid-related liability throughout the entire period of 2015-2018 when the Share Repurchase Transfers were approved and were ultimately implemented. As discussed in detail in this Amended Complaint, by January 22, 2015, when the Board approved the first round of share repurchases, Mallinckrodt was already aware that it was under investigation for opioid-related conduct and aware that litigations and enforcement actions had been commenced against other opioid manufacturers. By June 2017, Mallinckrodt had been added as a named defendant in the storm of opioid litigation, but Mallinckrodt nevertheless continued to transfer more than $340 million in Share Repurchase Transfers even after having been directly named in the opioid litigation.

(d) The Debtors were insolvent at the time of each of the Share Repurchase Transfers, including due to their liabilities for present and future Opioid Claims that exceeded their ability to pay.

365. The Share Repurchase Transfers should be avoided in their entirety and recovered for the benefit of the Debtors' estates.

366. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), 28 U.S.C. § 3304(b)(1)(A), and/or other applicable law, the Trust is entitled to (a) avoid the transfers of assets or property made in connection with the Share Repurchase Transfers; and (b) recover the value of assets or property transferred to the Defendants in connection with, or as a result of, the Share Repurchase Transfers, with interest.

COUNT III
Avoidance of the Share Repurchase Transfers as Constructive Fraudulent Transfers – UFTA or Other Applicable State Law

367. The Trust repeats and re-alleges the preceding allegations as if more fully set forth herein.

368. In connection with the Share Repurchase Transfers, Mallinckrodt plc transferred close to $1.6 billion to shareholders between August 2015 and April 2018.

369. Specifically, Mallinckrodt plc made Share Repurchase Transfers to the Defendants, in the total amounts set forth in this Amended Complaint and in more detail in the attached Exhibit B. Each of the Defendants sold Mallinckrodt shares to Mallinckrodt in the amounts set forth herein and in Exhibit B. Each of the Defendants owned the relevant shares that were sold to Mallinckrodt. Each of the Defendants received proceeds from Mallinckrodt in the amounts set forth herein and in Exhibit B.

370. For each of the Share Repurchase Transfers, Mallinckrodt received only its own worthless stock. Mallinckrodt did not receive, and the Defendants did not give, reasonably equivalent value in connection with the Share Repurchase Transfers. Rather, the Share Repurchase Transfers were made for no value to Mallinckrodt at all.

371. At the time of each Share Repurchase Transfer, Mallinckrodt was insolvent, including due to its massive opioid liabilities.

372. At the time of each Share Repurchase Transfer, Mallinckrodt was engaged or was about to engage in a business or a transaction for which the remaining assets of the Debtors were unreasonably small in relation to the business or transaction.

373. At the time of each Share Repurchase Transfer, Mallinckrodt intended to incur, or believed or reasonably should have believed that it would incur, debts beyond its ability to pay as they became due.

374. The Share Repurchase Transfers should be avoided in their entirety and recovered for the benefit of the Debtors' estates.

375. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), the UFTA, and/or other applicable state law, the Trust is entitled to (a) avoid the transfers of assets or property made in connection with the Share Repurchase Transfers; and (b) recover the value of assets or property transferred to the Defendants in connection with, or as a result of, the Share Repurchase Transfers, with interest.

COUNT IV
Avoidance of the Share Repurchase Transfers as Constructive Fraudulent Transfers – 28 U.S.C. § 3304(a)(1) and (b)(1)(B) or Other Applicable Law

376. The Trust repeats and re-alleges the preceding allegations as if more fully set forth herein.

377. In connection with the Share Repurchase Transfers, Mallinckrodt plc transferred close to $1.6 billion to shareholders between August 2015 and April 2018.

378. Specifically, Mallinckrodt plc made Share Repurchase Transfers to the Defendants, in the total amounts set forth in this Amended Complaint and in more detail in the attached Exhibit B. Each of the Defendants sold Mallinckrodt shares to Mallinckrodt in the amounts set forth herein and in Exhibit B. Each of the Defendants owned the relevant shares that were sold to Mallinckrodt. Each of the Defendants received proceeds from Mallinckrodt in the amounts set forth herein and in Exhibit B.

379. For each of the Share Repurchase Transfers, Mallinckrodt received only its own worthless stock. Mallinckrodt did not receive, and the Defendants did not give, reasonably equivalent value in connection with the Share Repurchase Transfers. Rather, the Share Repurchase Transfers were made for no value to Mallinckrodt at all.

380. At the time of each Share Repurchase Transfer, Mallinckrodt was insolvent, including due to its massive opioid liabilities.

381. At the time of each Share Repurchase Transfer, Mallinckrodt was engaged or was about to engage in a business or a transaction for which the remaining assets of the Debtors were unreasonably small in relation to the business or transaction.

382. At the time of each Share Repurchase Transfer, Mallinckrodt intended to incur, or believed or reasonably should have believed that it would incur, debts beyond its ability to pay as they became due.

383. The Share Repurchase Transfers should be avoided in their entirety and recovered for the benefit of the Debtors' estates.

384. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), 28 U.S.C. § 3304(a)(1) and (b)(1)(B), and/or other applicable law, the Trust is entitled to (a) avoid the transfers of assets or property made in connection with the Share Repurchase Transfers; and (b) recover the value of assets or property transferred to the Defendants in connection with, or as a result of, the Share Repurchase Transfers, with interest.

RESERVATION OF RIGHTS

The Trust reserves the right, to the extent permitted under the Bankruptcy Code, the Federal Rules of Civil Procedure, the Federal Rules of Bankruptcy Procedure, the Plan, or by agreement, to assert any claims relating to the subject matter of this action or otherwise relating to the Debtors and their estates against any third party.

PRAYER FOR RELIEF

WHEREFORE, by reason of the foregoing, the Trust respectfully requests that this Court enter judgment against the Defendants as follows:

a. entering a judgment against the Defendants finding that the Share Repurchase Transfers constitute intentionally fraudulent transfers;

b. entering a judgment against the Defendants finding that the Share Repurchase Transfers constitute constructively fraudulent transfers;

c. avoiding each of the Share Repurchase Transfers set forth herein and in Exhibit B as intentionally fraudulent under applicable law;

d. avoiding each of the Share Repurchase Transfers set forth herein and in Exhibit B as constructively fraudulent under applicable law;

e. recovering the value of each of the Share Repurchase Transfers set forth herein and in Exhibit B from the Defendants pursuant to Bankruptcy Code sections 544, 550, and applicable law;

f. awarding the Trust damages in an amount to be determined at trial;

g. imposing a constructive trust on assets of the Defendants in the amount of all proceeds received by such Defendant through the Share Repurchase Transfers;

h. awarding the Trust its attorneys' fees, costs, and other expenses incurred in this action;

i. awarding the Trust pre- and post-judgment interest at the maximum rate permitted by law; and

j. awarding the Trust such other and further relief as the Court deems just and proper.

Dated: October 24, 2023
Wilmington, Delaware

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EXHIBIT A

[Filed Under Seal]

EXHIBIT B

[Filed Under Seal]

EXHIBIT C

[Filed Under Seal]