

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:)	Chapter 11
MALLINCKRODT PLC, <i>et al.</i> ,)	Case No. 20-12522 (JTD)
Reorganized Debtors. ¹)	Jointly Administered
<hr/>		
OPIOID MASTER DISBURSEMENT TRUST II,)	
Plaintiff,)	
v.)	
ARGOS CAPITAL APPRECIATION MASTER FUND LP;)	Adv. Pro. No. 22-50435 (JTD)
BARCLAYS CAPITAL, INC.; BEC CAPITAL LLC;)	
BLACKROCK INSTITUTIONAL TRUST COMPANY,)	
N.A. (UK BRANCH); BLACKROCK INTERNATIONAL)	Re: Adv. Docket No. 2
LIMITED; BLACKSTONE SENFINA ADVISORS LLC;)	
BLUE RIDGE CAPITAL HOLDINGS LLC; BLUE RIDGE)	
CAPITAL LLC; CAPITAL FUND MANAGEMENT SA;)	
CAPITAL GROWTH MANAGEMENT LIMITED)	
PARTNERSHIP; CARLSON CAPITAL LP; CHESTER)	
DRIVE CAPITAL LP; CHIMERA SECURITIES LLC;)	
CITADEL SECURITIES LLC; CLEAR STREET)	
MARKETS LLC a/k/a SUMMIT SECURITIES GROUP)	
LLC; CONSONANCE CAPITAL MANAGEMENT LP;)	
CUTLER GROUP LLC a/k/a CUTLER GROUP LP; D.E.)	
SHAW ASYMPOTE PORTFOLIOS LLC; D.E. SHAW)	
VALENCE PORTFOLIOS LLC; DEUTSCHE BANK AG;)	
EG MARKET TECHNOLOGIES LLC; ELEMENT)	
CAPITAL MANAGEMENT LLC; ENGINEERS GATE)	
MANAGER LP; ERGOTELES LLC; EVERPOINT)	
ASSOCIATES LLC; G1 EXECUTION SERVICES LLC;)	
GF TRADING LLC; GTS SECURITIES LLC;)	
HEALTHCOR MANAGEMENT LP; HEHMEYER LLC;)	
HOPLITE CAPITAL LLC; HRT EXECUTION SERVICES)	
LLC; HRT EXECUTION SERVICES, LLC a/k/a SUN)	
TRADING LLC; HRT FINANCIAL LP; HRT FINANCIAL)	
L P a/k/a HRT FINANCIAL LLC; IMC-CHICAGO LLC)	
d/b/a IMC FINANCIAL MARKETS; JANE STREET)	
CAPITAL LLC; JUMP TRADING LLC; KOREA)	
INVESTMENT CORPORATION; LATOUR TRADING)	
LLC; LION CAVE CAPITAL LLC; LION CAVE)	
MANAGEMENT LLC; MERRILL LYNCH, PIERCE,)	
FENNER & SMITH INCORPORATED; MOORE)	
CAPITAL MANAGEMENT LP; PALOMINO LIMITED;)	
PAULSON & CO., INC.; PFM HEALTH SCIENCES LP)	
a/k/a PARTNER FUND MANAGEMENT LP; POTAMUS)	
HOLDINGS LLC a/k/a POTAMUS TRADING LLC;)	

¹ A complete list of the Debtors in the chapter 11 cases may be obtained on the website of the Debtors' claims and noticing agent at <http://restructuring.primeclerk.com/Mallinckrodt>.

QUANTBOT MANAGEMENT MASTER FUND SPC)
 LTD; QUANTITATIVE INVESTMENT MANAGEMENT)
 LLC; QUANTLAB SECURITIES LP; QUANTLAB)
 TRADING PARTNERS US LP; RESILIENT CAPITAL)
 LLP; RGM SECURITIES LLC; RIEF RMP LLC; RIEF)
 TRADING LLC; ROCK CREEK MB LLC; SIMPLEX)
 TRADING LLC; SPIRE X TRADING LLC;)
 SQUAREPOINT OPS LLC; SUSQUEHANNA)
 SECURITIES LLC; SVB SECURITIES LLC a/k/a)
 LEERINK PARTNERS LLC; T. ROWE PRICE)
 ASSOCIATES, INC., AND JOHN DOE FUNDS; T3)
 TRADING GROUP LLC; TEWKSBURY INVESTMENT)
 FUND LTD; THESYS TECHNOLOGIES LLC; TOWER)
 RESEARCH CAPITAL LLC; TRADEBOT SYSTEMS,)
 INC.; TRILLIUM TRADING LLC; VA MANAGEMENT)
 LP a/k/a VISIUM ASSET MANAGEMENT LP; VIRTU)
 AMERICAS LLC a/k/a KCG AMERICAS LLC; VIRTU)
 AMERICAS, LLC a/k/a VIRTU FINANCIAL BD LLC;)
 WILLIAM BLAIR & COMPANY LLC; XTX MARKETS)
 LLC, and JOHN DOE DEFENDANTS, and)
)
 HRT FINANCIAL LP, PAULSON & CO., INC. and)
 CUTLER GROUP LP on behalf of themselves and a class of)
 similarly situated persons and legal entities,)
 Defendants.)

NOTICE OF FILING OF PROPOSED REDACTED VERSION OF COMPLAINT

PLEASE TAKE NOTICE that, on October 12, 2022, the Opioid Master Disbursement Trust II, established pursuant to the *Modified Fourth Amended Joint Plan of Reorganization (with technical modifications) of Mallinckrodt plc and its Debtor Affiliates under Chapter 11 of the Bankruptcy Code* [Docket No. 7670] in the above-captioned chapter 11 cases, filed the **Complaint** [Adv. Docket No. 2] in the above-captioned adversary proceeding under seal with the Court.

PLEASE TAKE FURTHER NOTICE that pursuant to Del. Bankr. L.R. 9018-1(d)(ii), attached hereto as Exhibit A is the proposed redacted public version of the Complaint.

Dated: October 17, 2022
Wilmington, Delaware

COLE SCHOTZ P.C.

/s/ Justin R. Alberto _____

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Counsel to the Opioid Master Disbursement Trust II

EXHIBIT A

Redacted Public Version of Complaint [Adv. Docket No. 2]

PUBLIC VERSION OF ADV. DOCKET NO. 2

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

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Debtors. ¹)	Jointly Administered
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Plaintiff,)	
v.)	Adv. No. 22-50435 (JTD)
ARGOS CAPITAL APPRECIATION MASTER FUND)	
LP; BARCLAYS CAPITAL, INC.; BEC CAPITAL LLC;)	
BLACKROCK INSTITUTIONAL TRUST COMPANY,)	
N.A. (UK BRANCH); BLACKROCK)	
INTERNATIONAL LIMITED; BLACKSTONE)	
SENFINA ADVISORS LLC; BLUE RIDGE CAPITAL)	
HOLDINGS LLC; BLUE RIDGE CAPITAL LLC;)	
CAPITAL FUND MANAGEMENT SA; CAPITAL)	
GROWTH MANAGEMENT LIMITED PARTNERSHIP;)	
CARLSON CAPITAL LP; CHESTER DRIVE CAPITAL)	
LP; CHIMERA SECURITIES LLC; CITADEL)	
SECURITIES LLC; CLEAR STREET MARKETS LLC)	
a/k/a SUMMIT SECURITIES GROUP LLC;)	
CONSONANCE CAPITAL MANAGEMENT LP;)	
CUTLER GROUP LLC a/k/a CUTLER GROUP LP; D.E.)	
SHAW ASYMPTOTE PORTFOLIOS LLC; D.E. SHAW)	
VALENCE PORTFOLIOS LLC; DEUTSCHE BANK)	
AG; EG MARKET TECHNOLOGIES LLC; ELEMENT)	
CAPITAL MANAGEMENT LLC; ENGINEERS GATE)	
MANAGER LP; ERGOTELES LLC; EVERPOINT)	
ASSOCIATES LLC; G1 EXECUTION SERVICES LLC;)	
GF TRADING LLC; GTS SECURITIES LLC;)	
HEALTHCOR MANAGEMENT LP; HEHMEYER LLC;)	
HOPLITE CAPITAL LLC; HRT EXECUTION)	
SERVICES LLC; HRT EXECUTION SERVICES, LLC)	
a/k/a SUN TRADING LLC; HRT FINANCIAL LP; HRT)	

¹ A complete list of the Debtors in the chapter 11 cases may be obtained on the website of the Debtors' claims and noticing agent at <http://restructuring.primeclerk.com/Mallinckrodt>.

FINANCIAL L P a/k/a HRT FINANCIAL LLC; IMC-)
 CHICAGO LLC d/b/a IMC FINANCIAL MARKETS;)
 JANE STREET CAPITAL LLC; JUMP TRADING LLC;)
 KOREA INVESTMENT CORPORATION; LATOUR)
 TRADING LLC; LION CAVE CAPITAL LLC; LION)
 CAVE MANAGEMENT LLC; MERRILL LYNCH,)
 PIERCE, FENNER & SMITH INCORPORATED;)
 MOORE CAPITAL MANAGEMENT LP; PALOMINO)
 LIMITED; PAULSON & CO., INC.; PFM HEALTH)
 SCIENCES LP a/k/a PARTNER FUND MANAGEMENT)
 LP; POTAMUS HOLDINGS LLC a/k/a POTAMUS)
 TRADING LLC; QUANTBOT MANAGEMENT)
 MASTER FUND SPC LTD; QUANTITATIVE)
 INVESTMENT MANAGEMENT LLC; QUANTLAB)
 SECURITIES LP; QUANTLAB TRADING PARTNERS)
 US LP; RESILIENT CAPITAL LLP; RGM SECURITIES)
 LLC; RIEF RMP LLC; RIEF TRADING LLC; ROCK)
 CREEK MB LLC; SIMPLEX TRADING LLC; SPIRE X)
 TRADING LLC; SQUAREPOINT OPS LLC;)
 SUSQUEHANNA SECURITIES LLC; SVB)
 SECURITIES LLC a/k/a LEERINK PARTNERS LLC; T.)
 ROWE PRICE ASSOCIATES, INC., AND JOHN DOE)
 FUNDS; T3 TRADING GROUP LLC; TEWKSBURY)
 INVESTMENT FUND LTD; THESYS TECHNOLOGIES)
 LLC; TOWER RESEARCH CAPITAL LLC;)
 TRADEBOT SYSTEMS, INC.; TRILLIUM TRADING)
 LLC; VA MANAGEMENT LP a/k/a VISIUM ASSET)
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 HRT FINANCIAL LP, PAULSON & CO., INC. and)
 CUTLER GROUP LP on behalf of themselves and a class)
 of similarly situated persons and legal entities,)
)
)
 Defendants.)

COMPLAINT

Plaintiff the Opioid Master Disbursement Trust II, also known as the Opioid MDT II (the “Trust”), a statutory trust created by the confirmed plan of reorganization (the “Plan”) of the debtors and debtors-in-possession in the above-captioned chapter 11 cases (collectively, the “Debtors” and, together with certain non-debtor affiliates, “Mallinckrodt”), respectfully alleges 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 equity owners 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, receiving nothing of value in return. At that time, Mallinckrodt’s vast accrued liability for its role in creating and 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 made by Mallinckrodt to its shareholders therefore were textbook fraudulent conveyances, and must be returned 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 who have incurred massive costs from the destruction wrought by Mallinckrodt’s opioid products.

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. It engaged in highly aggressive marketing tactics for its branded opioid products and dominated the generic opioids market, [REDACTED]

[REDACTED]

[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 resulted in a dramatic increase in opioid prescriptions and addiction to opioid drugs. Indeed, the Drug Enforcement Administration (“DEA”) called the company “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 more than 3,000 lawsuits being filed against Mallinckrodt around the country seeking massive damages because of bodily injuries alleged to have been caused by Mallinckrodt’s opioid products and, because of Mallinckrodt’s unbranded promotional campaign, the opioid products of other pharmaceutical companies and illicit opioid drugs. 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 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 at issue in this 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 that followed from 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”). Communities have been ravaged. Many who became addicted to their prescribed drugs were later 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. 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.”² 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

² Declaration of Stephen A. Welch, Chief Transformation Officer, in Support of Chapter 11 Petitions and First Day Motions, *In re Mallinckrodt PLC, et. al.*, No. 20-12522-JTD [ECF No. 128] (Bankr. D. Del. Oct. 12, 2020) (“Welch Decl.”) ¶ 76.

governments, who have incurred, and continue to incur, astronomical costs to address and alleviate the social and public health problems caused by Mallinckrodt's conduct. This "tidal wave of litigation" rendered Mallinckrodt "hopelessly insolvent" and ultimately drove Mallinckrodt 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. Altogether, Mallinckrodt repurchased approximately 36 million shares, for close to \$1.6 billion, and received no value in return for those repurchases.

8. The share repurchase transactions 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 state 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 Complaint, the Trust seeks to recover the funds Mallinckrodt unlawfully transferred to equity through the share repurchase transactions, 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 commenced by the Debtors on October 12, 2020 ("Petition Date") under chapter 11 of the Bankruptcy Code, which are jointly administered under the caption *In re Mallinckrodt plc, et al.*, Case No. 20-12522 (JTD) and remain pending in this Court.

11. This Court has jurisdiction over this adversary proceeding under 28 U.S.C. §§ 157 and 1334 and the Standing Order of Reference of the United States District Court for the District of Delaware (the "District of Delaware") referring to the Bankruptcy Judges of the District of Delaware all cases and proceedings arising under title 11 of the United States Code (the "Bankruptcy Code"). This Court also has jurisdiction pursuant to Article X of the Plan.

12. This adversary proceeding constitutes a "core" proceeding as defined in 28 U.S.C. § 157(b)(2)(A). In the event that this or any other appropriate court finds any part of this adversary proceeding to be "non-core," the Trust consents to the entry of final orders and judgments by this Bankruptcy Court, pursuant to Rule 7008 of the Federal Rules of Bankruptcy Procedure and Local Rule 7008-1.

13. Venue in the District of Delaware is proper under 28 U.S.C. §§ 1408 and 1409 because this adversary proceeding arises under and in connection with cases commenced under the Bankruptcy Code.

14. Pursuant to 11 U.S.C. § 544(b) and the Plan, the Trust has standing to avoid any transfer of an interest of the Debtors in property that is voidable under applicable law by a creditor holding an allowable unsecured claim on the Petition Date. Here, as of the Petition Date, the Debtors' creditors include, among others, the United States, numerous federal agencies, and numerous state and local governments, including the State of New Jersey and its agencies. As such, applicable law available to the Trust in this case includes the law available to those creditors, including but not limited to the Federal Debt Collection Procedures Act (28 U.S.C. § 3001, *et seq*), the law governing civil actions commenced by the state of New Jersey (N.J. Rev. Stat. § 2A:14-1.2), and the law available to sovereign creditors. The unsecured creditors also include children who were born within one year prior to the Petition Date with NAS as a result of being exposed to opioids during pregnancy, creditors who were injured by direct exposure to opioids within one year prior to the Petition Date, and creditors with asbestos injuries that manifested within one year prior to the Petition Date, and thus in each case did not know, and could not reasonably discover, that they were creditors of Mallinckrodt or that their recourse against Mallinckrodt had been impaired by the share repurchase transactions. As such, applicable law available to the Trust in this case also includes avoidance claims by creditors who are entitled to avoid the share repurchase transactions within one year after the relevant claims and conduct were or could have been reasonably discovered by these recent creditors.

THE PARTIES

I. Opioid MDT II

15. The Trust is a Delaware statutory trust formed under the Plan and created pursuant to the provisions of the Delaware Statutory Trust Act, Del. Code Ann. tit. 12, §§ 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.

16. The Trust was created pursuant to the Plan for the benefit of the individuals and entities who 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, the “Opioid Claimants”). The Opioid Claimants comprise the individuals, entities, and communities that were harmed by Mallinckrodt’s 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 by opioids, and other claimants with claims arising out of the opioid crisis. They also include state and local governments, Native American Tribes, and other public entities that incurred massive costs due to Mallinckrodt’s products and conduct. 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 and Mallinckrodt’s products and conduct.

17. 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. Nevertheless, given the size of the Opioid Claims, the Opioid Claimants, will receive only a fraction of their value on account of their claims.

18. Pursuant to the Plan, certain claims and causes of action were transferred to the Trust, and the Trust was vested with sole authority to pursue those claims and causes of action. In particular, the Plan vests in the Trust, “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” (the “Share Repurchase Claims”).

19. 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.

20. Following an evidentiary confirmation hearing, the United States Bankruptcy Court for the District of Delaware confirmed the Plan on March 2, 2022, and the Plan went into effect on June 16, 2022.

II. The Debtors

21. 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.

22. 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”). Since that time, Mallinckrodt has undergone a series of corporate transactions, sales, and restructurings. Nevertheless, since 1867, Mallinckrodt has always continued the pharmaceutical 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.

23. Mallinckrodt has manufactured, developed, marketed, promoted and/or sold opioid pharmaceutical products and/or opioid APIs since at least 1995 and through today. At various times, Mallinckrodt’s opioid portfolio included branded opioid products which it actively promoted—including Magnacet, Exalgo, and Xartemis XR, which it manufactured, marketed, and promoted at various times between 2007 and at least 2015—and the branded opioid product, Roxycodone, which it continues to sell today. Mallinckrodt’s generic opioid portfolio includes both APIs and finished dosage products, including generic versions of oxycodone, hydrocodone, and other well-known opioids. 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.

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

[REDACTED]

[REDACTED]

[REDACTED]

25. The share repurchase program began approximately two years after a spinoff transaction from Mallinckrodt's former parent, Covidien plc ("Covidien"), in 2013. Specifically, Mallinckrodt's businesses were owned by Covidien from 2007 until 2013. In June 2013, Covidien completed a separation and spinoff (the "Spinoff") of its pharmaceuticals and imaging business into a newly created Irish public limited company, Mallinckrodt plc. The Spinoff was effected through a series of agreements between Covidien plc and Mallinckrodt plc, including a separation and distribution agreement (the "Separation Agreement") dated June 28, 2013.

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

27. 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. The majority 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 certain production facilities are located throughout the United States.

28. 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—although it continued to operate as a fully integrated enterprise, and to maintain 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.

29. 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.”

30. Since the Spinoff, Mallinckrodt plc has been managed by a board of directors (the “Board”) consisting of nine directors, none of whom are employees of Mallinckrodt plc. The Board received reports concerning, and 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

received reports concerning, and 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. The Board specifically received updates about the marketing of opioid products, such as Xartemis XR, and updates about how Mallinckrodt was "aggressively taking action" 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.

31. Mallinckrodt plc explicitly acknowledged 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 the "Board 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."

32. With respect to its opioid business, the Board wrote that "the Board and its committees . . . [are] actively engaged in monitoring the financial and reputational risks to the Company related to its subsidiaries' opioid business," that the Board "regularly receives detailed, privileged updates on the status of all material litigation . . . including opioid-related litigation,"

and that the Board's 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.

33. 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 has 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.

34. Mallinckrodt plc and its subsidiaries also share common officers and employees, many of whom execute documents on behalf of multiple entities. The Missouri headquarters provide 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 U.S., and the vast majority of its revenues come from the U.S. market.³

35. 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.

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

III. Defendants

37. Hundreds of entities and persons received transfers in connection with the Debtors' share repurchase program (the "Share Repurchase Transfers"). Upon information and belief, the defendants listed on Exhibit A, which is attached hereto and incorporated herein, received at least the Share Repurchase Transfers shown therein (and possibly more as yet-unidentified transfers). The details of the date, amount, and proceeds of these Share Repurchase Transfers are set forth in

³ 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 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.

Exhibit B. The Trust sues the parties listed on Exhibit A as individually named defendants (the “Defendants”).

38. Each of the Defendants listed on Exhibit A sold Mallinckrodt stock, which was traded on U.S.-based exchanges, and received transfers of Mallinckrodt value from those transactions. In addition, 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.

39. In addition, certain other as yet-unidentified parties received Share Repurchase Transfers on the dates set forth on Exhibit C. The Trust sues each shareholder that sold Mallinckrodt shares on the dates set forth on Exhibit C and received Share Repurchase Transfers (the “John Doe Defendants”).

40. As set forth below, the Trust also sues the remaining unnamed recipients of Share Repurchase Transfers as class members.

IV. The Class Representative Defendants

41. Upon information and belief, Defendant HRT Financial LP is a limited partnership organized under the laws of Delaware, with its principal place of business at 175 Greenwich Street, 76th Floor, New York, NY 10007. HRT Financial LP is an investment fund that engages in proprietary trading utilizing automated trading algorithms. [REDACTED]

42. Upon information and belief, Defendant Paulson & Co., Inc. is an investment management firm incorporated in Delaware, with its principal place of business at 1133 Avenue of the Americas, 33rd Floor, New York, NY 10036. [REDACTED]

43. Upon information and belief, Defendant Cutler Group LP is a limited partnership organized under the laws of Delaware, with its principal place of business at 101 Montgomery Street, Suite 700, San Francisco, California 94104. [REDACTED]

44. Defendants HRT Financial LP, Paulson & Co., Inc., and Cutler Group LP are collectively referred to as the “Class Representative Defendants.”

CLASS ALLEGATIONS

45. Pursuant to Rule 23(b)(1) & (b)(3) of the Federal Rules of Civil Procedure, made applicable to this adversary proceeding by Rule 7023 of the Federal Rules of Bankruptcy Procedure, the claims set forth in this Complaint are brought against the Class Representative Defendants individually and as representatives of a defendant class of similarly situated persons and legal entities (the “Share Repurchase Transferee Class”).

46. The Share Repurchase Transferee Class comprises (i) all persons or legal entities that directly or indirectly received payments, including the initial recipients and subsequent transferees, made by the Debtors in connection with the share repurchase program, and (ii) the guardians, trustees, partners, administrators, custodians, fiduciaries, estates, executors, owners, representatives, beneficiaries, members, and managers of such persons or legal entities, to the extent they must be named as defendants in order to pursue the claims set forth in this Complaint against such persons or legal entities. All persons and legal entities (other than the Class Representative Defendants) that are timely and effectively served with a summons and complaint in this action are excluded from the Share Repurchase Transferee Class as of the date of such service.

47. Upon information and belief, the Share Repurchase Transferee Class includes hundreds of recipients and thus joinder of all its members is impracticable.

48. There are questions of law and fact common to the Share Repurchase Transferee Class that predominate over any issues that may involve individual members of the class, including without limitation:

- a. Whether the Debtors were insolvent at the time that they undertook the Share Repurchase Transfers or the Debtors became insolvent as a result of the Share Repurchase Transfers;
- b. Whether the Debtors were engaged in a business or transaction, or were about to engage in a business or a transaction, for which the Debtors were left with unreasonably small capital, at the time that they undertook the Share Repurchase Transfers;
- c. Whether the Debtors intended to incur, or believed or reasonably should have believed that they would incur, debts that would be beyond their ability to pay as such debts became due, at the time that they undertook the Share Repurchase Transfers; and
- d. Whether the Debtors received less than reasonably equivalent value in exchange for the Share Repurchase Transfers.

49. The Class Representative Defendants will fairly and adequately protect the interests of the entire Share Repurchase Transferee Class. Any possible defenses of the Class Representative Defendants are typical of those in the Share Repurchase Transferee Class.

[REDACTED]

[REDACTED]

50. The prosecution of separate actions against the individual members of the Share Repurchase Transferee Class would create a risk of (i) inconsistent or varying adjudications with respect to individual members of the Share Repurchase Transferee Class that would establish incompatible standards of conduct, and/or (ii) adjudications with respect to individual members of the Share Repurchase Transferee Class that, as a practical matter, could be dispositive of the interest of the other members not parties to the individual adjudications or would substantially impair or impede their practical ability to protect their interests.

51. A defendant class is superior to other available methods for fairly and efficiently adjudicating this controversy because, *inter alia*, it avoids a multiplicity of individual adjudications with respect to the many thousands of individual members of the Share Repurchase Transferee Class, thereby conserving the resources of the parties and of the court.

CASE BACKGROUND

I. Mallinckrodt Dominated the Opioid Market Space

52. 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.

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

[REDACTED]

[REDACTED]

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

55. In some locations, Mallinckrodt had an even larger presence. For instance, at times, Mallinckrodt 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.

II. Mallinckrodt's Wrongful Opioid Practices

56. 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.

57. Lured by the promise of increased profits, Mallinckrodt, both directly and indirectly through groups that it 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.

58. Nevertheless, 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 Aggressive, Deceptive Marketing and Promotion of Opioids

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

59. Mallinckrodt employed an army of sales representatives, on whom it placed intense pressure to sell opioids. Compensation plans for Mallinckrodt’s sales representatives reveal that their performance was evaluated, and their compensation was determined, primarily by the number of opioid prescriptions that they sold. As one sales manager wrote in 2014, Mallinckrodt wanted “our sales force to be viewed as aggressive, money-motivated sales people. Money is the reason that we have a job . . . Every script this quarter puts money in the hands of the Sales Specialist, you, and me.”

60. To meet these quotas, Mallinckrodt sales representatives were encouraged to be bold in asking prescribers to increase their number of patients on Mallinckrodt’s drugs. For instance, in 2012, one sales representative commented that, as part of her action steps to get prescribers to get more Exalgo patients, she would explicitly ask “for 5 new Exalgo patients[.]” Another sales representative in 2010 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 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 . . .” [REDACTED]

61. Mallinckrodt put particularly high pressure on its sales force to promote Exalgo. For instance, in 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.” In another 2012 email to sales representatives, a Covidien district sales manager encouraged representatives to take advantage of improved insurance coverage for Exalgo, stating that “WE OBVIOUSLY HAVE AN OPPORTUNITY, AN EXCITING OPPORTUNITY! . . . WITH OUR MANAGED CARE SITUATION, WE CAN REACH NEW SCRIPT HIGHS WITH EXALGO!!!!” [REDACTED]

[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 at no cost to patients.” [REDACTED]

62. 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 “wide 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.

63. Mallinckrodt incentivized its sales representatives to maximize sales of opioids with the promise of large bonuses, lavish vacations and other incentive compensation. Mallinckrodt management applauded and encouraged such efforts to tie sales representatives' pay to their success in selling opioids. [REDACTED]

[REDACTED] In 2014, a district sales manager wrote to his sales representatives: "10 surgeon's prescribing, 3 XXR [Xartemis] per week over a 13 week period pays \$36,000 . . . I could use \$36,000. Could you?" In another email, sales representatives were told 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."

64. Mallinckrodt's single-minded focus was on meeting sales quotas. For instance, in one email, sales representatives were told 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 were

told that their “next milestone” was over 25 prescriptions per week. In another October 2014 email, a sales representative was told 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.”

65. The pressure Mallinckrodt put on sales representatives was intense and constant. 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, in reference to 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 of 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 customers 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.”

66. Mallinckrodt sales representatives used a number of tactics to try to increase prescriptions, ensure those prescriptions would be filled, and meet their high sales quotas. For instance, in 2014, sales representatives were instructed on the importance of making sure pharmacies were stocked with Mallinckrodt’s opioids at all times, and were encouraged 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. 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 Mallinckrodt called “protecting the script.” When faced with difficulties meeting sales quotas, some sales representatives sought alternatives to get prescriptions filled, with one representative expressing in 2014 that she “cant [sic] afford to have another physician stop writing or tell [her] they need to stop until the 1st of the month.”

ii. *Mallinckrodt Sales Representatives Used Meals, Snacks and Gifts to Gain Access to Prescribers*

67. Several studies have indicated that clinicians’ prescribing practices are influenced by the receipt of gifts from industry representatives, including meals. As such, despite regulations and industry guidance seeking to limit the use of meals in pharmaceutical marketing, Mallinckrodt sales representatives were encouraged to use free food and snacks as a means to build relationships with healthcare providers and encourage them to prescribe Mallinckrodt’s products.

68. In 2012, Mallinckrodt sales managers gave their teams monthly budgets to spend on their “targeted providers,” and encouraged them to schedule monthly meals and regular ice cream or pie parties with those providers. A 2013 document reflects that sales representatives kept track of the food preferences of the providers they were targeting, along with notes about who the providers’ most “influential” office staff were and which providers were “easily pushed.” Sales representatives also shared their strategies for using food events to reinforce Mallinckrodt’s marketing messages. For example, in 2012, one sales representative shared that she would plan “themed” meal days for a pain clinic customer, including Mocha Monday, Taco Tuesday, Thirsty Thursday (“discuss whether they are thirsty for more information to be confident in using

Exalgo”), and Float Friday (“root beer floats—I am not going to float away...I will aid in helping the docs/staff all the way in order to assure the patient receives Exalgo”).

69. These tactics proved successful in increasing opioid prescriptions. In one 2011 email, a Covidien sales representative explained that he had begun taking a particular physician out to unplanned lunches as a sales tactic, and noted that “the last two weeks after leaving lunch he took pictures with his phone . . . of both Pennsaid and Exalgo and sent them to my phone with the funny comment ‘Have you heard of these products?’” In a 2014 email, a sales representative explained how, after trying unsuccessfully to sell Exalgo to a particular doctor for four years, she was able to obtain a meeting with him to discuss Xartemis XR after learning the doctor’s Starbucks coffee order for the day. The representative wrote, “About an hour later the office manager sent me a follow up text saying they greatly appreciated the coffee, the persistence, and that he had just prescribed XXR [Xartemis] for a patient!” In another 2014 email, a district sales manager pushed her team to use lunch, coffee and snacks to win appointments with potential prescribers, instructing them that “the territories who have the most Scripts/PPI redemptions have the highest lunch/coffee/snack appointments as well as overall resources spent,” and that “FOCUSED activity/appointments=Product movement.” One sales representative noted that a particular doctor would “only see reps that have products he is a speaker for, unless it’s a lunch or breakfast,” and came up with a plan to increase meal visits with that physician to boost prescriptions; notably; that physician was later convicted of healthcare fraud for false diagnoses.

70. Mallinckrodt sales representatives pushed back on attempts to limit their use of food to sell to prescribers. For example, in 2014, after Mallinckrodt issued revised guidelines limiting the number and frequency of meals that sales representatives could use with healthcare providers, a sales representative expressed concern that “since I need to see them weekly its [sic]

imperative I utilize the resources needed for access”; her supervisor flippantly responded “[n]ot sure if they are watching or monitoring.”

iii. *Mallinckrodt Sales Representatives Were Trained to Use False and Misleading Messages to Sell Opioids*

71. To meet their goal of selling as many opioids as possible, Mallinckrodt encouraged its sales representatives to relay misleading claims about opioids’ benefits to prescribers, while downplaying risks of abuse and addiction.

72. As far back as the early 2000s, Mallinckrodt was aware that 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 include surveys and analysis of the abuse potential of various opioid products. With respect to its own products, Mallinckrodt 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.”

73. [REDACTED]

[REDACTED] For instance, 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, Mallinckrodt sales managers were being told certain pharmacies had flagged “Xartemis XR [a]s higher in abuse potential” and that “the State of New York advises against using this product!”

74. 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."

75. 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. Even in 2011, sales representatives were encouraged to draw false and misleading distinctions between Mallinckrodt's drugs 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." In 2012, Mallinckrodt sales representatives were instructed to encourage providers to "mov[e] Exalgo up in the treatment algorithm" by convincing them that "Exalgo is NOT a big gun and should be used sooner to optimize patient's success." Sales employees were given "pain cards" that instructed them to use messages like, "start doses low, go slow, but go!!!" and to tell prescribers that "most opioid agonists have no ceiling dose," i.e. a dose at which their pain-relieving effects begin to diminish.

76. Mallinckrodt sales representatives who succeeded in overcoming healthcare providers' concerns and selling large amounts of opioids won high praise. 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!"

iv. *Mallinckrodt Encouraged Prescribers to Keep Patients on Opioids at Higher Doses for Longer Periods of Time*

77. 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. The messaging was encapsulated in a video Mallinckrodt released of a reggae-style song in 2012 encouraging sales representatives to convince healthcare providers 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.”

78. Mallinckrodt sales managers insisted in 2012 that sales representatives “MUST ensure that patients stay on Exalgo once prescribed through proper dose initiation and titration.” In 2012, sales representatives were told 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.” In 2013, sales representatives also were told to “[e]ncourage use of the 32mg strength to reduce pill count.” 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 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 is double!!!” [REDACTED]

79. Mallinckrodt emphasized “proper dosing and titration” as a way to encourage continued prescriptions, even when their opioid products were “fail[ing] to demonstrate sustained efficacy” for patients, at even higher dosing than 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 notes: “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.”

80. 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.

v. Mallinckrodt Marketed its Branded Opioids as “Abuse-Deterrent” Despite Knowing that These Products Carried High Risks of Abuse

81. Mallinckrodt specifically marketed its branded opioids, Exalgo and Xartemis XR, as having abuse-deterrent qualities, despite knowing for years that they did not actually prevent abuse. For instance, 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.” 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 describe Exalgo as “specifically designed for gradual release over 24 hours . . . which contributes to steady plasma levels” and having a “barrier to crushing, chewing.” When attempting to overcome wholesalers’ caution about shipping Exalgo to pharmacies to “due to recent DEA actions,” one talking point Mallinckrodt used was that the drug was not subject to the same level of abuse as oxycodone.

82. Mallinckrodt promoted these drugs as abuse-deterrent despite being aware from the outset of their high potential for abuse. As early as 2009, Mallinckrodt employees forwarded an article from Reuters that noted Exalgo’s high abuse potential, and quoted a doctor who stated:

“Exalgo was ‘highly efficacious’ but very prone to crushing and other methods of abuse compared to other opioid pain killers. [He stated,] ‘On the spectrum of abuse, I think it’s toward the top.’”

[REDACTED]

83. In September 2009, a Reuters article circulated amongst Mallinckrodt employees described a FDA warning that their “experimental, longer-lasting opioid pain drug [Exalgo] is prone to abuse and overdose as it can easily be crushed by biting the tablet.” Similarly, a February 2010 Wells Fargo analysis of the potential financial opportunities from Exalgo, which was circulated among numerous Mallinckrodt employees, acknowledged that the “FDA panel [that reviewed Exalgo] believed that Exalgo has a significant potential for abuse.”

84. Moreover, at an FDA joint meeting in 2009, the representative for the FDA’s Controlled Substances Staff predicted that “Exalgo will have high levels of abuse and diversion.” In subsequent emails, Mallinckrodt employees acknowledged that the “FDA was originally reluctant to approve this ‘strong’ of an extended release EXALGO hydromorphone . . . FDA was

⁴ Palladone was Purdue’s hydromorphone ER drug that the FDA made Purdue pull off the market in 2005, less than a year after it was approved, due to increased risks of overdose death if combined with alcohol.

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.”

85. Despite the FDA’s warning and the other clear evidence of Exalgo’s abuse potential, Mallinckrodt sales representatives were praised for convincing doctors that the product was not addictive or prone to abuse and applauded 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 sales representative was praised for overcoming a prescriber’s reluctance to prescribe Exalgo due to his “belief that hydromorphone was more addictive than other ER opioids”—the representatives’ “persistence” was held up as an example to others at Mallinckrodt, who were told to “use the peaks and troughs graph” and to “Keep pushing!!!”

86. [REDACTED]

87. [REDACTED]

[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 “Engineered to discourage a common form of abuse” and “Demonstrated to be less liked for oral abuse vs Percocet.”

88. Mallinckrodt considered clever ways to suggest that its products were abuse-deterrent, while avoiding 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 as ‘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]

vi. *Mallinckrodt Employees Used Strategies to Evade Insurers’ Restrictions on Opioid Coverage in Order to Sell More Opioids*

89. 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 worked to bypass those restrictions, often working with healthcare providers to do so, in order to sell more pills.

90. 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.”

91. 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 Mallinckrodt employees worked to develop standard language 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.”

92. In 2014, Mallinckrodt faced challenges when 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). As one strategy, Mallinckrodt instructed sales representatives to discuss these 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 only be done orally, and never in writing.

b. Mallinckrodt Targeted Healthcare Providers Known to Be High Opioid Prescribers, Even Where They Had Reason to Know of the Prescribers’ Misconduct

93. As part of its efforts to maximize opioid sales, Mallinckrodt specifically targeted healthcare providers who were known to prescribe 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 their marketing efforts. Sales representatives were given 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.

94. Mallinckrodt sales representatives were told to grow their business by focusing on “large accounts” with potential to prescribe significant amounts of opioids “instead of spending time at practices with one physician and less TRx potential.” Rather than focus on the kinds of practices where opioid use would arguably be most appropriate—such as cancer pain practices—sales representatives were told to target large practices where uptake of Mallinckrodt’s branded opioids was quickest. These included such diverse practices as podiatry, plastic surgery, and orthopedics—hardly the kinds of practices where deadly, addictive pain drugs were necessary. As one demonstration of Mallinckrodt’s focus on generating as many new patients for its drugs as possible, Mallinckrodt employees were encouraged 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 “4-5 surgeons would be able to knock out about 50-100 XXR [Xartemis] patients per month!”

95. Mallinckrodt sales representatives were also instructed to target their efforts by focusing on prescribers who had been high prescribers of other branded opioids in the past. For example, training materials instructed sales representatives marketing Exalgo to focus on high prescribers of Dilaudid and other branded extended-release opioids. Similarly, sales

representatives marketing Xartemis were told 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.”

96. 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 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 is permanently barred from prescribing controlled substances, taking money from pharmaceutical companies, or keeping compensation received for practicing medicine.
- Quarterly playbook, FY2013Q3, Territory 60506-Huntsville, AL: 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.

97. Ultimately, and disturbingly, of the 239 medical professionals ranked by Mallinckrodt as top opioid prescribers during the height of the opioid crisis, more than a quarter 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. In many instances, Mallinckrodt had often continued working with certain prescribers even after they were suspected of diverting narcotics to the black market.

98. As just one example, in 2010, Mallinckrodt’s eastern regional sales director described a New York pain doctor, Dr. Eugene Gosy, as “the number one potential prescriber in the Northeast Region,” and commented that by “working together to make [the doctor] a product

advocate, the entire nation will benefit.” Similarly, in 2011, a regional sales director described Gosy as “the largest C2 [Schedule II] prescriber in NY and one of the biggest in the nation,” but added that Gosy was “under a bit of scrutiny.” Despite knowing that Gosy 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. Gosy issued more prescriptions for controlled substances annually than any other prescriber or prescribing entity in New York State, including hospitals. Then, in 2016, Gosy 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, Gosy 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 Gosy and worked to make him an “advocate” for opioids.

99. As another example, in January 2011, Dr. Fathalla Mashali, a pain management specialist who operated four busy clinics in Massachusetts and Rhode Island, was identified as a potential top prescriber. In September 2013—the same month Mashali lost his DEA license, necessary to prescribe controlled substances such as narcotics—a field contact report praised the Mallinckrodt sales representative for his performance in winning Mashali’s business. Mashali was ultimately arrested in 2014, and later pled guilty to health-care 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, not concern for patient safety. One sales representative wrote that “[l]osing Dr Mashali hurt 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 "absence of Dr. Mashali in the Worcester territory had a significant negative impact on this territory, the Boston District and likely the Northeast Region." In 2018, Mashali was sentenced to eight years in prison.

100. In 2010, a district manager identified Dr. Judson Somerville of Laredo, Texas as someone worth meeting, who 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 Somerville and persuaded him to prescribe the painkiller Exalgo. Somerville became one of Mallinckrodt's top opioid prescribers. In 2017, Somerville's Texas medical license was revoked for improper prescribing practices.

101. In yet another instance, until his 2021 conviction for accepting kickbacks in exchange for prescribing opioids, Dr. Howard Hoffberg of Baltimore was a top Exalgo prescriber. Hoffberg 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.

102. Mallinckrodt was often aware of the dubious prescribing practices of the healthcare providers it was targeting. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] For instance, 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 “kicked 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]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[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, who were “utilizing the Oxy problem” to prescribe more Exalgo. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

103. Further, after a Mallinckrodt sales representative described a success story promoting Exalgo to the largest pain clinic in Knoxville, Tennessee—which represented 80% of all OxyContin prescriptions in Knox County—another employee observed that the clinic was really a “big glorified pill mill.” And another clinic that represented a 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 [sic] period.” After another manager shared a success story about a sales representative successfully switching a doctor whose patients “come in bi-weekly for [Lortab] refills” to Exalgo, prompting another sales representative to comment, “They come in bi-weekly for [Lortab] refills? . . . Can you say Pill Mill?? I am not sure I would have published this.”

104. These unusually high-prescribers drove sales, and profits, for Mallinckrodt. When one 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 expressing concern about the impact on sales representatives’ ability to meet their quotas. In another case, when an Exalgo-prescribing doctor in Ohio lost his license, Mallinckrodt sales personnel observed that Ohio was “really getting hit”—in other words, when prescribers engaged in inappropriate conduct were identified and held accountable, Mallinckrodt lost business. In yet another instance, when a sales representative lost a prescriber who represented approximately 40-50% of his Exalgo business due to the suspension of the doctor’s prescribing license, his superiors refused to adjust his quota for Exalgo sales, with one commenting “one would hope that these scripts don’t just walk away from the territory” and that the patients would obtain Exalgo somewhere else.

105. Mallinckrodt emphasized the need to target high prescribers and grow its business even in areas where widespread diversion and abuse were well-known problems. On one occasion, a Mallinckrodt district manager emphasized the need to continue to grow business in Florida despite widespread diversion and physician arrests, noting that the “state of Florida is a tricky place. We have had more physician arrests than I can count and laws became very restrictive in 2011 . . . We need to constantly identify new pharmacies who can and will order Exalgo.” In another instance, a district business manager noted Mallinckrodt’s low market share in areas with significant numbers of “Opana ER [a competitor to Mallinckrodt] pill mills,” but noted 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.”

106. Even where doctors *were* suspected of inappropriate prescribing, they would often remain on Mallinckrodt’s sales representatives’ target lists, or would be removed temporarily only to be added back in 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]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

c. Mallinckrodt’s Efforts to Change the Legal, Regulatory and Cultural Environment and Facilitate Opioid Prescribing

107. Mallinckrodt’s efforts to drive up opioid prescriptions were not limited to its aggressive marketing of its own opioid products. Mallinckrodt also engaged in behind-the-scenes efforts to change the medical community’s view of opioids—from dangerous, addictive substances reserved for the most serious types of pain, to drugs that could safely and effectively be used to treat common, everyday pain. To accomplish this, Mallinckrodt paid individual experts, professional societies and advocacy organizations to spread Mallinckrodt’s messages about the supposed safety and efficacy of opioids, and lobby against regulatory and legal changes designed to limit opioid prescribing. This strategy allowed Mallinckrodt to remain in the shadows while using seemingly independent experts and organizations as mouthpieces to lend credibility to its dangerous messages.

- i. *Mallinckrodt Used Its Website and Other Media to Engage in an Unbranded Promotional Campaign that Changed the Medical Consensus Regarding Appropriate Use of, and Risks of, Opioids*

108. In addition to its targeted misleading marketing to healthcare providers, Mallinckrodt used websites and other media to promote false and misleading information about the efficacy of opioid pharmaceuticals generally and attendant risks of addiction and abuse.

109. As an example, between 2006 and 2007 Mallinckrodt sponsored a now-defunct website titled “pain-topics.org” that characterized reports of addiction in patients prescribed opioids for chronic pain as “misinformation.” The site also promoted the concept of “pseudoaddiction”—a false theory championed by the pharmaceutical industry positing that signs of addiction actually reflect undertreated pain and should be addressed by prescribing the individual *more* opioids. Pain-topics.org, published articles for healthcare providers and patients experiencing chronic pain that, among other things, overstated the benefits of opioids while downplaying risks of addiction, including through statements that (i) “the clinical benefits of opioid treatment dwarf the clinical risks”; (ii) “addiction to oxycodone in person without a recent history of alcohol or drug problems is rare”; (iii) “all indications are these problems [of addiction in opioid patients] may not be as many practitioners, regulators and the public seem[] to believe”; (iv) overdoses due to opioids are limited to a “minimal” number of “celebrities and street users”; (v) “[v]ery few patients taking opioids continuously for pain will exhibit addictive behavior”; (vi) “[p]atients’ fears of opioid addiction should be dispelled...they must be cautioned against reducing oxycodone dosing on their own”; and (vii) “there is no ceiling or maximum level of opioid dose in chronic [pain].” Pain-topics.org did not tie these assertions specifically to Mallinckrodt 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 concerns and perceptions regarding the risks attendant to opioid use.

110. In 2010, Mallinckrodt published “Opioid Safe Use and Handling Guide: A Resource for Patients” to falsely assure patients that “addiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but can occur.” The same guide promoted the false idea of pseudoaddiction, defining it 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.”

111. These statements stand in sharp contrast to the scientific evidence and data regarding drug overdoses, including numerous studies finding that opioid medications carry a high risk of addiction regardless of patient history or potential misuse.

ii. *Mallinckrodt Paid “Key Opinion Leaders” to Disseminate False and Misleading Information Promoting Use of Opioids Generally*

112. Mallinckrodt recruited and compensated top opioid prescribers, known as “Key Opinion Leaders,” to promote the use of opioids generally. Key Opinion Leaders spread the message throughout the medical community by speaking at or attending events to promote opioid prescription and use; delivering scripted talks and drafting misleading studies that promoted opioids; and presenting deceptive continuing medical education programs.

113. Mallinckrodt thereby actively promoted the purported benefits of opioid drugs to and through prescribers. Prescribers selected for these programs attended trainings hosted by Mallinckrodt and delivered presentations to medical community peers at expensive restaurants and resorts. To take just one example, Mallinckrodt paid a New York pain management doctor, one of the top Exalgo prescribers from 2011 to 2013, between \$15,000 and \$20,000 in honoraria from speaking engagements. 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, Mallinckrodt medical affairs expressed concern when new Senate legislation was proposed that would require pharmaceutical companies to disclose payments to doctors in promotional speaking roles.

114. Mallinckrodt was careful to select speakers who would extol the benefits of Mallinckrodt's products and spread its preferred messaging about opioids. Mallinckrodt's sales representatives, moreover, played a major role in organizing Key Opinion Leader events, such as by organizing speaker programs that "[t]arget[ed] physicians who are receptive to using" Mallinckrodt's opioid products. One common speaker was praised as "frequently instruct[ing] his audiences that there is no ceiling for pain medications" and "believes in Exalgo." The representatives were encouraged to schedule as many speaker programs as they could. For instance, in one email, a 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," noting that these efforts were "being watched and tracked not only by me but those much higher than me." In another 2012 email, a field manager 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.

115. These programs undoubtedly achieved Mallinckrodt's goal of winning business and increasing prescriptions. One sales representative was praised 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 was able to convince a prescriber that he “had under dosed the patient” and that he should “bump[] up his dose,” noting that “without 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 were encouraged by a Key Opinion Leader’s assurances that Exalgo had “minimal abuse potential.”

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

116. Another of Mallinckrodt’s tactics was to utilize and fund “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 convince lawmakers to loosen or forego restrictions on opioid prescribing, manufacturing and distribution.

117. For example, in 2010, Mallinckrodt founded the C.A.R.E.S. Alliance, 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 earliest efforts at advocacy, was to promote messaging that 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, in order to help assuage physician discomfort with opioids and increase their total prescriptions.

118. These books and fact sheets brushed aside the difficult and painful effects that many patients experience when opioid dosages are lowered and downplayed the relevance and risk of opioid addiction, instead promoting concepts like “pseudoaddiction.” The C.A.R.E.S. Alliance published reading materials that made false claims such as “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” and “[p]hysical dependence...is a normal bodily reaction that happens with lots of different types of medication, including medication not used for pain, and is easily remedied.”

119. Another front group sponsored by Mallinckrodt was the Alliance for Patient Access (the “APA”). In 2013, the APA published a paper titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse” that criticized prescription monitoring programs 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 funding from pharmaceutical companies.

120. The U.S. Pain Foundation was another front group connected to Mallinckrodt that aided lobbying efforts to reduce limits on over-prescription. The U.S. Pain Foundation put out misleading statements regarding opioids, including calling guidelines released by the Department of Veteran Affairs and Department of Defense as “problematic” due to their advice to prescribe

20-50 MME per day with caution and their warning against prescribing more than 90 MMEs per day.

iv. *Mallinckrodt Engaged in Lobbying Efforts to Forestall or Weaken Regulations on Opioid Marketing, Prescription and Sales*

121. Mallinckrodt engaged in significant behind-the-scenes efforts to influence state and federal legislators and executive branch officials, with the goal of blocking and weakening regulations designed to limit the marketing, prescription or sales of opioids. In some cases, Mallinckrodt conducted lobbying activity on its own behalf, while in others, it worked from the shadows through nominally independent policy institutes that, in reality, operated as front groups for Mallinckrodt.

122. For example, in an October 2013 email, Mallinckrodt sales personnel discussed their efforts to influence the Ohio Governor's Cabinet Opiate Action Team. One mentioned that "I need to schedule a lunch in there and pick [a member of the team's] brain and get on his good side," while another responded, "I have an idea around using him. He obviously knows more than we know. He will/could be instrumental." Similarly, in 2013, in response to the Louisiana Board of Medical Examiners' initiative to limit opioid prescribing, Mallinckrodt sales executives discussed how they might "slow the legislation."

123. Mallinckrodt was also a member of Pharmaceutical Research and Manufacturers of America ("phRMA"), a pharma lobbying group founded by Purdue to improve the perception of drug companies. Mallinckrodt joined the group in 2015, and in 2016 the group spent almost \$20 million lobbying Congress.

124. Mallinckrodt worked against beneficial legislation designed to curb the growing opioid crisis. For example, in 2011, Mallinckrodt actively worked to undermine legislative efforts

to limit the amount of controlled substances shipped into Florida—the epicenter of the pill mill epidemic, and a huge market for Mallinckrodt’s opioids.

125. Mallinckrodt front groups also waged significant efforts to lobby for Mallinckrodt’s interests with government officials and regulators, lobbying against new state legislation that would limit the size of initial opioid prescriptions and pursuing a plan to roll back one state’s “gift ban,” i.e. restrictions on pharmaceutical companies’ payments to prescribers for consulting and speaking engagements. This is just one of the many ways in which Mallinckrodt used seemingly objective, independent industry associations to fight government efforts to mitigate the harm of the growing opioid crisis, while itself remaining in the shadows.

126. [REDACTED]

127. As the opioid epidemic grew in intensity and notoriety, Mallinckrodt’s public relations strategy downplayed the growing crisis of addiction, abuse and death. In 2013, Mallinckrodt crafted public relations materials that specifically avoided acknowledging an epidemic of misuse, referring to the crisis as merely a “serious problem.” Also in 2013, Mallinckrodt also gave its representatives media training on how to address “real worst-case scenarios,” including on how to “play[] devil’s advocate around opioid abuse/misuse/diversion”

and “gracefully extract or bridge out of an interview that could be potentially damaging to the company.”

d. Mallinckrodt’s Failure to Properly Identify and Monitor Suspicious Orders

128. Mallinckrodt’s misconduct did not stop at its efforts to convince prescribers to overprescribe its opioids and to convince the medical profession to use opioids more generally. Mallinckrodt also failed to implement proper systems to prevent the massive amounts of its opioids that were being diverted into 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 itself to significant legal liability.

i. *Mallinckrodt Was Aware of its Legal Obligations to Detect, Prevent and Report Suspicious Orders.*

129. Under the Controlled Substances Act and analogous state law, Mallinckrodt was required to (i) 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 order of unusual frequency”; (ii) 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 (iii) report all suspicious orders to the DEA and analogous state agencies.

130. Mallinckrodt was well aware of these obligations. In 2008, the DEA sent a memo to Mallinckrodt and others highlighting that, “[i]n addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious

orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant ‘design and operate a system to disclose to the registrant suspicious orders of controlled substances’ . . . The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders *when discovered* by the registrant . . . Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether controlled substances are likely to be diverted from legitimate channels . . . Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders . . . [R]egistrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted . . . may be failing to maintain effective controls against diversion.” The DEA also provided Mallinckrodt with compliance training and materials to assist it in meeting its legal obligations.

131. Mallinckrodt employees discussed and otherwise acknowledged their awareness of these legal obligations. In 2007, a Mallinckrodt DEA compliance manager circulated a “strongly worded” DEA letter “offered as guidance for the industry,” noting that “the belief was that DEA had sufficiently warned controlled substance distributors and was now taking enforcement action,” and that “distributors must scrutinize orders shipping to existing DEA registrant customers.”

132. In 2008, Mallinckrodt employees emailed about DEA 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.”

133. But, despite all this, as discussed below, Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be detected, stopped and reported. Instead, Mallinckrodt continued to fill suspicious orders and supplied more opioids than were medically justified, leading to widespread diversion and abuse.

ii. Mallinckrodt was Aware that Diversion of its Opioid Products was a Major Problem

134. 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.

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

[REDACTED]

[REDACTED]

[REDACTED]

136. 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, 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 “Weekend 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.

137. 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.”

138. 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 further confirmed that same year,

when Mallinckrodt was informed by the Department of Justice (“DOJ”) 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 ex 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. 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].”

139. The high demand for Mallinckrodt’s various opioids in 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 it 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.”

iii. Mallinckrodt was Aware that Legal Liability for Failure to Monitor Suspicious Orders was a Significant Risk

140. Just as it knew about the widespread diversion of its own drugs, Mallinckrodt was aware that other opioid manufacturers, distributors and pharmacies were facing significant liability and penalties as a result of their failure to prevent diversion.

141. As early as the early 2000s, Mallinckrodt was aware of enforcement actions against manufacturers and distributors regarding suspicious order monitoring (“SOM”) 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.’”

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

143. 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.” Similarly, a Mallinckrodt director of security admitted that “We are very aware of the multi-million

dollar fines levied against Cardinal Health and McKesson for not being diligent with regard to sales.”

144. Nonetheless, Mallinckrodt adopted a 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.*” The manager was promptly warned to limit email discussion of the topic, presumably in order to avoid putting these incriminating facts—that widespread, illegal diversion of its products was generating massive profits for Mallinckrodt—in writing.

iv. Mallinckrodt Had Access to the Data Necessary to Detect, Stop and Report Suspicious Orders

145. Even a cursory review of the data available to Mallinckrodt should have alerted it that a high portion of its products were being diverted. Mallinckrodt products accounted for noticeably high percentages of sales of opioids in certain states known for significant rates of opioid diversion and abuse. For instance, between 2008 and 2012, 500 million of Mallinckrodt’s pills ended up in Florida—66% of all oxycodone sold in the state—and [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

146. Mallinckrodt was well aware that Florida was a hotbed of diversion, and that many of its opioids were ending up there. In November 2009, reacting to an article regarding the prevalence of pill mills in Florida, a Mallinckrodt accounts director observed that “our biggest

customers like McKesson, Cardinal, Optisource, HD Smith, Masters etc. . . . all ship to Florida.” Moreover, Mallinckrodt was aware that certain customers purchased disproportionately large amounts of its most commonly abused opioids—such as its 30mg oxycodone dose—and sent a stunningly large percentage of those drugs to Florida. [REDACTED]

[REDACTED]

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

[REDACTED]

148. [REDACTED]

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

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

149. Despite having ready access to the data necessary to detect and investigate suspicious orders, and analysis that clearly showed suspicious patterns, Mallinckrodt consistently failed to design and implement an effective system for doing so. While Mallinckrodt's SOM system changed over time, it always suffered from serious flaws, including, without limitation, at various times using numeric algorithms that required far too high a size threshold for when an order would be flagged as "suspicious"; conducting suspicious order monitoring by product family or DEA classification rather than by specific product, which made it difficult to detect large increases in specific abuse-prone drugs; and overreliance on sales representatives to identify and flag suspicious orders, despite their obvious conflict of interest. These flaws and others led Mallinckrodt to consistently fail to detect problematic orders, leading these orders to be shipped without question, and the drugs therein to be diverted and abused.

150. Among other problems, Mallinckrodt's SOM 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 incentives,⁵ (iv) failed to track customers identified as suspicious by other pharma companies, (v) failed to follow suspicious customers if they changed their address, (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 SOM programs, 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 ship opioids to customers even *after* putting shipping restrictions on them, revealing a “clear gap” in the SOM process.

151. The problems with Mallinckrodt’s faulty SOM system reflected, and were compounded by, the company’s culture. In September 2010, a Mallinckrodt director of security admitted that Mallinckrodt’s SOM program up to that point “did little to truly monitor suspicious orders,” and that employees continued to “take shortcuts with DEA rules and regulations because it might take a little longer or be inconvenient to do things right.”

⁵ Notably, sales personnel’s role in the process remained significant, and only increased, as Mallinckrodt updated its SOM policies throughout 2009 and 2010.

152. As a result of having such a faulty SOM 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 SOM system include:

- [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.”

153. In a November 2010 memorandum, an outside consultant criticized Mallinckrodt’s SOM program—which, up to that point, had been based simply on a 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 SOM “‘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.”

154. In 2011, the DEA began to investigate Mallinckrodt itself 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.

155. In the 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. 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’”

156. The DEA further noted 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 excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious sales,” and that Mallinckrodt “never notified the DEA of suspicious orders in violation of the CSA.”

vi. Mallinckrodt Failed to Meet its Obligation to Refuse to Fill Suspicious Orders and Report them to the DEA

157. 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.

158. [REDACTED]

[REDACTED]

159. 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.

160. The example of Sunrise Wholesalers illustrates Mallinckrodt’s attitude towards its SOM obligations. In May 2008, Mallinckrodt employees noticed that one of its customers, Sunrise Wholesalers, was placing unusually large orders, such as an order for 2520 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. Notably, around this same period, Sunrise returned shipments of Mallinckrodt’s extended-release oxycodone formulation to Mallinckrodt because it was “having a very difficult time moving it out to their customers” and it “isn’t a very fast mover for their clientele.” Sunrise’s particularly large orders of immediate-release drugs, Mallinckrodt’s most commonly abused opioids, combined with its apparent inability to sell the less commonly abused extended-release opioids, constituted serious red flags that Mallinckrodt ignored.

161. In early July 2009, Bill Ratliff, a director of security for Mallinckrodt, was advised by a police officer in Tennessee that Mallinckrodt oxycodone 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. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

162. [REDACTED]

163. Thus, Mallinckrodt continued to ship its products to Sunrise, even as the DEA began investigating Sunrise for supplying opioids to pill mills. During this period, Mallinckrodt received “several inquiries” from the DEA and local law enforcement in Florida and the surrounding states, and was aware that these inquiries related to diverted products that Mallinckrodt had shipped to Sunrise, but Mallinckrodt “did not always divulge that information unless requested specifically” and “never provided any information in writing.”

164. Ultimately, Sunrise’s DEA license was suspended in June 2010. Mallinckrodt Product Manager Kate Muhlenkamp explained, “we are under the impression that it is...due to the sale of Oxycodone in the state of Florida.” [REDACTED]

* * *

165. 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 that healthcare professionals relied on 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 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. By 2012, more than 280 million prescriptions were issued in that year 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.

III. The Cost of the Opioid Crisis

166. The widespread aggressive-prescription of opioids, and the diversion, abuse, addiction, injury, and death that followed, have devastated lives and communities across the country.

167. Overdose fatalities are one measure of the human toll taken by the opioid epidemic. 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.” Altogether, the CDC estimates that more than 564,000 Americans have died from an overdose involving opioids between 1999 and 2020. Many more Americans continue to live with opioid use disorder, their lives ruined by the prescriptions that were supposed to provide pain relief. Children are born with NAS, the effects of which can last a lifetime. Countless families have lost loved ones to addiction and death.

168. Moreover, studies have shown that patients who can no longer obtain prescription opioids often turn to illicit opioids to feed their addiction. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade began with prescription opioids. Other studies report that people addicted to prescription opioids are 40 times more likely to become addicted to heroin. As such, the CDC has identified prescription opioid addiction as the strongest risk factor for heroin addiction.

169. The opioid crisis in the U.S. has also caused devastating socio-economic fallout, and staggering financial costs. The CDC concluded that in 2017, when more than 47,000⁶ 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 healthcare and opioid use disorder treatment; and \$14.8 billion in criminal justice spending.⁷ The CDC had previously calculated that prescription opioid misuse alone imposed total economic costs of \$78.5 billion each year. In another 2018 study, from Altarum, a non-profit healthcare research and consulting institute, measured the cost of the opioid crisis through 2016, and estimating its growth beyond. The burden of the crisis comes in many forms; lost wages and productivity, increased healthcare costs, lost tax revenue at the local, state and federal levels, higher spending on social services, education and criminal justice. The Altarum study estimates the socio-economic impact of the opioid crisis between 2001 and 2016 alone to be \$1 trillion.

⁶ This number likely underestimates the actual number of opioid overdose deaths due to inconsistent reporting across the country regarding the causes of overdose deaths, as well as the fact that many overdose deaths include more than one substance, and such overdoses may have a different substance listed as the cause of death.

⁷ The Economics of Injury and Violence Prevention, CDC, <https://www.cdc.gov/injury/features/health-econ-cost-ofinjury/index.html>.

170. The Altarum study also highlights 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 impact rose to \$48.7 billion. By 2007 it was \$60.9 billion, and then \$95.8 billion in 2016, when the study was conducted. Based on the rapidly increasing 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.

IV. Investigations and Litigations from the Opioid Crisis

171. Evidence of the abuse and diversion of opioid pharmaceutical products, was available since at least the early 2000s, and evidence of the liability related to marketing such opioids followed shortly thereafter. As just one noteworthy example, by 2007, Purdue Pharma had entered into a notorious and massive settlement for \$635 million to settle claims about its practices for marketing opioids.

172. [REDACTED]

[REDACTED]

[REDACTED]

173. 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 piled up.

174. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

175. By June 2017, Mallinckrodt had been added as a named defendant in the storm of opioid litigation, and by December 2017, so many lawsuits had been filed that a multidistrict opioid litigation had been consolidated in the Northern District of Ohio (the “MDL”). These lawsuits alleged Mallinckrodt’s liability for opioid-related misconduct that spanned over a decade or more.

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

- a. Multiple state court lawsuits, 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 in California, Florida,

Louisiana, Maryland, New Jersey, Ohio, Pennsylvania, Tennessee, and West Virginia.

- b. A subpoena from the DOJ, sent on July 26, 2017.
- c. Civil Investigative Demands from the Missouri Attorney General's Office, Kentucky Attorney General's Office, and the Attorney General's Office for the State of Washington.
- d. Subpoenas from the New Hampshire Attorney General's Office, the Attorney General's Office from the State of Alaska, and the U.S. Attorneys' Office for the Southern District of Florida.
- e. An investigation by a coalition of State Attorneys General regarding Mallinckrodt's role in contributing to the increased use of opioids in the U.S.

177.

[REDACTED]

178. 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 program. 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”

179. Ultimately, over the three years preceding Mallinckrodt’s bankruptcy filing, Mallinckrodt plc and its subsidiaries were involved in 3,034 cases concerning the production, marketing, promotion, and sales of its opioid products.

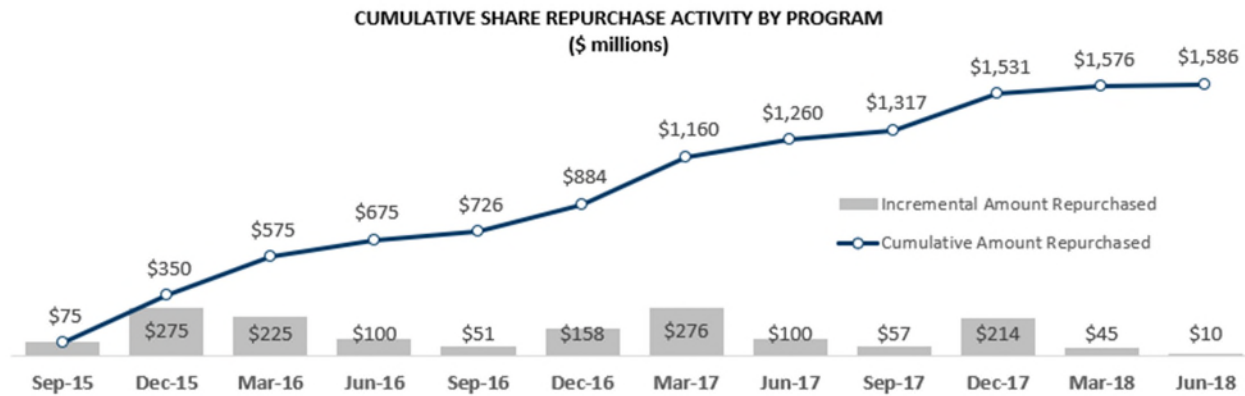
180. This “enterprise-threatening litigation” forced Mallinckrodt into bankruptcy in October 2020.

V. The Share Repurchasing Program

181. By early 2015, Mallinckrodt was hopelessly insolvent due to significant opioid liabilities, and the company was aware that opioid liability was mounting. Nevertheless, between 2015 and 2018, Mallinckrodt engaged in a costly share repurchase program by which it transferred close to \$1.6 billion to its equity owners, for no value in return.

182. 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 incremental \$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.

183. Mallinckrodt’s first share repurchase transaction occurred on August 4, 2015, and the final repurchase transaction occurred on April 23, 2018. The details about the date, amount, and shareholder recipient involved in each share repurchase transaction subject to this complaint is set forth in Exhibits A, B and C. As set forth in the following table, altogether Mallinckrodt repurchased approximately 35.57 million shares, for approximately \$1.6 billion.



184. Mallinckrodt routinely reported to the Board, and to the Audit Committee of the Board, regarding the status of repurchases under the share repurchase program.

185. Mallinckrodt’s primary motivation in authorizing the share repurchase program was 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. It was a complete failure. The stock continued to plummet. The business continued to erode. The opioid liability continued to mount. The share repurchase program fell on “deaf ears” and simply transferred value away for no value in return.

186. 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,⁸ under which the brokers agreed to purchase outstanding ordinary shares, par value \$0.20 per share, on behalf of Mallinckrodt.

187. Under the Purchase Agreements, the brokers were authorized 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 must comply with the requirements of Rule 10b5-1(c)(1)(i) and, to the extent applicable, Rule 10b-18 under the Securities Exchange Act of 1934. Consistent with the Purchase Agreements, the Board retained no control over the Brokers' actual purchasing decisions and the Brokers were merely authorized to perform contractual services and serve as a conduit for the Share Repurchase Transfers. This approach was specifically and carefully designed to create distance between the Board and the share repurchase transactions, in an attempt to shield Mallinckrodt from potential liability that might arise from the timing of specific purchases.

188. The share repurchase transactions 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*

189. Since the time it was formed at the Spinoff, the Board was informed about the ongoing investigation by the USAO for the Eastern District of Michigan and the DEA regarding Mallinckrodt's SOM violations, as well as the investigation by the USAO for the Northern District of New York regarding security violations at Mallinckrodt's Hobart facility. The Board was

⁸ 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.

informed that it was likely that the “DEA will bring administrative and civil penalty actions against” Mallinckrodt due to “issues with [Mallinckrodt’s] biennial inventory, reconciliation recordkeeping and security.” [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

190. Even while it faced these potential liabilities (and others that were certain to materialize as a result of Mallinckrodt’s conduct), Mallinckrodt was under pressure from certain equity-holders who stood to benefit from the opportunity to sell back their shares in exchange for cash. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

191. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

192. [REDACTED]

193. At the same time, Mallinckrodt's business continued to decline sharply, largely due to problems with Mallinckrodt's opioid business, including increased regulatory scrutiny. Yet the Board continued and expanded the share repurchase program in an attempt to shovel value to equity and try to prop up shareholder value temporarily.

194. [REDACTED]

195. [REDACTED]

[REDACTED]

196. [REDACTED]

[REDACTED]

197. 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. [REDACTED]

[REDACTED]

[REDACTED]

198. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

199. [REDACTED]

[REDACTED]

200. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

201. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

202. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

203. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

204. [REDACTED]

205. Mallinckrodt’s final share repurchase transaction occurred on April 23, 2018, after Mallinckrodt had spent close to \$1.6 billion on share repurchases over the tenure of the program.

206. [REDACTED]

VI. Mallinckrodt Was Insolvent, Inadequately Capitalized, and Unable to Pay Debts as they Became Due between 2015 and 2018

207. Mallinckrodt was insolvent, inadequately capitalized, and unable to pay debts as they became due while undertaking the share repurchase program, as a result of its massive opioid-related liabilities.

208. Any approach to valuing Mallinckrodt's crushing opioid liabilities shows that such liabilities greatly exceeded Mallinckrodt's assets, by many multiples, throughout the share repurchase period.

209. *First*, the thousands of lawsuits filed against Mallinckrodt alleged claims worth trillions of dollars for conduct and sales that preceded and spanned the period in which Mallinckrodt conducted the share repurchase program. By the Petition Date, Mallinckrodt had been sued in more than 3,000 opioid-related cases in a self-described "tidal wave of litigation." Opioid lawsuits filed against Mallinckrodt included claims by: (a) states, municipalities, and tribes, which incurred damages along with the harm suffered by their citizens because of bodily injuries, and sought recovery based on, *inter alia*, public nuisance and false or deceptive marketing theories; (b) the DOJ, which alleged violations of federal law, including the CSA and False Claims Act; (c) personal injury victims, who 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; (d) children suffered from NAS caused by opioid use by pregnant mothers; (e) hospitals which bore 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; (f) independent emergency room prescribers who incurred operational and other costs because of bodily injuries resulting from the opioid epidemic; and (g) third-party payors and insurance

ratepayers, who incurred higher medical benefits costs and/or insurance costs as a result of the opioid epidemic. Collectively, these creditor groups alleged claims worth trillions of dollars arising from Mallinckrodt's opioid practices, based on conduct and sales that occurred prior to, and during, the 2015 to 2018 share repurchase program. Even this is the tip of the iceberg, as it does not include litigation claims that would have been filed but for the bankruptcy proceeding.

210. **Second**, the Debtors admitted during the chapter 11 proceedings that they faced “potentially trillions of dollars in damages” and that the opioid litigation posed a threat to viability of Mallinckrodt's business. The Debtors testified, based on an assessment of the settlements they had actually been able to achieve (including \$30 million to settle the claims of just two counties), that the company realistically faced a liability in excess of \$30 billion, an amount that renders Mallinckrodt deeply insolvent at all relevant times. The Debtors understood that judgments in the “tens of billions of dollars” could result “even if a fraction of plaintiffs [were] successful in winning all the damages they seek.”

211. **Third**, using reasonable extrapolation methods from settlements reached by other opioid manufacturer defendants 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 million. Extrapolating from those settlements indicates that these manufacturers (who collectively had a MME 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 also 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 for 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.

212. *Fourth*, 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).

213. Thus, no matter how one measures Mallinckrodt's opioid liabilities during the share repurchase period, the obligation dwarfs any plausible estimation of Mallinckrodt's enterprise value which irrefutably demonstrates the substantial degree of Mallinckrodt's insolvency.

214. Accordingly, and correctly, during the bankruptcy proceedings, the Court determined that Mallinckrodt was "hopelessly insolvent."

CAUSES OF ACTION

Count 1

**Intentional Fraudulent Transfer
against the Defendants, the John Doe Defendants, and the Class Representative Defendants
individually and as representatives of the Share Repurchase Transferee Class
under 11 USC §§ 544(b), 550(a) and
Mo. Rev. Stat. § 428.024(1)**

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

216. In connection with the Share Repurchase Transfers, the Debtors transferred close to \$1.6 billion to shareholders between August 2015 and April 2018.

217. Specifically, the Debtors made Share Repurchase Transfers to the Defendants named in Exhibit A, in the total amounts set forth in Exhibit A, and as set forth in further detail in Exhibit B. In addition, the Debtors made additional Share Repurchase Transfers to the John Doe Defendants and members of the Share Repurchase Transferee Class on the dates set forth on Exhibit C.

218. Each of the Defendants sold Mallinckrodt shares to Mallinckrodt in the amounts, set forth in Exhibit A. Each of the John Doe Defendants and members of the Share Repurchase Transferee Class sold Mallinckrodt shares to Mallinckrodt on the dates set forth in Exhibit C. Each of the Defendants, John Doe Defendants, and members of the Share Repurchase Transferee Class owned the relevant shares that were sold to Mallinckrodt. Each of the Defendants received proceeds from Mallinckrodt in the amounts set forth in Exhibit A. Each of the John Doe Defendants and members of the Share Repurchase Transferee Class received proceeds from Mallinckrodt in connection with Share Repurchase Transfers.

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

220. 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, John Doe Defendants, and members of the Share Repurchase Transferee Class.

221. 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, the Debtors 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 when the Share Repurchase Transfers were approved and were ultimately implemented between 2015 and 2018. As discussed in detail in this 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.

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

223. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), Mo. Rev. Stat. § 428.024(1), 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 2

Intentional Fraudulent Transfer against the Defendants, the John Doe Defendants, and the Class Representative Defendants individually and as representatives of the Share Repurchase Transferee Class under 11 USC §§ 544(b), 550(a) and 28 U.S.C. § 3304(b)(1)(A)

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

225. In connection with the Share Repurchase Transfers, the Debtors transferred close to \$1.6 billion to shareholders between August 2015 and April 2018.

226. Specifically, the Debtors made Share Repurchase Transfers to the Defendants named in Exhibit A, in the total amounts set forth in Exhibit A, and as set forth in further detail in Exhibit B. In addition, the Debtors made additional Share Repurchase Transfers to the John Doe Defendants and members of the Share Repurchase Transferee Class on the dates set forth on Exhibit C.

227. Each of the Defendants sold Mallinckrodt shares to Mallinckrodt in the amounts, set forth in Exhibit A. Each of the John Doe Defendants and members of the Share Repurchase Transferee Class sold Mallinckrodt shares to Mallinckrodt on the dates set forth in Exhibit C. Each of the Defendants, John Doe Defendants, and members of the Share Repurchase Transferee Class owned the relevant shares that were sold to Mallinckrodt. Each of the Defendants received proceeds from Mallinckrodt in the amounts set forth in Exhibit A. Each of the John Doe Defendants and members of the Share Repurchase Transferee Class received proceeds from Mallinckrodt in connection with Share Repurchase Transfers.

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

229. 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, John Doe Defendants, and members of the Share Repurchase Transferee Class.

230. 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, the Debtors 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 when the Share Repurchase Transfers were approved and were ultimately implemented between 2015 and 2018. As discussed in detail in this 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.

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

232. 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 3

**Constructive Fraudulent Transfer
against the Defendants, the John Doe Defendants, and the Class Representative Defendants
individually and as representatives of the Share Repurchase Transferee Class
under 11 USC §§ 544(b), 550(a) and
Mo. Rev. Stat. §§ 428.024(2), 428.029**

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

234. In connection with the Share Repurchase Transfers, the Debtors transferred close to \$1.6 billion to shareholders between August 2015 and April 2018.

235. Specifically, the Debtors made Share Repurchase Transfers to the Defendants named in Exhibit A, in the total amounts set forth in Exhibit A, and as set forth in further detail in Exhibit B. In addition, the Debtors made additional Share Repurchase Transfers to the John Doe Defendants and members of the Share Repurchase Transferee Class on the dates set forth on Exhibit C.

236. Each of the Defendants sold Mallinckrodt shares to Mallinckrodt in the amounts, set forth in Exhibit A. Each of the John Doe Defendants and members of the Share Repurchase Transferee Class sold Mallinckrodt shares to Mallinckrodt on the dates set forth in Exhibit C. Each of the Defendants, John Doe Defendants, and members of the Share Repurchase Transferee Class owned the relevant shares that were sold to Mallinckrodt. Each of the Defendants received proceeds from Mallinckrodt in the amounts set forth in Exhibit A. Each of the John Doe Defendants and members of the Share Repurchase Transferee Class received proceeds from Mallinckrodt in connection with Share Repurchase Transfers.

237. For each of the Share Repurchase Transfers, Mallinckrodt received only its own worthless stock. Mallinckrodt did not receive, and the Defendants, John Doe Defendants, and members of the Share Repurchase Transferee Class 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.

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

239. 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.

240. 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.

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

242. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), Mo. Rev. Stat. §§ 428.024(2), 428.029 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 4

**Constructive Fraudulent Transfer
against the Defendants, the John Doe Defendants, and the Class Representative Defendants
individually and as representatives of the Share Repurchase Transferee Class
under 11 USC §§ 544(b), 550(a) and 28 U.S.C. §§ 3304(a)(1), 3304(b)(1)(B)**

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

244. In connection with the Share Repurchase Transfers, the Debtors transferred close to \$1.6 billion to shareholders between August 2015 and April 2018.

245. Specifically, the Debtors made Share Repurchase Transfers to the Defendants named in Exhibit A, in the total amounts set forth in Exhibit A, and as set forth in further detail in Exhibit B. In addition, the Debtors made additional Share Repurchase Transfers to the John Doe Defendants and members of the Share Repurchase Transferee Class on the dates set forth on Exhibit C.

246. Each of the Defendants sold Mallinckrodt shares to Mallinckrodt in the amounts, set forth in Exhibit A. Each of the John Doe Defendants and members of the Share Repurchase Transferee Class sold Mallinckrodt shares to Mallinckrodt on the dates set forth in Exhibit C. Each of the Defendants, John Doe Defendants, and members of the Share Repurchase Transferee Class owned the relevant shares that were sold to Mallinckrodt. Each of the Defendants received proceeds from Mallinckrodt in the amounts set forth in Exhibit A. Each of the John Doe Defendants and members of the Share Repurchase Transferee Class received proceeds from Mallinckrodt in connection with Share Repurchase Transfers.

247. For each of the Share Repurchase Transfers, Mallinckrodt received only its own worthless stock. Mallinckrodt did not receive, and the Defendants, John Doe Defendants, and members of the Share Repurchase Transferee Class 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.

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

249. 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.

250. 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.

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

252. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), 28 U.S.C. §§ 3304(a)(1), 3304(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 or 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. certifying the Share Repurchase Transferee Class;
- b. entering a judgment against the Defendants, the John Doe Defendants, and the Class Representative Defendants individually and as representatives of the Share Repurchase Transferee Class, finding that the Share Repurchase Transfers constitute intentionally fraudulent transfers;
- c. entering a judgment against the Defendants, the John Doe Defendants, and the Class Representative Defendants individually and as representatives of the Share Repurchase Transferee Class, finding that the Share Repurchase Transfers constitute constructively fraudulent transfers;
- d. avoiding each of the Share Repurchase Transfers set forth in Exhibits A and B, and the additional Share Repurchase Transfers on the dates on Exhibit C as intentionally fraudulent under applicable law;
- e. avoiding each of the Share Repurchase Transfers set forth in Exhibits A and B, and the additional Share Repurchase Transfers on the dates on Exhibit C as constructively fraudulent under applicable law;
- f. recovering the value of each of the Share Repurchase Transfers set forth in Exhibits A and B, and the additional Share Repurchase Transfers on the dates on Exhibit C from the Defendants, the John Doe Defendants, and the members of the Share Repurchase Transferee Class pursuant to Bankruptcy Code sections 544, 550, and applicable law;
- g. awarding the Trust damages in an amount to be determined at trial;
- h. imposing a constructive trust on assets of the Defendants in the amount of all proceeds received by such Defendant through Share Repurchase Transfers;
- i. awarding the Trust its attorneys' fees, costs, and other expenses incurred in this action;

- j. awarding the Trust pre- and post-judgment interest at the maximum rate permitted by law; and
- k. awarding the Trust such other and further relief as the Court deems just and proper.

Dated: October 12, 2022
Wilmington, Delaware

COLE SCHOTZ P.C.

/s/ Justin R. Alberto

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II*

EXHIBITS A, B AND C

FILED UNDER SEAL