IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	:	Chapter 11
MALLINCKRODT PLC, *et al.*,	:	Case No. 20-12522 (JTD)
Reorganized Debtors.[1]	:	(Jointly Administered)
OPIOID MASTER DISBURSEMENT TRUST II,	:	Adv. Proc. No. 22-50433 (JTD)
Plaintiff,	:	**Re: Adv. Docket No. 2**
v.	:	
COVIDIEN UNLIMITED COMPANY (formerly known as Covidien Ltd. and Covidien plc), COVIDIEN GROUP HOLDINGS LTD. (formerly known as Covidien Ltd.), COVIDIEN INTERNATIONAL FINANCE S.A., COVIDIEN GROUP S.À R.L., and DOE DEFENDANTS 1-500,	:	
Defendants.	:	

NOTICE OF FILING OF PROPOSED REDACTED VERSION OF COMPLAINT

PLEASE TAKE NOTICE that, on October 11, 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.

[1] A complete list of the Reorganized Debtors in these chapter 11 cases may be obtained on the website of the Reorganized Debtors' claims and noticing agent at http://restructuring.primeclerk.com/Mallinckrodt. The Reorganized Debtors' mailing address is 675 McDonnell Blvd., Hazelwood, Missouri 63042.

Dated: October 14, 2022
Wilmington, Delaware

COLE SCHOTZ P.C.

/s/ Justin R. Alberto
Justin R. Alberto (No. 5126)
Patrick J. Reilley (No. 4451)
500 Delaware Avenue, Suite 1410
Wilmington, Delaware 19801
Telephone: (302) 652-3131
Facsimile: (302) 652-3117
jalberto@coleschotz.com
preilley@coleschotz.com

Seth Van Aalten, Esq. (admitted *pro hac vice*)
Anthony De Leo, Esq. (admitted *pro hac vice*)
1325 Avenue of the Americas
19th Floor
New York, NY 10019
Telephone: (212) 752-8000
Facsimile: (212) 752-8393
svanaalten@coleschotz.com
adeleo@coleschotz.com

-and-

CAPLIN & DRYSDALE, CHARTERED
Kevin C. Maclay, Esq. (admitted *pro hac vice*)
Todd E. Phillips, Esq. (admitted *pro hac vice*)
Jeffrey A. Liesemer, Esq. (admitted *pro hac vice*)
Quincy M. Crawford, III, Esq. (admitted *pro hac vice*)
One Thomas Circle, NW, Suite 1100
Washington, D.C. 20005
Telephone: (202) 862-5000
Facsimile: (202) 429-3301
kmaclay@capdale.com
tphillips@capdale.com
jliesemer@capdale.com
mcrawford@capdale.com

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

In re:	:	Chapter 11
MALLINCKRODT PLC, *et al.*,	:	Case No. 20-12522 (JTD)
Reorganized Debtors.[1]	:	(Jointly Administered)
OPIOID MASTER DISBURSEMENT TRUST II,	:	Adversary Proceeding
Plaintiff,	:	No. 22-50433 (JTD)
v.	:	
COVIDIEN UNLIMITED COMPANY (formerly known as Covidien Ltd. and Covidien plc), COVIDIEN GROUP HOLDINGS LTD. (formerly known as Covidien Ltd.), COVIDIEN INTERNATIONAL FINANCE S.A., COVIDIEN GROUP S.À R.L., and DOE DEFENDANTS 1-500,	:	
Defendants.	:	

COMPLAINT

Plaintiff, the Opioid Master Disbursement Trust II, also known as the Opioid MDT II ("**Trust**"), a statutory trust formed under the Fourth Amended Plan of Reorganization ("**Plan**")[2] of the debtors and debtors-in-possession in the above-captioned chapter 11 cases (collectively,

[1] A complete list of the Reorganized Debtors in these chapter 11 cases may be obtained on the website of the Reorganized Debtors' claims and noticing agent at http://restructuring.primeclerk.com/Mallinckrodt. The Reorganized Debtors' mailing address is 675 McDonnell Blvd., Hazelwood, Missouri 63042.

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

"**Debtors**" and, together with certain nondebtor affiliates, "**Mallinckrodt**"[3]). Under the Plan, the Trust received, among other assets, certain claims and causes of action of the Debtors, *see* Plan art. IV.W.6 at 97, including claims and causes of action arising under chapter 5 of the Bankruptcy Code, which are defined in the Plan as "Assigned Medtronic Claims." *See* Plan art. I.A.56 at 7. The Trust has sole authority to pursue the Assigned Medtronic Claims (*see* Plan art. IV.T. at 90), and the claims and causes of action being asserted in this proceeding are Assigned Medtronic Claims. Accordingly, the Trust files this Complaint against Defendants named above, alleging as follows:

NATURE OF THE ACTION

1. The Trust has commenced this proceeding to avoid and recover the fraudulent transfers described below and to pursue related claims against Defendants named in the caption above. Among other things, the Trust seeks to avoid and recover well over a billion dollars in value that Mallinckrodt's former parent holding companies, collectively "Covidien" (defined below), siphoned out of the Mallinckrodt pharma business in the face of mounting liabilities stemming from Mallinckrodt's prescription opioid drugs. In addition, the Trust seeks to avoid and recover the value of the Covidien business transferred away from Mallinckrodt in connection with Covidien's spinoff of the Mallinckrodt pharmaceutical and medical imaging businesses. Covidien engaged in the spinoff in an attempt to shield its assets from substantial opioid claims arising from Mallinckrodt's conduct that occurred while Mallinckrodt was under Covidien's domination and

[3] In the Bankruptcy Case, the Debtors described their corporate history by using "Mallinckrodt" as a summary term for the Debtors' business that historically has operated under that name, rather than using specific corporate entity names. *See, e.g.*, Declaration of Stephen A. Welch, Chief Transformation Officer, in Support of Chapter 11 Petitions and First Day Motions, at 11 n.5, D.I. 128 ("**Welch Decl.**"). Except where the Trust has additional clear and complete information, the Trust takes the same approach herein. If and when the Trust learns additional relevant information concerning historic corporate transactions, whether through discovery or otherwise, it will provide that detail through amendment of this Complaint or other appropriate means consistent with the rules of procedure or other applicable law.

control. The Trust also seeks to avoid certain spinoff-related obligations that Covidien forced Mallinckrodt to incur through its domination and control of Mallinckrodt.

2. 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 before, during, and after 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.

3. Mallinckrodt is a global pharmaceutical enterprise, which, among other things, is the largest manufacturer and seller of opioid medications in the United States, and one of the largest in the world. While under Covidien's domination and control (and after the spinoff), Mallinckrodt engaged in highly aggressive branded and unbranded promotional activities for its opioid products and opioids generally. It, along with other pharmaceutical companies, engaged in an extensive 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 and resulted in a dramatic increase in opioid prescriptions and addiction to opioid drugs. During this period

Mallinckrodt dominated the generic opioids market, achieving a market share of at least 23.7% of the nationwide opioid market (excluding methadone and buprenorphine) between 2006 and 2014. Indeed, in March 2011, the Drug Enforcement Administration ("**DEA**") called Mallinckrodt "the kingpin within the drug cartel" of pharma companies driving the opioid epidemic.[4]

4. The consequences of flooding communities with opioids was predictable and 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 overdoses involving opioids. Countless more have become addicted or suffered other health 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. Americans became addicted to their prescribed drugs and then were forced to turn to pill mills and street drugs to feed those addictions. The consequences have been so widespread and severe throughout the United States that they are often called the "opioid epidemic" and the "opioid crisis." In addition to its tragic human costs, the opioid crisis has also resulted in staggering financial costs. The financial toll of the opioid epidemic is estimated to be in the trillions.

5. Mallinckrodt played a substantial role in the opioid epidemic. Given its outsized market share, Mallinckrodt's opioids comprised a large percentage of the opioids that were diverted and abused throughout the nation. Through deceptive marketing and willful disregard of its duties to report and block suspicious orders, Mallinckrodt encouraged the widespread and unnecessary overprescribing of its opioids and willfully turned a blind eye to the diversion of

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

opioids to the black market where they could be sold "on the street" for purposes of recreation and abuse.

6. Mallinckrodt faced crushing liability as a result of its conduct. It was subject to government investigations and beset by an "all-consuming tidal wave of litigation" concerning the production and sales of its opioid products and unbranded promotional activities regarding those products.[5] This litigation included claims by diverse groups of plaintiffs, including, among others, individuals who suffered addiction, illness and death as a result of Mallinckrodt's opioids; hospitals and insurance companies burdened with increased expenses associated with opioid-related health problems; and states, municipalities, and tribal governments that have incurred, and continue to incur, hundreds of billions of dollars or more in 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 the Debtors into bankruptcy. Although most of the lawsuits against Mallinckrodt were filed after 2013, the factual predicates for Mallinckrodt's opioid liabilities occurred prior to that time, such that it was reasonably certain that Mallinckrodt was liable for damages in an amount greatly in excess of the total value of the company by at least 2009. In the chapter 11 proceedings before this Court, the Debtors acknowledged claims that Mallinckrodt was insolvent by 2013 – the year it was spun off by Covidien.

7. As detailed below, from June 2007 to June 2013, the Debtors were direct or indirect subsidiaries of Covidien.[6] During this time, certain events occurred that made Covidien

[5] Welch Decl. ¶ 76.

[6] In 2009, Covidien changed its name from Covidien Ltd. to Covidien plc, and after it was acquired by Medtronic plc in 2015, changed its name back to Covidien Ltd.; on March 15, 2022, after filing objections to the proposed disclosure statement and reorganization plan in these chapter 11 proceedings, Covidien Ltd. converted to an unlimited liability company organized and registered under the laws of Ireland, and is now known as Covidien Unlimited Company.

increasingly aware that it was facing enormous civil and criminal liability stemming from opioid pharmaceuticals and Mallinckrodt's sales, marketing, and promotional practices. These events included at least three economic studies being published, starting in 2006, that pointed to tens of billions of dollars in societal harm from prescription opioid dependence and abuse. They included several settlements between governmental entities and other opioid manufacturers and distributors, with settlement amounts in the hundreds of millions of dollars. In 2008, Mallinckrodt's senior compliance manager alerted her superiors that Mallinckrodt was not capable of detecting unusually large or frequent orders for its opioid pharmaceuticals, known as "suspicious" or "peculiar" orders. Internal documents also showed, significantly before 2009, that Covidien was fully aware that its products were being abused and aware of the financial and human consequences of that abuse. Additionally, in late 2011, the DEA subpoenaed Mallinckrodt for documents related to its suspicious order monitoring system.

8. Recognizing the anticipated and escalating liability from Mallinckrodt's opioid pharmaceuticals and promotional practices, Covidien decided in 2010 that it needed to try and protect the assets of its medical supply and device companies from the consequences of its opioid-related conduct. To that end, the Covidien board of directors decided that it would either sell Mallinckrodt and its opioid-related business or spin off Mallinckrodt as a stand-alone enterprise. In either event, Covidien would require the new entity to assume all opioid-related liabilities. In fact, Covidien refused a $4 billion offer for Mallinckrodt, an amount at least $700 million above the value of its assets, because the purchaser would not assume the opioid liabilities.

9. Additionally, Covidien engaged in several fraudulent transfers. First, starting in 2010, it siphoned huge sums of cash out of the Mallinckrodt business, in the aggregate amount of approximately $867 million. Covidien did so not only to enjoy the fruits and benefits of

Mallinckrodt's misdeeds but also to make Mallinckrodt relatively "cash poor" to reduce the recourse that otherwise would be available to opioid claimants. Second, unable to sell Mallinckrodt's pharmaceutical business to a company that would assume its opioid liabilities, Covidien spun off that business to newly formed Mallinckrodt plc to separate the valuable assets comprising Covidien's medical device and supply business from the burgeoning opioid liabilities. (Indeed, Covidien announced the spinoff of Mallinckrodt about two weeks after Mallinckrodt received the aforementioned 2011 DEA subpoena).

10. Moreover, shortly before completing the spinoff, Covidien caused one of its Mallinckrodt subsidiaries, Mallinckrodt International Finance S.A. ("**MIFSA**"), to issue two series of notes that generated proceeds totaling $889.3 million. Covidien received $721 million of the proceeds while Mallinckrodt was ultimately responsible for repayment of the notes. Further, in connection with the spinoff, Covidien shifted hundreds of millions in tax liability onto Mallinckrodt. Covidien also imposed on Mallinckrodt a putative obligation to indemnify Covidien for all opioid-related liabilities.

11. At the time of the fraudulent transfers, Mallinckrodt's liability for its role in the opioid crisis – the worst manmade public health crisis in American history – dwarfed the value of its assets and capital and was far beyond Mallinckrodt's ability to pay. The transfers made by Mallinckrodt to Covidien, and the obligations incurred by Mallinckrodt, were textbook fraudulent conveyances and must be avoided for the benefit of Mallinckrodt's opioid creditors, including the countless individual victims of the opioid epidemic whose lives were devastated by Mallinckrodt's products and conduct.

12. As detailed below, the Trust asserts claims and causes of action against Defendants to avoid and recover as actual and/or constructive fraudulent transfers (a) the approximately $867

million in cash transfers paid to Covidien from 2010 through 2012 for no apparent consideration, (b) the approximately $721 million in Mallinckrodt note proceeds that Covidien kept for itself before completing the spinoff, and (c) the value of the Covidien enterprise (without the Mallinckrodt business) at the time of the spinoff. The Trust also seeks to avoid as fraudulent transfers the pre-spin tax liabilities in the hundreds of millions of dollars that Mallinckrodt was saddled with as part of the spinoff as well as putative indemnification obligations imposed on Mallinckrodt under the spinoff agreement. Additionally, the Trust asserts related claims arising from the aforementioned transactions.

JURISDICTION AND VENUE

13. 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 (collectively "**Bankruptcy Case**").

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

15. This is a core proceeding under 28 U.S.C. § 157(b)(2)(A), (H), and (O).

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

THE PARTIES

I. PLAINTIFF

17. The Trust is a Delaware statutory trust formed under the Plan and in accordance with the Delaware Statutory Trust Act, Del. Code 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. *See* 26 U.S.C. § 468B.

18. The Trust was formed for the benefit of the individuals and entities that hold claims against Mallinckrodt based in whole or in part on its role in creating, perpetuating, and exacerbating the opioid crisis (as defined in the Plan, "**Opioid Claims**" and the holders of such claims, the "**Opioid Claimants**").[7] The Opioid Claimants comprise the individuals, entities, and communities that were harmed by Mallinckrodt's widespread distribution and deceptive marketing of opioid products and of opioids generally. They include individuals who suffered bodily injuries, including addiction, overdose, other sickness and disease, and death due to Mallinckrodt's opioid products and related marketing, and non-Mallinckrodt opioid drugs, licit and illicit, that were used as result of Mallinckrodt's unbranded promotional campaign. They include personal injury claims for babies born with NAS. They also include all states and territories, their political subdivisions,

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

Native American tribes, hospitals, emergency room physicians, insurance ratepayers, and third-party payors.[8] 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 entities that incurred costs because of those bodily injuries. The Opioid Claimants have claimed in the aggregate trillions of dollars, yet will receive on account of their claims only a fraction of their value.

II. DEFENDANTS

19. Defendant Covidien Unlimited Company, formerly known as Covidien Ltd. and Covidien plc (hereinafter referred to as "**Covidien plc**"), is currently an unlimited liability company organized and registered under the laws of Ireland. Covidien plc's principal place of business is located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432, and it has offices and facilities located at 15 Hampshire Street, Mansfield, Massachusetts 02048. At the time of the 2013 spinoff, Covidien plc was the ultimate parent holding company of its enterprise group, and its shares were publicly traded on the New York Stock Exchange. On June 15, 2014, Medtronic, Inc. entered into an agreement to acquire Covidien. On January 26, 2015, Covidien and Medtronic, Inc. became wholly owned subsidiaries of newly formed Medtronic plc ("**Medtronic**") as part of a cash and stock transaction valued at approximately $50 billion. Under that scheme, a wholly owned subsidiary of Medtronic acquired all outstanding shares of Covidien, and Covidien shareholders were issued new shares in Medtronic. Simultaneously with that transaction, Medtronic, Inc. became a wholly owned subsidiary of Medtronic by way of a merger with another subsidiary of Medtronic. Medtronic is a public limited company organized and registered under

[8] 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.

the laws of Ireland. Medtronic's executive offices and principal place of business are located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

20. Defendant Covidien Group Holdings Ltd., formerly known as Covidien Ltd. (hereinafter referred to as "**Covidien Ltd.**"), is a limited liability company organized and registered under the laws of Bermuda and Ireland. Its registered office is located at 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland. At the time of the 2013 spinoff, Covidien Ltd. was a wholly owned subsidiary of Covidien plc and directly or indirectly owned numerous subsidiaries within Covidien plc's enterprise group.

21. Defendant Covidien International Finance S.A. (hereinafter referred to as "**CIFSA**") is a limited liability company (*société anonyme*) organized and registered under the laws of Luxembourg. Its registered office is located at 3b Bd. Prince Henri L-1724 Luxembourg. At the time of the 2013 spinoff, CIFSA was a wholly owned subsidiary of Covidien Ltd. and directly or indirectly owned numerous subsidiaries within Covidien plc's enterprise group.

22. Defendant Covidien Group S.à r.l. (hereinafter referred to as "**Covidien Group SARL**") is a private limited liability company (*société à responsabilité limitée*) organized and registered under the laws of Luxembourg. Its registered office is located at 3b Bd. Prince Henri L-1724 Luxembourg. At the time of the 2013 spinoff, Covidien Group SARL was a wholly owned subsidiary of CIFSA and directly or indirectly owned numerous subsidiaries within Covidien plc's enterprise group. Covidien plc, Covidien Ltd., CIFSA, and Covidien Group SARL are hereinafter referred to, collectively, as "**Covidien**."

23. Each of the Doe Defendants 1-500 is a prospective defendant that, as subsequent discovery may reveal, was involved in the transactions or transfers challenged in this Complaint and/or is a transferee of property involved or affected by such transactions or transfers.

FACTS COMMON TO ALL COUNTS

I. THE OPIOID EPIDEMIC

24. Beginning in the mid-1990s, physicians spurred by aggressive and deceptive marketing and promotional campaigns such as Mallinckrodt's had, contrary to earlier-established medical guidance, prescribed opioid pain relievers for a range of non-cancerous pain conditions. The widespread over-prescription, diversion, and abuse of opioid drugs, and the associated addiction, other injury, and death that followed have devastated lives and communities across the country.

25. 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."[9] More recently, the CDC reported that "[o]verdoses involving opioids killed nearly 69,000 people in 2020, and over 82% of those deaths involved synthetic opioids."[10] In total, between 2000 and 2020, more than 270,000 people died of prescription opioid overdoses in the United States. When looking at deaths involving any opioid, including illicit and prescription opioids, the number increases dramatically to approximately 650,000 deaths from 2000 to 2020.

26. Prescription opioids also have a causal relationship to overdoses from illicit substances. Studies have shown that patients who can no longer obtain prescription opioids turn to illicit substances such as fentanyl-laced narcotics and heroin, which are molecularly similar to opioids. According to the American Society of Addiction Medicine, 80% of people who initiated

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

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

heroin use in the past decade began with prescription opioids.[11] Based on data—including findings that people addicted to prescription opioids are 40 times more likely to become addicted to heroin—the CDC identified prescription opioid addiction as the strongest risk factor for heroin addiction.

27. The opioid crisis in the United States has caused devastating socio-economic fallout. The CDC concluded that in 2017, when more than 47,000 people died of an opioid overdose and 2.1 million people over the age of 12 suffered from opioid use disorder, the opioid crisis cost the United States as a whole $1.02 trillion: $480.7 billion in the value of lives lost; $471 billion in the costs of opioid use disorder; almost $35 billion in health care and opioid use disorder treatment; and $14.8 billion in criminal justice spending.[12] The CDC had previously calculated that prescription opioid misuse alone imposed total economic costs of $78.5 billion each year.[13] In 2018, the Altarum Institute, a nonprofit healthcare research and consulting firm, released a study underscoring the cost of the opioid crisis through 2016 and estimating its growth beyond.[14] The burden of the opioid crisis comes in many forms: lost wages and productivity; increased health care costs; lost tax revenue at the local, state, and federal levels; and higher spending on social

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

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

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

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

services, education, and criminal justice. The Altarum study estimates the socio-economic impact of the opioid crisis between 2001 and 2016 to be $1 trillion.[15]

28. 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.[16] By 2007, it was $60.9 billion and then $95.8 billion in 2016 when the study was conducted.[17] Based on the rapidly escalating costs observed from 2011 to 2016, Altarum estimated that, between 2017 and 2020, the opioid crisis would cause an additional $500 billion in economic harm.[18]

II. MALLINCKRODT'S OPIOID PHARMACEUTICAL BUSINESS

29. From 1996 to 2000, Mallinckrodt was a standalone company without a corporate parent. In 2000, Mallinckrodt became a wholly owned subsidiary of Tyco International Ltd. ("**Tyco**") and one of the primary units in Tyco's healthcare business. In 2007, Tyco separated into three publicly traded companies, including Covidien. As part of this transaction, Tyco's healthcare business—including the development, manufacture, marketing, promotion, and sale of opioid pharmaceuticals—was transferred to Covidien, which became the parent company of Mallinckrodt.

30. 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**"). Mallinckrodt has manufactured, developed, marketed, promoted, or sold opioid pharmaceutical products or opioid APIs since at least 1995. At various

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

[16] *Id.*

[17] *Id.*

[18] *Id.*

times, Mallinckrodt's opioid portfolio included branded opioid products that it manufactured, and marketed, such as Exalgo. Mallinckrodt entered the opioid business decades ago, and obtained a dominant market share. Mallinckrodt's generic opioid portfolio includes both APIs and finished dosage products, including generic versions of oxycodone, hydrocodone, and other well-known opioids. Mallinckrodt's finished dosage opioid products have included the following:

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

31. Mallinckrodt's opioid business was substantial. Indeed, Mallinckrodt became the most significant manufacturer, marketer, and producer of opioid products in the United States as measured by market share. According to the DEA, from 2006 to 2012, Mallinckrodt produced 28.9 billion opioid pills—more than 80 pills for each American.[19] [redacted]

[redacted]

[19] Aaron C. Davis et al., *Little-Known Makers of Generic Drugs Played Central Role in Opioid Crisis, Records Show*, Wash. Post (July 27, 2019), https://www.washingtonpost.com/investigations/little-known-generic-drug-companies-played-central-role-in-opioid-crisis-documents-reveal/2019/07/26/95e08b46-ac5c-11e9-a0c9-6d2d7818f3da_story.html [hereinafter "***Little-Known Makers***"].

[redacted] In some markets, Mallinckrodt had an even larger presence. For example, *The Washington Post* reported that from 2008 to 2012, Mallinckrodt supplied more than 500 million pills across the State of Florida, which accounted for 66% percent of the total opioids sold in the state. At times, over half of all immediate-release oxycodone produced by Mallinckrodt was sold into Florida, despite that state having less than 10% of the U.S. population.

32. With large levels of production and market share, Mallinckrodt and its products had a concomitant role in fueling the nationwide opioid epidemic prior to the spinoff. "Everybody thinks of Purdue when they think about the opioid epidemic," a former DEA supervisor explained.[20] But Mallinckrodt, he said, was up to its "eyeballs in oxycodone, and they [Mallinckrodt] knew exactly what they were doing. Their drugs had become the most popular on the street and they jumped in with both feet."[21] Indeed, Mallinckrodt's 30mg oxycodone tablet, colored baby-blue, was so ubiquitous that the opioid smuggling route from Florida to Appalachia became known as the "Blue Highway."[22]

III. MALLINCKRODT'S MISCONDUCT GIVING RISE TO OPIOID CLAIMS

33. Due to concerns about addiction, opioid pain-relievers had traditionally been reserved for patients with the most serious conditions, such as cancer. But Mallinckrodt's success was driven by concerted efforts by it and others in the pharma industry to persuade prescribers and patients that opioids were in fact safe, effective, non-addictive and appropriate for individuals experiencing virtually any type of chronic pain, when in fact, opioids were dangerous, addictive, and ineffective at treating chronic pain. Mallinckrodt also engaged in deceptive marketing and

[20] *Kingpin*, *supra* note 4.

[21] *Id.*

[22] *Id.*

sales tactics and other wrongful business practices that prioritized increasing opioid prescriptions and corporate profits at the expense of human lives. In September 2008, Mallinckrodt's deceptive marketing and sales efforts caused its profits to skyrocket, and were so successful that they led one Mallinckrodt vice president of sales to refer to Mallinckrodt's growing oxycodone business as a "new economy."

34. Mallinckrodt, both directly and indirectly through advocacy front groups that it sponsored, overstated the benefits of opioid pharmaceuticals generally, particularly for long-term use, while understating associated risks of addiction and abuse. Mallinckrodt made these claims even though it knew them to be false, as demonstrated by its awareness since the early 2000s of scientific studies, articles, government determinations, and other resources linking opioids, including those manufactured by Mallinckrodt, with addiction and abuse.

35. Even as it was directly and indirectly encouraging physicians to overprescribe its opioid products, Mallinckrodt was well aware of the widespread diversion of its products to the black market. It also had the prescriber-level data necessary to (a) identify orders that were likely to be diverted, (b) stop those orders from being shipped, and (c) report suspicious customers to the DEA. Nonetheless, Mallinckrodt failed to design and implement an effective system for doing so, in contravention of its duties under federal and state law. By willfully turning a blind eye to these suspicious orders, Mallinckrodt actively encouraged the widespread diversion and abuse of its products, exacerbating the deadly and costly consequences of the opioid crisis even further.

A. Mallinckrodt's False and Deceptive Marketing of Opioids

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

36. Mallinckrodt commissioned an army of sales representatives to target and develop profitable relationships with prescribers who were willing to liberally prescribe opioids for chronic

pain. [redacted]

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

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

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

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

41. 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, a sales representative in July 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 December 2010 "I am getting more aggressive with asking for the business . . . there should be no excuse not to write Exalgo . . . hungry for scripts, so I am asking for the business more aggressively." Still another sales representative commented in January 2012 that, as part of her action steps to get prescribers to get more Exalgo patients, she would explicitly ask "for 5 new Exalgo patients." [redacted]

42. The pressure Mallinckrodt put on sales representatives was intense and constant, and 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, as to the Exalgo free-trial program referenced above, a Mallinckrodt regional sales director emphasized to his colleagues that "[w]e have to hit home with the representatives that they have NO CHANCE for success if this 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 Mallinckrodt district manager wrote in February 2013, "YOU ARE MAKING ME LOOK BAD. Why can't we get our speakers to use them? Why won't our current customer's 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—k] is going on because I'm lost."

43. Mallinckrodt incentivized its sales representatives to sell as many opioids as possible 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. This led Mallinckrodt sales representatives to use a number of tactics to try to increase prescriptions, ensure those prescriptions would be filled, and meet their high sales quotas. For instance, in the face of pharmacies' reluctance to accept new pain patients due to concerns about opioid misuse, Mallinckrodt sales representatives would work directly with these pharmacies and/or direct pain patients to specific pharmacies to ensure their prescriptions would get filled, a process that in January 2012 Mallinckrodt called "protecting the script."

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

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

45. As far back as the early 2000s, Mallinckrodt was well 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 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 January 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."

46. [redacted]

[redacted] Common objections that sales representatives received concerning Exalgo were that it was too powerful, that it was "just as addicting as Dilaudid[,]"that it was perceived as a desirable street drug, that prescribers were "very concerned with abuse potential," and that there were concerns about "abuse, overdosing, pricing."

47. Nonetheless, Mallinckrodt trained its sales representatives to use misleading reassurances about the purported benefits and low addiction risk of its products to overcome prescribers' concerns. Sales representatives were encouraged to draw distinctions between Mallinckrodt's drugs and other addictive opioids, and to push back on the belief by some prescribers that "hydromorphone [the active ingredient in Exalgo] was more addictive than other ER opioids." 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" in a patient's treatment process.

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

48. In addition, Mallinckrodt encouraged sales representatives to work with prescribers to ensure that, once patients had been prescribed Exalgo, they stayed on the drug and continued to take increasingly higher doses. For example, in January 2012 one district sales manager insisted that sales representatives "MUST ensure that patients stay on Exalgo once prescribed through proper dose initiation and titration." In July 2012, Mallinckrodt 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." As such, "titration," the process of consistently increasing a patient's dosage of opioids over time, was a focus of sales representatives' conversations with prescribers. As one sales representative noted in September 2012, the stronger 32 milligram dose was "the biggest thing we have going for us

right now. For the next 4 weeks, every 32 MG script is double!!!" [redacted]

49. Mallinckrodt pushed dosing higher than consistent with the FDA-approved labels. For example, although FDA-approved labels for Exalgo permitted once-a-day use, a December 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."

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

4. Mallinckrodt Marketed its Branded Opioids as "Abuse-Deterrent," Despite Knowing that These Products Carried High Risks of Abuse

51. Between 2010 and 2013 Mallinckrodt marketed its branded opioid pain reliever, Exalgo, as abuse-deterrent, despite knowing for years that its purported "abuse-deterrent" qualities did not actually deter abuse.

52. Mallinckrodt promoted Exalgo as abuse-deterrent, stating that the "pharmacological and physical properties of . . . [Exalgo's] formulation are performing as designed to make it less susceptible to blood plasma level peaks and troughs and potentially difficult to manipulate." When attempting to overcome wholesalers' caution about shipping Exalgo to pharmacies "due to recent DEA actions," a key talking point Mallinckrodt used was that the drug was not subject to the same level of abuse as oxycodone. Mallinckrodt further stated in marketing materials that "the physical properties of EXALGO may make it difficult to extract the active

ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving." Training materials for sales representatives also describe Exalgo as "specifically designed for gradual release over 24 hours . . . which contributes to steady plasma levels" and having a "barrier to crushing, chewing."

53. Mallinckrodt was acutely aware that its "abuse deterrent" claims were invalid. [redacted][23]

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

[23] Palladone was an opioid manufactured by Purdue Pharma that was the same type of opioid as Exalgo that the FDA halted sales of in 2005, less than a year after it was put on the market, due to the risk of death when the drug was combined with alcohol. Associated Press, *FDA Halts Sales of Painkiller Palladone,* NBC News, https://www.nbcnews.com/health/health-news/fda-halts-sales-painkiller-palladone-flna1C9441709 (July 14, 2005).

55. In December 2009, the company held a meeting of the Exalgo executive advisory board. In attendance were numerous Covidien representatives, including Chuck Bramlage, president of pharmaceuticals; Eddie Darton, director of global drug safety and pharmacovigilance; Ken McBean, vice president and general manager of specialty pharmaceuticals; Rod Novak, director of marketing for specialty pharmaceuticals; and Mike Wessler, product director for specialty pharmaceuticals. The meeting notes indicate that "Exalgo is not intended to resist abuse." Further, "[t]he advisors recommended not overstating the abuse-resistant characteristics of Exalgo, since addicts will find ways to abuse Exalgo. Methods for extracting hydromorphone from Exalgo will likely become common knowledge among addicts within months after launch and be available via internet forums . . . ."

56. In March 2010, a pharmaceutical consultant retained by Mallinckrodt indicated common objections to Exalgo from prescribers that should be addressed, including: "it can be tampered with, and potentially fatal?" and "it is not tamper-resistant, when newer medications have tamper resistant features?"

57. In May 2010, a regional sales director for Covidien specialty pharmaceuticals forwarded an email from a Mallinckrodt sales representative to Mike Wessler, stating that physicians "were surprised and disappointed that Exalgo did not have any kind of tamper proof properties to the product. They felt like the FDA as well as Covidien would have made that a requirement with this product."

58. Mallinckrodt published abuse-deterrent claims for Exalgo even after the FDA concluded in 2010 that Exalgo "will increase the potential risks for overdose or abuse in those seeking to defeat the extended-release system" and predicted that "Exalgo will have high levels of abuse and diversion." Indeed, in subsequent emails, Mallinckrodt employees acknowledged that

the "FDA was originally reluctant to approve this 'strong' of an extended release [EXALGO] hydromorphone (the first ER hydromorphone product) . . . FDA was concerned that abuse could go the way of OxyContin. They actually disallowed approval for the strongest dosage strength we wanted to launch, but approved 4 strengths of 5." [redacted]

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

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

60. Due to opioids' high risk of addiction and abuse, insurance policies often included restrictions designed to limit the amount that a patient could access. These restrictions included coverage and reimbursement limits, as well as "utilization management" strategies such as step therapy, quantity limits, and prior authorization requirements. Mallinckrodt employees routinely worked to bypass those restrictions, often working with health care providers to do so, in order to sell more pills.

61. 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 "[p]hysician push back is vital to our initiative and will support the other tactics that we are applying to effect

change." Another Mallinckrodt employee followed up noting that "[o]ur 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."

62. In May 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."

6. Mallinckrodt Targeted Physicians Known to Be High Opioid Prescribers

63. To sell as many opioids as it could, prior to the spinoff Mallinckrodt targeted physicians known to prescribe opioids in unusually large quantities. Mallinckrodt categorized physicians based on "deciles" and focused its marketing efforts on physicians who would prescribe the largest amounts of opioids without regard to whether those physicians were prescribing opioids responsibly.

64. Mallinckrodt sales representatives were told to grow their business by focusing on "top volume prescribers" and "large accounts" with potential to prescribe significant amounts of opioids. Rather than focus on the kinds of practices where opioid use would be more appropriate—such as cancer pain practices—sales representatives were told to target large practices where the uptake of Mallinckrodt's branded opioids was the fastest, including such diverse practices as podiatry, plastic surgery, and orthopedics.

65. Mallinckrodt sales representatives were also instructed to target their efforts by focusing on physicians 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.

66. The depth of Mallinckrodt's misconduct went well beyond targeting large practices or inappropriate specialties. Mallinckrodt ranked 239 medical professionals as top prescribers of opioids during the height of the pill mill epidemic.[24] Ultimately, more than 25% of those prescribers were convicted of crimes related to their medical practices, had their medical licenses suspended or revoked, or paid state or federal fines after being accused of wrongdoing.[25] In many instances, Mallinckrodt continued working with certain prescribers even after they were suspected of diverting narcotics to the black market.

67. As just one example, in 2010, Mallinckrodt's eastern regional sales director described a New York pain doctor as "the largest C2 [Schedule II] prescriber in NY and one of the biggest in the nation," but added that the doctor was "under a bit of scrutiny." At this time, Mallinckrodt assigned seven people to work on the doctor's account. Mallinckrodt-manufactured opioid pills comprised approximately one-third of the doctor's opioid prescriptions, and Mallinckrodt sales representatives visited the doctor over 100 times. The doctor issued more prescriptions for controlled substances annually than any other prescriber or prescribing entity in New York State, including hospitals. In January 2020, the doctor pleaded guilty to conspiracy to distribute controlled substances and healthcare fraud. The doctor admitted to writing prescriptions without a legitimate medical purpose and that the unlawful conduct began in 2006 and thus lasted

[24] *Kingpin*, *supra* note 4.

[25] *Id.*

the entire period that Mallinckrodt promoted its products to the doctor and worked to make him an "advocate" for opioids.

68. Mallinckrodt was well aware of the dubious prescribing practices of the physicians it was targeting. In February 2012, a district business manager noted Mallinckrodt's low market share in areas with significant numbers of "Opana ER [a competitor to 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." In May 2012, a clinic that represented a Mallinckrodt sales representative's largest extended-release volume was shut down because of "state allegations of being a pill mill clinic," in part based on its involvement with a pharmacy that was "missing 400,000 hydrocodone pills over a 4 yr period." In March 2013, after another sales representative described a success story promoting Exalgo to the largest pain clinic in Knox County, Tennessee—which represented 80% of all OxyContin prescriptions in Knox County—another employee described the clinic as a "big glorified pill mill."

69. [redacted] After another manager shared a success story in March 2012 about a Mallinckrodt sales representative successfully switching a prescriber whose patients "come in bi-weekly for Lortab® refills" to Exalgo, prompting another sales representative to comment, "[t]hey come in bi-weekly for Loratab [sic] refills? . . . Can you say Pill Mill?? I am not sure I would have published this." [redacted]

[redacted]

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

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

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

72. Mallinckrodt used promotional videos, websites, pamphlets, and other materials to encourage physicians to prescribe more opioids. In one particularly notorious example, Mallinckrodt released a video in April 2012 with a reggae-style song encouraging physicians to prescribe ever-higher amounts of opioids, with the lyrics, "You can start at the middle / You can

start at the top / You can start with very little / But that's not where you should stop / Cause your patient needs relief, mon."

73. Between 2006 and 2007, Mallinckrodt sponsored a now-defunct website called "pain-topics.org," which characterized reports of addiction in patients prescribed opioids for chronic pain as misinformation and promoted the concept of "pseudoaddiction"—an unproven and false theory championed by the pharma industry positing that signs of addiction actually reflect undertreated pain and should be addressed with more opioids.[26]

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

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

(b) "[a]ddiction to oxycodone in person without a recent history of alcohol or drug problems is rare";[27]

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

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

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

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

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

(f) "[p]atients' fears of opioid addiction should be dispelled . . . they must be cautioned against reducing oxycodone dosing on their own";[28] and

(g) "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 consensus and perceptions regarding the risks attendant to opioid use.

75. In 2010, Mallinckrodt published its *Opioid Safe Use and Handling Guide: A Resource for Patients*, which, among other false and misleading claims, stated that "[a]ddiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur."[29] The same guide defined "pseudoaddiction" as "[d]rug-seeking behavior that appears similar to addiction but is due to a need for more medication to control pain rather than addiction."[30]

76. These false statements disseminated directly or indirectly by Mallinckrodt 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. Indeed, the CDC's guidelines for prescribing opioids for chronic pain reject the concept of pseudoaddiction.[31]

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[28] *Id.* at 2.

[29] Opioid Safe Use and Handing Guide: A Resource for Patients at 7, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804-DAP (N.D. Ohio Aug. 13, 2019), D.I. 2251-22.

[30] *Id.* at 13.

[31] *CDC Guideline for Prescribing Opioids for Chronic Pain*, CDC, https://emergency.cdc.gov/coca/transcripts/2016/call-transcript-062216.asp (June 22, 2016, 2:00 PM).

77. Likewise, Mallinckrodt's promotion of its opioid products' "patient function" and "quality of life" benefits was deceptive and deliberately ignored public health guidance. Mallinckrodt claimed on its website, for instance, that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society." But this statement directly contradicts positions taken by the FDA and the CDC, which, following a review of scientific studies, issued guidelines concluding that "there is not good evidence that . . . [opioids] improve pain or function with long term use."[32]

78. Ultimately, Mallinckrodt and its industry peers succeeded in persuading prescribers, regulators, and patients that opioids were a safe and effective treatment for chronic pain. By the mid-2000s, nearly every source of information that healthcare providers 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 virtually any type of pain, and prescriptions for opioids skyrocketed. At the same time, Mallinckrodt's failure to detect, stop and report suspicious orders, despite having both a legal obligation and ample opportunities to do so, caused widespread diversion of its opioid products to illicit drug markets around the country. As explained below, this combination of overprescribing and widespread diversion led to a crisis of abuse, addiction and death of historic proportions.

[32] *CDC Guideline for Prescribing Opioids for Chronic Pain*, CDC, https://emergency.cdc.gov/coca/transcripts/2016/call-transcript-062216.asp (June 22, 2016, 2:00 PM).

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

79. Mallinckrodt also recruited and compensated top prescribers, known as "Key Opinion Leaders," to help promote its opioid products (and opioids generally) by speaking at or attending events designed to promote certain opioid products; delivering scripted talks that included false information promoting Mallinckrodt's opioids; drafting misleading studies; presenting deceptive continuing medical education programs; and serving in leadership positions of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy.

80. Mallinckrodt actively promoted the purported benefits of its opioid drugs to and through physicians. Physicians selected for these programs attended trainings hosted by Mallinckrodt and delivered presentations to medical community peers at expensive restaurants and resorts. These payments were vital to Mallinckrodt's ability to win these 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 prescribers in promotional speaking roles.

81. Mallinckrodt was careful to select speakers who would extol the benefits of Mallinckrodt's products and spread its preferred messaging about opioids. For example, one common speaker was described in April 2011 as "frequently instruct[ing] his audiences that there is no ceiling for pain medications" and "believes in Exalgo." To ensure favorable messaging, Mallinckrodt instructed key opinion leaders to use—and not deviate from—slide decks prepared by the company.

82. Mallinckrodt's sales representatives played a major role in organizing Key Opinion Leader events. Mallinckrodt encouraged its sales representatives to organize speaker programs that "[t]arget[ed] physicians who are receptive to using" Mallinckrodt's opioid products. The representatives were encouraged to schedule as many speaker programs as they could. For instance, in a 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. In a June 6, 2013 email, another Mallinckrodt district manager expressed disappointment that his district had "only 10 [speaker] programs on the books for" the latter half of the fiscal year, and instructed sales representatives that if they were "not tracking ABOVE 100% for Exalgo," they should be "scheduling as many of these teleconferences and lunch speaker programs as you possibly can," noting that these efforts were "being watched and tracked not only by me but those much higher than me."

83. 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."

9. Mallinckrodt Used Unbranded Marketing to Encourage Prescribers to Prescribe Opioids for All Kinds of Chronic Pain

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

85. For example, in 2010, Mallinckrodt founded the C.A.R.E.S. Alliance,[33] an advocacy organization whose stated goal was to "promote safe prescribing, dispensing, use, storage, and disposal" of opioid medication. The C.A.R.E.S. Alliance distributed free books and fact sheets for prescribers that contained false and 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 prescribers to help assuage prescriber discomfort with opioids and increase their total opioid prescriptions.

86. In 2012, the C.A.R.E.S. Alliance published and promoted the book *Defeat Chronic Pain Now!*, which was aimed at chronic pain patients. The book was available for sale and

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

promoted online at the now-defunct www.defeatchronicpainnow.com. The book included numerous false claims and representations, including:

(a) "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."[34]

(b) "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."[35]

(c) "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."[36]

(d) "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medication, including medications not used for pain, and is easily remedied."[37]

(e) "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."[38]

(f) "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."[39]

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

[35] *Id.* at 172.

[36] *Id.* at 174.

[37] *Id.* at 175.

[38] *Id.* at 176.

[39] *Id.* at 177.

(g) "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."[40]

(h) "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."[41]

87. These books and fact sheets published by the advocacy organization founded by Mallinckrodt 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 false and misleading concepts like "pseudoaddiction."

88. Another front group sponsored by Mallinckrodt and other opioid manufacturers was the Alliance for Patient Access ("**APA**"). In 2013, the APA published a paper titled *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse* that criticized prescription monitoring programs as overly burdensome. The APA's paper also claimed that policies enacted to police increasingly prevalent pill mills "made it difficult for legitimate pain management centers to operate." The APA's board members received substantial funding from pharmaceutical companies. For example, several board members—Dr. Robert A. Yapundich, Dr. Jack D. Schim, and Dr. Howard Hoffberg—received substantial payments from Mallinckrodt.

89. Another front group connected to Mallinckrodt, the U.S. Pain Foundation ("**USPF**"), made misleading claims regarding risks associated with opioid use, including through false statements published on the group's website. One article published by the USPF criticized

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

[41] *Id.*

as "problematic" opioid guidelines released by the Department of Veteran Affairs and the Department of Defense that, among other things, warned prescribers to exercise caution when prescribing opioids with higher MMEs.[42] Materials published by the USPF also stated that untreated chronic pain creates a risk of suicide and therefore prescribers should not be overly-cautious in prescribing opioids to patients experiencing suicidal ideations.[43]

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

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

91. In addition to its deceptive marketing practices, Mallinckrodt failed to meet its legal obligations to design and implement an effective system to detect and report suspicious opioid orders, *i.e.* those most likely to lead to diversion of its products to the black market to be sold for recreational use and abuse. Among other problems, Mallinckrodt's suspicious order monitoring protocols at various times, (i) relied on a simple numerical formula (based on an order's size relative to the customer's average order) to identify potentially suspicious orders, despite the DEA's clear warnings that reliance on such "rigid formulas" fell short of meeting Mallinckrodt's legal obligations, (ii) unjustifiably exempted Mallinckrodt's largest customers, (iii) required sales personnel to make the initial determination of whether an unusually large order was peculiar enough to warrant further review—an obvious conflict of interest given their conflicting incentives,[44] (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

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

[43] *Id.*

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

orders" by product family, rather than by specific product, which masked increases in orders of particular products that were likely to be abused, (vii) failed to inquire about their customers' own suspicious order monitoring programs, which violated their obligation to "know your customer's customers," (viii) changed the algorithm 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, and (x) allowed shipment of opioids to customers even *after* putting restrictions on them, revealing a "clear gap" in the suspicious order monitoring process.

92. Under the Controlled Substances Act and analogous state laws, Mallinckrodt was required to (a) establish a system designed to detect and investigate suspicious orders of opioids, which were "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency"; (b) refuse to fill suspicious orders; (c) 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 (d) report all suspicious orders to the DEA and certain state agencies. Mallinckrodt failed to meet these legal obligations.

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

94. In 2008, the DEA reminded Mallinckrodt that pursuant to "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."

95. The DEA also provided Mallinckrodt with compliance training and materials to assist it in meeting its legal obligations. A Mallinckrodt report from an April 2011 DEA seminar repeats this mantra: "Again, 'know your customer's customer' was mentioned extensively. DEA is working their way back up the supply chain as part of their investigations." Mallinckrodt advertised on its own website that it "address[ed] diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances."[45] Despite all this, Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported, and instead continued to fill suspicious orders and supplied more opioids than were justified, leading to widespread diversion and abuse.

96. Between April 2007 and June 2013, Mallinckrodt was well aware that its products were being diverted and abused, and that there was a significant risk of government enforcement actions as a result, yet it continued to adopt a cavalier attitude toward its suspicious order monitoring obligations. In April 2007, a Mallinckrodt compliance manager circulated an article about the DEA's halting of AmerisourceBergen shipments to Florida, with a warning that a similar DEA enforcement action could happen to Mallinckrodt, and a note that "sometimes we are met

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

with internal pushback and the attitude that we are 'such big players' that DEA would never suspend our license."

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

98. Mallinckrodt's pills made up a stunningly high percentage of opioid supply for certain customers that distributed opioids in 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 large percentage of those drugs to Florida. [redacted]

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

100. In addition to this macro-level data, Mallinckrodt possessed robust, customer-level data enabling it to detect and report suspicious orders but failed to adequately report and stop suspicious orders consistent with its obligations. [redacted]

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

101. Despite having data at its fingertips that it could readily use to monitor, track, and prevent suspicious orders, Mallinckrodt's suspicious order monitoring program was ineffective, and Mallinckrodt's managers knew that it was so. As early as 2008, Karen Harper, a senior manager for controlled substance compliance at Mallinckrodt, alerted her superiors that Mallinckrodt was not capable of detecting suspicious orders and that its suspicious order monitoring system required updating.[46] In a later deposition, Karen Harper testified that she did not believe adequate measures were taken to correct the issues she identified and reported. She stated that one of the reasons behind the need to upgrade the system was guidance letters from the DEA that Mallinckrodt received in 2006 and 2007, which provided guidance for effective implementation of a suspicious order monitoring system.

102. Other individuals within Mallinckrodt were aware of the issues with diversion.

103. Moreover, according to the DEA, the reliance on a numeric formula to identify suspicious orders failed to maintain effective controls against diversion.

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

[redacted]

104. Despite this previous warning from the DEA, Mallinckrodt used a strict formula to detect suspicious orders. According to a former employee the algorithm used by Mallinckrodt to identify suspicious orders had gaps that made it possible for problematic orders to get through.

[redacted]

Howard Davis, a former DEA diversion program manager hired as a consultant by Mallinckrodt to assess its suspicious order monitoring program, was severely critical of Mallinckrodt's reliance on a formula, and warned that by doing so, Mallinckrodt "would be unnecessarily exposing itself to potential liability." Despite knowing from multiple sources that primarily using a strict formula was insufficient, Mallinckrodt continued to rely exclusively on a formula to identify suspicious orders.

105. Even when Mallinckrodt did detect suspicious or peculiar orders, it neither investigated nor stopped them from being filled. Between 2003 and 2011, Mallinckrodt shipped more than 53 million orders of opioid products.[47] During this time period, Mallinckrodt's suspicious order monitoring program formula—such as it was—identified 37,817 orders as

[47] Scott Higham et al., *Internal Drug Company Emails Show Indifference to Opioid Epidemic*, Wash. Post (July 19, 2019), https://www.washingtonpost.com/investigations/internal-drug-company-emails-show-indifference-to-opioid-epidemic-ship-ship-ship/2019/07/19/003d58f6-a993-11e9-a3a6-ab670962db05_story.html.

potentially suspicious. But, during this time frame, Mallinckrodt appears to have stopped and reported at most 33 orders out of 53 million.[48] [redacted]

106. The Mallinckrodt sales force, also known as national account managers ("**NAMs**"), responsible for selling generic opioids, was given key roles in investigating suspicious orders and had authority to clear them. According to Karen Harper, Mallinckrodt's manager of controlled substance compliance, the NAMs were the "eyes and ears and boots on the ground" for the compliance department. But this assignment of roles and responsibilities overlooked the fact that the compensation scheme for NAMs favored sales over compliance. The bonuses for the NAMs were based on sales volume, and could exceed $100,000 per year. In contrast, there is no indication that the NAMs were assessed based on their compliance responsibilities, or that the NAMs were ever disciplined for failing to stop suspicious orders. To the contrary, the NAMs were recognized to be as "advocates" for their distributor customers, as opposed to "boots on the ground" with a responsibility for stopping diversion.

107. Mallinckrodt was warned against using sales representatives to carry out its compliance functions. [redacted] In fact, documents demonstrate that Mallinckrodt cleared and fulfilled suspicious orders not because it had determined that they would

[48] *Id.*

not be diverted, but to keep the "momentum rolling" with a customer or allow the customer to secure favorable pricing.

108. In addition, Mallinckrodt's own consultants recognized that its suspicious order monitoring procedures were grossly inadequate. One consultant concluded in 2010 that Mallinckrodt's suspicious order monitoring procedures did not meet DEA standards and were in need of "immediate revision." That same year, a Mallinckrodt employee asked if the program was up and running and wrote, "I know that I should not submit [a suspicious order monitoring report] to DEA because it includes Distributors and such." And a year after that, Mallinckrodt's vice president of retail sales was not even aware of the suspicious order monitoring checklist process, although it had been purportedly been in place for two years. Additionally, in 2010, in response to an unusually large order of oxycodone for a distributor that had gone through Mallinckrodt's system, Ginger Collier, senior director of marketing for specialty generics, replied to Karen Harper, "YIKES! I guess this is why you have a team pulled together to improve our process."

109. But the "process" was not improved. Indeed, in some respects it was undermined. In 2010, Karen Harper removed from a suspicious order monitoring customer questionnaire a question regarding whether Mallinckrodt's direct customers monitored subsequent purchasers of opioids. This question was removed despite specific guidance from the DEA that it expected Mallinckrodt to monitor its "customer's customer." Additionally, that same year, Mallinckrodt changed an algorithm for flagging suspicious orders, from those twice as large as the average from the previous year to those three times as large, because there were too many orders to review.[49] By altering the algorithm, Mallinckrodt believed there would be fewer reports for the suspicious order monitoring team to examine.

[49] *Little-Known Makers*, *supra* note 19.

110. Despite these known problems, Mallinckrodt declined to hire an outside vendor to enhance the suspicious order monitoring system.[50] In fact, in a September 30, 2010 email to Karen Harper, Bill Ratliff, Mallinckrodt's director of security, admitted: "[Before 2010] [t]here was an existing program, but it did little to truly monitor suspicious orders," and that employees would take shortcuts when DEA regulations were "inconvenient."

111. Predictably, numerous failures to control suspicious orders occurred under this inadequate system. An example of Mallinckrodt's failure to control suspicious orders occurred in 2009, when a private shipment of opioids was sent to a former employee's aunt; one employee questioned the shipment, "this equates to 50 tablets per day. Is that even possible?" Also in 2009, after American Pharmacy Solutions placed a suspicious order, Mallinckrodt employees emailed that "it makes it difficult to not ship when Nick [the global director of bulk narcotics] told them we would." In yet another failure of the suspicious order monitoring program, Mallinckrodt did not put any provision or procedure in place to address a circumstance where a customer had not provided proof of a DEA license renewal.

112. Despite being aware of the widespread problem of opioid diversion (and the legal consequences that could result), to keep its sales high Mallinckrodt frequently turned a blind eye to customers who were ordering large amounts of opioids for purposes of diversion. For example, beginning in 2008, Mallinckrodt employees noticed that one of its new Florida customers, Sunrise Wholesale, was placing unusually large orders, such as 2,520 bottles of oxycodone 30mg tablets. At the time, Mallinckrodt employees commented that Victor Borelli, the manager with the Sunrise account, would "tell . . . [Sunrise] anything they want to hear just so he can get the sale." Later

[50] Eliza Ronalds-Hannon et al., *Mallinckrodt Mulls Restructuring as a Major Opioid Trial Nears*, Bloomberg News, https://www.bloomberg.com/news/articles/2019-09-04/opioid-maker-mallinckrodt-taps-restructuring-firms-as-suits-loom?leadSource=uverify%20wall (Sept. 5, 2019 12:32 PM).

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 raised to 3,000 bottles of 15mg oxycodone tablets per month and 12,000 bottles of 30mg oxycodone tablets per month.

113. In July 2009, Bill Ratliff, Mallinckrodt's director of security, was advised by a police officer in Tennessee that Mallinckrodt oxycodone tablets from Florida were found during the course of an investigation in his jurisdiction. Upon investigation, Ratliff traced this product back to Sunrise and concluded that there were "no reported losses" of product from Sunrise, which could mean that Sunrise is "involved" in the diversion of the oxycodone product.

114. Mallinckrodt continued to ship its products to Sunrise, even as the DEA began investigating Sunrise for supplying opioids to pill mills. During this time, 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." Ultimately, Sunrise's DEA license was suspended in June 2010. Mallinckrodt's product manager Kate Muhlenkamp explained, "we are under the impression that . . . [the suspension] is . . . due to the sale of Oxycodone in the state of Florida."

115. At approximately the same time Sunrise's license was suspended, the DEA also suspended the license of Harvard Drugs, another of Mallinckrodt's major Florida customers, as a result of its improper practices related to "the sale of Oxycodone in the state of Florida." Harvard's large orders "had not met or exceeded the excessive quantity calculation for Oxycodone sales" in Mallinckrodt's deficient suspicious order monitoring system, so Mallinckrodt failed to detect and

prevent these orders. [redacted]

116. In October 2010, Karen Harper wrote that neither Sunrise nor Harvard triggered the algorithms for direct customers because Mallinckrodt was "looking at overall purchase trends for each distributor, not reviewing where the distributors were sending . . . [the] product." Harper wrote that "during the last two years, all Peculiar Orders that were on [Mallinckrodt's daily suspicious order monitoring reports] were . . . deemed to be okay 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." These facts, and the examples of Sunrise and Harvard, highlight the woeful inadequacies of Mallinckrodt's suspicious order monitoring program due in part to their manipulation of the algorithm in order to thwart their reporting obligations to the DEA.

117. Shortly after Sunrise and Harvard had their licenses suspended, 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 "[i]f the state of Florida were to right-size [*i.e.*, correct its massive problem of 'pill mills' and illegal diversion], this has huge financial implications." The manager was promptly warned by David Silver, vice president of strategy and portfolio management, to "limit email discussion" of the topic to avoid putting these incriminating facts—that widespread diversion of its products was generating massive profits for Mallinckrodt—in writing.

118. Meanwhile, the parade of red flags continued. In an internal 2010 report on one of its customers, distributor Masters Pharmaceutical, Mallinckrodt noted that Tru Value Drugs, one of Masters' pharmacy customers, had signs indicating "cash only sales" to purchase Mallinckrodt

oxycodone. After receiving a letter from Mallinckrodt in November 2010, Masters cut off its sales to Tru Value. Mallinckrodt wrote that "Masters may not be acting upon the information obtained about customers from on-site pharmacy inspection reports or documentation gathered such as a 'Drug Dispensed' listing." Later, in 2011, Masters received two shipments of a significant amount of oxycodone inventory even after Mallinckrodt put shipping restrictions on it. Mallinckrodt employees acknowledged that this oversight revealed a "clear gap" in Mallinckrodt's suspicious order monitoring process. Masters eventually made the decision to "greatly curtail" shipments to Florida for oxycodone "because they saw a lot of red flags when visiting a bunch of clinics."

119. Despite these issues, Mallinckrodt halted shipments of oxycodone to Masters (and several other problematic customers) for only a few weeks before resuming sales in January 2011. Mallinckrodt later reached out to another customer, Keystone, regarding the high sales in Florida and expressly requested that Keystone not sell to certain pharmacies that ordered large quantities, but did not stop shipping orders to Keystone.

120. Despite the growing problems caused by the failures of Mallinckrodt's suspicious order monitoring program, Mallinckrodt avoided proactively addressing this issue with its customers during the sales process, preferring to focus on aggressively selling opioids rather than ensuring compliance with legal requirements. In 2011, a Mallinckrodt employee circulated an article describing increasing demand for high-dose, pure oxycodone following Purdue's release of an abuse-deterrent form of OxyContin. The employee commented, "I think it supports our suspicions in regard to the increased usage of the Oxy 30mg." These "suspicions" were that increasing demand for Mallinckrodt's generic oxycodone products were being driven by abusers and addicts who could no longer access easy-to-abuse OxyContin. These "suspicions" were further confirmed that same year, when Mallinckrodt was informed by the Department of Justice

that 30 mg oxycodone tablets had replaced the old formulation of OxyContin 80 mg tablets as the main illicit drugs on the streets in New England, and had "gained wide acceptance by New England Rx opiate abusers who refer to them as 'perc 30s'"; this led one controlled substance compliance manager to tastelessly joke that he would soon be out of a job. 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]."

121. Indeed, the high demand for Mallinckrodt's generic opioids in the black market was public knowledge. At one point, Mallinckrodt's drug was so popular on the street that a pharmacist at a McKesson trade show suggested that Mallinckrodt remove the "M" from the tablets to make them less recognizable. In 2012, the sales group noted that suspicious order monitoring discussions were not a topic sales representatives "should proactively bring to the table" and that they needed to "maintain an appropriate distance between sales and this Regulatory activity."

122. At the same time that Mallinckrodt was failing to implement an effective suspicious order monitoring system, Mallinckrodt was also aware that other opioid manufacturers, distributers, and sellers were facing significant liability and penalties as a result of their failure to prevent diversion. In 2009, Mallinckrodt sales representatives were aware of a $5 million DEA settlement with Rite Aid for opioid misconduct, a $13 million settlement by McKesson for failing to report suspicious sales, and other fines levied against Cardinal Health. In 2010, Mallinckrodt sales personnel discussed the fact that the DEA was making visits to opioid distributors, that the visits were seen as "warnings," and that Mallinckrodt could not "afford to be on the wrong side of the DEA." In 2011, Mallinckrodt was aware that the DEA suspended the licenses of KeySource, a Mallinckrodt customer, because of opioid diversion and abuse, and in 2012, it was aware of

government enforcement actions against CVS and AmerisourceBergen arising from opioid misconduct, and DEA raids on pharmacies.

123. By 2009, 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, "[w]e are very aware of the multi-million dollar fines levied against Cardinal Health and McKesson for not being diligent with regard to sales."

124. In 2011, McKesson asked Mallinckrodt to manufacture a 500-count bottle of oxycodone, but Mallinckrodt noted that "the DEA may not look kindly" on "a lot of pills for a very powerful (and abused) drug." Similarly, in 2012, Mallinckrodt employees discussed how Walgreens was "burning thru their Florida DC inventory" but that they may repurchase in smaller quantities for Florida, "just in case the DEA comes in to lock it up."

125. 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 Department of Justice and DEA determined that Mallinckrodt ignored its responsibility to report suspicious orders of as many as 500 million of its pills that were sent to Florida from 2008 to 2012, which was 66% of all oxycodone sold in the state. According to *The Washington Post*, an internal summary of the

federal case against Mallinckrodt found that "Mallinckrodt's response was that 'everyone knew what was going on in Florida but they had no duty to report it.'"[51]

126. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's 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.'"[52]

127. Among the allegations resolved by the settlement, the federal government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances - orders that are unusual in their frequency, size, or other patterns. . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[53]

128. Additionally, based on its investigation, the DEA claimed that Mallinckrodt "sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets,

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

[52] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[53] *Id.*

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 the suspicious orders in violation of the CSA."[54]

129. The Mallinckrodt settlement agreement with the DEA sets forth additional allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

i. conduct adequate due diligence of its customers;

ii. detect and report to the DEA orders of unusual size and frequency;

iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

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

iv. use 'chargeback' information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[55]

130. In connection with the settlement, Mallinckrodt admitted that "[a]s a registrant under the . . . [Controlled Substances Act], Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[56] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product."[57] Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[58]

131. Mallinckrodt's failure to detect 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, exacerbating the crisis of abuse and addiction that overprescribing of opioids was already causing.

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55 *Id.* at 2-3.

56 *Id.* at 1.

57 *Id.* at 4.

58 *Id.*

IV. COVIDIEN'S DOMINATION AND CONTROL OF MALLINCKRODT AND OPERATION OF ITS SUBSIDIARIES AS A SINGLE ECONOMIC ENTERPRISE

132. Prior to—and up to—the spinoff, Covidien and its various subsidiaries, including Mallinckrodt, operated as a single economic enterprise. Covidien's Massachusetts headquarters provided shared corporate services for Covidien and many of its U.S.-based subsidiaries, which shared assets used to manage the enterprise as a whole, including information technology, finance, human resources, corporate compliance, communications, and government affairs functions. Most of Covidien's employees, operations, and primary business activities were conducted in the United States, and the vast majority of its revenues came from the U.S. market.

133. During the relevant period, the Covidien enterprise (including Mallinckrodt) continued to operate as a fully integrated enterprise and to maintain an organizational structure that consolidated the design, manufacturing, marketing, sales, promotion, supply, reporting, compliance, administration, and cash management functions of the entire Covidien enterprise into a single, unified economic entity.

134. Covidien plc directed and controlled the other entities, including Mallinckrodt, and developed sales, marketing, and business strategies for the entire enterprise. Covidien plc's articles of association under the Irish Companies Act made clear that its role was to direct, control, and manage the entire enterprise as one united business. The articles of association, dated January 16, 2009, stated that Covidien plc's role was to "co-ordinate the administration, finances and activities of any subsidiary companies" and "direct or coordinate the management of other companies or of the business, property and estates of any company or person and to undertake and carry out all such services in connection therewith as may be deemed expedient."

135. In late 2011 or early 2012, Covidien selected Mark Trudeau to be in charge of the Mallinckrodt pharma business going forward, and Trudeau joined Covidien in February 2012 (after

the spinoff was announced). From the start, Trudeau understood that he would be Mallinckrodt's CEO after the spin. Prior to the spinoff, Trudeau was employed by Covidien and described his title as the president of the "Mallinckrodt pharmaceutical division." He explained that the spinoff was "driven very distinctly from Covidien." Trudeau believed that Mallinckrodt had a market capitalization of $2 billion at the time he joined Covidien.

136. Prior to the spinoff, the entire Covidien enterprise functioned as a combined unit, which presented challenges to spinning off Mallinckrodt. [redacted]

137. Even after the spinoff, Covidien continued to provide worldwide finance, accounting, treasury, customer service, supply chain planning, sales, information technology, and global sourcing among other services to Mallinckrodt entities for months in accordance with the Transition Services Agreement (an agreement executed between Covidien plc and Mallinckrodt plc where Covidien plc agreed to provide designated services to Mallinckrodt plc immediately after the spin). On information and belief, Covidien plc provided substantially similar shared services to its various entities, including Mallinckrodt, at all times prior to the spinoff.

138. Between June 2007 and June 2013, Covidien plc and its direct and indirect subsidiaries were managed by the board of directors of Covidien plc. Covidien plc's board received reports concerning and exercised control over the day-to-day affairs of the businesses and all of the subsidiaries' finances, revenues, transfer, sale and assignment of assets, assumption of debt, strategy, vision, policies, business practices, marketing, reporting, budgets, management compensation, and equity awards. Covidien plc's board also received reports concerning and exercised control over pharmaceutical sales and marketing strategies, including by implementing programs to review and approve product-specific materials; presentations and external communications; monitoring how approved promotional materials were used by particular subsidiaries on a daily basis; and keeping track of the expenses of the subsidiaries' sales representatives. Covidien plc's board received detailed updates about the marketing and sale of opioid products. Covidien plc's board also exercised ultimate control over the financing of the entire Covidien enterprise, including Mallinckrodt, and used earnings from the operations of its U.S. and foreign subsidiaries to fund its own overhead, administrative, and shared services costs.

139. Covidien plc and its board were responsible for monitoring and managing the risks the entire company faced, including liability related to the manufacturing, marketing, sale, promotion, and distribution of opioids. Indeed, Covidien plc's Form 10-Ks for the time period between June 2007 and June 2013, among other things, identified products liability and other actions against Mallinckrodt as risks to the company.

140. Covidien plc filed 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. Segment reporting also allowed Covidien plc's board and officers to exercise

control over the entire enterprise by determining how business segments were constructed, what business metrics were reported, and how resources were allocated across the enterprise.

141. Consistent with its conception as a unified business, Covidien plc routinely commingled funds and assets among its various entities through intercompany transfers. For example, Covidien plc maintained an integrated cash management system that revolved around two cash pools, one for its U.S. entities and one for its foreign entities. Covidien used these cash pools to collect substantially all revenue of participating subsidiaries, including Mallinckrodt. Cash was periodically collected from the participants through manual sweep, at which time the participating entity received a claim against the pool in the amount of its deposit. The cash was then distributed from the pools to the various Covidien entities as necessary to meet their needs regardless of the source of the cash. Through these mechanisms, cash was shared freely among the various Covidien entities.

142. Covidien plc also owned all or a significant majority of its subsidiaries' stock, including the stock of Mallinckrodt, and made the ultimate decisions about Mallinckrodt, including the decision to spin off the Mallinckrodt business, the segments that the spinoff would include, and the amount of capital and debt that Mallinckrodt would hold following the spinoff.

143. Covidien plc and its various subsidiaries (including Mallinckrodt) at all times acted as a single, unified enterprise. Even when employees worked for a Mallinckrodt entity, they indicated that they ultimately worked for Covidien (or worked simultaneously for the entities). Prior to the spinoff, employees working on opioid issues had email signatures that identified them as employees of either Covidien or both Covidien and Mallinckrodt. For example, Karen Harper's email signature stated "Senior Manager, Controlled Substances Compliance Group, Mallinckrodt/Covidien Pharmaceuticals." Sales representatives and sales managers for branded

opioids were identified in their email signatures as employees of "Covidien Specialty Pharmaceuticals." Employees who were identified as being a part of "Medical Affairs, Covidien" monitored drug abuse and referred to "Covidien employees" generally. Covidien and its subsidiaries shared common officers and employees, many of whom signed documents on behalf of multiple entities.

144. Accordingly, for the entire Covidien enterprise, there were shared employees, shared managers and supervisors, integrated sales and distribution systems, and a commonality of officers or directors.

145. Moreover, in 2010, the Covidien name and brand was used in connection with opioid sales marketing materials, demonstrating a commonality of corporate insignias and logos regardless of corporate boundaries. Additionally, pre-spin training materials from the C.A.R.E.S. Alliance included both Covidien and Mallinckrodt branding, and the training materials stated that the information was "for Covidien training purposes only." The same was true for an Exalgo communication plan from May 2012, which stated it was from the "Covidien Publication Team." These acts demonstrate common branding, marketing, and control over opioid products, and fail to distinguish between the various Covidien entities.

146. Through these mechanisms and others, Covidien dominated the finances, policies, and business practices of Mallinckrodt, so that the Debtors had no separate existence of their own. Thus, the Debtors were alter egos of Covidien and their non-pharmaceutical affiliates and/or were mere instrumentalities of Covidien. As such, the corporate separateness of the Debtors, Covidien, and their non-pharma affiliates should be disregarded.

V. COVIDIEN'S AWARENESS OF ITS OPIOID-RELATED LIABILITY

147. Prior to the spinoff, Covidien and Mallinckrodt were both acutely aware of Mallinckrodt's wrongful conduct and of the enormous financial consequences of that conduct.

Numerous studies had been widely publicized that demonstrated that the harm caused by the opioid epidemic was in the hundreds of billions of dollars. Details of the human, societal, and financial costs of prescription opioid use were widely publicized. Governmental fines and settlements relating to opioid-related conduct were public knowledge. Further, internal documents show not only was this information in the public arena, it was circulated within Mallinckrodt and Covidien. By November 2011, Mallinckrodt had received a subpoena from the DEA, demanding documents related to its suspicious order monitoring program. Within weeks of the subpoena, Covidien had decided to spin off its Mallinckrodt business in an attempt to avoid its opioid liabilities.

A. Public Information on Opioid Liabilities Before the Spinoff

148. In August 2004, doctors from the University of Wisconsin-Madison presented a study that showed the trends in the medical use and abuse of frequently prescribed opioid analgesics including oxycodone from 1997-2002.[59] The study showed that oxycodone usage increased by over 400% and abuse increased over 346% between 1997 and 2002.[60] The College on Problems of Drug Dependence noted that, as of April 1, 2003, "the prevalence of prescription opioid abuse appears to be similar to that of heroin and cocaine."[61]

149. In 2006, Howard Birnbaum and his coauthors published an economic study in the *Clinical Journal of Pain* estimating $8.6 billion of quantifiable societal harm from prescription opioid dependence for the year 2001.[62] It found that prescription opioid dependence generated

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

[60] *See id.*

[61] *Id.* at 215.

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

substantial health care costs ($2.6 billion), criminal justice costs ($1.4 billion), and workplace costs ($4.6 billion).[63]

150. In 2007, 26 states and the District of Columbia settled certain investigations into Purdue Pharma's aggressive and deceptive marketing of its opioid pain relievers, most notably OxyContin, for $19.5 million.[64] The investigations alleged that Purdue pushed prescribers to advise patients to take OxyContin every 8 hours instead of the 12-hour doses approved by the FDA.[65] The settlement required Purdue to implement further internal controls and to stop basing bonuses solely on the volume of OxyContin prescribed.[66] Reporting at the time noted that OxyContin "can be highly addictive," and "can produce a heroinlike high if crushed and then swallowed, inhaled or injected."[67]

151. Also in 2007, Purdue Frederick Company, an affiliate of Purdue Pharma, pleaded guilty to one felony count of misbranding OxyContin, with the intent to defraud or mislead.[68] Three corporate officers also pleaded guilty to a misdemeanor charge of misbranding, solely in their capacity as responsible corporate officers.[69] Among other things, Purdue Fredrick Company admitted that from 1995 to 2001 it "marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications," despite knowing that these claims were untrue.[70] As part of the plea agreement,

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63 *Id.*

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

65 *Id.*

66 *Id.*

67 *Id.*

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

69 *Id.* at 2.

70 *Id.*

Purdue Frederick agreed to pay over $600 million in fines and various other payments to settle related civil claims, one of the largest monetary sanctions imposed in the history of the pharmaceutical industry at that time.[71] The Purdue guilty pleas and settlements were national news and followed closely by those in the opioid industry.

152. In 2011, Ryan Hansen and his coauthors published an economic study in the *Clinical Journal of Pain* that estimated $53.4 billion of quantifiable societal harm from prescription opioid dependence for the year 2006.[72] Among other things, the study estimated that $2.2 billion went to substance abuse treatment, including for hospitals, physician services, and substance treatment facilities.[73] Deaths from opioid poisoning resulted in $12.4 billion in lost productivity, and unemployment and sub-employment that resulted from opioid abuse generated $14.7 billion in costs.[74] Incarceration accounted for $14.8 billion of the cost, while other criminal justice costs accounted for $8.8 billion of the total.[75] This study cited the 2006 Birnbaum study and noted that its increased estimate was largely "attributable to inflation and to the considerable increase in the prevalence of nonmedical use of prescription opioids during the period 2001 to 2006."[76]

153. In 2011, Howard Birnbaum and his coauthors published another economic study that estimated $55.7 billion of quantifiable societal harm from prescription opioid dependence for the year 2007.[77] The study concluded that in 2007 alone, lost workplace productivity accounted

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

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

[73] *Id.* at 197.

[74] *Id.*

[75] *Id.* at 198.

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

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

for $25.6 billion, health care costs accounted for $25.0 billion, and criminal justice costs accounted for $5.1 billion.[78] Included in lost workplace productivity were the costs of premature death ($11.2 billion) and lost wages or employment ($7.9 billion), among other costs.[79] The study noted that, in 2007, "12.5 million Americans had used prescription pain relievers for nonmedical purposes" and "that the number of patients admitted to substance abuse treatment facilities due to nonheroin opiate/opioid abuse nearly quadrupled from 23,000 to more than 90,000 from 1999 to 2007."[80] However, the study focused only "on costs of patients diagnosed with opioid abuse" and did "not account for *undiagnosed* opioid abuse."[81] The study concluded that "it is clear that the costs of opioid abuse have increased substantially due to changes in the prevalence of opioid abuse and associated costs."[82] Both of these studies were well known in the opioid industry.

154. By 2011, at least eight settlements totaling approximately $750 million were reached between governmental entities (specifically state governments and the Department of Justice) and certain opioid manufacturers and distributors. In addition to the well-publicized settlements with Purdue, those settlements included the following:

(a) In 2008, Cardinal Health agreed to pay $34 million in fines for failure to report suspicious orders.[83]

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78 *Id.*

79 *Id.*

80 *Id.* at 657.

81 *Id.* at 658.

82 *Id.* at 662.

83 Mary Beth Rhodes, *A Brief History of the Opioid Crisis and Current Environment*, Hanover, https://www.hanover.com/businesses/business-customer-resources/hanover-risk-solutions/brief-history-opioid-crisis-and (last visited Oct. 3, 2022).

(b) In 2008, McKesson agreed to pay a $13.25 million civil penalty for failure to properly monitor and report suspicious orders.[84]

It had become evident that the number of lawsuits and enforcement actions were increasing throughout the industry.

B. Mallinckrodt and Covidien Had Actual Knowledge of the Extent of Their Future Opioid Liabilities

155. In addition to information in the public domain and generally known by Covidien and Mallinckrodt, and throughout the opioid industry, numerous documents demonstrate that the officers and executives of Covidien and Mallinckrodt had actual knowledge of their wrongful conduct and the full extent of the companies' opioid-related liabilities prior to the date of the spinoff.

156. Covidien and Mallinckrodt were well aware of their opioid products' significant potential for addiction and abuse. Initial reports of abuse and diversion of OxyContin, Purdue's extended-release opioid product, began to circulate as early as 2000, [redacted]

157. In 2009, a "Covidien Daily News Report" was circulated throughout Covidien by email. It contained information on "Covidien Corporate News" and "Covidien Competitor News." The September 22, 2009 Covidien Daily News Report included a Reuters report entitled: "US FDA staff see potential to abuse Covidien drug." The article states that "Covidien's . . . experimental, longer-lasting opioid pain drug [Exalgo] is prone to abuse and overdose as it can easily be crushed

[84] Press Release, U.S. Dep't of Justice, McKesson agrees to pay record $150 million settlement for failure to report suspicious orders (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

by biting the tablet, according to U.S. Food and Drug Administration staff reviewers." On September 23, 2009, JoAnne Levy, Covidien's vice president, global logistics, forwarded the Covidien Daily News Report to George Saffold, director of global customer service; Karen Harper, senior manager of controlled substance compliance; Michael Pheney, director of global supply chain operations; Carla Johnson, director of supply chain planning, and Susan Moore, director of financial analysis at Covidien. She directed their attention to the Reuters article and stated "doesn't sound good."

158. On July 9, 2009, Mallinckrodt was named in a Tennessee drug task force sting operation. In response to the task force's inquiry about the source of illegally diverted oxycodone, Mallinckrodt stated that one of its Florida distributors, Sunrise Wholesale, initially provided the drugs to Dr. Barry Schultz, a Florida physician who prescribed the drugs at issue. As part of its own investigation, the DEA discovered that Schultz prescribed 1,000 oxycodone tablets to one patient in a single day, and that Sunrise distributed at least 92,400 oxycodone tablets to Schultz in just 11 months. Even more stunning, the DEA learned that Mallinckrodt shipped another 2.1 million oxycodone tablets to Sunrise after Mallinckrodt was informed about the 2009 sting operation and, therefore, indisputably knew about Sunrise's unlawful distribution practices. As the DEA explained in a letter to Mallinckrodt: "When Mallinckrodt continued to distribute oxycodone to Sunrise for such purposes, and continued to pay incentives in the form of chargebacks for the product sales to Barry Schultz, *Mallinckrodt was diverting oxycodone*."[85]

159. Mallinckrodt monitored news stories relating to its Exalgo product and generated a "Exalgo Media Monitoring Report." The January 22, 2010 Exalgo Media Monitoring Report

[85] Joe P. Leniski, Jr., *Taking A Drug Epidemic to Court: Tennessee's Drug Dealer Liability Act* (DDLA) at 7.

described a recent article in the *Annals of Internal Medicine* that highlighted how prescription opioid use was tied to overdoses. The article was highlighted in numerous mainstream media outlets, including *Businessweek*, Reuters, WebMD, and MedPage Today. The article and the media response to it were circulated within Mallinckrodt and Covidien. In 2011, a Covidien employee worked with its front group—the C.A.R.E.S. Alliance—and a public relations firm to find paid doctors to respond with op-eds of their own.[86]

160. Mallinckrodt also monitored online discussions of its opioids, which demonstrated that they were actually abused. In a May 2010 email, Mallinckrodt employees discussed an online chatroom in which abusers discussed obtaining and abusing Exalgo, leading one employee to remark, "[t]his 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."

161. A February 23, 2010 application for the approval of Exalgo acknowledged the risk of "abuse, misuse, and overdose" associated with Exalgo. Additionally, 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." Similar concerns were acknowledged by Mallinckrodt in connection with a 2009 FDA application for Exalgo. The FDA had commented that a "large portion of drug [was] unaccounted for," and Mallinckrodt was concerned that their

[86] The C.A.R.E.S. Alliance, in turn, was launched in response to the FDA's requirement in 2009 that drug manufacturers establish a REMS (Risk Evaluation and Mitigation Strategies) program to ensure that the benefits of a drug outweigh its harm.

competitors would use this fact against it "as evidence of the potentially high abuse with this product."

162. Communications among Mallinckrodt's sales, marketing, and promotional teams highlight their awareness of Mallinckrodt's opioids' high potential for abuse and addiction. In one especially telling email from January 2009, Mallinckrodt's vice president of purchasing wrote to a national account manager, joking "[i]ts like people are addicted to these things or something. Oh wait, people are." The account manager replied, "[j]ust like Doritos[,] keep eating, we'll make more." Another district sales manager flippantly suggested, "[h]ave we thought about a snortable form? Could appeal to substance abusers." Mallinckrodt employees also exchanged emails joking about diversion and abuse, including ideas about using "a hammer, coffee grinder, blender . . . Or a blow torch" to tamper with its products.

163. Covidien and Mallinckrodt personnel even went so far as to joke about the fact that their opioids were killing people. On February 14, 2011, Karen Harper forwarded a newspaper article to Bill Ratliff entitled "Dead woman found in car stopped by Kentucky troopers, passengers were traveling from Florida pill mills." Karen Harper stated: "Kinda like weekend at Bernie's, or not." Bill Ratliff acknowledged that it was "probably our Oxy" and also joked: "It just gets better and better. They must have known her pretty well or they would have dumped her along the way."

164. Covidien and Mallinckrodt were not only aware that their opioid products were highly addictive and subject to widespread abuse; they also knew of the extraordinary damage caused by that addiction and abuse. A 2011 internal document entitled "Opioids – What do we Know?" sets forth exactly what Mallinckrodt and Covidien knew at that time:

(a) opioid prescription painkillers have the same effect on the brain and body as heroin does – causing physical addiction;

(b) 2.4 million Americans abused opioids;

(c) the number of deaths caused by opioid overdose had quadrupled since 1999, pushing the CDC to declare pharmaceutical opioid overdose a national epidemic;

(d) drug overdoses killed nearly 40,000 people a year;

(e) nearly 60% of drug overdoses resulted from prescription medications;

(f) in 2010, opioid prescriptions attributed to 16,600 overdose deaths; and

(g) 100 people died from drug overdose every day in the United States.

165. In a 2013 email, Mallinckrodt's director of strategic marketing discussed studies demonstrating that the abusing population "routinely abuses by snorting" and that "hard core abusers [versus recreational users] may be more likely to tolerate the apap irritation, capable of inhaling large quantity of 'powder', and better at drug discrimination."

166. As the opioid epidemic grew in intensity and notoriety, Mallinckrodt crafted public relations materials that specifically avoided acknowledging an epidemic of misuse, referring to the crisis as merely a "serious problem." Mallinckrodt also gave its representatives media training on how to address "real worst-case scenarios," including 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."

167. A March 21, 2011 Covidien marketing group presentation acknowledged that (a) Covidien was aware of the DEA's requirements for suspicious order monitoring; (b) there was a growing problem with prescription opioid abuse; (c) numerous companies had been subject to multi-million dollar fines and lengthy suspensions; and (d) the DEA stated that it "viewed" Mallinckrodt as the "kingpin within the drug cartel[.]" Attached to the Covidien presentation was

an advertisement stating, "[t]here's a new dealer in town" and warning of the dangers of teen abuse of prescription opioids.

168. In a February 24, 2011 email, Douglas Ross, field intelligence officer for the National Drug Intelligence Center, said that he had posted to a prescription listserve that "Mallinckrodt 30 mg oxycodone tablets appear to have replaced the old formulation of OxyContin 80 mg tablets. They surfaced in New Englands [sic] over a year ago and now have gained wide acceptance by New England Rx opiate abusers who refer to them as 'perc 30s.'" The email was widely circulated within Mallinckrodt. Other publications also continued to inform Mallinckrodt that its products were being diverted and abused. In response to a June 2011 article about OxyContin from the *St. Louis Post Dispatch*, a Mallinckrodt employee noted "I think it supports our suspicions in regard to the increased usage of the Oxy 30mg."

169. [redacted]

[redacted]

170. In her April 23, 2011 notes from a DEA conference, Karen Harper wrote that Kyle Wright of the DEA said: "I am coming[.] You don't want me[.] I can 'tear you apart[.]' If DEA can see where drugs are going, Mallinckrodt knows full well where drugs are going[.]"

171. On August 23, 2011, Covidien's executives met with DEA officials at the agency's headquarters. At the meeting, the DEA officials provided evidence that Mallinckrodt was shipping hundreds of millions of doses of oxycodone to distributors as well as the number of arrests being made for oxycodone possession in the distributors' areas.

172. On November 30, 2011, the DEA subpoenaed Mallinckrodt for documents related to its suspicious orders monitoring program (which marked the start of an investigation culminating in Mallinckrodt's agreement to pay a $35 million penalty and acknowledgment that "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards" set by the DEA[87]). The investigation targeted Mallinckrodt for failing to comply with its responsibility to report suspicious orders during the pre-spin period of 2008 to 2011.[88] It also addressed the company's failure to keep records at its plant in Hobart, New York, which created discrepancies between the actual number of opioids manufactured and the number of opioids Mallinckrodt reported.[89] This settlement included admissions by Mallinckrodt that it was not in

[87] Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the DEA, and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC, at 4 (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download.

[88] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[89] *Id.*

compliance with DEA guidance letters on suspicious orders and that it was not in compliance with security and record-keeping requirements.[90]

173. Covidien announced its planned spinoff of Mallinckrodt on December 15, 2011, two weeks after it received the DEA subpoena.[91] Covidien was in such a hurry to announce the spinoff after it received the DEA subpoena that it announced the spinoff before it had even identified who would be president of the spun-off Mallinckrodt business. This fact did not go unnoticed. [redacted]

174. Not surprisingly, Covidien knew Mallinckrodt was the largest supplier of opioids in the United States. In its own presentations associated with the spinoff, Covidien acknowledged that it had a 40% share of the sales of controlled substances in the United States and a 32% market share of DEA Schedules II and III opiate oral solids.[92] Accordingly, it knew that its share of the liability arising from the opioid epidemic would be the largest or among the largest as well.

175. In connection with the spinoff, Covidien and Mallinckrodt prepared an information statement for the prospective Mallinckrodt shareholders acknowledging this fact. Specifically, the information statement observed that the companies faced "substantial" penalties and fines "involving substantial amounts of money" relating to their "controlled substance distribution practices."[93] It stated:

We are or may be involved in various legal proceedings and certain government

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[90] *Id.*

[91] Covidien plc, Current Report (Form 8-K), at 2 (Dec. 15, 2011), https://www.sec.gov/Archives/edgar/data/1385187/000119312511341572/d271723d8k.htm.

[92] Mallinckrodt plc, Information Statement, at 9 (Ex. 99.1 to Amendment No. to Form 10-K) (June 5, 2013), https://www.sec.gov/Archives/edgar/data/1567892/000119312513034750/d467783dex991.htm.

[93] *Id.* at 25-26.

> inquiries and investigations, including, but not limited to, patent infringement, product liability, antitrust matters, breach of contract, Medicare and/or Medicaid reimbursements claims, *or compliance with laws relating to marketing and sales or controlled substance distribution practices, including those relating to the establishment of suspicious order monitoring ("SOM") programs.* Such proceedings, inquiries and investigations may involve claims for, or the possibility of fines and penalties *involving substantial amounts of money or other relief,* including but not limited to civil or criminal fines and penalties and exclusion from participation in various government healthcare-related programs. *If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.*[94]

VI. THE SPINOFF, CASH TRANSFERS, AND OTHER VOIDABLE TRANSACTIONS

176. By 2011, Covidien had seen the large and ever-increasing number of fines and penalties being imposed on companies for their opioid-related practices. It was aware that Mallinckrodt had also engaged in similar misconduct. When the DEA followed up with a subpoena on Mallinckrodt, Covidien saw the writing on the wall. Within weeks of receiving the subpoena, Covidien announced its decision to spin off its opioid business in an attempt to protect its medical device companies and other assets from the opioid liabilities.

A. Covidien's Unsuccessful Attempt to Sell Mallinckrodt

177. [redacted]

[94] *Id.* (emphasis added).

178. Covidien knew that Mallinckrodt's opioid liabilities would make its sale difficult.

[redacted]

179. [redacted]

180. [redacted]

B. Massive Cash Transfers to Covidien

181. While it was trying to sell the Mallinckrodt business and contemplating the spinoff as an alternative, Covidien extracted substantial sums of cash out of Mallinckrodt, purportedly as part of "cash management" and funding arrangements. Covidien siphoned $867 million in a series

of transfers and did not provide reasonably equivalent value in exchange ("**Cash Transfers**"). For example, (a) in fiscal year 2010, Mallinckrodt transferred a net total of $505 million in cash to Covidien; (b) in fiscal year 2011, Mallinckrodt transferred a net total of $258 million in cash to Covidien; and (c) in fiscal year 2012, Mallinckrodt transferred a net total of $104 million to Covidien.

182. Covidien extracted the cash at a time when Mallinckrodt was undercapitalized and insolvent and with the intent to keep the funds out of the reach of Opioid Claimants.

C. Implementing the Spinoff

183. Unable to find a buyer willing to assume Mallinckrodt's opioid liabilities, on December 11, 2011, Covidien announced that it would spin off its pharmaceutical and imaging subsidiaries and assets, including the Mallinckrodt opioid business. Covidien made the announcement approximately two weeks after receiving the DEA subpoena relating to Mallinckrodt's opioid-related conduct. Covidien undertook the spinoff in an attempt to protect itself from the liability caused by Mallinckrodt's opioid-related misconduct.

184. As a key step to implementing the spinoff, in early 2013, Covidien organized and registered Mallinckrodt plc as a standalone Irish limited liability company to be publicly traded on the New York Stock Exchange. [redacted]

[redacted] The spinoff closed on June 28, 2013.

D. The Spinoff Note Proceeds

185. Before completing the spinoff, Covidien caused Mallinckrodt to incur a substantial amount of debt and to transfer most of the funds obtained from the debt obligation to Covidien. Specifically, in April 2013, Covidien caused MIFSA to issue approximately $300 million of 3.50% senior unsecured notes due 2018 and approximately $600 million of 4.75% of senior unsecured notes due 2023. As noted above, MIFSA and its newly created liability on the notes were transferred to Mallinckrodt plc as part of the spinoff, but Covidien pocketed approximately $721 million of the total note proceeds for itself ("**Note Proceeds**"), while forcing MIFSA to pay $11 million in related fees out of its remaining share of the proceeds. On information and belief, MIFSA transferred the Note Proceeds to Covidien by using the Note Proceeds to redeem its shares from Covidien (*see supra* para. 184). [redacted]

186. The spinoff debt transfers were made to further siphon funds from Mallinckrodt with the specific intent to make those funds unavailable to Opioid Claimants. As with the Cash Transfers, Mallinckrodt did not receive reasonably equivalent value for the spinoff debt transfers. Mallinckrodt agreed to the debt transactions because it was not an independent entity but was fully controlled by Covidien. Covidien knew that Mallinckrodt was undercapitalized and insolvent when it engaged in the debt transactions.

E. Mallinckrodt's Assumption of Covidien Tax Liability

187. As part of Covidien, Mallinckrodt was covered by a tax sharing agreement between Covidien plc, Tyco, and TE Connectivity Ltd. (formerly Tyco Electronics Ltd.) for U.S. income tax liabilities arising prior to Tyco's 2007 spinoff of Covidien ("**Pre-2007 Spinoff Tax Liabilities**"). Mallinckrodt, however, was not a party to the tax sharing agreement. Under the tax sharing agreement, Tyco, TE Connectivity, and Covidien plc were responsible for 27%, 31%, and 42%, respectively, of the Pre-2007 Spinoff Tax Liabilities.

188. In connection with the spinoff on June 28, 2013, Covidien and Mallinckrodt plc executed the Tax Matters Agreement. Mallinckrodt's November 25, 2014 10-K, states that "[u]nder the Tax Matters Agreement . . . [Mallinckrodt] will . . . be liable for certain taxes . . . arising during periods governed by the Tyco Tax Sharing Agreement. Although . . . [Mallinckrodt] will be liable to Covidien for certain taxes arising during periods governed by the Tyco Tax Sharing Agreement, . . . [it will not] share in the receivable that Covidien has from Tyco International or TE Connectivity Ltd. In addition, Covidien will retain all reimbursements from Tyco International or TE Connectivity Ltd. pursuant to the Tyco Tax Sharing Agreement, including reimbursements for taxes that are borne by . . . [Mallinckrodt] pursuant to the Tax Matters Agreement."[95]

189. In connection with the spinoff, Covidien shifted part of its Pre-2007 Spinoff Tax Liabilities, estimated to be in the hundreds of millions of dollars, to Mallinckrodt (hereinafter, "**Tax Liability**"). As a result, Covidien benefited from a decrease in its share of the Pre-2007 Spinoff Tax Liabilities, with no change to amounts owed to or due from Tyco and TE Connectivity, including Covidien's receivable from Tyco and TE Connectivity. In addition, on information and belief, Mallinckrodt has since made substantial payments on account of the Tax Liability imposed

[95] Mallinckrodt plc, Annual Report (Form 10-K), at 38-39 (Nov. 25, 2014), https://www.sec.gov/Archives/edgar/data/1567892/000156789214000040/mnk10-k92614.htm.

on Mallinckrodt. Mallinckrodt did not receive reasonably equivalent value in exchange for assuming the Tax Liability.

F. Putative Indemnity Obligations of Mallinckrodt

190. The terms of the spinoff were set forth in the Separation and Distribution Agreement, dated June 28, 2013, between Covidien plc and Mallinckrodt plc ("**Separation Agreement**").[96] Under the Separation Agreement, Covidien's position is Mallinckrodt plc assumed all 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 before and after the spinoff. As such, in Covidien's view, Mallinckrodt plc was saddled with liability for any and all claims relating to Mallinckrodt's opioid business, regardless of whether the underlying conduct took place before or after the spinoff. The Separation Agreement also purportedly saddled Mallinckrodt with substantial liabilities relating to certain of Covidien's legacy indebtedness, including a credit facility with JPMorgan and multiple tranches of secured and unsecured notes.

191. Section 4.2 of the Separation Agreement, in relevant part, states that the Debtors will "indemnify, defend and hold harmless Covidien, each member of the Covidien Group and each of their respective directors, officers, employees and agents . . . [defined collectively as "Covidien Indemnitees"] from and against any and all Liabilities of the Covidien Indemnitees *relating to*, arising out of or resulting from, *directly or indirectly*, any of the following items

[96] Separation and Distribution Agreement by and Between Covidien plc and Mallinckrodt plc Dated as of June 28, 2013, D.I. 4699-1. In the Bankruptcy Case, the Separation Agreement was rejected in accordance with §§ 365 and 1123 of the Bankruptcy Code. *See* Plan art. V.A. at 120; Confirmation Order ¶¶ 48, 243; *see also* Rejected Executory Contract/Unexpired Lease List (Ex. U to Plan Supplement), D.I. 6002.

(without duplication): . . . *the Mallinckrodt Business* . . . , any Mallinckrodt Liability or any Mallinckrodt Contract."[97]

192. The Separation Agreement defines "Mallinckrodt Business," in relevant part, as "the business and operations of the Pharmaceuticals Business."[98] The term "Pharmaceuticals Business" is, in turn, defined as "the pharmaceuticals business segment of Covidien . . . , which . . . develops, manufactures and distributes specialty pharmaceuticals, active pharmaceutical ingredients, contrast products and radiopharmaceuticals."[99]

193. On at least two occasions in the Bankruptcy Case, Covidien plc (which, at this point, was known as "Covidien Limited") asserted contingent rights to indemnification under the Separation Agreement and common law. On the first occasion, May 18, 2021, Covidien plc filed a limited objection to the Debtors' proposed disclosure statement.[100] In that objection, Covidien plc noted that it had spun off its pharmaceutical business in 2013 to Mallinckrodt plc and asserted that the "2013 spin-off agreement included standard, mutual rights of indemnification, in which Covidien and Mallinckrodt each agreed to indemnify the other for all defense costs and any liability arising out of each party's respective businesses."[101] Covidien plc further asserted, "in the event that any opioid-related suit were to proceed against Covidien one day, Covidien has an express right under the . . . [Separation Agreement] (and common law) to be indemnified by the Debtors for any costs that Covidien might incur in connection with those matters."[102] In a footnote,

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97 Separation Agreement § 4.2, at 43 (emphasis added).

98 *Id.* at 13.

99 *Id.* at 16.

100 Limited Objection of Covidien to Proposed Disclosure Statement for Joint Chapter 11 Plan of Reorganization of Mallinckrodt plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code, D.I. 2389.

101 *Id.* at 2.

102 *Id.*

Covidien plc stated that its issues with the disclosure statement and plan "could be avoided altogether by including Covidien as a 'Protected Party' under the Plan that would be protected under the Plan's channeling injunction from the assertion of any Opioid Claims against it."[103] Despite this footnoted plea, Covidien is neither a "Protected Party" nor protected by the channeling injunction under the confirmed Plan.

194. On the second occasion, October 13, 2021, Covidien plc filed a limited objection to the Debtors' first amended plan.[104] In that objection, Covidien plc asserted that it had been named in 50 stayed opioid suits as "one of many defendants in a laundry list of current or former affiliates of Mallinckrodt, simply because of Mallinckrodt's prior corporate history."[105] Covidien then repeated its contention that, if "any opioid-related suit were to proceed against Covidien in the future, Covidien has an express right under the parties' Separation and Distribution Agreement (and common law) to be indemnified by the Debtors for any costs and liability Covidien might incur."[106]

195. Covidien's asserted rights to indemnification under the Separation Agreement will be hereinafter referred to as the Debtors' "**Putative Indemnity Obligations**." In connection with the spinoff, Covidien exerted domination and control over Mallinckrodt plc and each of the other Debtors, which, until the completion of the spinoff, were direct or indirect subsidiaries of Covidien. As a consequence, *inter alia*, Covidien, under its own view of the Separation Agreement, imposed the overbroad Putative Indemnity Obligations on the Debtors not only to protect itself from the

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[103] *Id.* at 2 n.2.

[104] Limited Objection of Covidien Limited to First Amended Joint Chapter 11 Plan of Reorganization of Mallinckrodt plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code, D.I. 4699.

[105] *Id.* at 2.

[106] *Id.* The Debtors and Covidien subsequently resolved Covidien's objection with consensual modifications to the Plan. *See* Hr'g Tr. 188:8-191:13, Jan. 4, 2022.

eventual opioid-related lawsuits filed against it,[107] but also to deter or defeat any future challenge to the spinoff and related transactions, including an avoidance action brought under the Bankruptcy Code. Mallinckrodt did not receive reasonably equivalent value in exchange for shouldering the Putative Indemnity Obligations.

VII. MALLINCKRODT'S INSOLVENCY AT THE TIME OF THE TRANSACTIONS

196. Opioid Claimants have alleged trillions of dollars in damages against the Debtors. A significant portion of the alleged damages are for conduct that occurred prior to 2011. As one data point, in 2011 Howard Birnbaum estimated that the damages caused by the opioid crisis was over $50 billion for 2007 alone. That same year, Mallinckrodt's book value was less than $2 billion. As a company that consistently held at least 23.7% of the nationwide opioid market (excluding methadone and buprenorphine) between 2006 and 2014, Mallinckrodt's opioid-related liability in 2011 dwarfed the value of the company. All of the acts needed to give rise to Mallinckrodt's opioid liability had occurred by 2011, if not earlier. As a result, Mallinckrodt was insolvent at the time of the Cash Transfers and the spinoff.

A. Opioid-Related Liabilities Rendered Mallinckrodt Insolvent

197. As of the time of its bankruptcy filing in 2020, Mallinckrodt had been sued in more than 3,000 opioid-related cases.[108] Among them were lawsuits commenced by the federal government, state attorneys general, local governments, Native American tribes, and thousands of individual plaintiffs forming a coalition of private claimants seeking redress. The Debtors described these lawsuits as an "all-consuming tidal wave of litigation concerning the production

[107] Indeed, Covidien's appeal to the Debtors to become a "Protected Party" under their Plan revealed its conscious recognition of its own legal exposure to Opioid Claims.

[108] Welch Decl. ¶ 12.

and sales of its opioid products."[109] The facts and liability underlying these lawsuits rendered Mallinckrodt insolvent throughout the entire period it engaged in the Cash Transfers, the spinoff, and related transactions. While the "tidal wave of litigation" drove Mallinckrodt into bankruptcy in late 2020, the Opioid Claims underlying them arose well before then.

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

[109] *Id.* ¶ 76.

unjust enrichment, violation of the federal RICO provisions, and numerous violations of various other state laws relevant to Mallinckrodt's conduct.

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

200. Although the plaintiffs and claims varied across lawsuits, two common theories ran through the majority of the complaints.[110] First, plaintiffs alleged that Mallinckrodt engaged in misleading marketing that overstated the benefits of opioid products and understated their risks. Plaintiffs claimed that Mallinckrodt's misleading marketing caused health care providers to prescribe opioids inappropriately, increasing addiction, misuse, and abuse.[111] Second, plaintiffs alleged that Mallinckrodt did not comply with suspicious order monitoring obligations under federal and state law. As a result, Mallinckrodt flooded the market with opioids, increasing diversion of opioid products and thus increasing addiction, misuse and abuse.[112]

201. Faced with enterprise-crippling liabilities, and having exhausted all other options, the Debtors were forced to seek protection under chapter 11 to contain the opioid lawsuits. Stephen A. Welch, the Debtors' chief transformation officer, admitted as much in response to a question

[110] *Id.* ¶ 77.

[111] *Id.*

[112] *Id.*

about "what generally caused Mallinckrodt to file for Chapter 11."[113] Mr. Welch answered, without qualification, that the "debtors filed . . . to resolve enterprise-threatening litigation in the face of near-term debt maturities."[114] This enterprise-threating litigation included "nationwide opioid litigation against the Debtors."[115] [redacted][116]

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

203. The Debtors' admissions in their chapter 11 proceedings underscored Mallinckrodt's insolvency as a result of its opioid liabilities. Mr. Welch acknowledged "potentially trillions of dollars of damages" alleged by Opioid Claimants—which no company, let alone Mallinckrodt, could satisfy, even if judgments were a fraction of that amount—and the Debtors' opinion that opioid litigation posed a threat to the viability of Mallinckrodt's business.[117] Mr. Welch further admitted that Opioid Claims may have arisen in excess of the Debtors' ability to pay

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

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

[115] Welch Decl. ¶ 11.

[116] [redacted]

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

them as far back as 2013, noting there were "questions as to whether Mallinckrodt was even insolvent when it spun off from Covidien due to the opioid litigation."[118]

204. Mallinckrodt's insolvency during the years 2010-2013 (and beyond) is evident in Debtors' own estimates of their potential liabilities for Opioid Claims. Mr. Welch, who relied on commonly utilized methodologies for valuing litigation claims—primarily, by extrapolating settlement amounts paid by Mallinckrodt in 2019—estimated that the Debtors potentially faced more than $30 billion of liabilities on Opioid Claims.[119] According to Mr. Welch, "if even a fraction of plaintiffs . . . [were] successful in winning all the damages they seek," judgments on those claims "could quickly aggregate into the billions or tens of billions of dollars."[120]

205. The Debtors' estimates of historical opioid liabilities exceed, by far, the total value of Mallinckrodt's assets at any point in time, including during the years 2010-2013. The solvency analysis prepared by Houlihan Lokey in connection with the spinoff placed a value of approximately $3.1 billion on the Mallinckrodt assets. Mallinckrodt's opioid liabilities were far in excess of this value at the time of the spinoff and the transfers. This point was not lost on the Court, which, after reviewing the expert reports submitted in connection with chapter 11 proceedings, determined that the Debtors were "hopelessly insolvent."[121]

206. Although Mallinckrodt was insolvent from the weight of overwhelming opioid liability, it was pushed further into insolvency as a result of (a) the $857 million of Cash Transfers to Covidien; (b) being encumbered by approximately $900 million in note obligations while Covidien pocketed approximately $721 million of the note proceeds; and (c) being saddled with

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118 *Id.* at 62:2-5.

119 *Id.* at 62:21-63:5.

120 Welch Decl. ¶ 91.

121 Hr'g Tr. 76:16-17, June 16, 2021.

hundreds of millions of dollars in Tax Liability. Mallinckrodt also labors under the Putative Indemnity Obligations.

B. The Houlihan Lokey Solvency Letter

207. Covidien was acutely aware that one of the largest obstacles for the spinoff was obtaining a solvency analysis from a third party stating that Mallinckrodt would be solvent after the spinoff. [redacted] Neither Goldman Sachs nor Duff & Phelps provided a solvency opinion for Covidien.

208. [redacted] ," a rating widely considered to be "speculative grade" and just above "junk bond" status.

209. [redacted] Covidien, however, chose the opposite approach: it transferred money away from and imposed liabilities on Mallinckrodt.

210. [redacted]

211. [redacted]

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

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

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

Transfers and the transactions and obligations comprising the 2013 spinoff (hereinafter, "**Spinoff**") under applicable nonbankruptcy law, including, without limitation, the Uniform Voidable Transactions Act, as in force in several states, and the Uniform Fraudulent Transfer Act ("**UFTA**"), as in force in numerous states including Delaware[122] (together, "**Fraudulent Transfer Claims**").

214. These unsecured creditors 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.[123] These creditors also include individuals injured by direct exposure to opioids within one year prior to the Petition Date. Until these children were born and diagnosed with NAS, or until those individuals became injured as a result of direct opioid exposure, they and their family members did not know, and could not reasonably discover, that their recourse against Mallinckrodt had been impaired by the Cash Transfers to Covidien and the Spinoff. In accordance with the Confirmation Order and the Plan, the Trust wields all avoidance rights derived from these NAS children and opioid personal-injury victims under § 544(b)(1) of the Bankruptcy Code. Such rights include the right to avoid the Cash Transfers and the Spinoff under section 4(a)(1) of the UFTA within one year after the same "was or could reasonably have been discovered" by these recent creditors. *See* UFTA § 9(a).

215. Claims have been filed against one or more of the Debtors for personal injury or wrongful death arising from exposure to asbestos or asbestos-containing products. The Trust believes that at least some of these asbestos claims pertain to individuals who were diagnosed with an asbestos-related disease within one year prior to the Petition Date. Until those diseases

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122 *See* Del. Code tit. 6, §§ 1301-1311.

123 Between 50% and 80% of infants exposed to opioids in utero will develop NAS, and seven out of 1,000 newborns are born with NAS. Roschanak Mossabeb & Kevin Sowti, *Neonatal Abstinence Syndrome: A Call for Mother-Infant Dyad Treatment Approach*, 104 Am. Fam. Physician 222, 222-223 (2021).

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

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

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

Trust wields all avoidance rights derived from the NJ Division of Health Services as of the Petition Date, including the right to pursue avoidance rights and collection remedies by way of the Fraudulent Transfer Claims under the *Nullum Tempus* doctrine with respect to otherwise applicable statutes of limitations.

218. In addition to the IRS and the NJ Division of Health Services, one or more other governmental units, on information and belief, held allowable unsecured claims against one or more of the Debtors as of the Petition Date, including SpecGx LLC and Mallinckrodt Enterprises LLC, together with timely rights to avoid the Cash Transfers and the Spinoff by way of the Fraudulent Transfer Claims, pursuant to the *Nullum Tempus* doctrine as to otherwise applicable statutes of limitation. These governmental units include those holding Opioid Claims. In accordance with the Confirmation Order, the Plan, and 11 U.S.C. § 544(b)(1), the Trust wields all rights derived from these other governmental units.

CLAIMS FOR RELIEF

COUNT I
Avoidance of the Spinoff and Related Transactions Based on Intent to Hinder, Delay, or Defraud Creditors – UFTA or Other Applicable Law

219. The Trust repeats and realleges all the allegations in paragraphs 1 through 218.

220. In the Spinoff, the Debtors transferred property in which they held interests and incurred obligations 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 and such obligations were incurred.

221. At the time those transfers and obligations were undertaken, Covidien was the direct or indirect parent company of the Debtors and dominated and controlled the Debtors such that the Debtors were alter egos or mere instrumentalities of Covidien. Covidien used its control

over the Debtors to perpetrate the Spinoff to the detriment of the Debtors' estates and Opioid Claimants.

222. 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 Spinoff prejudicing the rights of Opioid Claimants by depriving the Debtors and their bankruptcy estates of the value of the Note Proceeds and the assets of Covidien and its direct and indirect subsidiaries and by burdening the Debtors and their bankruptcy estates with the Tax Liability and the Putative Indemnity Obligations.

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

(a) The Spinoff was to or for the benefit of an insider, namely Covidien. At the time of the Spinoff, Covidien was the Debtors' affiliate and ultimate parent holding company. Moreover, Covidien formed Mallinckrodt plc, which received and retained Covidien's pharmaceuticals business segment (that was housed with the Debtors) and the attendant opioid liabilities.

(b) At the time that the Spinoff was undertaken, Covidien was the direct or indirect parent company of the Debtors and dominated and controlled the Debtors such that the Debtors were alter egos or mere instrumentalities of Covidien. Covidien used its control over the Debtors to perpetrate the Spinoff to the detriment of the Debtors' estates and the Opioid Claimants.

(c) The Spinoff enabled Covidien to retain direct or indirect ownership of the valuable assets and subsidiaries comprising the medical device and supplies business.

(d) Until December 15, 2011, the potential sale or spinoff of the Mallinckrodt pharmaceuticals business was kept secret under the "Project Jameson" codename. And, although

the intended spinoff of the pharmaceuticals business was publicly announced on December 15, 2011, the entire purpose of the Spinoff and the prejudicial effect it would have on present and future creditors, including Opioid Claimants, were never disclosed but instead remained concealed.

(e) Covidien and Mallinckrodt were aware of the burgeoning opioid-related liabilities when the Spinoff was being planned and was ultimately implemented. Among other things, the planned Spinoff was publicly announced just 15 days after Mallinckrodt received the DEA's subpoena regarding Mallinckrodt's suspicious order monitoring program.

(f) Before the Spinoff closed on June 28, 2013, Covidien caused MIFSA to incur approximately $900 million of senior unsecured note obligations and then caused MIFSA to transfer $721 million of the Note Proceeds to or for the benefit of Covidien, even though MIFSA and the entirety of the note obligations were ultimately received by Mallinckrodt plc in the Spinoff.

(g) In connection with the Spinoff, Covidien received or retained more than 80% of the total assets. According to Covidien, in 2013, Mallinckrodt plc received $3.3 billion in total assets from the spinoff. That same year, Covidien claimed that it had $20 billion in total assets after the spinoff. In other words, Mallinckrodt was allocated less than 20% of Covidien's total assets in the Spinoff but all the opioid liabilities.

(h) The consideration received by the Debtors in connection with the Spinoff was not reasonably equivalent in value to (i) the rights and property that the Debtors relinquished, including, without limitation, the Debtors' loss of the Note Proceeds; and (ii) the obligations apportioned to or imposed on the Debtors, including, without limitation, the Tax Liability and the Putative Indemnity Obligations.

(i) The Debtors were insolvent at the time of the Spinoff, became insolvent soon thereafter, or had reason to know at the time of the Spinoff that their liabilities for present and future Opioid Claims would exceed their ability to pay.

224. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), the UFTA, and/or other applicable law, the Trust is entitled to (a) avoid the transfers of assets or property made in connection with the Spinoff, including, without limitation, the transfer of Covidien and its direct and indirect subsidiaries as well as the Note Proceeds; (b) avoid the incurrence of the Tax Liability and the Putative Indemnity Obligations; and (c) recover the value of assets or property transferred to Covidien, its affiliates, or third parties for the benefit of Covidien in connection with, or as a result of, the Spinoff, with interest.

225. Covidien's conduct set forth herein was fraudulent, wanton, malicious, and/or willful in complete disregard of the Debtors' rights. Accordingly, the Trust requests relief in the form of exemplary or punitive damages in an amount to be determined at trial.

COUNT II
Avoidance of the Spinoff and Related Transactions as
Constructive Fraudulent Transfers – UFTA or Other Applicable Law

226. The Trust repeats and realleges all the allegations in paragraphs 1 through 225.

227. In connection with the Spinoff, the Debtors transferred property in which they held interests, including, without limitation, the transfer of the Note Proceeds to Covidien, and incurred obligations, including the Tax Liability and Putative Indemnity Obligations.

228. Each of those transfers and obligations was made to or for the benefit of Covidien.

229. At the time those transfers and obligations were undertaken, Covidien was the direct or indirect parent company of the Debtors and dominated and controlled the Debtors such that the Debtors were alter egos or mere instrumentalities of Covidien. Covidien used its control

over the Debtors to perpetrate the Spinoff to the detriment of the Debtors' estates and the Opioid Claimants.

230. The Debtors did not receive reasonably equivalent value in exchange for the transfers made and the obligations incurred in connection with the Spinoff.

231. At the time of the Spinoff, the Debtors were faced with present, contingent, and future opioid-related liabilities that, collectively, were overwhelming.

232. The Debtors made the above-mentioned transfers and incurred the above-mentioned obligations when they were engaged or about to engage in a business or transaction for which their remaining assets were unreasonably small in relation to the business or transaction.

233. At the time of those transfers and obligations, the Debtors intended to incur, or believed or reasonably should have believed that they would incur, debts beyond their ability to pay as they became due.

234. At the time of those transfers and obligations, the Debtors were insolvent within the meaning of applicable law, or the Debtors became insolvent as a result of those transfers and obligations.

235. As a result of those transfers and obligations, the Debtors and their creditors have been harmed.

236. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), the UFTA, and/or other applicable law, the Trust is entitled to (a) avoid the transfers of assets or property made in connection with the Spinoff, including, without limitation, the transfer of Covidien and its direct and indirect subsidiaries as well as the Note Proceeds; (b) avoid the incurrence of the Tax Liability and the Putative Indemnity Obligations; and (c) recover the value of the assets or property

transferred to Covidien, its affiliates, or third parties for the benefit of Covidien in connection with, or as a result of, the Spinoff, with interest.

237. Covidien's conduct set forth herein was fraudulent, wanton, malicious, and/or willful in complete disregard of the Debtors' rights. Accordingly, the Trust requests relief in the form of exemplary or punitive damages in an amount to be determined at trial.

COUNT III
Avoidance of the Cash Transfers Based on Intent to Hinder, Delay, or Defraud Creditors – UFTA or Other Applicable Law

238. The Trust repeats and realleges all the allegations in paragraphs 1through 237.

239. The Debtors made the Cash Transfers 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 dates those transfers were made.

240. 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 Cash Transfers prejudicing the rights of Opioid Claimants by depriving the Debtors and their bankruptcy estates of the value of the Cash Transfers.

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

(a) The Cash Transfers were made to or for the benefit of an insider, namely Covidien. At the time of the Cash Transfers, Covidien was the Debtors' affiliate and direct or indirect parent holding company.

(b) The Cash Transfers enabled Covidien to retain direct or indirect ownership of the cash assets while depriving the Debtors of the same.

(c) At the time the Cash Transfers were made, Covidien was the direct or indirect parent company of the Debtors and dominated and controlled the Debtors such that the Debtors were alter egos or mere instrumentalities of Covidien. Covidien used its control over the Debtors to perpetrate the Cash Transfers to the detriment of the Debtors' estates and the Opioid Claimants.

(d) Although the amounts of the Cash Transfers may have been disclosed in publicly filed financial statements, the entire purpose of the Cash Transfers and the prejudicial effect it would have on present and future creditors, including Opioid Claimants, were never disclosed but instead were concealed.

(e) Covidien and Mallinckrodt were aware of the burgeoning opioid-related liabilities when the Cash Transfers were made.

(f) As a result of the Cash Transfers, the Debtors became relatively "cash poor," which reduced the recourse that otherwise would be available to Opioid Claimants, such as children with NAS and governmental entities.

(g) The consideration received by the Debtors was not reasonably equivalent in value to the cash or cash equivalents relinquished by the Debtors in making the Cash Transfers.

(h) The Debtors were insolvent at the time of the Cash Transfers, became insolvent soon thereafter, or had reason to know at the time of the Cash Transfers that their liabilities for present and future Opioid Claims would exceed their ability to pay.

242. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), the UFTA, and/or other applicable law, the Trust is entitled to avoid the Cash Transfers and recover the property or value transferred to Covidien, its affiliates, or third parties for the benefit of Covidien, with interest.

243. Covidien's conduct set forth herein was fraudulent, wanton, malicious, or willful in complete disregard of the Debtors' rights. Accordingly, the Trust requests relief in the form of exemplary or punitive damages in an amount to be determined at trial.

COUNT IV
Avoidance of the Cash Transfers as Constructive
Fraudulent Transfers – UFTA or Other Applicable Law

244. The Trust repeats and realleges all the allegations in paragraphs 1 through 243.

245. The Debtors made the Cash Transfers to or for the benefit of Covidien.

246. The Debtors did not receive reasonably equivalent value from Covidien in exchange for the Cash Transfers.

247. At the time of the Cash Transfers, Covidien was the direct or indirect parent holding company of the Debtors and dominated and controlled the Debtors such that the Debtors were alter egos or mere instrumentalities of Covidien. Covidien used its control over the Debtors to perpetrate the Cash Transfers to the detriment of the Debtors' estates and the Opioid Claimants.

248. At the time of the Cash Transfers, the Debtors were faced with present, contingent, and future opioid-related liabilities that, collectively, were overwhelming.

249. The Debtors made the Cash Transfers when they were engaged or about to engage in a business or transaction for which their remaining assets were unreasonably small in relation to the business or transaction.

250. At the time of the Cash Transfers, the Debtors intended to incur, or believed or reasonably should have believed that they would incur, debts beyond their ability to pay as they became due.

251. At the time of the Cash Transfers, the Debtors were insolvent within the meaning of applicable law, or the Debtors became insolvent as a result of the Cash Transfers.

252. As a result of the Cash Transfers, the Debtors and their creditors have been harmed.

253. Accordingly, under 11 U.S.C. §§ 544(b) and 550(a), the UFTA, and/or other applicable law, the Trust is entitled to avoid the Cash Transfers and recover the property or value transferred to Covidien, its affiliates, or third parties for the benefit of Covidien, with interest.

254. Covidien's conduct set forth herein was fraudulent, wanton, malicious, or willful in complete disregard of the Debtors' rights. Accordingly, the Trust requests relief in the form of exemplary or punitive damages in an amount to be determined at trial.

COUNT V
Breach of Fiduciary Duty as a Promoter

255. The Trust repeats and realleges all the allegations in paragraphs 1 through 254.

256. Covidien was a corporate promoter of Mallinckrodt plc. It caused Mallinckrodt plc to be formed, organized, and registered as a public limited company under the laws of Ireland in early 2013. In connection with the Spinoff, Covidien determined what assets, liabilities, and business lines the newly formed Mallinckrodt plc would hold within Mallinckrodt plc's corporate umbrella.

257. On information and belief, as the promoter of Mallinckrodt plc, Covidien selected the individuals who would serve as Mallinckrodt plc's officers and directors, including former Covidien employee Mark Trudeau.

258. Covidien's activities as a corporate promoter began no later than December 2011, with its announcement of the Spinoff and continued up through and including June 28, 2013, the date on which the Spinoff was completed.

259. As a promoter, Covidien owed fiduciary duties to Mallinckrodt plc, including a duty to act in good faith in all their dealings. Covidien breached its duty as a promoter while planning and implementing the Spinoff and related transactions, *inter alia*, by (a) stripping what would become Mallinckrodt plc of assets in the years leading up to the Spinoff via the Cash Transfers, (b) separating the profitable medical supply and medical device businesses from Mallinckrodt, (c) forcing Mallinckrodt plc to take on both Mallinckrodt's and Covidien's liabilities for opioid-related misconduct and Opioid Claims, and (d) imposing the Putative Indemnity Obligations on the Debtors, all without providing reasonably equivalent value in exchange. Covidien improperly profited from the foregoing conduct.

260. In addition, Covidien breached its duties to act in good faith by failing to disclose to Mallinckrodt plc, its future bondholders, and its future shareholders all material facts regarding Mallinckrodt plc, including, without limitation, the true nature and scope of the opioid-related liabilities that were being left with the Debtors. Moreover, Covidien failed to act in good faith by creating and promoting Mallinckrodt plc when it knew or should have known that Mallinckrodt plc could never survive as an independent company or going concern.

261. Covidien's breaches of its fiduciary duties as a promoter proximately caused substantial harm to Mallinckrodt plc. The Trust thus seeks an award of damages against Covidien for all damages or harm sustained as a result of its wrongdoing, in an amount to be determined at trial, with interest thereon.

262. Covidien's conduct set forth herein was fraudulent, wanton, malicious, or willful in complete disregard of Mallinckrodt plc's rights. Accordingly, the Trust seeks relief in the form of exemplary or punitive damages in an amount to be determined at trial.

COUNT VI
Reimbursement, Indemnification, or Contribution

263. The Trust repeats and realleges all the allegations in paragraphs 1 through 262.

264. Prior to the Petition Date, the Debtors were the subject of subpoenas, investigations, and more than 3,000 lawsuits arising from or related to the Debtors' substantial opioid liability. On information and belief, in connection with those subpoenas, investigations, and lawsuits, the Debtors paid in excess of $130,000,000 in indemnity and defense costs.

265. Moreover, the Debtors incurred substantial costs and expenses to reach a global settlement and resolution of their substantial opioid liability in the Bankruptcy Case, including the allowance and/or payment of professional fees and expenses in excess of $443,000,000, in addition to the approximately $1.725 billion that the Debtors are required to pay on account of Opioid Claims under the Plan.

266. Covidien is jointly and severally liable with the Debtors for all opioid-related liability and claims borne by or asserted against the Debtors. The Debtors have paid sums in excess of their fair share on account of, or as a result of, such opioid-related liability and claims.

267. Accordingly, as a matter of, *inter alia*, law, equity and/or good conscience, the Trust is entitled to reimbursement, indemnification, or contribution by or from Covidien for (a) payments of indemnity and defense costs made by one or more of the Debtors on or before the Petition Date in connection with, or as a result of, opioid-related subpoenas, investigations, litigation, judgments, fines, and settlements, and (b) payments made by one or more of the Debtors to satisfy (i) all professional fees and costs, allowed administrative expenses, quarterly fees, and other costs related to the Bankruptcy Case and (ii) obligations under the Plan, in an amount to be determined at trial.

COUNT VII
Equitable Subordination

268. The Trust repeats and realleges all the allegations in paragraphs 1 through 267.

269. In the Bankruptcy Case, Covidien has twice asserted a right to indemnification against the Debtors under the Separation Agreement and common law, and will likely assert the same by filing one or more claims against the Trust.

270. The initial capitalization of the Debtors at the time of the Spinoff was wholly inadequate, and Covidien was responsible for the gross undercapitalization.

271. Covidien was an insider at the time of the Spinoff and controlled the allocation of assets and liabilities to the Debtors through the Spinoff.

272. It was inequitable for Covidien to force Mallinckrodt plc to enter into the Separation Agreement and the Spinoff described above. As a result of Covidien's inequitable conduct, the Debtors' creditors—chiefly, the Opioid Claimants—have been injured.

273. Covidien also misled Mallinckrodt plc's shareholders and the market generally regarding the true nature and magnitude of the opioid-related liabilities left with the Debtors in connection with the Spinoff.

274. Any and all claims asserted by Covidien should be equitably subordinated for purposes of distribution under 11 U.S.C. § 510(c), and Covidien should not be permitted to receive any distributions from the Trust on any claims asserted by Covidien, or any of its respective affiliates until payment in full with interest is made to all non-defendant creditor-beneficiaries of the Trust.

COUNT VIII
Equitable Disallowance

275. The Trust repeats and realleges all the allegations in paragraphs 1 through 274.

276. In accordance with its fraudulent and inequitable conduct, Covidien forced the Debtors to effect the Cash Transfers and the Spinoff.

277. To the extent Covidien asserts claims against the Trust based on opioid-related liabilities or for indemnification under the Separation Agreement or common law, those claims should be disallowed and expunged.

COUNT IX
Disallowance of Claims Under
Section 502(d) of the Bankruptcy Code

278. The Trust repeats and realleges all the allegations in paragraphs 1 through 277.

279. Covidien is the transferee of transfers avoidable under section 544 of the Bankruptcy Code.

280. To the extent Covidien asserts any claims, those claims should be disallowed in accordance with section 502(d) of the Bankruptcy Code.

COUNT X
Disallowance of Contingent Indemnity Claims
Under Section 502(e)(1)(B) of the Bankruptcy Code

281. The Trust repeats and realleges all the allegations in paragraphs 1 through 280.

282. Section 502(e)(1)(B) of the Bankruptcy Code requires the Bankruptcy Court to disallow any claim for reimbursement or contribution by an entity that is liable with the debtor and such claim for reimbursement or contribution is contingent at the time of the allowance or disallowance of such claim.

283. From 2007 through 2013, Covidien was the direct or indirect parent company of the Debtors and dominated and controlled the Debtors such that the Debtors were alter egos or mere instrumentalities of Covidien. As a result, Covidien is liable with the Debtors with respect

to the underlying claims for which Covidien seeks reimbursement, contribution, or indemnification.

284. To the extent Covidien (a) asserts claims for reimbursement, contribution, or indemnification against the Trust, and (b) Covidien has not expended funds related to such underlying claims, such claims must be disallowed in accordance with section 502(e)(1)(B) of the Bankruptcy Code.

RESERVATION OF RIGHTS

285. The Trust intends to conduct further investigation and discovery in relation to the Cash Transfers and the Spinoff. The Trust therefore expressly reserves the right to bring additional claims, including, without limitation, claims discovered as a result of the Trust's ongoing efforts to obtain additional information from the Debtors, Defendants, and parties affiliated with Defendants related to the Cash Transfers, the Spinoff, and the resulting bankruptcies of the Debtors.

PRAYER FOR RELIEF

WHEREFORE, based on the foregoing, the Trust requests judgment in its favor and relief as follows:

A. finding that Covidien dominated and controlled the Debtors and operated the Debtors and their non-pharma affiliates as a single enterprise, such that the Debtors were the alter egos of Covidien and the non-pharma affiliates and/or mere instrumentalities of Covidien;

B. avoiding all transfers of assets or property made in connection with, or as a result of, the Spinoff in accordance with section 544(b) of the Bankruptcy Code, including, without limitation, avoidance of (1) the transfer of Covidien and its direct and indirect subsidiaries and (2) the transfer of the Note Proceeds to Covidien;

C. avoiding the incurrence of the Tax Liability and the incurrence of the Putative Indemnity Obligations in accordance with section 544(b) of the Bankruptcy Code;

D. avoiding each of the Cash Transfers in accordance with section 544(b) of the Bankruptcy Code;

E. in accordance with section 550 of the Bankruptcy Code, awarding recovery by the Trust of the value of all assets or property transferred in connection with, or as a result of, the Spinoff, including, without limitation, the value of (1) Covidien and its direct and indirect subsidiaries, (2) the Note Proceeds, and (3) all payments made by Mallinckrodt on account of the avoided Tax Liability;

F. in accordance with section 550 of the Bankruptcy Code, awarding recovery by the Trust of the value of all avoided Cash Transfers;

G. awarding compensatory damages in favor of the Trust for all damages sustained as a result of transfers or obligations avoided, or any of Defendants' wrongdoing, in an amount to be determined at trial;

H. awarding the Trust punitive and/or exemplary damages where such damages are available, in an amount to be determined at trial;

I. awarding in favor of the Trust reimbursement, indemnification, or contribution by or from Defendants for (1) payments of indemnity and defense costs made by one or more of the Debtors on or before the Petition Date in connection with, or as a result of, opioid-related subpoenas, investigations, litigation, judgments, and settlements, and (2) payments made by one or more of the Debtors to satisfy (i) all professional fees and costs, allowed administrative expenses, quarterly fees, and other costs related to the Bankruptcy Case and (ii) obligations under the Debtors' confirmed Plan, in an amount to be determined at trial;

J. awarding the Trust reasonable costs and expenses incurred in this proceeding, including attorneys' fees and expert fees;

K. equitably subordinating and/or equitably disallowing any and all claims asserted by any Defendant;

L. disallowing any and all claims asserted or filed by any Defendant;

M. prejudgment and post-judgment interest; and

N. granting such other and further relief as the Court deems just and appropriate.

Dated: October 11, 2022
Wilmington, Delaware

COLE SCHOTZ P.C.

/s/ Justin R. Alberto
Justin R. Alberto (No. 5126)
Patrick J. Reilley (No. 4451)
500 Delaware Avenue, Suite 1410
Wilmington, Delaware 19801
Telephone: (302) 652-3131
Facsimile: (302) 652-3117
jalberto@coleschotz.com
preilley@coleschotz.com

Seth Van Aalten, Esq.
Anthony De Leo, Esq.
1325 Avenue of the Americas
19th Floor
New York, NY 10019
Telephone: (212) 752-8000
Facsimile: (212) 752-8393
svanaalten@coleschotz.com
adeleo@coleschotz.com

-and-

CAPLIN & DRYSDALE, CHARTERED
Kevin C. Maclay, Esq. (admitted *pro hac vice*)
Todd E. Phillips, Esq. (admitted *pro hac vice*)
Jeffrey A. Liesemer, Esq. (admitted *pro hac vice*)
Quincy M. Crawford, III, Esq.
(*pro hac vice* to be filed)
One Thomas Circle, NW, Suite 1100
Washington, D.C. 20005
Tel: (202) 862-5000
Fax: (202) 429-3301
kmaclay@capdale.com
tphillips@capdale.com
jliesemer@capdale.com
mcrawford@capdale.com

Co-Counsel to the Opioid
Master Disbursement Trust II