UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

In re: MALLINCKRODT PLC, et al., Debtors.	Chapter 11 Case No. 20-12522 (JTD) (Jointly Administered)
MALLINCKRODT PLC, et al., Plaintiffs, v. STATE OF CONNECTICUT, et al. Defendants.	Adv. Pro. No. 20-50850 (JTD)

FIRST MONITOR REPORT

Comes now, R. Gil Kerlikowske, as duly appointed Monitor for Mallinckrodt LLC, Mallinckrodt Enterprises LLC, and SpecGx LLC (collectively, "Mallinckrodt"), and reports as follows:

I. EXECUTIVE SUMMARY

Since Mallinckrodt and the undersigned Monitor agreed to the Draft Preliminary Work Plan on March 10, 2021, in accordance with Section VI.B.3 of the Operating Injunction, the following forty-five (45) days, prior to the submission of this First Monitor Report, have primarily consisted of "scoping" activities intended to guide and structure the Monitor's continuing work. Specifically, this has involved reviewing documents and conducting preliminary interviews with key officials and employees in order to determine how the compliance responsibilities set forth in Section VI of the Operating Injunction will be carried out during the five-year monitorship term.

Docket No. 2117
Adv. DI 212
Filed: 4/26/21

This First Monitor Report outlines the actions taken to date to understand the key components of Mallinckrodt's Specialty Generics business related to the Operating Injunction. It reflects the Monitor's preliminary analysis of Mallinckrodt's compliance with the terms and conditions of the Operating Injunction (which contains approximately one hundred and seventy (170) independent provisions), and includes a general description of the documents reviewed and requested, and an overview of interviews conducted to date. This First Monitor Report also identifies anticipated actions to be undertaken in the coming months and years. This assessment is, of course, preliminary and subject to ongoing review and refinement, as the Monitor's work is necessarily iterative, and continued findings inform the Monitor's continued approach.

Mallinckrodt's executives, employees, and outside counsel have been responsive and cooperative. They have provided more than five hundred (500) pages of documentation at the Monitor's request in a timely and complete fashion and arranged multiple interviews with key executives in a relatively short period of time. Additionally, Mallinckrodt has taken the initiative to establish a secure platform for information to be shared electronically with the Monitor, and is making adjustments to the confidential hotline reporting system to facilitate reports relating directly to the Monitor's responsibilities.

Based on the information reviewed to date, Mallinckrodt appears to be making a good faith effort to comply with the terms and conditions of the Operating Injunction.

II. THE OPERATING INJUNCTION

1. On October 12, 2020, Mallinckrodt and the Settling States agreed to the Mallinckrodt Injunctive Relief Draft Term Sheet (hereinafter the "Operating Injunction"). A copy of the Operating Injunction is attached hereto and made a part hereof as **Exhibit One.**

2. On January 8, 2021, this Court entered the *Order Granting Certain Debtors' Motion for Injunctive Relief Pursuant to 11 U.S.C. § 105 with respect to the Voluntary Injunction*

[Adv. Pr. No. 20-50850, D.I. 196], enjoining Mallinckrodt pursuant to the Operating Injunction as was modified in a limited manner by agreement between Mallinckrodt, the Settling States, and the Opioid Claimants Committee ("OCC").

3. In Section VI of the Operating Injunction, Mallinckrodt agreed to retain a Monitor responsible for reporting on its compliance with the terms of the Operating Injunction no later than forty-five (45) days after finalizing the Monitor's Work Plan. The Operating Injunction provides that subsequent reports are to be submitted every ninety (90) days thereafter, until the Effective Date, as defined in the Operating Injunction, at which time the Monitor may decrease the frequency of such reports to every one hundred and eighty (180) days.

4. The operative sections of the Operating Injunction, for purposes of the monitorship, are Sections III (Injunctive Relief), IV (Clinical Data Transparency), and V (Public Access To Mallinckrodt Documents).

5. Section III (Injunctive Relief) is comprised of the following sub-sections: (1) a ban on promotion (OI § III.A); (2) a prohibition on financial reward or discipline based on volume of opioid sales (OI § III.B); (3) a ban on funding/grants to third parties (OI § III.C); (4) lobbying restrictions (OI § III.D); (5) a ban on certain high dose opioids (OI § III.E); (6) a ban on prescription savings programs (OI § III.F); (7) monitoring and reporting of direct and downstream customers (OI § III.G); (8) general terms (OI § III.H); (9) compliance with all laws and regulations relating to the sale, promotion, and distribution of any opioid product (OI § III.I); (10) compliance deadlines (OI § III.J); and (11) training (OI § III.K).

6. Section IV (Clinical Data Transparency) is comprised of the following sub-sections: (1) data to be shared (OI § IV.A); (2) third-party data archive (OI § IV.B); (3) non-interference (OI § IV.C); (4) data use agreement (OI § IV.D); and (5) cost (OI § IV.E).

7. Section V (Public Access To Mallinckrodt Documents) is comprised of the following sub-sections: (1) documents subject to public disclosure (OI § V.A); (2) information that may be redacted (OI § V.B); (3) redaction of documents containing protected information (OI § V.C); (4) review of trade secret redactions (OI § V.D); (5) public disclosure through a document repository (OI § V.E); (6) timeline for production (OI § V.F); (7) costs (OI § V.G); and (8) suspension (OI § V.H).

III. THE MONITOR AGREEMENT & WORK PLAN

8. On January 15, 2021, the Monitor and Mallinckrodt executed the Mallinckrodt Monitor Agreement, attached hereto and made part hereof as **Exhibit Two**. The Monitor promptly undertook steps to comply with the compliance responsibilities outlined in Section VI of the Operating Injunction.

9. On February 8, 2021, the Court entered the order appointing the Monitor and approving his retention of the law firm Saul Ewing Arnstein & Lehr LLP as counsel.

10. On February 16, 2021, Mallinckrodt's outside counsel, Ropes & Gray LLP, hosted an introductory meeting via Zoom for the Monitor and his counsel, as well as the General Counsel and Compliance Manager for Specialty Generics and the Chief Compliance Officer of Mallinckrodt plc. During this meeting, the Mallinckrodt executives provided an overview of Mallinckrodt's Specialty Generics business and its key personnel, its opioid supply chain and efforts to combat diversion, including suspicious order monitoring, the national opioid litigation initiated against Mallinckrodt, the steps Mallinckrodt has taken since the entry of the Operating Injunction, and the generics pharmaceutical market generally.

11. On February 28, 2021, the Monitor held a meeting via Zoom with over fifteen representatives from the Governmental Plaintiff Ad Hoc Committee.[1] This provided an opportunity for representatives of the state Attorneys General to share with the Monitor areas of particular interest and priority for the states, including suspicious order monitoring and monitoring of downstream customers to prevent diversion.

12. On March 12, 2021, the Monitor held an introductory meeting via Zoom with the President and Chief Financial Officer/Chief Transformation Officer for Specialty Generics.

13. In accordance with Section VI.B.3 of the Operating Injunction, within thirty (30) days of the Monitor's appointment, on March 10, 2021, Mallinckrodt agreed to the Independent Monitor's Draft Preliminary Work Plan (the "Work Plan"), which was developed with input from representatives of the Governmental Plaintiff Ad Hoc Committee.

14. The Work Plan is described as both a "Draft" and "Preliminary," given the breadth and scope of the Operating Injunction and the five-year duration of the monitorship. In the Work Plan, the Monitor expressed his intent to spend the first forty-five (45) to sixty (60) days defining the scope of work, including refining a preliminary approach to each area and developing a methodology to audit Mallinckrodt's compliance with Sections III-V of the Operating Injunction.

15. In the next ninety (90) days, prior to the submission of the Monitor's second report to this Court, the Monitor will continue these efforts, which include prioritizing the auditing of certain areas and developing a regular timeline for monitoring compliance at varying frequency intervals throughout the monitorship.

[1] The Governmental Plaintiff Ad Hoc Committee consists of the Debtors' guaranteed unsecured noteholders, the Attorneys General of 50 States and U.S. Territories, and the Plaintiffs' Executive Committee in *In re National Opioid Litigation*, MDL No. 2804.

16. The Work Plan outlines specific tasks the Monitor anticipates will be necessary to assess Mallinckrodt's compliance with the Operating Injunction, associates those tasks with each relevant subsection of the Operating Injunction, and identifies the frequency with which those tasks are expected to be conducted.

17. Likewise, Mallinckrodt and the Monitor agreed that, generally, Mallinckrodt's relevant promotional materials, policies, employee certifications, suspicious order monitoring reports, grants awarded to third-parties, trainings, contracts with lobbyists, product catalogues, websites, and social media presence will be reviewed. Additionally, the Monitor will interview appropriate Mallinckrodt employees and other relevant individuals, conducting follow-up interviews periodically, as necessary

18. Following agreement on the Work Plan, the Monitor conducted approximately seven (7) interviews (lasting over twelve (12) hours), via Zoom, of the following executives: Senior Vice President, Chief Compliance Officer; Director, Controlled Substances Compliance; Vice President, Global Security; Compliance Manager, Specialty Generics; Director, Digital Communications and Community Relations; Senior Director, Government Affairs and Advocacy; and Director, Post-Market Surveillance.

19. Additionally, at the Monitor's request, Mallinckrodt produced over five hundred (500) pages of documents and records, including the documents listed in **Exhibit Three** attached hereto and made a part hereof, on March 17, 18, 24, and 29, 2021. These documents and records have been reviewed, as of the submission of this First Monitor Report.

20. Based on the information obtained from the document review and interviews conducted to date, on April 22, 2021, the Monitor submitted a request to Mallinckrodt for the production of additional categories of documents and data. The requested materials include,

among other things: 2021 Sales Incentive Compensation Plans; complaints received through the Integrity Hotline related to Opioid Products[2] from Q4 2020 through Q1 2021; third-party lobbying contracts and lobbyists' compliance certifications; employee conflict of interest certifications; data related to orders for Opioid Products, the Suspicious Order Monitoring (SOM) algorithm, chargeback restrictions, and chargeback reinstatement; SOM Work Orders; certain communications with the Drug Enforcement Agency (DEA); the minutes and notes from meetings of the Promotional Review and the Specialty Generics Grant and Sponsorship Approval Committee and other related records. Where relevant, the additional documents requested are referenced *infra*.

IV. THE INTEGRITY HOTLINE

21. Based on input from the Governmental Plaintiff Ad Hoc Committee, the Monitor and Mallinckrodt established a process by which compliance concerns related to the Operating Injunction can be reported to the Monitor through his counsel. Mindful of the Operating Injunction's directive to use existing compliance mechanisms, if possible, the Monitor and Mallinckrodt agreed to establish this process by making changes to Mallinckrodt's existing Integrity Hotline, which is serviced by a third-party vendor Navex. The modifications to the existing system are described below.

22. Mallinckrodt maintains an Integrity Hotline that employees may use to share compliance concerns. Employees may report their concerns by telephone or through a secure third-party website using EthicsPoint software. These reports may be made anonymously.

23. Mallinckrodt modified EthicsPoint to allow reporters to identify a reported issue type as "Opioid Product Operating Injunction," and to categorize their report, based upon "drop

[2] Any capitalized terms used in this report that are not defined herein have the same definitions as ascribed to them in the Operating Injunction.

down" categories, as "Opioid Product Operating Injunction." Any reports categorized with either of these designations are automatically forwarded to the Monitor's counsel. To the extent any reports related to the Operating Injunction are incorrectly reported and categorized in EthicsPoint, Mallinckrodt's Chief Compliance Officer has committed to sharing those reports with the Monitor, via his counsel.

24. On occasion, the Monitor may request a random inspection of a sample of reports to ensure that Operating Injunction-related reports are being adequately captured and shared. If necessary, further modifications will be made to ensure the adequacy of the reporting process.

25. On April 12, 2021, the Chief Compliance Officer of Mallinckrodt plc and the General Counsel for Specialty Generics sent an email to Specialty Generics employees informing them that anyone who has concerns about Mallinckrodt's compliance with the Operating Injunction can make a report through the Integrity Hotline, either by phone or through the web-based interface described above. Additionally, these employees were informed that they may report concerns directly to the Monitor through his counsel. The contact information for these attorneys was also shared with the employees.

V. INITIAL EFFORTS TO ASSESS MALLINCKRODT'S COMPLIANCE WITH THE OPERATING INJUNCTION

A. Ban on Promotion (§ III.A)

26. Under Section III.A of the Operating Injunction, Mallinckrodt agreed not to engage in certain promotional activities relating to the promotion of Opioids, Opioid Products, products used for the treatment of Opioid-induced side effects, and the Treatment of Pain.

27. To date, Mallinckrodt has produced the following documents related to this subsection, which have been reviewed: Guide to Business Conduct; Operating Injunction for Opioid Business Policy; Operating Injunction for Opioids Business Training Session

PowerPoints; Operating Injunction Training Deck – Discussion Scenarios; Specialty Generics Product Catalogue; Promotional Review Committee Charter; Promotional Review Committee (PRC) Initiation, Review, and Approval of Advertising and Promotional Materials Standard Operating Procedure ("SOP"); Guidance for Frequently Asked Product Questions – Pharmaceuticals SOP; and Generics Medical Information Request SOP.

28. According to the Chief Compliance Officer for Mallinckrodt plc, more than two hundred (200) employees have received a copy of the Operating Injunction and certified that they understand and will comply with its terms, and the Compliance Department sends out employee certifications annually. The Monitor will review the employee certifications for 2021 after they are sent out and returned to the Compliance Department. The Monitor also anticipates conducting spot interviews of employees to confirm their understanding of the OI's terms.

29. Additionally, all of the relevant departments, including the Commercial and Communications Departments, have received training on the requirements of the Operating Injunction. This training included an overview of the Ban on Promotion provision's key definitions and permissible and impermissible practices thereunder. For the Commercial Department's trainings, compliance with this provision was particularly emphasized. The Chief Compliance Officer and Compliance Manager for Specialty Generics have attended various department meetings to answer any questions regarding the Ban on Promotion and other provisions of the Operating Injunction, generally.

30. The Monitor interviewed three of the nine core members of the Promotional Review Committee, which reviews all materials that are disseminated in connection with Mallinckrodt's products. One other member, the Vice President of Commercial Operations, will be interviewed as well. This additional interview will provide greater insight into Mallinckrodt's

review process for its written materials. Additionally, the Monitor has requested the notes and meeting minutes from any meetings the Promotional Review Committee has held since the entry of the Operating Injunction.

31. Before filing the next report, the Monitor will complete an independent review of Mallinckrodt's corporate website, the websites for each Opioid Product it manufactures, and its social media accounts, including its accounts on Twitter and LinkedIn. The Monitor will also review certain journals, publications, magazines and newsletters for promotional materials in violation of this subsection.

32. The Monitor has requested that Mallinckrodt produce its Office of Prescription Drug Promotion Filing Process for Ad Promo Material SOP.

B. No Financial Reward or Discipline Based on Volume of Opioid Sales (§ III.B)

33. Section III.B of the Operating Injunction restricts financial incentives provided to sales and marketing employees based on sales volume and data.

34. The Chief Compliance Officer explained in her interview that Mallinckrodt performs an annual review of the Sales Incentive Compensation Plans ("SICPs") for the Specialty Generics business.[3] This process includes a multi-department review.

35. In 2021, Mallinckrodt added a "clawback" provision to the SICPs for all executives and employees, which the OCC required as part of the bankruptcy proceeding. The Monitor understands that there are presently no pending investigations related to potentially criminal employee misconduct that may violate the "clawback." The Chief Compliance Officer has agreed to inform the undersigned Monitor in the event of any such investigations.

[3] This review also includes SICPs for the sale of active pharmaceutical ingredients and addiction treatment medicines, but such products are not defined as "Opioid Product(s)" in the Operating Injunction and so are beyond the scope of the Monitor's work. *See* OI § I.P

36. The Monitor has requested copies of all of the 2021 SICPs and any related terms and conditions. The Monitor will review the provisions related to metrics used to calculate employee compensation, including the weights attributed to net sales of Specialty Generics and the net contribution margin of Specialty Generics, to verify that any changes made to the SICPs for the 2021 fiscal year comply with Section III.B of the Operating Injunction

C. Ban on Funding/Grants to Third Parties (§ III.C)

37. Section III.C of the Operating Injunction restricts Mallinckrodt's ability to provide financial support or In-Kind Support to any Third Party that Promotes (or is for education about) Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects. Section III.C also restricts directors, officers, and management-level employees from serving on boards of entities engaging in Opioid Promotion.

38. The Monitor has reviewed Mallinckrodt's Specialty Generics Grant & Sponsorship Approval Committee SOP and the Specialty Generics Grant & Sponsorship Approval Committee Charter.

39. The Monitor has also interviewed the Senior Director of Government Affairs and Advocacy and the Director of Post-Market Surveillance, who are members of this committee. An interview of the Vice President of the Commercial Department, who is also a member of this committee, will be conducted in due course.

40. Since the entry of the Operating Injunction, the Specialty Generics Grant and Sponsorship Approval Committee has formalized certain processes, and maintains documentation related to any grant requests. The Monitor will assess the adequacy of this review process and determine whether the grants Mallinckrodt currently funds comply with Section III.C.

41. Mallinckrodt requires employees to complete an annual conflict of interest certification and has created a survey requiring all directors, officers, and management-level employees to disclose their board service in connection with any third-party that may violate Section III.C.7.

42. In order to monitor compliance with this provision, the Monitor requested the following additional documents and data: a list of all grants Mallinckrodt has awarded third-parties since 2018; copies of any requests for grants, including any Specialty Generics Grant and Sponsorship Request Forms submitted to Mallinckrodt since 2018; copies of any Letters of Decline or Agreement sent by the Specialty Generics Grant and Sponsorship Approval Committee in accordance with its SOP; the meeting minutes and notes for any meetings the Specialty Generics Grant and Sponsorship Approval Committee has held since the entry of the Operating Injunction; and a copy of the survey regarding board service the Compliance Department created with any responses thereto, including executed conflict certifications.

D. Lobbying Restrictions (§ III.D)

43. Section III.D of the Operating Injunction sets forth various restrictions on Mallinckrodt's Lobbying activities, including Lobbying activities related to legislation encouraging the prescription of Opioid Products or limiting access to non-Opioid treatments.

44. The Monitor will verify that all third-party state and federal lobbyists received an updated Statement of Work for their contracts and a copy of the Operating Injunction with a compliance certification, which Mallinckrodt required them to execute. The Monitor will assess the adequacy of the training provided to these lobbyists.

45. As detailed in the Work Plan, Mallinckrodt is required to notify the Monitor of its federal, state, and local Lobbying activities and when it engages lobbyists or amends its contracts with them. The Monitor and Mallinckrodt will develop a methodology for ensuring that this

information is reported in a useful and timely fashion. Additionally, the Monitor will interview certain third-party lobbyists and review the federal lobbying disclosure database.

46. The Monitor has requested that Mallinckrodt produce copies of the Scope of Work for any third-party state and federal lobbyists, along with copies of the executed compliance certifications for those individuals. The Monitor expects to request periodic reports from Mallinckrodt related to its Lobbying activities.

E. Monitoring and Reporting of Direct and Downstream Customers (§ III.G)[4]

47. Section III.G.I. of the Operating Injunction requires Mallinckrodt to operate an effective monitoring and reporting system in compliance with 21 C.F.R. § 1301.71(a), 21 C.F.R. §v 1301.74(b), 21 U.S.C. § 823(d) and Section 3292 of the SUPPORT for Patients and Communities.

48. The Monitor has reviewed the following documents concerning SOM that Mallinckrodt has produced: ST Hold Daily Audit Report SOP; Suspicious Order Monitoring Program Review of Reinstatement Requests from Downstream Registrants SOP; Suspicious Order Monitoring Program Review of Direct Customer Orders SOP; Suspicious Order Monitoring Program: Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants SOP; and Mallinckrodt's comments on the Notice of Proposed Rulemaking for Suspicious Orders of Controlled Substances.

[4] As Mallinckrodt does not currently engage in the activities prohibited by Sections III.E (Ban on Certain High Dose Opioids) and III.F (Ban on Prescription Savings Programs) of the Operating Injunction, this Report does not address any specific compliance-related activities undertaken relevant to these subsections, though the Monitor will continue to verify that there has been no change in Mallinckrodt's practices.

49. At this time, significant effort has been made to understand the complexities of Mallinckrodt's SOM, and Mallinckrodt appears committed to further strengthening this program. Monitoring compliance with this provision is a priority for the Monitor.

50. The Monitor interviewed two members of the Suspicious Order Monitoring Team (the "SOMT"), the Director of Controlled Substances Compliance and the Vice President of Global Security. These interviewees provided an overview of the changes Mallinckrodt made in connection with Mallinckrodt's 2017 Memorandum of Agreement with the DEA, how direct orders are processed and reviewed, and the manner in which Mallinckrodt currently conducts monitoring of downstream registrants. The Monitor anticipates that a follow-up interview with the Director of Controlled Substances Compliance will be required, as well as interviews of other SOMT members.

51. A better understanding of the thresholds the algorithm uses in connection with SOM, which detects changes in the pattern, frequency, and size of customers' orders, and the manner in which Mallinckrodt monitors downstream registrants is needed prior to making any recommendations in this area. However, initial interviews suggest that increasing Mallinckrodt's access to timely downstream data -- an industry-wide challenge -- would bolster the SOMT's downstream monitoring capabilities.

52. The Monitor supports Mallinckrodt's work with the third-party consultant, Analysis Group, Inc. ("AGI"), to analyze its SOM, including the artificial intelligence Mallinckrodt employs to perform automated reviews of direct orders and chargeback data. As AGI's review of Mallinckrodt's practices continues, the Monitor will keep abreast of any relevant changes concerning Mallinckrodt's SOM.

53. The Monitor has requested the following additional documents and data: orders for Opioid Products, chargeback restrictions and reinstatements, and the thresholds the algorithm uses in connection with SOM; a sample annual customer questionnaire and file for a downstream registrant; SOM Work Orders; Mallinckrodt's contract with AGI; relevant communications with the DEA; lists of any internet and social media search terms used in connection with SOM; and any requests for assistance from state licensing boards and law enforcement to Mallinckrodt concerning the sale of Opioid Products in Q1 2021, including Mallinckrodt's response to any such request.

F. General Terms (§ III.H) and Compliance with All Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid Product (§ III.I)

54. Subsection III.H prohibits Mallinckrodt from making any written or oral statement about Opioids or any Opioid product that is unfair, false, misleading, deceptive or unconscionable and requires Mallinckrodt to provide certain information at the request of any state Attorney General.

55. Subsection III.I requires Mallinckrodt to comply with all state and federal laws, regulations, and guidance relating to the sale, promotion, distribution, and disposal of any Opioid Products.

56. During a two-hour interview, the Chief Compliance Officer of Mallinckrodt plc provided a detailed overview of Mallinckrodt's compliance programs at both the corporate and management levels. Currently, the Compliance Department reports directly to the Chief Executive Officer, and the Chief Compliance Officer has seven team members. The Compliance Manager for Specialty Generics indirectly reports to Chief Compliance Officer. There are other committees and teams, such as the Controlled Substances Compliance Team, that are responsible for particular compliance-related activities as well.

57. The Compliance Manager for Specialty Generics provided additional information related to Specialty Generics' compliance program specifically, and Mallinckrodt is in the process of filling at least one position in the Legal Department with Specialty Generics compliance responsibilities. The Monitor will evaluate the appropriateness of Mallinckrodt's overall compliance structure, given the obligations set forth in the Operating Injunction.

58. The manner in which Mallinckrodt's compliance with respect to Section III.I will be monitored is still being determined and will naturally overlap with the monitoring of Mallinckrodt's compliance with other sections. Under the agreed upon Work Plan, Mallinckrodt is required to notify the Monitor upon receipt of any government communications including subpoenas, Civil Investigative Demands related to Opioid Products, and other requests for information related to the sale, promotion, or distribution of Opioids, so the Monitor can assess Mallinckrodt's compliance with these provisions.

G. Training (§ III.K)

59. Section III.K requires Mallinckrodt to provide regular training, at least once per year, to relevant employees on the obligations the Operating Injunction creates.

60. The Monitor has completed a review of the following documents that Mallinckrodt has produced: Operating Injunction for Opioid Business Policy; the Operating Injunction for Opioids Business Training Sessions PowerPoints for various departments; and the Operating Injunction Training Deck – Discussion Scenarios, explaining the conduct permissible and impermissible under the Operating Injunction.

61. During their interviews, the Chief Compliance Officer and the Compliance Manager for Specialty Generics provided an overview of the education and training for employees the Compliance Department provides. Mallinckrodt utilizes the learning management system ComplianceWire to train employees and maintain records related to employees'

completion of their training. ComplianceWire has three training components specific to the Operating Injunction. First, employees must review the Operating Injunction for Opioid Business Policy and certify they have done so electronically. Second, employees receive live training from an instructor via WebEx, which consists of a PowerPoint presentation with hypothetical factual scenarios and related questions. Third, employees must complete the survey discussed *supra* regarding any board service that may violate Subsection III.C.

62. The Monitor will review the trainings contained in ComplianceWire and evaluate the adequacy of the training Mallinckrodt provides and whether it sufficiently tests employees' understanding of the terms of the Operating Injunction.

H. Clinical Data Transparency (§ IV)

63. Section IV of the Operating Injunction requires Mallinckrodt to share certain clinical data related to its Opioid Products through a third-party data archive that makes such information available to Qualified Researchers with a bona fide scientific research proposal.

64. Mallinckrodt has contracted with the company Vivli Inc. ("Vivli"), and, according to its Chief Compliance Officer, all of the data required to be shared pursuant to Section IV is available through that platform.[5]

65. Any research proposals submitted through Vivli are reviewed for scientific merit by Wellcome Trust Independent Review Panel members. At this time, there have not been any requests for access to this data.

66. The Monitor will verify that the clinical data specified in Section IV is available through Vivli and assess the appropriateness of the review criteria applied by the panel of

[5] Additional information regarding Mallinckrodt's clinical data archive is available at: https://vivli.org/ourmember/specgx-llc-a-subsidiary-of-mallinckrodt-plc/.

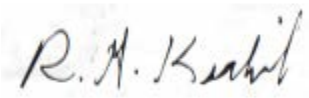
reviewers in evaluating any proposals submitted to them, as well as the extent of Mallinckrodt's involvement with that process.

I. Public Access to Mallinckrodt's Documents (§ V)

67. Section V of the Operating Injunction requires Mallinckrodt to produce certain documents to the Settling States within nine months of October 12, 2020 (*i.e.*, on or before July 12, 2020).

68. The Monitor's second report to this Court will contain a status report as to Mallinckrodt's compliance with this provision.

Wherefore, the undersigned Monitor respectfully submits this First Monitor Report.



R. Gil Kerlikowske
Gil Kerlikowske L.L.C.

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EXHIBIT 1

Exhibit 2

Operating Injunction

MALLINCKRODT INJUNCTIVE RELIEF
DRAFT TERM SHEET

I. DEFINITIONS

A. "Bankruptcy Court" shall mean the United States Bankruptcy Court for the District of Delaware.

B. "Cancer-Related Pain Care" shall mean care that provides relief from pain resulting from a patient's active cancer or cancer treatment, as distinguished from treatment provided during remission.

C. "CDC Guideline Recommendations" shall mean the 12 enumerated Recommendations published by the U.S. Centers for Disease Control and Prevention (CDC) for the prescribing of opioid pain medication for patients 18 and older in primary care settings as part of its 2016 Guideline for Prescribing Opioids for Chronic Pain (CDC Guidelines), as updated or amended by the CDC.

D. "Chapter 11 Cases" means the proceedings to be commenced by Mallinckrodt Enterprises LLC, Mallinckrodt LLC, and SpecGX LLC and certain of their affiliates under chapter 11 of the United States Bankruptcy Code.

E. "Chapter 11 Plan" shall mean the plan of reorganization under chapter 11 of the United States Bankruptcy Code that includes Mallinckrodt Enterprises LLC, Mallinckrodt LLC and SpecGx LLC.

F. "Confirmation Order" shall mean the order of the Bankruptcy Court (or other court of competent jurisdiction) confirming the Chapter 11 Plan.

G. "Downstream Customer Data" shall mean transaction information that Mallinckrodt collects relating to its direct customers' sales to downstream customers, including but not limited to chargeback data tied to Mallinckrodt providing certain discounts, "867 data," and IQVIA data.

H. "Effective Date" shall mean the date on which the Chapter 11 Plan goes effective.

I. "End-of-Life Care" shall mean care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home.

J. "Health Care Provider" shall mean any U.S.-based physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products and any medical facility, practice, hospital, clinic or pharmacy.

K. "In-Kind Support" shall mean payment or assistance in the form of goods, commodities, services, or anything else of value.

L. "Lobby" and "Lobbying" shall have the same meaning as "lobbying activities" and "lobbying contacts" under the federal lobbying disclosure act, 2 U.S.C. § 1602 *et seq*., and any analogous state or local provisions governing the person or entity being lobbied in that particular state or locality. As used in this document, "Lobby" and "Lobbying" include Lobbying directly or indirectly, through grantees or Third Parties.

M. "Mallinckrodt" shall mean Mallinckrodt Enterprises LLC, Mallinckrodt LLC, and SpecGX LLC, and each of their current and former subsidiaries, predecessors, successors, joint ventures, divisions and assigns. It shall also mean officers, directors, independent contractors, consultants, agents, employees, partners, and principals, provided that they are acting within the scope of their engagement or employment.

N. "Mallinckrodt's Opioid Business" shall mean Mallinckrodt's business operations relating to the manufacture and sale of Opioid Product(s) in the United States and its territories.

O. "Opioid(s)" shall mean all naturally occurring, synthetic, or semisynthetic substances that interact with opioid receptors and act like opium.

P. "Opioid Product(s)" shall mean all current and future medications containing Opioids approved by the U.S. Food & Drug Administration (FDA) and listed by the DEA as Schedule II, III, or IV drugs pursuant to the federal Controlled Substances Act, including but not limited to codeine, fentanyl, hydrocodone, hydromorphone, meperidine, morphine, oxycodone, oxymorphone, tapentadol, and tramadol. The term "Opioid Products(s)" shall not include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage"; methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities; or raw materials, active pharmaceutical ingredients and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials, active pharmaceutical ingredients and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories.

Q. "OUD" shall mean opioid use disorder defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5)*, as updated or amended.

R. "Petition Date" shall mean the date on which the Chapter 11 Cases are commenced.

S. "Promote," "Promoting," and "Promotion" shall mean dissemination of information or other practices intended or that could be reasonably anticipated to increase sales, prescriptions, the utilization of prescription products, or that attempt to influence prescribing practices or formulary decisions in the United States.

T. "Qualified Researcher" shall mean any researcher holding a faculty appointment or research position at an institution of higher education, a research organization, a nonprofit organization, or a government agency.

U. "Settling State" means any State that becomes a party to a restructuring support agreement with respect to the Chapter 11 Plan or otherwise votes to accept the Chapter 11 Plan.

V. "Suspicious Order" shall have the same meaning as provided by the Controlled Substances Act, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder and analogous state laws and regulations.

W. "Third Party" shall mean any person or entity other than Mallinckrodt or a government entity.

X. "Treatment of Pain" shall mean the provision of therapeutic modalities to alleviate or reduce pain.

Y. "Unbranded Information" shall mean any information that does not identify one or more specific products.

II. SCOPE AND ENFORCEMENT

A. All of the provisions of this Agreement shall apply both while Mallinckrodt is in bankruptcy and after Mallinckrodt emerges from bankruptcy, and they shall apply to the operation of Mallinckrodt's Opioid Business by any subsequent purchaser (regardless of whether Mallinckrodt is sold through the bankruptcy process or after bankruptcy, and regardless whether the purchaser buys all or just a portion of Mallinckrodt's Opioid Business). For the avoidance of doubt, nothing in this Agreement applies to the operation of a subsequent purchaser(s)' pre-existing opioid business.

B. The provisions of this Agreement will not apply to Mallinckrodt's parent or its parent's subsidiaries, other than those subsidiaries included in the above definition of Mallinckrodt, so long as Mallinckrodt's parent agrees in a legally binding manner that neither it, nor any of its other subsidiaries, will be involved in the sale or distribution of opioids classified as DEA Schedule II–IV drugs in the future.

C. In connection with its Chapter 11 Cases, Mallinckrodt consents to the entry of a final judgment or consent order upon the Effective Date imposing all of the provisions of this Agreement in state court in each of the Settling States. During the pendency of the Chapter 11 Cases, this Agreement is enforceable in the Bankruptcy Court. After the Effective Date, this Agreement is enforceable in state court in each of the Settling States. Mallinckrodt agrees that seeking entry or enforcement of such a final judgment or consent order will not violate any other injunctions or stays that it will seek, or that may otherwise apply, in connection with its Chapter 11 Cases or the confirmation of its Chapter 11 Plan.

D. **Term**

1. Unless addressed in Section II.D.2–3, each provision of this Agreement shall apply for 8 years from the Petition Date.

2. The provisions of Section III.A ("Ban on Promotion"), Section III.B ("No Financial Reward or Discipline Based on Volume of Opioid Sales"), Section III.F ("Ban on Prescription Savings Program"), Section III.G ("Monitoring and Reporting of Direct and Downstream Customers"), Section III.H ("General Provisions"), Section III.I ("Compliance with All Laws and Regulations Relating to the Sale Promotion and Distribution of Any Opioid Product"), and Section V ("Public Access to Documents") shall not be subject to any term.

3. The provisions of Section VI ("Independent Monitor") shall apply for five years from the Petition Date. If, at the conclusion of the Monitor's five-year term, the Settling States determine in good faith and in consultation with the Monitor that justifiable cause exists, the Monitor's engagement shall be extended for an additional term of up to two years, subject to the right of Mallinckrodt to commence legal proceedings for the purpose of challenging the decision of the Settling States and to seek preliminary and permanent injunctive relief with respect thereto. For purposes of this paragraph "justifiable cause" means a failure by Mallinckrodt to achieve and maintain substantial compliance with the substantive provisions of this Agreement.

E. Notice and Cure

1. For the purposes of resolving disputes with respect to compliance with this Agreement, should any State Attorney General have reason to believe that Mallinckrodt has violated a provision of this Agreement subsequent to the Petition Date, then such Attorney General shall notify Mallinckrodt in writing of the specific objection, identify with particularity the provisions of this Agreement that the practice appears to violate, and give Mallinckrodt 30 days to respond to the notification.

2. Upon receipt of written notice from such State Attorney General, Mallinckrodt shall provide a written response, containing either a statement explaining why Mallinckrodt believes it is in compliance with this Agreement or a detailed explanation of how the alleged violation occurred and a statement explaining how and when Mallinckrodt intends to remedy or has remedied the alleged violation.

3. Such State Attorney General may not take any action concerning the alleged violation of this Agreement during the 30-day response period. Nothing shall prevent such State Attorney General from agreeing in writing to provide Mallinckrodt with additional time beyond the 30 days to respond to the notice. However, such State Attorney General may take any action, including, but not limited to legal action to enforce compliance with the consent judgment specified by Section II.C, without delay if such State Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

4. Such State Attorney General may bring an action against Mallinckrodt to enforce the terms of the consent judgment specified by Section II.C, but only after

providing Mallinckrodt an opportunity to respond to the notification as described above or within any other period as agreed to by Mallinckrodt and such State Attorney General.

5. Nothing in this Agreement shall be interpreted to limit any State Attorney General's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable state law, and Mallinckrodt agrees to comply with a CID or investigative subpoena issued pursuant to such authority.

6. Nothing herein shall be construed to exonerate any failure to comply with any provision of this Agreement after the Petition Date, or to compromise the authority of any State Attorney General to take action for any failure to comply with this Agreement.

III. INJUNCTIVE RELIEF

A. Ban on Promotion

1. Mallinckrodt shall not engage in the Promotion of Opioids or Opioid Products, including but not limited to, by:

   a. Employing or contracting with sales representatives or other persons to Promote Opioids or Opioid Products to Health Care Providers or patients or to persons that influence or determine the Opioid Products included in formularies;

   b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of Opioids or Opioid Products;

   c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to Opioids or Opioid Products;

   d. Creating, sponsoring, operating, controlling, or otherwise providing financial support or In-Kind Support to any website, network, and/or social or other media account for the Promotion of Opioids or Opioid Products;

   e. Creating, sponsoring, distributing, or otherwise providing financial support or In-Kind Support for materials Promoting Opioids or Opioid Products, including but not limited to brochures, newsletters, pamphlets, journals, books, and guides;

   f. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote Opioids or Opioid Products, including but not limited to internet advertisements or similar content, and

providing hyperlinks or otherwise directing internet traffic to advertisements; and

g. Engaging in Internet search engine optimization or other techniques designed to Promote Opioids or Opioid Products by improving rankings or making content appear among the top results in an Internet search or otherwise be more visible or more accessible to the public on the Internet.

2. Notwithstanding Section III.A.1, III.A.5, and III.C, Mallinckrodt may:

a. Maintain a corporate website;

b. Maintain a website for any Opioid Product that contains principally the following content: the FDA-approved package insert, medication guide, and labeling, and a statement directing patients or caregivers to speak with a licensed Health Care Provider;

c. Provide information or support the provision of information as expressly required by law or any state or federal government agency with jurisdiction in the state where the information is provided;

d. Provide the following by mail, electronic mail, on or through Mallinckrodt's corporate or product websites or through other electronic or digital methods: FDA-approved package insert, medication guide, approved labeling for Opioid Products or other prescribing information for Opioid Products that are published by a state or federal government agency with jurisdiction in the state where the information is provided;

e. Provide scientific and/or medical information in response to an unsolicited request by a Health Care Provider consistent with the standards set forth in the FDA's Draft Guidance for Industry, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011, as updated or amended by the FDA) and Guidance for Industry, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009, as updated or amended by the FDA);

f. Provide a response to any unsolicited question or request from a patient or caregiver, directing the patient or caregiver to the FDA-approved labeling or to speak with a licensed Health Care Provider without describing the safety or effectiveness of Opioids or any Opioid Product or naming any specific provider or healthcare institution; or directing the patient or caregiver to speak with their insurance carrier regarding coverage of an Opioid Product;

g. Provide Health Care Economic Information, as defined at 21 U.S.C. § 352(a), to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis consistent with standards set forth in the FDA's Draft Questions and Answers Guidance for Industry and Review Staff, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities* (Jan. 2018*)*, as updated or amended by the FDA;

h. Provide information, through a product catalog or similar means, related to an Opioid or Opioid Product, including, without limitation, pricing information, weight, color, shape, packaging size, type, reference listed drug, National Drug Code label, and such other descriptive information (including information set forth in a standard Healthcare Distribution Alliance Form or technical data sheet and the FDA approval letter) sufficient to identify the products available, to place an order for a product, and to allow the product to be loaded into a customer's inventory and ordering system or a third party pricing compendia;

i. Sponsor or provide financial support or In-Kind Support for an accredited or approved continuing medical education program required by either an FDA-approved Risk Evaluation and Mitigation Strategy (REMS) program or other federal or state law or regulation applicable in the state where the program is provided through an independent Third Party, which shall be responsible for the continuing medical education program's content without the participation of Mallinckrodt;

j. Provide Unbranded Information in connection with managing pain in End-of-Life Care and/or Cancer-Related Pain Care relating to: the use of Opioids for managing such pain, as long as the Unbranded Information identifies Mallinckrodt as the source of the information;

k. Promote medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage" or methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities;

l. Promote raw materials, active pharmaceutical ingredients and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such raw materials, active pharmaceutical ingredients and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories; And, notwithstanding this exception, Mallinckrodt will not promote raw materials, active pharmaceutical ingredients and/or immediate precursors to Healthcare Providers or patients; and

m. Provide rebates, discounts, and other customary pricing adjustments to DEA-registered customers and contracting intermediaries, such as Buying

Groups, Group Purchasing Organizations, and Pharmacy Benefit Managers, except as prohibited by Section III.G.

3. Mallinckrodt shall not engage in the following specific Promotional activity relating to any products for the treatment of Opioid-induced side effects (for the avoidance of doubt, "Opioid-induced side effects" does not include addiction to Opioids or Opioid Products):

   a. Employing or contracting with sales representatives or other persons to Promote products for the treatment of Opioid-induced side effects to Health Care Providers or patients;

   b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of products for the treatment of Opioid-induced side effects;

   c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to products for the treatment of Opioid-induced side effects;

   d. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote products for the treatment of Opioid-induced side effects, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements; and

   e. Engaging in any other Promotion of products for the treatment of Opioid-induced side effects in a manner that encourages the utilization of Opioids or Opioid Products or normalizes the use of Opioids or Opioid Products for chronic pain.

4. Notwithstanding Section III.A.3 directly above, Mallinckrodt may engage in other Promotional activity for products that may be used for the treatment of Opioid-induced side effects but also have non-Opioid related indications, so long as such Promotion does not explicitly or implicitly associate the product with Opioids or Opioid Products, except for linking to the FDA label associated with that product.

5. Treatment of Pain

   a. Mallinckrodt shall not, either through Mallinckrodt or through Third Parties, engage in Promotion of the Treatment of Pain in a manner that directly or indirectly encourages the utilization of Opioids or Opioid Products.

   b. Mallinckrodt shall not, either through Mallinckrodt or through Third Parties, Promote the concept that pain is undertreated in a manner that

directly or indirectly encourages the utilization of Opioids or Opioid Products.

c. Mallinckrodt shall not disseminate Unbranded Information, including Unbranded Information about a medical condition or disease state, that contains links to branded information about Opioid Products or generates leads for sales of Opioid Products.

6. To the extent that Mallinckrodt engages in conduct permitted by Sections III.A.2 and A.4 above, Mallinckrodt shall do so in a manner that is:

a. Consistent with the CDC Guideline Recommendations, as applicable; and

b. Truthful, non-misleading, accurate, non-deceptive, and does not omit any relevant information.

B. No Financial Reward or Discipline Based on Volume of Opioid Sales

1. Mallinckrodt shall not provide financial incentives to its sales and marketing employees or discipline its sales and marketing employees based upon sales volume or sales quotas for Opioid Products. Notwithstanding the foregoing, this provision does not prohibit financial incentives (*e.g.*, customary raises or bonuses) based on the performance of the overall company or Mallinckrodt's generics business, as measured by EBITDA, revenue, cash flow or other similar financial metrics.

2. Mallinckrodt shall not offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, to or from any person in return for the prescribing or use of an Opioid Product. For the avoidance of doubt, this shall not prohibit the provision of rebates and/or chargebacks to the extent permitted by Section III.A.2.m.

3. Mallinckrodt's compensation policies and procedures shall be designed to ensure compliance with this Agreement and other legal requirements.

C. Ban on Funding/Grants to Third Parties

1. Mallinckrodt shall not directly or indirectly provide financial support or In-Kind Support to any Third Party that Promotes or is for education about Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects, including educational programs or websites that Promote Opioids, Opioids Products, or products intended to treat Opioid-related side effects but excluding financial support otherwise allowed by this Agreement or required by a federal or state agency.

2. Mallinckrodt shall not create, sponsor, provide financial support or In-Kind Support to, operate, or control any medical society or patient advocacy group

relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.

3. Mallinckrodt shall not provide links to any Third Party website or materials or otherwise distribute materials created by a Third Party relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.

4. Mallinckrodt shall not use, assist, or employ any Third Party to engage in any activity that Mallinckrodt itself would be prohibited from engaging in pursuant to this Agreement.

5. Mallinckrodt shall not enter into any contract or agreement with any person or entity or otherwise attempt to influence any person or entity in such a manner that has the purpose or foreseeable effect of limiting the dissemination of information regarding the risks and side effects of using Opioids.

6. Mallinckrodt shall not compensate or support Health Care Providers, other than Mallinckrodt employees, or organizations to advocate for formulary access or treatment guideline changes that would have the effect of increasing access to any Opioid Product by third-party payers, *i.e.*, any entity, other than an individual, that pays or reimburses for the dispensing of prescription medicines, including but not limited to managed care organizations and pharmacy benefit managers. Nothing in this provision affects the limitations on Mallinckrodt employees set forth in Section III.A. Notwithstanding anything to the contrary in this Agreement, this provision does not prohibit the payment of customary rebates or other pricing concessions to third party payors, including state Medicaid programs, as part of an overall pricing agreement, except as prohibited by Section III.F.

7. No director, officer, or management-level employee of Mallinckrodt may serve as a director, board member, employee, agent, or officer of any entity, other than Mallinckrodt plc or a wholly owned subsidiary thereof, that not incidentally engages in Promotion relating to Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects. Any director, officer, or management-level employee of Mallinckrodt that serves as a director, board member, employee, agent or officer of any entity shall recuse himself or herself from any decisions in that capacity that are related to the Promotion of Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.

8. Mallinckrodt shall play no role in appointing persons to the board, or hiring persons to the staff, of any entity that not incidentally engages in Promotion relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.

9. The prohibitions in Section III.C shall not apply to engagement with Third Parties based on activities related to (1) medications with a FDA-approved label that lists

only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage" or methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities; (2) raw materials, active pharmaceutical ingredients and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials, active pharmaceutical ingredients and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories; or (3) education warning about drug abuse or promoting prevention or treatment of drug misuse.

10. Mallinckrodt will be in compliance with Sections III.C.2 and III.C.3 with respect to support of an individual Third Party to the extent that the Independent Monitor or the Settling States determines that such support does not increase the risk of the inappropriate use of Opioids and that Mallinckrodt has not acted for the purpose of increasing the use of Opioids.

D. Lobbying Restrictions

1. Mallinckrodt shall not Lobby for the enactment of any provision of any federal, state, or local legislation or promulgation of any provision of any rule or regulation that:

   a. encourages or requires Health Care Providers to prescribe Opioid Products or sanctions Health Care Providers for failing to prescribe Opioids or failing to treat pain with Opioids;

   b. would have the effect of limiting access to any non-Opioid alternative pain treatments; or

   c. pertains to the classification of any Opioid or Opioid Product as a scheduled drug under the Controlled Substances Act.

2. Mallinckrodt shall not Lobby against the enactment of any provision of any federal, state or local legislation or promulgation of any provision of any rule or regulation that supports:

   a. The use of non-pharmacologic therapy and/or non-Opioid pharmacologic therapy to treat chronic pain over or instead of Opioid use, including but not limited to third party payment or reimbursement for such therapies;

   b. The use and/or prescription of immediate release Opioids instead of extended release Opioids when Opioid use is initiated, including but not limited to third party reimbursement or payment for such prescriptions;

   c. The prescribing of the lowest effective dose of an Opioid, including but not limited to third party reimbursement or payment for such prescription;

   d. The limitation of initial prescriptions of Opioids to treat acute pain;

e. The prescribing and other means of distribution of naloxone to minimize the risk of overdose, including but not limited to third party reimbursement or payment for naloxone;

f. The use of urine testing before starting Opioid use and annual urine testing when Opioids are prescribed, including but not limited to third party reimbursement or payment for such testing;

g. Evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for OUD, including but not limited to third party reimbursement or payment for such treatment; or

h. The implementation or use of Opioid drug disposal systems.

3. Mallinckrodt shall not Lobby against the enactment of any provision of any federal, state or local legislation or promulgation of any provision of any rule or regulation creating or expanding the operation or use of PDMPs, including but not limited to provisions requiring Health Care Providers to review PDMPs when Opioid use is initiated and with every prescription thereafter. For the avoidance of doubt, Mallinckrodt may Lobby in support of a particular PDMP proposal.

4. Notwithstanding the foregoing restrictions in Sections III.D.1–3, III.A, and III.C, the following conduct is not restricted:

a. Lobbying against the enactment of any provision of any state, federal, municipal, or county taxes, fees, assessments, or other payments;

b. Challenging the enforcement of, or suing for declaratory or injunctive relief with respect to legislation, rules or regulations referred to in Section III.D.1;

c. Communications made by Mallinckrodt in response to a statute, rule, regulation, or order requiring such communication;

d. Communications by a Mallinckrodt representative appearing before a federal or state legislative or administrative body, committee, or subcommittee as a result of a mandatory order or subpoena commanding that person to testify;

e. Responding, in a manner consistent with this Agreement, to an unsolicited request for the input on the passage of legislation or the promulgation of any rule or regulation when such request is submitted in writing specifically to Mallinckrodt from a government entity directly involved in the passage of that legislation or promulgation of that rule or regulation;

f. Communicating with a federal or state agency in response to a Federal Register or similar notice or an unsolicited federal or state legislative committee request for public comment on proposed legislation; and

g. Responding to requests from the DEA, the FDA, or any other Federal or state agency and/or participating in FDA or other agency panels at the request of the agency.

h. Participate in meetings and other proceedings before the FDA, FDA advisory committee or other FDA committee in connection with the approval, modification of approval, or oversight of its own products.

5. Mallinckrodt shall require all of its officers, employees, and agents engaged in Lobbying to certify in writing or by appropriate electronic means to Mallinckrodt that they are aware of and will fully comply with the provisions of this Agreement with respect to Lobbying on behalf of Mallinckrodt.

E. Ban on Certain High Dose Opioids

1. Mallinckrodt shall not commence manufacturing, promoting, or distributing any Opioid Product that exceeds 30 milligrams of oxycodone per pill.

F. Ban on Prescription Savings Programs

1. Mallinckrodt shall not directly or indirectly offer any discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.

2. Mallinckrodt shall not directly or indirectly provide financial support to any Third Party that offers coupons, discounts, rebates or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.

3. Mallinckrodt shall not directly or indirectly assist patients, Health Care Providers, or pharmacies regarding the claims and/or prior authorization process required for third-party payers to approve claims involving any Opioid Product.

G. Monitoring and Reporting of Direct and Downstream Customers

1. Mallinckrodt shall operate an effective monitoring and reporting system in compliance with 21 C.F.R. § 1301.71(a), 21 C.F.R. §1301.74(b), 21 U.S.C. § 823(d) and Section 3292 of the SUPPORT for Patients and Communities Act, that shall include processes and procedures that:

a. Utilize all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer;

b. Utilize all reasonably available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product;

c. Utilize all information Mallinckrodt receives that bears upon a direct customer's or a downstream customer's diversion activity or potential for diversion activity, including reports by Mallinckrodt's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media; and

d. Upon request (unless otherwise required by law), report to any requesting State Attorney General or State controlled substances regulatory agency any direct customer or downstream customer in such requesting State Attorney General's or agency's State identified as part of the monitoring required by (a)-(c), above, and any customer relationship in such State terminated by Mallinckrodt relating to diversion or potential for diversion. These reports shall include the following information, to the extent known to Mallinckrodt:

i. The identity of the downstream registrant and the direct customer(s) identified by Mallinckrodt engaged in the controlled substance transaction(s), to include each registrant's name, address, business type, and DEA registration number;

ii. The dates of reported distribution of controlled substances by direct customers to the downstream registrant during the relevant time period;

iii. The drug name, drug family or NDC and dosage amounts reportedly distributed;

iv. The transaction or order number of the reported distribution; and

v. A brief narrative providing a description of the circumstances leading to Mallinckrodt's conclusion that there is a risk of diversion.

2. Mallinckrodt shall not provide to any direct customer an Opioid Product to fill an order identified as a Suspicious Order unless Mallinckrodt's DEA Compliance Department investigates and finds that the order is not suspicious. Where Mallinckrodt has investigated a potentially Suspicious Order and determined that the order is not suspicious, Mallinckrodt must document the bases for its determination, and provide such documentation to any State Attorney General, or State controlled substances regulatory agency, upon request.

3. Upon request, Mallinckrodt shall provide full cooperation and assistance to any federal, state or local law enforcement investigations of potential diversion or

suspicious circumstances involving Opioid Products, including criminal law enforcement agencies, drug control agencies, professional licensing boards, and Attorney General's offices.

4. Mallinckrodt agrees that it will refrain from providing an Opioid Product directly to a retail pharmacy location or Health Care Provider. Nothing in this provision, however, prevents Mallinckrodt from (i) acting as a distributor of medications relating to (x) the treatment of opioid use disorders; (y) the treatment of opioid abuse, addiction, dependence, or overdose, including medication-assisted treatment for opioid addiction; and (z) rescue medications for opioid overdose; or (ii) providing an Opioid Product directly to a mail order pharmacy, distribution center serving a chain pharmacy, or pharmacy provider that exclusively serves long-term care or hospice providers and their patients.

H. General Terms

1. To the extent that any provision in this Agreement conflicts with federal or relevant state law or regulation, the requirements of the law or regulation will prevail. To the extent that any provision in the Agreement is in conflict with federal or relevant state law such that Mallinckrodt cannot comply with both the statute or regulation and a provision of this Agreement, Mallinckrodt may comply with such statute or regulation. Mallinckrodt will provide advance written notice to the affected State Attorney(s) Generals of the statute or regulation that Mallinckrodt intends to comply under this paragraph, and the provision of this Agreement that is in conflict with the statute or regulation. In the event any State Attorney General disagrees with Mallinckrodt's interpretation of the conflict, such State Attorney General reserves the right to pursue any remedy or sanction that may be available regarding compliance with this Agreement.

2. Mallinckrodt shall not make any written or oral statement about Opioids or any Opioid Product that is unfair, false, misleading, deceptive or unconscionable. For purposes of this paragraph, "Opioid Product" shall also include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage" as well as methadone 5 and 10 mg tablets.

3. Mallinckrodt shall not represent that Opioids or any Opioid Product(s) have approvals, characteristics, uses, benefits, or qualities that they do not have. For purposes of this paragraph, "Opioid Product" shall also include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage" as well as methadone 5 and 10 mg tablets.

4. For the avoidance of doubt, nothing in this Agreement is intended to or shall be construed to prohibit Mallinckrodt in any way whatsoever from taking legal or factual positions with regard to its Opioid Product(s) in defense of litigation or other legal proceedings or investigations.

5. Upon the request of any State Attorney General, Mallinckrodt shall provide the requesting State Attorney General with copies of the following, within 30 days of the request:

   a. Any litigation or civil or criminal law enforcement subpoenas or Civil Investigative Demands relating to Mallinckrodt's Opioid Product(s); and

   b. Warning or untitled letters issued by the FDA regarding Mallinckrodt's Opioid Product(s) and all correspondence between Mallinckrodt and the FDA related to such letters.

I. Compliance with All Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid Product

1. Mallinckrodt shall comply with all laws and regulations that relate to the sale, promotion, distribution, and disposal of any Opioid Product including but not limited to:

   a. State controlled substances acts, including all guidance issued by applicable state regulator(s), and related regulations;

   b. The Federal Controlled Substance Act, including all guidances issued by the DEA;

   c. The Federal Food, Drug and Cosmetic act, or any regulation promulgated thereunder;

   d. FDA Guidances;

   e. State consumer protection and unfair trade practices acts; and

   f. State laws and regulations related to opioid prescribing, distribution and disposal.

J. Compliance Deadlines

1. As of the Petition Date, Mallinckrodt must be in full compliance with the provisions included in this Agreement with the exception of the provisions in Section V ("Public Access to Mallinckrodt Documents").

K. Training

1. Mallinckrodt shall provide regular training, at least once per year, to relevant employees on their obligations imposed by this Agreement.

IV. CLINICAL DATA TRANSPARENCY

A. Data to Be Shared

1. Mallinckrodt shall share the following clinical data through a third-party data archive that conforms to the requirements defined below to increase the transparency of its clinical research.

   a. Mallinckrodt shall make available all previously disclosed data and/or information regarding Mallinckrodt Opioid Products;

   b. Mallinckrodt shall make available all previously unreleased data regarding Mallinckrodt Opioid Products, for both approved and unapproved indications, including:

      i. Full analyzable data set(s) (including individual participant-level data de-identified by an independent biostatistician);

      ii. The clinical study report(s) redacted for commercial or personal identifying information;

      iii. The full protocol(s) (including the initial version, final version, and all amendments); and

      iv. Full statistical analysis plan(s) (including all amendments and documentation for additional work processes) and analytic code.

   c. Mallinckrodt shall make available the above information for all studies for any new Mallinckrodt Opioid Product or new indications that are approved within 30 days after regulatory approval or 18 months after study completion, whichever occurs later.

B. Third-Party Data Archive

1. Mallinckrodt shall share the above information via a third-party data archive that makes clinical data available to Qualified Researchers with a bona fide scientific research proposal.

2. The data archive shall have a panel of reviewers with independent review authority to determine whether the researchers are qualified, whether a research application seeks data for bona fide scientific research, and whether a research proposal is complete.

3. The panel may exclude research proposals with a commercial interest.

C. Non Interference

1. Mallinckrodt shall not interfere with decisions made by the staff or reviewers associated with the third-party data archive.

D. Data Use Agreement

1. Any data sharing agreement with a Qualified Researcher who receives shared data via the third-party data archive shall contain contact information for Mallinckrodt's pharmacovigilance staff. Every agreement shall require the lead qualified researcher to inform Mallinckrodt's pharmacovigilance staff within 24 hours of any determination that research findings could detrimentally impact the risk-benefit assessment regarding the product. The lead Qualified Researcher may also inform regulatory authorities of the safety signal impacting the risk-benefit assessment. Mallinckrodt's pharmacovigilance staff shall take all necessary and appropriate steps upon receipt of such safety information, including but not limited to notifying regulatory authorities or the public.

E. Cost

1. Mallinckrodt shall bear all costs for making data and/or information available.

V. PUBLIC ACCESS TO MALLINCKRODT DOCUMENTS

A. Documents Subject to Public Disclosure

1. The following documents shall be produced by Mallinckrodt to each Settling State and are subject to public disclosure in perpetuity as part of an industry-wide document disclosure program, except for the redactions authorized by Section V.B:

   a. All documents, indices, and privilege logs Mallinckrodt produced to any of the Settling States prior to the Petition Date, including in litigation and in response to investigative demands or other formal or informal requests related to opioids.

   b. All documents, indices, and privilege logs Mallinckrodt produced in the Opioid Multi-District Litigation (*In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804 (N.D. Ohio)) and the New York litigation (*In re Opioid Litigation*, 400000/2017 (Suffolk County)) prior to the Petition Date.

   c. All documents, indices, and privilege logs Mallinckrodt has produced in other litigation related to opioids, excluding patent litigation.

   d. All filings, motions, orders, court transcripts, deposition transcripts, and exhibits in the possession, custody, or control of Mallinckrodt from litigation related to opioids, excluding patent litigation.

2. All documents produced under this provision shall be provided in electronic format with all related metadata. Mallinckrodt and the Settling States will work cooperatively to develop technical specifications for the productions.

B. Information That May Be Redacted

1. The following categories of information are exempt from public disclosure:

   a. Information subject to trade secret protection. A "trade secret" is information, including a formula, pattern, compilation, program, device, method, technique or process, that (a) derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure and use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Even if the information falls within the definition, "trade secret" does not include information reflecting sales or promotional strategies, tactics, targeting, or data, or internal communications related to sales or promotion.

   b. Confidential personal information. "Confidential personal information" means individual Social Security or tax identification numbers, personal financial account numbers, passport numbers, driver license numbers, home addresses, home telephone numbers, personal email addresses, and other personally identifiable information protected by law from disclosure. "Confidential personal information" does not include the names of Mallinckrodt's officers, directors, employees, agents, or attorneys.

   c. Information that is inappropriate for public disclosure because it is subject to personal privacy interests recognized by law (*e.g.*, HIPAA), or contractual rights of third parties that Mallinckrodt may not abrogate.

   d. Information regarding Mallinckrodt employees' personal matters unrelated to Mallinckrodt, including emails produced by Mallinckrodt custodians discussing vacation or sick leave, family, or other personal matters.

C. Redaction of Documents Containing Protected Information

1. Whenever a document contains information subject to a claim of exemption pursuant to Section V.B, Mallinckrodt shall produce the document in redacted form. Such redactions shall indicate that trade secret and/or private information, as appropriate, has been redacted. Redactions shall be limited to the minimum redactions possible to protect the legally recognized individual privacy interests and trade secrets identified above.

2. Mallinckrodt shall produce to each Settling State a log noting each document redacted. The log shall also provide fields stating the basis for redacting the document, with sufficient detail to allow an assessment of the merits of the assertion. The log is subject to public disclosure in perpetuity. The log shall be

produced simultaneously with the production of documents required by Section V.F.

3. In addition to the redacted documents, Mallinckrodt shall, upon any Settling State's request, also produce all documents identified in Section V.A above in unredacted form to such Settling State at the same time. The redacted documents produced by Mallinckrodt may be publicly disclosed in accordance with Section V.E below. The unredacted documents produced by Mallinckrodt to a Settling State shall be available only to such State unless Mallinckrodt's claim of exemption under Section V.B is successfully challenged in accordance with Section V.C.4 or the trade secret designation expires in accordance with Section V.D.

4. Anyone, including members of the public and the press, may challenge the appropriateness of redactions by providing notice to Mallinckrodt. If the challenge is not resolved by agreement, it must be resolved in the first instance by a third party jointly appointed by the Settling States and Mallinckrodt to resolve such challenges. The decision of the third party may be appealed to a court with enforcement authority over this Agreement. If not so appealed, the third party's decision is final. In connection with such challenge, a Settling State may provide copies of relevant unredacted documents to the parties or the decisionmaker, subject to appropriate confidentiality and/or in camera review protections, as determined by the decisionmaker.

D. Review of Trade Secret Redactions

1. Ten years after Mallinckrodt completes the production of its documents in accordance with Section V, Mallinckrodt shall review all trade secret assertions made in accordance with Section V.B.1 and all non-manufacturing trade secret designations shall expire. The newly unredacted documents may then be publicly disclosed by a Settling State in accordance with Section V.E. Mallinckrodt shall produce to each Settling State an updated redaction log justifying its designations of the remaining trade secret redactions as manufacturing trade secrets.

E. Public Disclosure through a Document Repository

1. Each Settling State may publicly disclose all documents covered by Section V through a public repository maintained by a governmental, non-profit, or academic institution. Each Settling State may specify the terms of any such repository's use of those documents, including allowing the repository to index and make searchable all documents subject to public disclosure, including the metadata associated with those documents. When providing the documents covered by Section V to a public repository, no Settling State shall include or attach within the document set any characterization of the content of the documents. For the avoidance of doubt, nothing in this paragraph shall prohibit any Settling State from publicly discussing the documents covered by Section V.

F. Timeline for Production

1. Mallinckrodt shall produce all documents required by Section V.A within nine months from the Petition Date.

G. Costs

1. Mallinckrodt shall be responsible for its allocable share of all reasonable costs and expenses associated with the public disclosure and storage of Mallinckrodt's documents through any public repository.

H. Suspension

1. Mallinckrodt's obligation in Section V shall be suspended on the nine-month anniversary of the Petition Date, unless and until two corporate defendants in opioid-related litigation other than Mallinckrodt have agreed or been ordered to publicly disclose opioid-related documents. For the avoidance of doubt, Insys Therapeutics, Inc. shall constitute one of the two necessary defendants based on the "Liquidating Trustee Disclosure Requirement" provisions of the Second Amended Joint Chapter 11 Plan of Liquidation confirmed by the United States Bankruptcy Court for the District of Delaware on January 16, 2020.

VI. INDEPENDENT MONITOR

A. Appointment of Monitor

1. Mallinckrodt agrees that it will retain an outside, independent individual (the "Monitor") to evaluate and monitor Mallinckrodt's compliance with this Agreement.

2. Experience with internal investigations or the investigative process (which may include prior monitorship or oversight experience) and expertise in the pharmaceutical industry, relevant regulatory regimes, and internal controls and compliance systems may be considered in selecting the Monitor.

3. Within 30 days of the Petition Date, Mallinckrodt and the Settling States shall exchange pools of recommended candidates based in part on the above qualification and considerations to serve as the Monitor. The pools shall each contain the names of three individuals, groups of individuals or firms.

4. After receiving the pools of Monitor candidates, Mallinckrodt and the Settling States shall have the right to meet with the candidates and conduct appropriate interviews of the personnel who are expected to work on the project. Mallinckrodt and the Settling States may veto any of the candidates, and must do so in writing within 30 days of receiving the pool of candidates. If all three candidates within a pool are rejected by either Mallinckrodt or the Monitor States,

the party who rejected the three candidates may direct the other party to provide up to three additional qualified candidates within 15 days of receipt of said notice.

5. If Mallinckrodt or the Settling States do not object to a proposed candidate, Mallinckrodt or the Settling States shall so notify the other in writing within 30 days of receiving the pool of candidates. If more than one candidate remains, the Settling States shall select the Monitor from the remaining candidates. Mallinckrodt and the Settling States shall jointly seek the Bankruptcy Court's approval of the selected Monitor candidate.

6. Unless justifiable cause exists, the Monitor appointed by the Bankruptcy Court shall continue to serve after the Effective Date. For purposes of this paragraph, justifiable cause exists if the Monitor resigns or a court finds that the Monitor: (a) develops a conflict of interest that would undermine public confidence in the objectivity of his or her work; (b) has unreasonably failed to fulfill his or her material obligations under this Agreement or pursuant to the Work Plan (as defined in Section VI.B3), (c) has engaged in any act of dishonesty, misappropriation, embezzlement, intentional fraud, or similar conduct; or (d) has engaged in an intentional act of bias or prejudice in favor or against either party. Justifiable cause shall not include Mallinckrodt's or the Settling States' disagreements with the decisions of the Monitor pursuant to this Agreement, unless there is a clear pattern in the Monitor's decisions that demonstrates that the Monitor has not been acting as an independent third party in rendering decisions.

7. If a new Monitor must be appointed, Mallinckrodt and the Settling States shall follow the procedures and timeline set out above in subparagraphs 3-5. Court approval shall not be sought if Mallinckrodt is no longer under the Bankruptcy Court's jurisdiction..

B. Monitor's Responsibilities

1. Between the Petition Date and the Effective Date, the Monitor's duties shall be as follows:

   a. The Monitor shall perform its duties according to the terms of this Agreement and shall be vested all rights and powers reasonably necessary to carry out such powers, duties, and responsibilities enumerated herein.

   b. The Monitor shall work with all diligence perform his or her duties in a manner that does not unreasonably disrupt the operation of Mallinckrodt's business to confirm and oversee compliance with this Agreement.

   c. The Monitor shall review and provide reports as outlined below.

   d. Subject to any legally recognized privilege and as reasonably necessary to perform his or her duties hereunder, the Monitor shall have full and complete access to Mallinckrodt's personnel, books, records, and

facilities, and to any other relevant information, as the Monitor may request. Mallinckrodt shall develop such information as the Monitor may request and shall fully, completely and promptly cooperate with the Monitor. The Monitor may raise with the Bankruptcy Court any issues relating to any failure of or delay in such cooperation for an expedited resolution by the Bankruptcy Court.

e. The Monitor shall serve, without bond or other security, at the cost and expense of Mallinckrodt, with the Monitor's fees subject to final approval by the Bankruptcy Court. The Monitor shall have the authority to employ, upon written consent from Mallinckrodt, such consent not to be unreasonably withheld, delayed or conditioned, and upon Court approval, at the cost and expense of the Debtors' estates, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's responsibilities. Requests to employ such individuals should be directed to Mallinckrodt's General Counsel, and will be decided upon no later than ten (10) days from their receipt. The Monitor will work in good faith with Mallinckrodt to ensure such approved consultants will follow Mallinckrodt's policies and procedures with respect to any payments remitted directly by Mallinckrodt.

f. The Monitor shall have no obligation, responsibility, or liability for the operations of Mallinckrodt.

g. The Monitor shall sign onto any Protective Order entered by the Bankruptcy Court, and any confidentiality agreement consistent with any Protective Order as deemed necessary by the parties, and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants shall also sign onto any Protective Order entered by the Court, and any confidentiality agreement consistent with any Protective Order as deemed necessary by the parties; provided, however, that nothing shall restrict the Monitor from providing any information to the Court and the parties consistent with the terms of any Protective Order.

h. The Monitor shall promptly seek an order from the Bankruptcy Court requiring compliance or such other remedies as may be appropriate under the circumstances should Mallinckrodt not comply with this Agreement.

i. The Monitor shall make a good faith effort to leverage Mallinckrodt's existing compliance mechanisms when reviewing Mallinckrodt's compliance with this Agreement.

j. The Monitor shall make a good faith effort to perform his or her duties in a manner that does not unreasonably disrupt Mallinckrodt's business operations. In this regard, Mallinckrodt shall designate senior officials within the Office of the General Counsel to serve as the primary points of

contact for the Monitor in order to facilitate the Monitor's access to documents, materials, or staff necessary to review Mallinckrodt's compliance with this Agreement. The Monitor shall communicate any request for documents, materials, or access to staff to the designated contacts, unless otherwise instructed. For the avoidance of doubt, nothing in this paragraph shall be interpreted to prohibit the Monitor from speaking with a current or former employee of Mallinckrodt.

2. **Reporting**:

a. Within 45 days of the Petition Date, Mallinckrodt shall file a report with the Bankruptcy Court regarding its compliance with the terms of this Agreement (the "Mallinckrodt Compliance Report"). To the extent permissible by law, this report (in whole or in part) may be filed under seal or subject to such other confidentiality restrictions contained in a Protective Order.

b. The Monitor must file a report with the Bankruptcy Court regarding compliance by Mallinckrodt with the terms of this Agreement no later than 45 days after the Work Plan (as defined in Section VI.B.3) is finalized, and then additional reports every 90 days thereafter (the "Monitor Reports"). The Court may, in response to such reports, provide further direction to the Monitor as it deems appropriate. To the extent permissible by law, these reports (in whole or in part) may be filed under seal or subject to such other confidentiality restrictions contained in a Protective Order. The content of Monitor Reports shall be set forth in the Work Plan. The frequency of Monitor Reports may decrease to every 180 days after the Effective Date.

c. Prior to issuing any Monitor Report, the Monitor shall confer with Mallinckrodt regarding its preliminary findings and the reasons for those findings. Mallinckrodt shall have the right to submit written comments to the Monitor, which shall be appended to the final version of the Monitor Report.

d. In the event the Monitor Report identifies a potential violation of this Agreement, Mallinckrodt shall have the right to cure any potential violation within 30 days.

3. **Work Plan**: The manner in which the Monitor will carry out his or her compliance responsibilities under this Agreement, the general scope of information that the Monitor will seek to review in fulfilling his or her duties and, where applicable, the methodologies to be utilized shall be set forth in a work plan (the "Work Plan"). Within 30 days after the Monitor's appointment by the Bankruptcy Court, the Settling States and Mallinckrodt shall agree with the Monitor on the Work Plan. If the Monitor, the Settling States, and Mallinckrodt fail to reach agreement on the Work Plan within the designated time frame, the

Monitor, Settling States, and Mallinckrodt will submit any disputed issues to the Bankruptcy Court for resolution.

4. **Post-Emergence**: Before the Effective Date, the parties will work in good faith to establish procedures for resolving disputes (including disputes over the Work Plan) and overseeing the Monitor's obligations after Bankruptcy Court approval of the Plan, and to make any other adjustments the parties agree to be reasonably necessary. The parties expect and agree that the principal obligations and conditions imposed by Section VI.B will otherwise remain in effect. After the Effective Date, all reasonable and necessary fees and costs of the Monitor shall be paid by Mallinckrodt.

EXHIBIT 2

Mallinckrodt Monitor Agreement

This monitor agreement (the "Agreement") dated as January 15, 2021 ("Effective Date"), is entered into between R. Gil Kerlikowske and Gil Kerlikowske L.L.C. ("Monitor") and Mallinckrodt Enterprises LLC, Mallinckrodt LLC, and SpecGx LLC ("Mallinckrodt" and together with the Monitor, the "Parties").

Recitals

WHEREAS, on October 12, 2020, Mallinckrodt plc and certain of its affiliates (collectively, the "Debtors") commenced voluntary cases under chapter 11 of title 11 of the United States Code (the "Bankruptcy Code") in the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"), which cases are being jointly administered under Case No. 20-12522 (the "Chapter 11 Cases");

WHEREAS, Mallinckrodt agreed to an operating injunction as part of a global settlement, which was attached as Exhibit 2 to the Debtors' restructuring support agreement filed in the Chapter 11 Cases, *In re Mallinckrodt plc, et al.*, No. 20-12522 (Bankr. D. Del. 2020) (Dkt. No. 128 Ex. A) (as amended, the "Operating Injunction");

WHEREAS, on January 8, 2021, the Bankruptcy Court entered an order, among other things, subjecting Mallinckrodt to the Operating Injunction and authorizing and directing Mallinckrodt to take any and all actions necessary to implement and perform their obligations under the Operating Injunction, *Mallinckrodt plc v. State of Conn. (In re Mallinckrodt plc),* Adv. Proc. No. 20-50850 (Bankr. D. Del.), Dkt No. 196;

WHEREAS, Section VI of the Operating Injunction provides, in relevant part, that Mallinckrodt agrees that it will retain a Monitor to evaluate and monitor Mallinckrodt's compliance with the Operating Injunction; and

WHEREAS, pursuant to the process set forth in Section VI.A of the Operating Injunction, the Bankruptcy Court has been asked to approve the selection of R. Gil Kerlikowske to serve as Monitor pursuant to the terms set forth in Section VI of the Operating Injunction.

NOW THEREFORE, in consideration of the mutual covenants contained herein, the Parties agree as follows:

Agreement

Appointment of Monitor. Subject to the Bankruptcy Court's approval of the Monitor's appointment and this Agreement, Mallinckrodt hereby appoints the Monitor to undertake those duties and responsibilities of the Monitor set forth in the Operating Injunction. All terms in this Agreement are to be interpreted in a manner consistent with the Operating Injunction.

Term. The term of the Monitor shall begin on the date that it is approved by the Bankruptcy Court and shall continue until October 12, 2025, unless (i) otherwise ordered by the Bankruptcy Court or, if after Mallinckrodt's emergence from bankruptcy, any other court of competent jurisdiction or (ii) justifiable cause exists pursuant to Section VI.A.6 of the Operating Injunction.

This Agreement may be extended for an additional two years pursuant to Section II.E.3 of the Operating Injunction.

Termination. The Monitor may terminate his appointment under this Agreement, without cause, no earlier than ninety (90) days after the delivery to, and receipt by, the Vice President and General Counsel for Specialty Generics of notice of such termination.

Duties, Rights, Powers and Responsibilities of the Monitor. The Monitor shall have all of the duties, rights, powers and responsibilities set forth in Section VI.B of the Operating Injunction, which is incorporated by reference herein, as well as any other rights, powers and responsibilities as may hereafter be ordered by the Bankruptcy Court, or, if after Mallinckrodt's emergence from bankruptcy, any other court of competent jurisdiction. The Monitor acknowledges and agrees that he will abide by the terms of the Operating Injunction as of the Effective Date, and acknowledges and agrees that any relevant subsequent orders entered by the Bankruptcy Court, or, if after Mallinckrodt's emergence from bankruptcy, any other court of competent jurisdiction, relating to the Operating Injunction will be incorporated herein upon entry, and that the Monitor will then have all of the rights, powers, and responsibilities set forth in the Operating Injunction as amended by any such subsequent order.

The Monitor shall make a good faith effort to perform his or her duties in a manner that does not unreasonably disrupt Mallinckrodt's business operations. In this regard, Mallinckrodt shall designate senior officials within the Office of the General Counsel to serve as the primary points of contact for the Monitor in order to facilitate the Monitor's access to documents, materials, or staff necessary to review Mallinckrodt's compliance with the Operating Injunction. The Monitor shall communicate any request for documents, materials, or access to staff to the designated contacts, unless otherwise instructed. For the avoidance of doubt, nothing in this paragraph shall be interpreted to prohibit the Monitor from speaking with a current or former employee of Mallinckrodt.

Agreements of Mallinckrodt. Mallinckrodt agrees to fully, completely and promptly cooperate with the Monitor as set forth in the Operating Injunction. Mallinckrodt shall provide full and complete access to its personnel, books, records, and facilities, and to any other relevant information, as the Monitor may request.

Monitor Compensation and Expenses. The Monitor shall serve without bond or other security and shall be compensated by Mallinckrodt for reasonable fees and expenses in connection with this engagement at a rate of $800 per hour.

In addition, Mallinckrodt shall pay all reasonable out of pocket expenses reasonably incurred by the Monitor in performance of the engagement. All invoices for fees and expenses shall be sent to Mallinckrodt at Generics.APinvoices@mnk.com or to:

SpecGx LLC
Attn: Compliance Department
385 Marshall Ave.
Webster Groves, MO 63119

Mallinckrodt shall wire payment to Gil Kerlikowske L.L.C. pursuant to wire instructions provided to Mallinckrodt by the Monitor. The Monitor shall invoice Mallinckrodt on a monthly basis for the fees for billable hours in the applicable month. The Monitor will submit receipts and any other back-up documentation reasonably requested by Mallinckrodt for any expenses for which the Monitor seeks reimbursement hereunder ("Expense Documentation"), and the Monitor agrees Mallinckrodt shall not be liable for any expenses for which there is no adequate Expense Documentation. Mallinckrodt will pay the Monitor within forty-five (45) days of its receipt of a correct, undisputed invoice, provided that the Monitor's compensation is subject to final approval by the Bankruptcy Court.

The Monitor shall prepare a budget reflecting his anticipated costs and expenses pursuant to this Agreement within 14 days of the Effective Date and every six months thereafter during the Term of this Agreement. Such budget should be directed to the Vice President and General Counsel for Specialty Generics.

Other Consultants. The Monitor shall have the authority to employ, upon Mallinckrodt's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned, and upon the approval of the Bankruptcy Court or, if after Mallinckrodt's emergence from bankruptcy, any other court of competent jurisdiction, such consultants as may be necessary to carry out his responsibilities, at Mallinckrodt's cost and expense.

Requests to employ consultants should be directed to the Vice President and General Counsel for Specialty Generics, and will be decided upon no later than ten (10) days from their receipt. In considering any such request, Mallinckrodt may negotiate fees directly with the proposed consultant. The Monitor will work in good faith with Mallinckrodt to ensure such approved consultants will follow Mallinckrodt's policies and procedures and terms of this paragraph with respect to any payments remitted directly by Mallinckrodt.

Miscellaneous.

Standard of Performance; Representations. The Monitor will conduct business in accordance with all applicable (i) ethical code requirements; (ii) regulatory requirements; (iii) government- issued rules and guidance, including those relating to data privacy and security; and (iv) all applicable federal, state and local laws, regulations and orders. The Monitor represents and covenants that the Monitor is, and during the term of this Agreement will remain, in compliance with all applicable federal, state and local laws, regulations and orders.

Conflict of Interest. In the event the Monitor becomes aware that he, or any consultants working under this Agreement, has or may have a conflict of interest that may affect, or could have the appearance of affecting, the Monitor or persons working with the Monitor from performing any of the duties under this Agreement, the Monitor shall promptly inform Mallinckrodt and the Settling States (as defined in the Operating Injunction). If the Monitor or a consultant works for, or provides services to, the federal or a state government, whether as a full-time or part-time federal or state government employee or a special federal or state government employee or consultant, the Monitor represents by signing this Agreement that no real or apparent conflict of interest exists by entering into this Agreement with Mallinckrodt. Except for disclosures expressly contemplated herein, the Monitor represents and warrants that he is not required to give any notice or obtain any consent from any person or entity in connection with the execution and delivery of this Agreement.

Confidentiality. The Monitor agrees that he will promptly sign onto any Protective Order entered by the Bankruptcy Court or, if after Mallinckrodt's emergence from bankruptcy, any other court of competent jurisdiction, and any confidentiality agreement consistent with any Protective Order as deemed necessary by the Parties, and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants shall also sign onto any Protective Order entered by the Bankruptcy Court or, if after Mallinckrodt's emergence from bankruptcy, any other court of competent jurisdiction, and any confidentiality agreement consistent with any Protective Order as deemed necessary by the Parties. To the extent there is no governing Protective Order, the parties shall enter an appropriate confidentiality agreement. Provided, however, nothing shall restrict the Monitor from providing any information to the Bankruptcy Court, or, if after Mallinckrodt's emergence from bankruptcy, any other court of competent jurisdiction, or the Settling States consistent with the terms of any Protective Order.

Records and Audit Rights. Monitor shall maintain accurate and complete records evidencing its compliance with this Operating Injunction and Work Plan (as defined in Section VI.B.3 of the Operating Injunction). Such records shall be maintained in accordance with all applicable laws and shall be kept in a secure area reasonably protected from fire, theft and destruction.

Choice of Law. This Agreement is governed by and construed in accordance with the laws of the State of New York (without giving effect to the principles thereof relating to conflicts of law) applicable to contracts negotiated, executed and performed entirely.

Waiver amendment modification. This Agreement sets forth all terms of engagement between the Monitor and Mallinckrodt. No waiver, amendment or any other modification of this Agreement shall be effective unless in writing and signed by each Party to be bound thereby.

Independent Contractor. The Monitor is an independent contractor and not an agent, employee, joint venture or partner of Mallinckrodt for income tax purposes or otherwise. No life, casualty, or disability insurance, workers' compensation, or health, retirement or any other employment benefits shall be paid by Mallinckrodt to or for the benefit of the Monitor.

Counterparts. This Agreement may be executed in counterparts each of which shall be considered effective as an original signature.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.

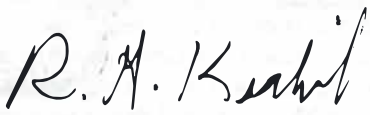
BY:

Mallinckrodt LLC, Mallinckrodt Enterprises LLC, and SpecGx LLC

DONALD LOHMAN

Vice President, General Counsel
for Specialty Generics

Monitor



R. Gil Kerlikowske

Gil Kerlikowske L.L.C.

EXHIBIT 3

AS OF THE FIRST MONITOR REPORT, THE MONITOR HAS RECEIVED DOCUMENTS AND MATERIALS FROM MALLINCKRODT INCLUDING:

- Global Anti-Bribery Anti-Corruption Policy
- Global Conflict of Interest Policy
- Integrity Hotline Investigation Process SOP
- Internal Investigations US Policy
- Non-Retaliation Policy
- Third Party Due Diligence Policy
- Operating Injunction for Opioid Business Policy
- Operating Injunction for Opioid Business Training Session PowerPoints and related Training Deck - Discussion Scenarios
- Promotional Review Committee (PRC) Charter
- ST Hold Daily Audit Report SOP
- The Suspicious Order Monitoring Program Review of Reinstatement Requests from Downstream Registrants SOP
- The Suspicious Order Monitoring Program Review of Direct Customer Orders SOP
- Suspicious Order Monitoring Program: Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants SOP
- Promotional Review Committee (PRC) Initiation, Review, and Approval of Advertising and Promotional Materials SOP
- Guidance for Frequently Asked Product Questions – Pharmaceuticals SOP
- Suspect Product and Notification Compliance Policy
- Generics Medical Information Request SOP
- Product Complaint Handling - Drug Products SOP
- Specialty Generics Grant & Scholarship Approval Committee SOP
- Management and Reporting of Adverse Reactions to Medicinal Products SOP
- Specialty Generics Grant & Sponsorship Approval Committee Charter
- January 4, 2021 Letter to DEA concerning the Notice of Proposed Rulemaking for Suspicious Orders of Controlled Substances

Miscellaneous:

20-12522-JTD Mallinckrodt plc

Type: bk Chapter: 11 v Office: 1 (Delaware)
Assets: y Judge: JTD
Case Flag: LEAD, SealedDoc(s), MEGA, STANDOrder, CLMSAGNT, APPEAL

U.S. Bankruptcy Court

District of Delaware

Notice of Electronic Filing

The following transaction was received from Amanda R. Steele entered on 4/26/2021 at 5:20 PM EDT and filed on 4/26/2021
Case Name: Mallinckrodt plc
Case Number: 20-12522-JTD
Document Number: 2117

Docket Text:
Exhibit(s) *//First Monitor Report* Filed by Mallinckrodt plc. (Steele, Amanda)

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:FIRST Mallinckrodt Monitor Report - Final with Exhibits.PDF
Electronic document Stamp:
[STAMP bkecfStamp_ID=983460418 [Date=4/26/2021] [FileNumber=17014314-0
] [231648c1febc8a583dee8f901a8a442f01075f85a26f6055b959bd8a0dbad86726b
5e94d6569db5a812de75b4f998e031da6b5902e28550c75faba0c3ee34bb1]]

20-12522-JTD Notice will be electronically mailed to:

Justin R. Alberto on behalf of Interested Party Official Committee of Opioid Related Claimants
jalberto@coleschotz.com, pratkowiak@coleschotz.com;jford@coleschotz.com;bankruptcy@coleschotz.com;lmorton@coleschotz.com

Justin R. Alberto on behalf of Other Prof. Cole Schotz P.C.
jalberto@coleschotz.com, pratkowiak@coleschotz.com;jford@coleschotz.com;bankruptcy@coleschotz.com;lmorton@coleschotz.com

Justin R. Alberto on behalf of Other Prof. Official Committee of Opioid Related Claimants
jalberto@coleschotz.com, pratkowiak@coleschotz.com;jford@coleschotz.com;bankruptcy@coleschotz.com;lmorton@coleschotz.com

Sameer M. Alifarag on behalf of Interested Party Wilmington Savings Fund Society, FSB, as indenture trustee
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Nader Amer on behalf of Interested Party Humana, Inc.
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Miscellaneous:

20-50850-JTD Mallinckrodt plc v. State of Connecticut et al

Type: ap	Office: 1 (Delaware)	Judge: JTD
Lead Case: 1-20-bk-12522	Case Flag: SealedDoc(s), APPEAL, MEDDue	

U.S. Bankruptcy Court

District of Delaware

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Case Name: Mallinckrodt plc v. State of Connecticut et al
Case Number: 20-50850-JTD
Document Number: 212

Docket Text:
Exhibit(s) *//First Monitor Report* Filed by Mallinckrodt plc. (Steele, Amanda)

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:FIRST Mallinckrodt Monitor Report - Final with Exhibits.PDF
Electronic document Stamp:
[STAMP bkecfStamp_ID=983460418 [Date=4/26/2021] [FileNumber=17014326-0
] [743a48d89248c7870243c5cb5ba0ef1b184f1de169e0a7e5e7bde795f4d4cd372cf
3e41943cbbf7d15457cd47cb6c8f4069d4aee8432c8e359c04387c2d5529c]]

20-50850-JTD Notice will be electronically mailed to:

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