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)

SECOND REPORT OF R. GIL KERLIKOWSKE, INDEPENDENT COURT-APPOINTED MONITOR FOR MALLINCKRODT LLC, MALLINCKRODT ENTERPRISES LLC, AND SPECGX LLC

July 23, 2021

Docket No. 3409
Adv. Docket No. 223
Filed: 7/23/21

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SECOND 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:

1. EXECUTIVE SUMMARY

1.1 This Second Monitor Report covers the period from the filing of the First Monitor Report on April 26, 2021, to the present (the "Second Reporting Period"). The Second Monitor Report: (1) reviews the Monitor's actions during the Second Reporting Period, including the review of documents and data and interviews of Mallinckrodt employees; (2) summarizes observations based upon the Monitor's fact-finding, and provides recommendations on the basis of those observations; and (3) describes anticipated next steps during the next reporting period.

1.2 Having now substantially completed the majority of "scoping" tasks at the outset of the monitorship, the Monitor anticipates an increase in ongoing auditing and monitoring functions, as described below.

1.3 In addition, with pandemic-related restrictions now easing, the prospect of holding meetings and site visits that were put on hold becomes more promising. Although conference calls and video conferencing have been a helpful substitute, the Monitor hopes to engage in more in-person interactions in the Fall.

1.4 The Monitor's recommendations are summarized in Section 4, and are elaborated upon in Section 11 of this Report. The recommendations relate to Mallinckrodt's controlled substances suspicious order monitoring ("SOM") program.

1.5 Mallinckrodt's executives, employees, and outside counsel continue to be responsive, cooperative, and helpful to the Monitor. They have provided over 213 additional documents at the Monitor's request in a timely and complete fashion, and have assisted in arranging multiple interviews with key executives and employees in a relatively short period of time. The secure platform Mallinckrodt has established to share information with the Monitor appears to be functioning effectively, and adjustments to the confidential hotline reporting system have been made to facilitate the sharing of reports with the Monitor relating directly to the Monitor's responsibilities (although, as noted below, no such reports have been shared with the Monitor to date).

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

2. THE OPERATING INJUNCTION

2.1 On October 12, 2020, Mallinckrodt and the Settling States agreed to the Mallinckrodt Injunctive Relief Draft Term Sheet. *See* 20-12522, Dkt. No. 128, Ex. 2. An amended and final Term Sheet was adopted by the Court on January 8, 2021 (hereinafter the "Operating Injunction"). *See* 20-50850, Dkt. No. 196-1. A copy of the Operating Injunction is attached hereto and made a part hereof as **Exhibit One**.

2.2 In Section VI of the Operating Injunction, Mallinckrodt agreed to retain a Monitor who would submit a report on Mallinckrodt's compliance with the terms of the Operating Injunction no later than 45 days after finalizing the Monitor's Work Plan. The Operating Injunction provides that subsequent reports are to be submitted every 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 180 days.

2.3 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).

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

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

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

3. PRIOR MONITOR REPORTS

3.1 ***The First Monitor Report.*** The undersigned Monitor submitted the First Monitor Report in this matter on April 26, 2021. *See* Case No. 20-12522, Dkt. No. 2117; Adv. Pro. No. 20-50850, Dkt. No. 212. The First Monitor Report summarized actions taken to understand the key components of Mallinckrodt's SpecGx business related to the Operating Injunction since this Court's appointment of the Monitor on February 8, 2021. *See* Dkt. No. 1306. That Report also provided a preliminary assessment of Mallinckrodt's compliance with the terms and conditions of the Operating Injunction, described documents reviewed and requested, provided an overview of interviews conducted, and identified additional steps to undertake.

4. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Section 11, *infra*, the Monitor has made the following 21 recommendations to Mallinckrodt. Mallinckrodt has agreed to implement all of the recommendations, many of which are in the process of being addressed:

(a) Modernize and enhance the SOM function with the use of big data, artificial intelligence, and automated processes and algorithms.

(b) Select one or more candidates with suitable qualifications, and with flexibility to hire from outside the Hobart, New York market, to fill the vacant role of Compliance Auditor / Analyst.

(c) Consider the sufficiency of both short-term and long-term human resource allocation in the SOM function.

(d) Use best efforts to ensure chargeback restrictions restrict not only chargeback payments, but also the supply of Opioid Products[1] to a restricted pharmacy.

(e) Use best efforts to obtain timely provision of chargeback data from direct customers.

(f) Evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data.

(g) After analyzing turnaround times for chargeback reviews and restrictions, amend relevant SOPs to memorialize firm timelines.

(h) Incorporate all existing data sources available to Mallinckrodt, and use best efforts to reach agreements with direct customers to provide more detailed retail data to conduct more effective chargeback reviews.

(i) Assess the potential value of additional factors to consider in conducting chargeback reviews.

(j) Continue to actively pursue the opportunity for a public-private "clearinghouse" concept, in collaboration with the U.S. Drug Enforcement Administration ("DEA") and industry partners.

(k) Amend relevant SOPs to create a chargeback review task checklist, provide an audit trail, and ensure second-level review and approval.

(l) Memorialize and routinize the periodic review of (1) pharmacies reviewed but not restricted, and (2) pharmacies that are reinstated.

(m) Re-evaluate direct customer order thresholds with the assistance of AGI.

(n) Re-evaluate chargeback thresholds with the assistance of AGI.

(o) In collaboration with AGI, determine whether the flagging and releasing of direct customer orders can be refined to better identify potentially suspicious orders.

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[1] Capitalized terms used in this Report, unless otherwise defined herein, incorporate by reference the definitions of those terms set forth in the Operating Injunction.

(p) Implement two-level review and approval for release of flagged orders.

(q) Memorialize the confidentiality of thresholds, consistent with current practice.

(r) Establish minimum standards and criteria for conducting retail pharmacy due diligence, potentially with the advice and input of a third-party compliance consultant.

(s) Revise direct customer questionnaires to yield helpful, actionable, and verifiable information and determine a method for sampling or randomly auditing questionnaires.

(t) Establish regularly scheduled interactions with direct customers.

(u) Explore options for making media review more effective.

5. THE INTEGRITY HOTLINE AND MALLINCKRODT'S "TONE AT THE TOP"

5.1 As previously reported in the First Monitor Report, 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. Mallinckrodt modified its EthicsPoint reporting system to enable reporters to identify a reported issue type as "Opioid Product Operating Injunction" based upon a "drop down" menu of categories. Any reports so categorized 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 under some other category, Mallinckrodt's Chief Compliance Officer has committed to sharing those reports with the Monitor, via his counsel, as soon as reasonably practicable.

5.2 To date, the Monitor has not been made aware of any reports to the hotline related to the focus of the Operating Injunction.

5.3 Since the fall of 2020, Mallinckrodt has set aside a portion of its SpecGx virtual Town Hall meetings to update its employees on the bankruptcy proceedings and the resulting restructuring. The Monitor has reviewed recordings of these meetings, including the March 2,

2021, session in which Mallinckrodt's General Counsel for SpecGx gave a brief, general update on the steps Mallinckrodt has taken to implement the Operating Injunction, and emphasized the importance of compliance with its terms.

6. BAN ON PROMOTION (§ III.A)

6.1 Section III.A of the Operating Injunction prohibits Mallinckrodt from engaging in certain activities relating to the Promotion of Opioids, Opioid Products, products used for the treatment of Opioid-induced side effects, and the Treatment of Pain in a manner that directly or indirectly encourages the utilization of Opioids or Opioid Products.

6.2 As noted in its Compliance Report, Mallinckrodt does not promote its generic Opioid Products to physicians, nor does it create related promotional materials for those products. Mallinckrodt Compliance Report, 20-50850-JTD, Dkt. No. 174-1 (Nov. 30, 2020) (hereafter, "Mallinckrodt Compliance Report") § 4.6. However, Mallinckrodt does have a structure in place for multilayered review of all product-related materials intended for public dissemination. The Promotional Review Committee ("PRC"), comprised of representatives from Mallinckrodt's Marketing, Legal, Regulatory and Medical Affairs/Pharmacovigilance groups, is charged with "reviewing all written materials regarding [Mallinckrodt's] products, including website information, other internet materials, and product catalogs, to insure that such materials are truthful, balanced and accurate, as well as in compliance with government regulations, internal compliance policies, and industry standards." *Id*.

6.3 Since filing the First Monitor Report, the Monitor has reviewed the PRC's operating policy, the meeting minutes from two recent PRC meetings and promotional materials presented to the PRC in those meetings, (*i.e.*, a "sell sheet" for a product related to treatment of opioid addiction). To gain a better understanding of the PRC's deliberative process, the Monitor

also interviewed four Standing Core PRC Members:[2] the Product Manager of Commercial (who serves as the PRC Chair), the Vice President of Commercial, the Director of Post-Market Surveillance, and the Senior Director of Government Affairs.[3] Based on these interviews and review of the materials provided, it appears that the PRC is operating in a manner consistent with Section III.A of the Operating Injunction.

6.4 The PRC's operating policy, *Promotional Review Committee (PRC) Initiation, Review, and Approval of Advertising and Promotional Materials*, requires periodic review of active promotional materials unless the PRC notes an exception. This requirement can be waived for materials intended for single use or use less than two years, but the origination date for all other materials is tracked by Mallinckrodt's internal software program, Metric Stream. The program generates automatic alerts approximately 90 days prior to the two-year expiration date notifying the Commercial Lead of the need for re-review of active items.

6.5 Although Mallinckrodt does not currently promote its Opioid Products, the Product Manager of Commercial, who chairs the PRC, has begun to identify active items and materials that, while not yet scheduled for re-review under the two-year standard, are opioid-related and, as such, should be flagged and fast-tracked for submission to the PRC to assess compliance with the Operating Injunction. Mallinckrodt has not established a timeline for this review of legacy materials. In the next reporting period, the Monitor intends to determine what steps Mallinckrodt will undertake to complete this task in a timely manner.

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[2] According to its operating charter, there are two categories of PRC participants: Standing Core Members, who meet regularly to review and approve advertising and promotional materials, and Ad Hoc Members and Presenters, who join PRC meetings on an as-needed basis.

[3] The Monitor also interviewed the Director of Digital Communications and Community Relations who serves as an Ad Hoc Member of the PRC. During the First Reporting Period, the Monitor met with Mallinckrodt's Compliance Manager, who serves as the PRC's Secretary.

6.6 Section III.A.2 of the Operating Injunction permits Mallinckrodt to, *inter alia*, maintain a corporate website and a website for any Opioid Product and to respond to unsolicited questions or requests from healthcare providers, patients or care-givers provided that the response does not constitute promotion of Opioids or Opioid Products.

6.7 Since filing the First Monitor Report, the Monitor has interviewed the Director of Digital Communications and Community Relations and the Senior Director of Digital Communications to learn about Mallinckrodt's processes and procedures for managing its website and its social media accounts. The Monitor has also begun to review Mallinckrodt's corporate website, the websites for each Opioid Product it manufactures, and its Twitter and LinkedIn social media accounts, to ensure that no content Promotes Opioids, Opioid Products, or products for the treatment of Opioid-induced side effects. *See* Operating Injunction § III.C.3. The Monitor anticipates an ongoing and continuing review of these websites and social media accounts in the next reporting period and beyond.

6.8 The Monitor also interviewed the Director of Post-Market Surveillance who coordinates Mallinckrodt's Medical Information, Product Monitoring, and Pharmacovigilance efforts to ensure that communications with patients and caregivers are consistent with the Operating Injunction. In addition, the Monitor reviewed Mallinckrodt's policies relating to post-market communications including the *Guidance for Frequently Asked Product Questions* SOP and the *Generics Medical Information Request* SOP, which guide Product Monitoring Team members in their responses to unsolicited requests for information about certain products.

6.9 The Product Monitoring Team operates a call center for fielding and responding to customer questions and complaints. The calls are not recorded but are logged in an internal system called Trackwise. While Mallinckrodt maintains the logs, there has not been a process

for periodic review and auditing of the logs to confirm that the Product Monitoring Team's responses to customer questions and complaints are consistent with the Operating Injunction and Mallinckrodt's existing policies and procedures. Mallinckrodt has advised the Monitor that it is now in the process of establishing an auditing protocol. In the next reporting period, the Monitor will review Trackwise data and continue discussions with Mallinckrodt regarding the implementation of its auditing protocol.

6.10 The Monitor requested that Mallinckrodt produce its annual marketing budget for Opioid Products from January 1, 2020 to present; and a record of any changes made to the Mallinckrodt website following the adoption of the Operating Injunction. The Monitor has also requested, and received: a list of the Twitter accounts that Mallinckrodt (1) controls and (2) follows; a copy of Mallinckrodt's Social Media Policy; and a list of current active items / pieces in Metric Stream, as well as copies of those items / pieces.

6.11 The Monitor requested that certain documents related to this subsection be produced on a quarterly basis. These documents include all promotional materials reviewed by the PRC, in order for the Monitor to conduct an independent review of the materials for compliance with Section III.A of the Operating Injunction and, where applicable, Centers for Disease Control and Prevention Guideline Recommendations. *See* Operating Injunction § III.A.6.a.

7. NO FINANCIAL REWARD OR DISCIPLINE BASED ON VOLUME OF OPIOID SALES (§ III.B)

7.1 Section III.B.1 of the Operating Injunction states that "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." However, the same Section permits Mallinckrodt to create more holistic financial incentives, even if Opioid

Products are included: "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."

7.2 To verify Mallinckrodt's compliance with the above-quoted provisions of the Operating Injunction, the Monitor requested, and reviewed, a copy of Mallinckrodt's Field Sales Compensation Plan for 2021 ("FSCP"), and an accompanying explanatory document. In addition, the Monitor conducted an interview with the Vice President of Commercial, to discuss the FSCP.

7.3 The FSCP is designed to "reward qualified, profitable and ethical sales representatives." Under the plan, payments are made to qualified sales representatives based on Mallinckrodt's attainment of its targets for five financial and non-financial metrics. The five financial metrics are: (1) Specialty Generics Financial Net Revenue;[4] (2) Specialty Generics Financial Net Contribution Margin targets; (3) Non-Opioid Generics (excluding Addiction Treatment) Financial Net Revenue; (4) Non-Opioid Generics (excluding Addiction Treatment) Financial Net Contribution Margin; and (5) Non-Opioid New Product (excluding Addiction Treatment) Launch Market Share (weighted by Net Revenue). The total payout to each qualified sales representative is determined by applying different weights to each of these metrics.

7.4 As noted in Mallinckrodt's Compliance Report, "the Specialty Generics business manufactures and sells products other than Opioid Products, and the net sales and net

[4] Financial Net Revenue is defined in the FSCP as "gross sales less rebates, returns, chargebacks, wholesale differential and fees processed during the period," whereas "Financial Net Contribution Margin" is defined as "Financial Net Revenue less associated variable standard product costs."

contribution margin metrics relate to all products sold by Specialty Generics (including API, addiction treatment medicines, and acetaminophen)." Mallinckrodt Compliance Report § 5.2. Accordingly, although sales of Opioid Products do contribute in some degree to the rewards of the generics sales force, they do so as one among several factors, which the Operating Injunction permits.

7.5 In sum, Mallinckrodt's compensation of qualified sales representatives based upon the performance of its SpecGx business as a whole, including its sale of Opioid Products, comports with the Operating Injunction's requirement that neither incentives nor discipline be based exclusively upon the sales volume or sales quota of Opioid Products. None of the metrics set forth in the FSCP compensate sales representatives based solely upon sales volume or sales quotas for Opioid Products. Accordingly, based upon the information available to the Monitor at this time, it appears that Mallinckrodt's FSCP complies with Section III.B of the Operating Injunction.

7.6 The Monitor will continue to review and audit future FSCPs to ensure there is no change in Mallinckrodt's compliance with Section III.B of the Operating Injunction.

8. BAN ON FUNDING / GRANTS TO THIRD PARTIES (§ III.C)

8.1 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 educates 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.

8.2 As detailed in its Compliance Report, Mallinckrodt established the Specialty Generics Grant and Sponsorship Approval Committee ("SGGSAC") to review and approve

third-party requests for grants and sponsorships to ensure compliance with the Operating Injunction. *See* Mallinckrodt Compliance Report § 5.4.

8.3 Since the filing of the First Monitor Report, the Monitor has reviewed the SGGSAC's operating policy, the meeting minutes from its most recent meeting (March 2021), application materials reviewed during that meeting ("Request Forms"), and Letters of Agreement ("LOA") for grant recipients. The Committee did not decline any requests. To better understand the SGGSAC's review process, the Monitor also interviewed four Standing Core Members:[5] the Vice President of Commercial (who serves as the Committee Chair), the Senior Director of Government Affairs, the Director of Post-Market Surveillance, and the Product Manager of Commercial.[6]

8.4 The SGGSAC reviewed and approved seven requests: six related to grants and one conference sponsorship. The grant recipients were largely comprised of organizations dedicated to improving substance use disorder treatment access. Each grant recipient was required, under the LOA and as a condition for receipt of any funds, to confirm its understanding of the Operating Injunction's provisions, specifically those prohibiting the use of the grant funds for the promotion of Opioid Products or education about Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects. Based on the Monitor's review of the Request Forms and the LOA to each grant recipient, it appears that the

[5] According to its operating charter, there are two categories of SGGSAC participants: Standing Core Members, who meet annually and on an ad hoc basis to review grant and sponsorship requests, and Ad Hoc Members and Presenters, who join SGGSAC meetings on an as-needed basis.

[6] During the first reporting period, the Monitor met with Mallinckrodt's Compliance Manager, who serves as the SGGSAC's Secretary.

SGGSAC is operating in a manner consistent with Section III.C of the Operating Injunction as it relates to its awarding of grants to third parties.

8.5 The SGGSAC also approved a $15,000 sponsorship request from the Association of Accessible Medicine ("AAM") for its May 2021 Annual Meeting. As detailed in Mallinckrodt's Compliance Report, the President of Specialty Generics and the Associate Director of State Government Affairs, who each have professional affiliations with AAM, formally recused themselves from decision-making activities for AAM related to Opioids or the Treatment of Pain, to the extent they arise. *See* Mallinckrodt Compliance Report § 5.4. During this reporting period, the Monitor reviewed communications from Mallinckrodt to AAM confirming these recusals, similar communications from Mallinckrodt to other trade associations/groups, and an employee survey regarding board service, created by the Compliance Department, with any responses thereto, including executed conflict certifications.

8.6 The AAM Sponsorship Request Form was submitted by the Product Manager, Commercial, who also serves on the SGGSAC. In addition to the AAM Sponsorship Request Form, the Monitor also reviewed supporting materials including AAM's initial sponsorship solicitation and the 2021 Annual Meeting agenda.

8.7 The SGGSAC's operating policy, in effect at the time of the March 2021 meeting, required that the SGGSAC send the requestor an award email and LOA detailing the terms applicable to Specialty Generics grants and sponsorships and that the LOA be signed and returned to the SGGSAC before the sponsorship funds are dispersed. As previously stated, the LOA requires award recipients to confirm their understanding and agreement to abide by the Operating Injunction's prohibitions on Mallinckrodt's funding to third parties. In contrast to the SGGSAC SOP, the SGGSAC Request Form expressly states that an LOA is <u>not</u> required for

awarded sponsorships unless the SGGSAC opts to condition the award on the recipient's execution of the LOA. Mallinckrodt did not issue an LOA to AAM prior to awarding the sponsorship.

8.8 In May 2021, Mallinckrodt revised the SGGSAC operating policy to remove the requirement for issuance of an LOA for sponsorship award recipients. As a result, both the SGGSAC operating policy and the Request Form provide that the SGGSAC may, but is not required to, condition a sponsorship award on the recipient's execution of a LOA.

8.9 During the next reporting period, the Monitor will continue his discussions with SGGSAC members to better understand the committee's deliberative process for awarding sponsorships and for determining whether to waive the LOA requirement, particularly where the potential recipient is an organization or trade group engaging in Opioid-related activities from which Mallinckrodt's officials have formally recused.

8.10 The Monitor has requested that certain documents related to this subsection be produced for the Monitor's review on a quarterly basis. These documents include all grant/sponsorship request forms and any accompanying materials the SGGSAC reviews, regardless of whether the request is approved or denied, in order for the Monitor to conduct an independent review of the requests for compliance with Section III.C of the Operating Injunction.

9. LOBBYING RESTRICTIONS (§ III.D)

9.1 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.

9.2 As described in its Compliance Report, Mallinckrodt amended its contracts with its external lobbyists to include the requirement that each lobbyist "certify that they are aware of and will fully comply with the Lobbying restrictions" outlined in Section III.D.5 of the Operating Injunction. Mallinckrodt Compliance Report § 5.5.

9.3 Since the filing of the First Monitor Report, the Monitor has verified that all external state and federal lobbying firms engaged by Mallinckrodt received an updated Statement of Work ("SOW") and a copy of the Operating Injunction and that each signed the amended SOW certifying compliance with the Operating Injunction's relevant terms. The Monitor has also interviewed the Vice President of Government Affairs and Patient Advocacy, who provided a detailed overview of Mallinckrodt's Lobbying priorities, its engagement of external lobbyists, its processes for reporting and disclosing Lobbying activities at the state and federal levels, and its relationship with Stateside Associates, a third-party consultant Mallinckrodt engages to track pertinent state legislative initiatives. In the next reporting period, the Monitor will review recent Stateside reports as well as the search terms Stateside uses to track legislation for Mallinckrodt.

9.4 The Monitor expects to request periodic reports from Mallinckrodt related to its Lobbying activities. In the next reporting period, 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, as needed, review federal and state lobbying disclosure databases.

10. BAN ON CERTAIN HIGH DOSE OPIOIDS (§ III.E), BAN ON PRESCRIPTION SAVINGS PROGRAMS (§ III.F), BAN ON PROVIDING OPIOID PRODUCTS DIRECTLY TO PHARMACIES OR HEALTHCARE PROVIDERS (§ III.G), GENERAL TERMS (§ III.H), AND COMPLIANCE WITH ALL LAWS AND REGULATIONS RELATING TO THE SALE, PROMOTION, AND DISTRIBUTION OF ANY OPIOID PRODUCT (§ III.I)

10.1 Certain aspects of the Operating Injunction establish outright bans on certain activity, or establish requirements that do not readily lend themselves to independent verification. These include the Operating Injunction's ban on the manufacture, promotion, or distribution of "high dose opioids" (*i.e.*, "any Opioid Product that exceeds 30 milligrams of oxycodone per pill") (Operating Injunction § III.E.1); its ban on prescription savings programs (*id.* § III.F); its requirement that Mallinckrodt not provide an Opioid Product directly to a pharmacy or Healthcare Provider (*id.* § III.G.4); its requirement that Mallinckrodt comply with a number of miscellaneous general provisions (*e.g.*, in the event of a conflict between the Operating Injunction and federal or state law; truthful statements about Opioids and Opioid Products; the sharing of any subpoenas, Civil Investigative Demands, or warning letters) (*id.* § III.H); and compliance with laws and regulations relating to the "sale, promotion, distribution, and disposal of any Opioid Product" (*id.* § III.I).

10.2 Regarding the ban on high dose Opioid Products, Mallinckrodt confirmed in its Compliance Report that it is "in compliance with this provision," and that "[t]he highest dose oxycodone product that [it] manufacture[s] and distribute[s] contains 30 milligrams of oxycodone per tablet." Mallinckrodt Compliance Report § 5.6.

10.3 The Monitor has verified this statement through his review of Mallinckrodt's

Specialty Generics Product Catalog,[7] which contains a list of Mallinckrodt's Specialty Generics products, and through interviewing Mallinckrodt's Controlled Substances Compliance Director.

10.4 The Monitor will continue to review future product catalogues annually to ensure there is no change to Mallinckrodt's compliance with Section III.E of the Operating Injunction.

10.5 At the Monitor's request, Mallinckrodt has provided certain certifications with respect to Sections III.E-I of the Operating Injunction. Specifically, Mallinckrodt Specialty Generics' Associate General Counsel for Compliance and Data Privacy has certified that, since October 1, 2020:

(a) Mallinckrodt has "not commence[d] manufacturing, promoting, or distributing any Opioid Product that exceeds 30 milligrams of oxycodone per pill" (§ III.E.1), and will not do so while that provision is in effect. Furthermore, in the event that Mallinckrodt decides to manufacture, promote, or distribute such high-dose opioid products, Mallinckrodt will inform the Monitor promptly and in advance of any such manufacture, promotion, or distribution.

(b) Mallinckrodt has "refrain[ed] from providing an Opioid Product directly to a retail pharmacy location or Health Care Provider" (§ III.G.4), unless otherwise allowed by § III.G.4, and will not do so while that provision is in effect. Furthermore, in the event of any future plans by Mallinckrodt to begin such direct shipment, Mallinckrodt will inform the Monitor promptly and in advance of any such shipment.

(c) Mallinckrodt has not identified any provision of the Operating Injunction that conflicts "with federal or relevant state law or regulation" (§ III.H.1). Furthermore, in the event Mallinckrodt identifies such a conflict, Mallinckrodt will inform the Monitor promptly.

(d) Mallinckrodt has not made "any written or oral statement about Opioids or any Opioid Product that is unfair, false, misleading, deceptive or unconscionable" (§ III.H.2). Furthermore, in the event that Mallinckrodt discovers such a statement made on Mallinckrodt's behalf, Mallinckrodt will inform the Monitor promptly.

[7] *See* Mallinckrodt Pharmaceuticals, Specialty Generics Product Catalog, *available at* https://www.mallinckrodt.com/globalassets/documents/products/generic-products/v2b-mal-3333.sg-catinteractive_update_112019.pdf (2019).

(e) Mallinckrodt has not represented that "Opioids or any Opioid Product(s) have approvals, characteristics, uses, benefits or qualities that they do not have" (§ III.H.3). Furthermore, in the event Mallinckrodt discovers such a representation made on its behalf, Mallinckrodt will inform the Monitor promptly.

(f) Mallinckrodt has not received any requests from state Attorneys General for "[a]ny litigation or civil or criminal law enforcement subpoenas or Civil Investigative Demands relating to Mallinckrodt's Opioid Product(s)" (§ III.H.5) that Mallinckrodt reasonably believes relates to wrongdoing or suspected wrongdoing by Mallinckrodt or "[w]arning 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." Furthermore, in the event Mallinckrodt receives such request or letter, it will inform the Monitor promptly.

(g) Mallinckrodt remains in compliance with "all laws and regulations that relate to the sale, promotion, distribution, and disposal of any Opioid Products including but not limited to" those listed in Section III.I.a-f. Furthermore, in the event Mallinckrodt receives any government communications related to Opioid Products that Mallinckrodt reasonably believes relate to wrongdoing or suspected wrongdoing by Mallinckrodt related to Mallinckrodt's sale, promotion, distribution, or disposal of any Opioid Product, including any such subpoenas, civil investigative demands, and requests for information or is served with a lawsuit alleging a violation of any law or regulation by Mallinckrodt related to Mallinckrodt's sale, promotion, distribution, or disposal of any Opioid Product, Mallinckrodt will inform the Monitor promptly.

10.6 The Monitor will request re-certification of the above statements annually.

11. MONITORING AND REPORTING OF DIRECT AND DOWNSTREAM CUSTOMERS (§ III.G)

11.1 Section III.G.1 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. § 1301.74(b), 21 U.S.C. § 823(d) and Section 3292 of the SUPPORT for Patients and Communities Act."

11.2 Mallinckrodt (through its counsel) has advised the Monitor of several improvements to its SOM program over time:

> Over the last ten years, [Mallinckrodt ("MNK")] has made certain changes to its Suspicious Order Monitoring (SOM) program. With respect to direct orders, MNK revised its suspicious order monitoring algorithm to generate reports and to send information to DEA regarding flagged orders twice each business day. MNK lowered its SOM algorithm multiplier to make it more conservative, and expanded the review period for historical sales. MNK further made "Do Not Ship" controls automatic instead of manual so that an order could not be shipped while investigation was ongoing. MNK also expanded its customer audit program and has updated its Direct Customer Questionnaires. With respect to downstream customers, MNK formalized the chargeback restriction process and developed pharmacy information sheets to standardize the pharmacy investigation process. MNK has also updated its practice to restrict customers on the same day as the chargeback letter is issued. MNK reduced chargeback review thresholds for oxycodone and hydrocodone in 2019, resulting in a more rigorous review of downstream customers.

11.3 While the Monitor has been limited, during the period of the coronavirus (COVID-19) pandemic, in his ability to fully assess compliance with some aspects of these requirements, other aspects of Mallinckrodt's SOM program have been reviewed in detail.

11.4 Given the circumstances of the Monitor's appointment by the Court, and the interests of the parties, the Monitor has prioritized the review and assessment of key features of Mallinckrodt's controlled substances compliance and SOM program. The Monitor has similarly endeavored to use his best judgment in recommending areas that could benefit from improvement beyond the existing guidance from the DEA.[8]

11.5 As stated in the First Monitor Report, the Monitor has found Mallinckrodt willing to further strengthen its SOM program – including through its work with its third-party consultant, Analysis Group, Inc. ("AGI") – and receptive to the Monitor's recommendations. The Monitor is particularly encouraged by Mallinckrodt's retention of AGI to analyze its SOM program. There is little doubt that the use of "big data" and artificial intelligence to perform

[8] Although beyond the scope of the Monitor's duties in monitoring compliance with the Operating Inunction, the Monitor is of the opinion that continuing and additional guidance from the DEA would benefit industry participants greatly.

automated analyses will make Mallinckrodt's SOM efforts more efficient and effective, as a complement to human analysis. The Monitor looks forward to the opportunity to meet with AGI representatives in order to better understand AGI's anticipated proposal and recommendations prior to the filing of the Third Monitor Report.

11.6 Since filing the First Monitor Report, the Monitor has received and reviewed the following documents and data relating to Mallinckrodt's SOM program:

(a) a sample file on a downstream registrant / indirect customer (*i.e.*, a pharmacy) under a chargeback restriction review;

(b) data on chargeback restrictions, certain reinstatements following restrictions, and the length of time between restriction and reinstatement;

(c) Google news alert search criteria;

(d) a sample direct customer due diligence questionnaire;

(e) a sample compliance consultant report based upon the review of a downstream customer;

(f) reinstatement notices to DEA;

(g) Suspicious Order Monitoring Team ("SOMT") meeting minutes;

(h) "Work Instructions" providing more detailed guidance in connection with certain standard operating procedures ("SOPs");

(i) direct customer thresholds;

(j) chargeback restriction thresholds;

(k) data related to direct customer Opioid Product orders, including the number of orders flagged and subsequently released by the SOMT; and

(l) requests for assistance from state licensing boards and law enforcement to Mallinckrodt concerning the sale of Opioid Products.

11.7 Additionally, the Monitor conducted over nine hours of interviews with the Director of Controlled Substances Compliance; with one of the two Managers of Controlled Substances Compliance; and with the now departed Controlled Substances Compliance Auditor /

Analyst. The Controlled Substances Compliance Director and Manager are current members of the six-person SOMT, as was the Auditor / Analyst prior to her departure from Mallinckrodt in May. These interviewees provided greater insight into the complexities of Mallinckrodt's SOM, including the manner in which Mallinckrodt monitors the orders of both direct customers and downstream registrants, Mallinckrodt's relationships with its direct customers, and the chargeback review and reinstatement process.

11.8 A brief discussion of the chargeback review and restriction decision-making process is in order, given the centrality of chargeback data to Mallinckrodt's anti-diversion efforts, and hence the critical importance of this data, as well as its limitations. A chargeback request is a request from one of Mallinckrodt's direct customers for reimbursement from Mallinckrodt when the sale of Mallinckrodt's products by a direct customer to a downstream registrant results in a loss to Mallinckrodt's direct customer (*e.g.*, the direct customer purchases product from Mallinckrodt at a price of $20, but sells the product to a downstream registrant at a price of $15, entitling the direct customer to a "chargeback," or reimbursement, from Mallinckrodt of the difference of $5.)

11.9 The Monitor has gained a greater and more detailed understanding of Mallinckrodt's practice of issuing chargebacks and restrictions of downstream customers based on chargeback data. Indeed, many of the recommendations made below relate to chargebacks. To the extent such chargeback data yields information about the quantity of product sold by direct customers to certain downstream registrants, this provides Mallinckrodt with helpful intelligence about the nature of a downstream registrant's purchasing practices, and is therefore a useful input in the SOM process.

11.10 Mallinckrodt has successfully used such data to make chargeback restriction decisions. In other words, if the chargeback data reveals suspicious indicia to Mallinckrodt, and further investigation and inquiry does not allay Mallinckrodt's suspicions, Mallinckrodt will refuse to make a chargeback reimbursement payment to the direct customer. Mallinckrodt will also refuse to reinstate chargeback payments to a direct customer for a particular downstream registrant until Mallinckrodt is satisfied that its concerns have been addressed, either through due diligence by the direct customer, or through the downstream registrant's hiring of a consultant to satisfy Mallinckrodt that its concerns are addressed. Mallinckrodt reports its chargeback restrictions to the DEA, as well as to all of Mallinckrodt's direct customers. Those direct customers (which number in the hundreds) are also advised of Mallinckrodt's report to DEA. Naturally, such chargeback restrictions can provide a powerful incentive for Mallinckrodt's direct customers to discontinue supplying a downstream registrant, and in turn, for the downstream registrant to demonstrate its compliance in order to achieve reinstatement.

11.11 Chargeback data is useful, although severely limited. For example, for those downstream customers for whom Mallinckrodt's direct customer may not make a chargeback request at all, Mallinckrodt presently has no insight into the purchasing practices of those downstream customers.[9] And even where chargeback data is available, a chargeback restriction does not stop the supply of product to the downstream registrant if the direct customer chooses to continue the supply; it merely means that Mallinckrodt will not reimburse the direct customer for

[9] Mallinckrodt has established a media review protocol using Google alerts for key terms that are designed to reveal law enforcement activity relating to pharmacies. But that identification is only helpful if Mallinckrodt has chargeback data from that particular pharmacy. Otherwise, Mallinckrodt presently has no way of knowing whether a pharmacy identified in a news report is a downstream registrant obtaining product from a Mallinckrodt direct customer.

the direct customer's loss.[10] Additionally, Mallinckrodt may not receive chargeback data in a timely manner because a direct customer may only submit a chargeback request a month or more after the product is supplied. This can result in continued shipment of product to a downstream registrant that Mallinckrodt would otherwise not wish to be supplied with Mallinckrodt's product.

11.12 As a result of the monitoring efforts identified above, the Monitor makes the following observations and recommendations regarding Mallinckrodt's SOM program.[11]

General SOM-Related Recommendations

(a) ***Modernize and enhance the SOM function with the use of big data, artificial intelligence, and automated processes and algorithms.***

[10] Although a direct customer would likely not sell product at a loss, there are conceivably ways in which it could make up for the loss, such as by raising prices charged to the downstream registrant. In that event, Mallinckrodt's chargeback restriction would have no effect upon the continued supply of product to a downstream customer whom Mallinckrodt otherwise intended to restrict. To be sure, it is Mallinckrodt's practice to share with a direct customer the basis for its chargeback restriction decisions, and any continued supply of the downstream registrant by the direct customer notwithstanding the direct customer's awareness of Mallinckrodt's concern could create liability for the direct customer. But it is conceivable that Mallinckrodt and its direct customers may not always agree on the appropriateness of a chargeback restriction, and such disagreement could result in continued supply that Mallinckrodt itself would not otherwise approve. *See* Recommendation (d), *infra*.

[11] A draft of this Report was shared with Mallinckrodt, the Ad Hoc Committee of governmental entities (the "Ad Hoc Committee"), and with the Official Committee of Opioid Related Claimants ("OCC"). Mallinckrodt has accepted all of the recommendations set forth herein. The Ad Hoc Committee, similarly, has expressed no objection to them.

The Ad Hoc Committee consists of (1) seven States and (2) the court-appointed Plaintiffs' Executive Committee (the "PEC") in the multi-district litigation captioned *In re National Prescription Opiate Litigation*, Case No. 17-md-02804, MDL No. 2804 (N.D. Ohio) (the "MDL"). The seven states on the Ad Hoc Committee are part of a group of 50 states that are signatories to the Restructuring Support Agreement filed as Exhibit A to Docket No. 128 of Case No. 20-12522.

(i) **Observation**: The Monitor recognizes the steps Mallinckrodt has taken during the last several years to improve its SOM program. This Monitorship presents an opportunity to build upon Mallinckrodt's progress. Specifically, through the Monitor's review of documents and interviews, it appears that a number of Mallinckrodt's SOM processes and procedures could be updated and modernized, and that Mallinckrodt recognizes this and is taking steps to achieve this necessary modernization. Mallinckrodt's legacy processes and procedures are frequently manual and labor intensive, in that they require a significant degree of human data collection and manipulation from disparate sources of information – largely with the help of a single Controlled Substances Compliance Auditor / Analyst (who recently departed the company). This results in records related to individual pharmacies maintained in separate folders with very limited searchability across records for comparison purposes. Consequently, this fosters a reactive approach to diversion control that does not facilitate system-wide analysis or permit the SOMT to draw macro inferences from the data available to Mallinckrodt.

(ii) **Recommendation: Mallinckrodt should continue its steps toward modernizing its SOM program by engaging in a thoroughgoing review of its SOM architecture, and its full potential. With AGI's assistance, Mallinckrodt should utilize available technology to design a system to fuse the inflow of data and intelligence from disparate sources to make it available for analysis in a more timely, efficient, and user-friendly way that will also permit analysts to draw system-wide inferences proactively, rather than reactively. Indeed, many of the recommendations below feed into this general recommendation. The Monitor is encouraged that Mallinckrodt has contracted with AGI to automate some aspects of the SOM program. The Monitor looks forward to learning more about what AGI proposes and the timeline for implementation. The Monitor's hope**

is that this partnership with AGI will involve a wide-ranging and all-encompassing assessment of the processes Mallinckrodt currently uses to identify suspicious orders, with recommendations for improvement. To be clear, the Monitor views AGI as a force multiplier – *i.e.,* as an additional element to supplement and to enhance human analysis – not as a replacement for human analysis.

Mallinckrodt is actively working with AGI to implement this recommendation.

(b) ***Select one or more candidates with suitable qualifications, and with flexibility to hire from outside the Hobart, New York market, to fill the vacant role of Compliance Auditor / Analyst.***

(i) **Observation**: During this reporting period the Monitor learned about the pending departure of Mallinckrodt's Compliance Auditor / Analyst to pursue other professional opportunities. Mallinckrodt has informed the Monitor that it is hiring two new members of the controlled substances compliance team to fill the place of the departed Compliance Auditor / Analyst. One of these two positions, the more junior position, is the Compliance Consultant. Mallinckrodt has advised of the hiring of a new employee with a Masters in Predictive Analytics and experience with coding, inputting, and interpreting data sets, who has now filled this position. The more senior position will be the Lead Controlled Substances Compliance Consultant, who will report to the Director of Controlled Substances Compliance. That role will have responsibility "for implementing, executing, and enhancing [Mallinckrodt's] internal controlled substances analytics and compliance program."[12] Mallinckrodt seeks someone with eight years of experience in controlled substances compliance

[12] *See* Lead Controlled Substances Compliance Consultant Job Posting, *available at* https://mallinckrodt.wd5.myworkdayjobs.com/en-US/MallinckrodtCareers/job/St-Louis-MO-Pharma---USA032/Lead-Controlled-Substances-Compliance-Consultant_JR000011580 (last visited July 12, 2021).

as an investigator or regulator to fill this position, and is actively reviewing candidates at the time of the filing of this Report.

(ii) **Recommendation: The Monitor is encouraged that Mallinckrodt is keeping an open mind as to whether a former DEA Diversion Investigator and / or an individual with training in data analytics or programming would be advisable to fill the gap left by the former Auditor / Analyst, particularly given the above recommendation to increase use of data analytics. Given the nature of the role, the importance of the position to Mallinckrodt's SOM efforts, and the need to select a highly competent candidate, the Monitor is also encouraged that Mallinckrodt is not limiting itself only to candidates willing to work from Mallinckrodt's Hobart, New York facility.**

Mallinckrodt is in the process of implementing this recommendation.

(c) ***Consider the sufficiency of both short-term and long-term human resource allocation in the SOM function.***

(i) **Observation: The** SOMT is comprised of six members. Until recently, the team functioned with a single (now departed) Compliance Auditor / Analyst during the period in which SOM relied heavily upon manual analysis and reporting, as noted above. This single resource may have been sufficient for the nature and scope of Mallinckrodt's SOM activity at that time. Going forward, Mallinckrodt has decided to hire additional staff to support the SOM function, and has made one hire already, as noted above.

(ii) **Recommendation: The Monitor is encouraged that Mallinckrodt is considering the need for additional SOM human resources in the immediate term. Mallinckrodt should also assess, in the longer term – after integrating any new AGI platforms, processes, and recommendations – whether its planned deployment of**

resources will be sufficient to update its developing SOM program in a manner consistent with the Monitor's recommendations.

Mallinckrodt agrees to regularly evaluate human resource allocation in the SOM function.

Recommendations Related to Chargebacks

(d) ***Use best efforts to ensure chargeback restrictions restrict not only chargeback payments, but also the supply of Opioid Products to a restricted pharmacy.***

(i) **Observation:** The principle motivating chargeback restrictions is sound – *i.e.*, to utilize available data to restrict chargeback payments in order to disincentivize the distribution of Opioid Products to downstream registrants demonstrating a risk of diversion. However, because Mallinckrodt restricts chargeback payments without also expressly restricting the sale of associated Opioid Products, a chargeback restriction does not guarantee a restriction on the supply of Mallinckrodt's opioids. And although, as a practical matter, no distributor will wish to continue supplying Opioid Products at a loss (*i.e.*, without a chargeback payment), there is nothing presently preventing a distributor from doing so.

(ii) **Recommendation: Mallinckrodt should use its best efforts to obtain representations and warranties from its direct customers assuring Mallinckrodt that, in the event of a chargeback restriction, the direct customer will *not* supply the downstream registrant with Mallinckrodt's Opioid Products unless and until the restriction is removed and the downstream registrant is reinstated.**

Mallinckrodt agrees to use its best efforts to address this recommendation.

(e) ***Use best efforts to obtain timely provision of chargeback data from direct customers.***

(i) **Observation:** Chargeback reviews may be delayed because Mallinckrodt does not receive chargeback requests from some direct customers in a timely fashion. Currently, Mallinckrodt does not require direct customers to make requests for chargebacks within a specific timeframe. And although the "big three" distributors (AmerisourceBergen, McKesson, and Cardinal Health) typically make their chargeback requests promptly, a smaller percentage of direct customers do not.

Recommendation: Mallinckrodt could encourage tardy direct customers to make more timely chargeback requests, enabling Mallinckrodt to more timely review and act upon chargeback data. For example, as Mallinckrodt renegotiates contracts with its direct customers, it should use best efforts to negotiate the inclusion of language providing that chargebacks will be paid on a decreasing percentage schedule based on the length of time between the order and the request. Finally, Mallinckrodt should analyze the degree to which these efforts are successful in increasing the timeliness of direct customer chargeback requests and improve Mallinckrodt's ability, in turn, to implement more timely chargeback restrictions.

Mallinckrodt has agreed to use best efforts to address these recommendations.

(f) ***Evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data.***

(i) **Observation:** Currently, the SOMT meets on the last Thursday of every month for about an hour to review chargeback data, which provides only a week for the Controlled Substances Compliance Auditor / Analyst to review the chargeback data that is typically shared with the Auditor / Analyst on the third Thursday every month. The Auditor / Analyst takes a month to analyze the data and conduct follow-up in order to report back to the

SOMT the next month, although the Auditor / Analyst typically has only one to six pharmacies for which to conduct due diligence each month. In addition, the SOMT meets every third Thursday to review potential restrictions based on social media.

Although there are no other regular SOMT meetings, SOMT members may have pre-chargeback meetings on the Monday or Tuesday before the last Thursday meeting and the SOMT will hold ad hoc meetings when the information it obtains through the SOM process warrants a more immediate restriction determination. As noted below (*see* recommendation (g), *infra*), the typical time to implement a restriction is a matter of weeks.

(ii) **Recommendation: Mallinckrodt should evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data, by changing the timing and sequencing of (1) obtaining chargeback data from the Finance Department and (2) scheduling meetings to review the data in order to report to the SOMT and make decisions in a shorter time frame. For example, Mallinckrodt could space SOMT monthly meetings so that the Auditor / Analyst has the opportunity to report chargeback data within a shorter period within the same month (*e.g.*, a two-week period, twice per month). Additionally, Mallinckrodt should require, in a written policy or Work Instruction, ad hoc SOMT meetings to be held whenever the need for an expedited restriction determination arises.**

Mallinckrodt has agreed to evaluate this issue.

(g) ***After analyzing turnaround times for chargeback reviews and restrictions, amend relevant SOPs to memorialize firm timelines.***

(i) **Observation:** Though the chargeback review process generally appears to be completed in a matter of weeks, the procedure outlining chargeback reviews (in the SOP titled *Social Media & Chargeback Reviews of Direct Customers and Downstream*

Registrants) does not establish any formal timeline for the performance of routine tasks, such as the acquisition of chargeback data, and its review, analysis, and reporting to the SOMT on flagged chargeback data. Similarly, there is no detailed "Work Instruction" accompanying this SOP. The departure of Mallinckrodt's long-time Controlled Substances Compliance Auditor / Analyst highlights the need for more specific written guidance and formalized rules for chargeback review, analysis, and reporting to the SOMT. Finally, even after determining that there is a need for restriction, sometimes the "effective date" of the restriction has lagged several days after the decision due to a "grace period" that Mallinckrodt offered to its direct customers prior to the Operating Injunction.

(ii) **Recommendation: Since Mallinckrodt currently has no system in place to track and measure the turnaround time from acquisition of chargeback requests to review, analysis, reporting, and restriction decisions, Mallinckrodt should establish a system to track and measure the timing of these events in order to inform the setting of strict deadlines for such activities. With the guidance of findings from this analysis, the SOP should be updated and revised to incorporate rules for the timing of critical chargeback review functions. Additionally, although chargeback data is provided by the Finance Department typically on the third Thursday of each month, this is not necessarily "set in stone," or codified in a SOP. Given the critical importance of the timely analysis of this data and prompt action on the basis of that analysis, the time for assembling and sharing this data should be fixed in a SOP.**

Mallinckrodt's chargeback SOP and practice should be premised on the presumption that a chargeback request under review must be resolved as promptly as possible. Even if a chargeback request is not viewed by Mallinckrodt as equivalent to a

"suspicious order" within the technical meaning of 21 C.F.R. § 1301.74 – or, in the language of the new DEA Proposed Rule, as an "order received under suspicious circumstances (ORUSC)" – (in part, because the request is for payment, and not an order for controlled substances; and because it addresses an already-filled order, not a future order) the request is under review because the data it provides indicates a flag that Mallinckrodt appropriately recognizes.

The SOP should convey a sense that time is of the essence and that each day of delay could result in additional potential diversion, so that the restriction decision should be promptly implemented. For example, direct customers should be given a narrower window in which to respond to Mallinckrodt's request for due diligence.

The Monitor understands that Mallinckrodt has altered the approach of allowing a "grace period" for restriction decisions to be implemented by direct customers, and that direct customers are no longer given a courtesy period of several days to implement the restriction. This practice should now be memorialized in the relevant SOP.

Implementation of this more proactive approach may necessitate an increase in the number of monthly SOMT meetings to ensure faster turnaround time.

Mallinckrodt has agreed to implement these recommendations and is in the process of doing so.

(h) ***Incorporate all existing data sources available to Mallinckrodt, and use best efforts to reach agreements with direct customers to provide more detailed retail data to conduct more effective chargeback reviews.***

(i) **Observation:** Chargeback data, although helpful, provides incomplete and delayed insight into potential diversion. And in those instances where a direct customer may not share any chargeback data at all, the absence of a chargeback request provides no alert to potential diversion.

(ii) **Recommendation: Mallinckrodt should (1) incorporate all relevant data sources it already possesses, including but not limited to so-called "867 data" (*i.e.*, sales data) and any newly available data from the DEA's Automated Reports and Consolidated Ordering System ("ARCOS") into its SOM program, and (2) use its best efforts to reach agreements with direct customers to obtain retail-level data when conducting due diligence on individual pharmacies in the context of a chargeback restriction review.**

Mallinckrodt's use of all data already available to it would fulfill the Operating Injunction's requirement that Mallinckrodt: (1) "[u]tilize all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer;" and (2) "[u]tilize all reasonably available Downstream Customer data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product." Operating Injunction § III.G.1.a-b.

Mallinckrodt should use best efforts to obtain more detailed retail-level data from its direct customers when requesting due diligence in connection with chargeback reviews. Mallinckrodt should discuss with direct customers the manner in which such data could be shared with Mallinckrodt in a sufficiently anonymized way to enable more robust SOM, without the limitations of chargeback data. If necessary, appropriate confidentiality and non-disclosure agreements may be entered into. This would permit more rigorous data analysis for key "dashboard" indicators, potentially including (1) ratio of sales of controlled ("CS") to non-controlled substances ("NCS"); (2) ratio of cash payments to non-cash payments for CS and NCS; and (3) identification of customer zip codes to automatically identify unusual driving distances or out-of-state customer origins.

Mallinckrodt has agreed to implement this recommendation and is actively working with AGI to do so.

(i) ***Assess the potential value of additional factors to consider in conducting chargeback reviews.***

(i) **Observation:** The criteria Mallinckrodt uses for conducting chargeback reviews include volume-based thresholds, analysis of ARCOS data, media reviews, and some limited geographic information and population data, among other factors.

(ii) **Recommendation: Mallinckrodt should assess the value of additional relevant factors to inform its chargeback restriction analysis. For example, Mallinckrodt could add: (1) census information and consideration of the proportion of distribution to local population density; (2) to the extent such data is available or can be obtained, distance between a patient's registered address and pharmacy, as well as out-of-state addresses (based upon patient zip code); (3) additional internet searches and customer comments; (4) social media searches; (5) public/private database searches (by way of example, RX Patrol,[13] the National Association of Drug Diversion Investigators, Inc. ("NADDI"), or streetrx.com[14]); (6) overdose statistics for local & state areas; (7) ARCOS**

[13] "In an ongoing effort to combat the abuse and diversion of prescription drugs, Purdue Pharma L.P. has conceived, developed and funded an information clearinghouse for data related to pharmacy robberies, burglaries and theft that involve the loss of controlled substances. RxPATROL® (Pattern Analysis Tracking Robberies and Other Losses) is an initiative designed to collect, collate, analyze and disseminate pharmacy theft intelligence to law enforcement throughout the nation." https://www.rxpatrol.com/aboutrxpatrol/. "The RxPatrol® Searchable Database contains data from hundreds of incidents involving pharmacy robberies, burglaries, fraud, forgery, cargo theft, etc. You can also view maps and create charts indicative of theft trends in your area." https://reports.rxpatrol.com/APXPRD/f?p=104:LOGIN:13727801040566.

[14] "Inspired by the principles of crowdsourcing, StreetRx is a one-of-a-kind program that identifies and tracks the street value of prescription and illicit drugs. StreetRx gathers user-submitted data to map the street price of a variety of drugs across the country." https://streetrx.com/

retail buyer statistics; and (8) State Prescription Drug Monitoring Program ("PDMP") details if available. These and any other relevant factors should be memorialized in a revised SOP and accompanying checklist.

Mallinckrodt has agreed to evaluate additional factors and is consulting with AGI on this issue.

(j) ***Continue to actively pursue the opportunity for a public-private "clearinghouse" concept, in collaboration with the DEA and industry partners.***

(i) **Observation:** Mallinckrodt has shared with the Monitor that Mallinckrodt is exploring with the DEA the possibility of creating a public-private collaboration involving a "clearinghouse" of supply chain data. In addition, in public comments on the DEA's Notice of Proposed Rulemaking,[15] SpecGx's Director of Controlled Substances Compliance noted Mallinckrodt's proposal of a public-private partnership for the collection of supply chain data that could more effectively assist in suspicious order monitoring.[16] Specifically, Mallinckrodt noted the following:

> It is clear that industry took inconsistent approaches with each registrant developing disparate strategies and procedures with various degrees of success. We believe this also highlights the need for better coordination of suspicious order systems between government and industry. Leveraging technological innovations could yield a significantly better, more advanced system to both improve registrant compliance as well as deliver actionable information to help improve DEA's ability to combat diversion in real time. Such a system could

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[15] The DEA's Notice of Proposed Rulemaking ("NPRM") for Suspicious Orders of Controlled Substances was published in the Federal Register on November 2, 2020. *See* 85 Fed. Reg. 69282.

[16] *See* Letter of Scott Collier, SpecGx LLC Director of Controlled Substances Compliance, to William T. McDermott, DEA Assistant Administrator, Diversion Control Division (Jan. 4, 2021), attached as **Exhibit Two**.

> leverage big data processes, including systems capable of providing machine learning (*i.e.*, artificial intelligence).
>
> . . . [DEA's] decision to provide access to limited ARCOS data through the ARCOS tool as part of DEA's implementation of the SUPPORT Act gave industry visibility to 6 months of transactions for direct and to indirect downstream transactions. However, that data is somewhat limited as ARCOS reporters are only required to report on a quarterly basis, thereby creating a substantial lag. We believe that development of a data analysis system that provides industry with access to real-time drug distribution transactions (masked or blinded as to the identity of the "seller") would provide industry with a significant tool to detect and thereby prevent suspicious orders from being filled. This is a serious data challenge that could be met by developing a system through a private-public partnership long advocated by SpecGx that would provide industry with the information necessary to make better real time "sell-don't sell" decisions while simultaneously providing DEA with unmasked data to aid the agency in exercising their oversight and investigative authority.

Relatedly, a recent report to U.S. congressional committees by the Government Accountability Office identified deficiencies in the DEA's "proactive and robust analysis of industry-reported data" that DEA collects.[17] Indeed, many of the very same "big data" analytics improvements that private industry is undertaking could be embraced by DEA. The potential for such partnership and collaboration in reducing diversion is promising.

(ii) **Recommendation: Mallinckrodt is undoubtedly correct that the technological means do exist to mine and analyze the full spectrum of supply chain data, from production by manufacturers like Mallinckrodt, to prescription filling at the retail pharmacy level. Thus, Mallinckrodt's proposal is a timely and important one that offers deeper insight at all nodes in the supply chain and would greatly enhance compliance efforts by Mallinckrodt and other industry participants, while also providing law enforcement with a more holistic assessment. Implementation of this initiative will require**

[17] Government Accountability Office, Report to Congressional Committees, "Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders," GAO-20-118 (Jan. 2020).

concerted effort by Mallinckrodt and many other actors and entities that is well beyond the scope of the Operating Injunction. The Monitor encourages Mallinckrodt to continue to pursue these efforts by taking a leadership role in assembling all interested stakeholders, including Mallinckrodt's industry peers, potential third-party data analytics and hosting firms, and the DEA, and developing a timeline to move such discussions forward.

In the meantime, in parallel, Mallinckrodt should pursue best efforts to assemble supply chain data relating to Mallinckrodt's own direct and indirect customers. It could do so, as noted above, by making best efforts to obtain agreements with direct customers to provide Mallinckrodt with downstream customer data. The Monitor believes this will have substantial benefits for Mallinckrodt's SOM efforts beyond the limits of its reliance upon chargeback data, and that piloting such a program will demonstrate the value of an industry-wide framework.

The Monitor encourages Mallinckrodt's continued discussion and collaboration with the DEA and other industry partners to establish the clearinghouse, which has the potential to greatly improve transparency, and therefore aid the SOM efforts of not just Mallinckrodt, but of the industry as a whole.

Mallinckrodt plans to continue its efforts in support of an industry-wide controlled substances clearinghouse.

(k) ***Amend relevant SOPs to create a chargeback review task checklist, provide an audit trail, and ensure second-level review and approval.***

(i) **Observation:** The SOP titled *Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants* outlines steps for the Controlled Substances Compliance Auditor / Analyst to take during a chargeback review, but does not attach a checklist to ensure both (1) a consistent approach in each case review as well as (2) a

documented research trail for auditing purposes. It also does not require supervisory review and approval of chargebacks that are ***not*** elevated for SOMT review.

(ii) **Recommendation: Either the SOP or an associated "Work Instruction" should provide a detailed checklist of the steps the Controlled Substances Compliance Auditor / Analyst must undertake to make a restriction recommendation to the SOMT, and such checklists should be maintained to facilitate audits. Additionally, if the Auditor / Analyst determines that no chargeback restriction is warranted, this decision should be reviewed and approved by a second individual.**

Mallinckrodt is in the process of implementing this recommendation.

(l) ***Memorialize and routinize the periodic review of (1) pharmacies reviewed but not restricted, and (2) pharmacies that are reinstated.***

(i) **Observation:** It was the routine (but unwritten) practice of Mallinckrodt's former Controlled Substances Compliance Auditor / Analyst to create a "tickler" reminder on her Outlook calendar to follow up on the chargeback data of reinstated pharmacies. For pharmacies reviewed, but not restricted, she would create a similar reminder to check back on those pharmacies quarterly.

(ii) **Recommendation: The practice of the prior Auditor / Analyst is advisable, and should be memorialized in applicable operating procedures. Ideally, to minimize the risk of human error, Mallinckrodt should consider adopting more automated processes to prompt routine alerts, rather than manually created reminders that only one employee (*i.e.*, the now departed Auditor / Analyst) maintains.**

Mallinckrodt has agreed to implement this recommendation.

Recommendations Related to Order Thresholds and Release of Suspicious Orders

(m) ***Re-evaluate direct customer order thresholds with the assistance of AGI.***

(i) **Observation:** Mallinckrodt has established a single threshold for all direct customer orders that is triggered if the volume or quantity of a product order is a fixed multiple of the prior 18-month average ordered. This is a somewhat blunt instrument because the same multiple applies to all direct customers, regardless of their relevant idiosyncrasies (including customer size, geography of customer's distributions, etc.).

(ii) **Recommendation: Mallinckrodt, with the assistance of AGI's analysis and recommendations, should re-evaluate its direct customer thresholds in order to determine (1) whether other factors should inform the creation of thresholds (including, perhaps, the impact of decreasing DEA quotas on direct customer ordering trends, as well as ARCOS data analyses), (2) whether they should be uniformly applied to all direct customers without distinction, or more specifically tailored, and (3) whether lower thresholds would be more appropriate.**

Mallinckrodt is re-evaluating direct customer order thresholds with AGI.

(n) ***Re-evaluate chargeback thresholds with the assistance of AGI.***

(i) **Observation:** Mallinckrodt has established chargeback metrics for all of its Opioid Products, and precise thresholds for three categories of Opioid Products (Oxycodone 15 mg; Oxycodone 30 mg; and Hydrocodone 10 mg). Although these thresholds were reduced in mid-2019, they have not been adjusted since. As is the case with direct customer thresholds, the chargeback thresholds take a one-size-fits-all approach that applies without distinction to all downstream customers, and do not appear to be informed by relevant idiosyncrasies, including customer size, geography of pharmacy location, patient population, or other relevant factors.

In addition, although the relevant SOP (*Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants*) requires review of "[a]ll Opioid Products with heightened review of Oxycodone 15 mg, Oxycodone 30 mg, Hydrocodone 10 mg products," (§ 5.1), the chargeback thresholds provided to the Monitor relate solely to Oxycodone 15 mg, Oxycodone 30 mg, and Hydrocodone 10 mg. Mallinckrodt's thresholds for other products are based upon the degree of deviation of the order from the historical mean of prior orders.

(ii) **Recommendation: Mallinckrodt, with the assistance of AGI's analysis and recommendations, should re-evaluate its chargeback metrics and thresholds in order to determine (1) whether other factors should inform the creation of thresholds (including, for example, ARCOS data analyses), (2) whether they should be uniformly applied to all downstream customers without distinction or more specifically tailored, and (3) whether lower thresholds would be more appropriate.**

Additionally, all metrics Mallinckrodt uses to conduct chargeback reviews for all Opioid Products should be clearly identified in a written policy. In coordination with AGI, Mallinckrodt should establish a consistent and well-reasoned analytical approach to all threshold metrics for all Opioid Products.

Mallinckrodt is re-evaluating chargeback restriction thresholds with the assistance of AGI.

(o) ***In collaboration with AGI, determine whether the flagging and releasing of direct customer orders can be refined to better identify potentially suspicious orders.***

(i) **Observation:** The Monitor requested data sufficient to determine what percentage of direct customer orders are flagged for further review on a monthly basis, and what percentage of those flagged orders are released, following review. The data provided indicates that 100% of flagged orders are released following review.

(ii) **Recommendation: Mallinckrodt's release of 100% of all flagged orders warrants further inquiry by the Monitor. On the one hand, direct customer orders are likely to raise fewer suspicions than downstream customers (such as pharmacies). On the other hand, further investigation is necessary to determine whether the release rate observed is appropriate, or whether the review process can be further refined or made more sensitive to identify diversion risks. The Monitor anticipates that AGI's work may be helpful in this regard, and looks forward to understanding AGI's efforts.**

Mallinckrodt is analyzing its direct customer order review process with AGI.

(p) ***Implement two-level review and approval for release of flagged orders.***

(i) **Observation:** Previously, the former Controlled Substances Compliance Auditor / Analyst alone, without the need for supervisory approval, was permitted to release flagged orders, consistent with the guidance in the SOP titled *Suspicious Order Monitoring Program Review of Direct Customer Orders*, § 5.9.6.

(ii) **Recommendation: Mallinckrodt should ensure that release of flagged orders occurs only after two-level review and approval.**

Mallinckrodt is in the process of implementing a two-level review and approval.

(q) ***Memorialize the confidentiality of thresholds, consistent with current practice.***

(i) **Observation:** Although Mallinckrodt's unwritten practice is to maintain the confidentiality of its thresholds for both direct customer orders and downstream customer orders (from chargeback requests), no confidentiality requirement is stated explicitly in any SOPs.

(ii) **Recommendation: As it is Mallinckrodt's policy to maintain the strict confidentiality of order thresholds (both direct and downstream), this should be made clear in the SOPs.**

Mallinckrodt is in the process of implementing this recommendation.

Recommendations Related to Due Diligence

(r) ***Establish minimum standards and criteria for conducting retail pharmacy due diligence, potentially with the advice and input of a third-party compliance consultant.***

(i) **Observation:** Mallinckrodt presently permits one of two due diligence options for a downstream customer to achieve reinstatement for additional chargeback payments after a restriction: (1) the downstream customer may engage a compliance consultant from a list Mallinckrodt provides; or (2) the direct customer may conduct a due diligence review or engage a compliance consultant to do so. The lack of a source of common guidance is likely to result in variability among the factors different customers or consultants consider, as well as variability in the degree of scrutiny and the robustness of audits. For example, one sample provided to the Monitor appears to be extremely cursory and seems to rely almost entirely on the restricted pharmacists' own responses to questions, without requiring the provision of corroborating backup information.

(ii) **Recommendation: Mallinckrodt should develop its own detailed and thorough questionnaire and baseline due diligence requirements to be provided to compliance consultants to ensure that Mallinckrodt is obtaining consistent information and that the audits are consistently rigorous and sufficiently probative to reveal meaningful information to address diversion risk. To avoid the concern that a consultant might feel limited by Mallinckrodt's questionnaire, Mallinckrodt could make clear that its requirements establish the bare minimum threshold, and are intended to**

supplement, not substitute for, the independent expertise of the consultant. Where reasonably possible (such as when review of pharmacist and employee disciplinary history is required), the auditor should independently verify the self-reported information from the interviewee, and should require documentary support for the answers provided.

Mallinckrodt is in the process of implementing this recommendation.

(s) ***Revise direct customer questionnaires to yield helpful, actionable, and verifiable information and determine a method for sampling or randomly auditing questionnaires.***

(i) **Observation:** Mallinckrodt utilizes a two-page questionnaire for direct customer due diligence, which is filled out and emailed, faxed, or mailed to Mallinckrodt's Customer Data Integrity Group ("CDIG"). Under the SOP titled *Suspicious Order Monitoring Program Review of Direct Customer Orders*, the CDIG forwards for SOMT review questionnaires containing any "no" response or written answers. Otherwise, Mallinckrodt appears to generally accept the responses provided.

(ii) **Recommendation: Mallinckrodt should redraft the questionnaire in order to yield helpful, actionable, and verifiable information that contributes meaningfully to Mallinckrodt's SOM program. For example, questions regarding customers' use of a SOM program, training, compliance with laws, and onsite inspections, among many other examples, all warrant verification, even if the large number of direct customers requires that such verification be accomplished on a random sample basis or on the basis of a strategic risk assessment.**

Some of the current questions on the questionnaire may also be insufficient to detect diversion risks. For example, the questionnaire asks merely "Does your company monitor pharmacy customers engaged in dispensing controlled substances for *one or more* of the following characteristics in the pattern of ordering controlled substances?" (emphasis

added). Mallinckrodt should instead create its own list of suspicious issues to put pharmacies on notice, and do more to discern what "know your customer" efforts its direct customers undertake.

Mallinckrodt is in the process of implementing this recommendation.

(t) ***Establish regularly scheduled interactions with direct customers.***

(i) **Observation:** Other than sending the annual customer questionnaire, Mallinckrodt does not have a regular schedule for "check ins" with direct customers or for conducting onsite visits.

(ii) **Recommendation: Mallinckrodt could benefit from having more frequent and more regularly scheduled interactions with direct customers. Additionally, Mallinckrodt could obtain commitments from direct customers to learn promptly of adverse information the direct customers obtain about any downstream registrants (whether with Mallinckrodt's products or other products).**

Mallinckrodt has agreed to use its best efforts to implement this recommendation.

Recommendation Related to Media and Social Media Reviews

(u) ***Explore options for making media review more effective.***

(i) **Observation:** Although perhaps not explicitly required by any applicable law or regulation,[18] Mallinckrodt has proactively undertaken to utilize media reviews

[18] As noted above, given the limited DEA guidance, there is in fact very little that is explicitly required by applicable SOM-related statutes and regulations. And the language of § 1301.74(b) suggests its guidance is illustrative, not exhaustive. *See* 21 C.F.R. § 1301.74(b) ("Suspicious orders ***include*** orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." (emphasis added)); *see also Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 221 (D.C. Cir. 2017) ("Section 1301.74(b) defines suspicious orders as 'includ[ing]' orders of an unusual size, pattern, or frequency, and it is well established that the word 'include' often precedes a list of 'illustrative' examples, rather than an exclusive list of indicia of an identified wrong.").

in its SOM program. Thus, Mallinckrodt uses a Google news search to identify downstream registrants posing a risk of diversion. The Google news search contains certain key terms designed to return search results for relevant articles. Recently (since the onset of the monitorship), Mallinckrodt has added such terms as "Pharmacist arrested," "Pharmacist indicted," and "search warrant."

(ii) **Recommendation: Although the media review system has helped to identify some suspicious pharmacies and assisted in chargeback restriction decisions, the mechanism used to return relevant media reports is rudimentary. Mallinckrodt should explore available options to make its media review more robust and efficient.**

Mallinckrodt is actively exploring options to make media review more effective.

11.13 **Anticipated SOM-Related Next Steps**

(a) Monitoring compliance with Section III.G of the Operating Injunction will remain a priority for the Monitor, and the Monitor intends to meet with AGI and review and analyze additional SOM-related data prior to filing his Third Monitor Report.[19] The Monitor

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At a minimum, Mallinckrodt's use of media reviews is a prudent use of good judgment in light of the minimal cost and the potential benefit from enhanced diversion mitigation. It is also consistent with the approach of the recently proposed DEA rule on SOM, which defines "due diligence" as "a reasonable and documented investigation into persons and orders (coupled with other appropriate investigations, including previous investigations into persons and orders) that ***includes, but is not limited to***" certain basic facts, and requires "examination of each suspicious circumstance surrounding an order, and ***examination of all facts and circumstances that may be relevant indicators of diversion*** in determining whether a person (or a person submitting an order) is engaged in, or is likely to engage in, the diversion of controlled substances." DEA Proposed Rule, Suspicious Orders of Controlled Substances, 85 Fed. Reg. 69282-01 (Nov. 2, 2020) (emphasis added).

[19] Mallinckrodt expects that AGI will be prepared to meet with the Monitor and provide him with an update on AGI's development of recommendations and enhanced procedures for direct and downstream customer SOM within sixty days.

also anticipates that the initial "scoping" activity will naturally evolve into more auditing and monitoring of implementation of the above recommendations and future recommendations. The Monitor will include an update on Mallinckrodt's progress in implementing these recommendations in future reports.

(b) Mallinckrodt has either provided, or is in the process of gathering, documents and materials in response to the Monitor's second document request seeking, among other things, the following categories of documents and data: customer data; '852, '867, and ARCOS data; copies of various internal SOM reports; chargeback data; data related to chargeback requests and reinstatements; reports prepared in connection with requests for chargeback reinstatements; information reviewed by the SOMT prior to meetings and the team's meeting minutes; copies of any audits or reports prepared in connection with auditing direct customers; direct customer questionnaire responses; data concerning Mallinckrodt's procurement quotas; documents related to the public-private "clearinghouse" Mallinckrodt proposed to the DEA; and contracts with distributors.

(c) The Monitor has also requested that Mallinckrodt supplement its production of some of these categories of documents with varying degrees of frequency (*e.g.*, quarterly, semi-annually, annually), to permit the Monitor's auditing of Mallinckrodt's ongoing compliance with Section III.G.

12. COMPLIANCE DEADLINES (§ III.J)

12.1 As of the Petition Date – *i.e.*, on or about October 12, 2020 – the Monitor's assessment is that Mallinckrodt was in full compliance with the provisions of the Operating Injunction, with the exception of the provisions in Section V ("Public Access to Mallinckrodt

Documents"). As noted below, *see* Section 15, *infra*, the Monitor believes that, as of July 12, 2021, Mallinckrodt is now also in full compliance with Section V.

13. TRAINING (§ III.K)

13.1 Section III.K requires Mallinckrodt to provide regular training, at least once per year, to relevant employees on the obligations the Operating Injunction creates. Mallinckrodt's employee trainings comply with the terms and conditions of the Operating Injunction.

13.2 Since filing the First Monitor Report, the Monitor attended an almost two-hour demonstration of ComplianceWire, Mallinckrodt's learning management system. Mallinckrodt uses ComplianceWire for all employee trainings, including trainings related to the Operating Injunction's obligations, and to track employees' completion of their trainings.

13.3 ComplianceWire is a sophisticated tool and the Monitor was impressed by Mallinckrodt's integration of its learning management system with the software used by Mallinckrodt's human resources department, which ensures that the information in ComplianceWire is accurate and updated on a timely basis.

13.4 Mallinckrodt's training on the Operating Injunction's obligations has three components, which are implemented using ComplianceWire. 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 a survey regarding any board service that may violate Section III.C.

13.5 The relevant employees who must receive training on the Operating Injunction's requirements have a limited period of time in which to complete those trainings, and these deadlines can only be extended with prior approval. If an employee does not complete each of

the three components of Operating Injunction training within the requisite time period, Mallinckrodt can manually "lock" the employee's profile. Employees whose accounts are locked must then speak with their manager or the Compliance Manager for SpecGx in order to regain access to their accounts, ensuring that the employees' trainings are completed in a timely manner.

13.6 In the next reporting period, the Monitor intends to determine what steps Mallinckrodt takes, or should take, to test Mallinckrodt employees' retained knowledge after completion of the trainings.

13.7 At the time of the filing of this Report, Mallinckrodt advised that all relevant employees had completed the Operating Injunction trainings assigned to them for 2021.

14. CLINICAL DATA TRANSPARENCY (§ IV)

14.1 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.

14.2 Mallinckrodt contracted with the company Vivli Inc. ("Vivli") to make such data available. Mallinckrodt has advised the Monitor that all of the data required to be shared under Section IV is available through that platform.[20] Any research proposals submitted through Vivli will be reviewed for scientific merit by an independent review panel.

14.3 The Monitor inquired regarding the Vivli website's reference to "certain" Opioid Products in the following statement: "SpecGx will share clinical trial data for certain of its opioid products." Mallinckrodt has advised that its use of the word "certain" in this context

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

simply indicates that Mallinckrodt is only sharing clinical data related to its "Opioid Products" as defined in the Operating Injunction.[21]

14.4 As of the filing of this Second Monitor Report, there have been no requests for access to this data. Mallinckrodt has agreed to inform the Monitor in the event of any such request.

14.5 Similarly, as of the filing of this Second Monitor Report, there have been no new Mallinckrodt Opioid Products or new indications for existing Mallinckrodt Opioid Products. *See* Operating Injunction § IV.A.1.c. Mallinckrodt has agreed to inform the Monitor in the event of any such new products or indications.

15. PUBLIC ACCESS TO MALLINCKRODT'S DOCUMENTS (§ V)

15.1 Section V of the Operating Injunction required Mallinckrodt to produce certain documents to the Settling States within nine months of October 12, 2020 (*i.e.*, on or before July 12, 2021).

15.2 Mallinckrodt apprised the Monitor of its discussions with the Settling States, including with the Massachusetts and Minnesota Attorneys General Offices, concerning establishing an electronic document repository to house the documents Mallinckrodt was

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[21] Under the Operating Injunction, the definition of Opioid Products excludes:

> medications with an 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 marketing exclusively to DEA registrants or sold outside the United States or its territories.

Operating Injunction § I.Q.

required to produce in accordance with Section V.A.1 of the Operating Injunction. The document repository will not just contain Mallinckrodt's own documents but will be an industry-wide repository for many other manufacturer defendants in multi-district opioid litigation, with the costs to be shared among them.

15.3 Mallinckrodt entered a "Mutual Letter of Understanding" with the University of California San Francisco, Johns Hopkins University, and the Minnesota Attorney General's Office to transfer Mallinckrodt's documents to the Opioid Industry Documents Archive, under Section V of the Operating Injunction.

15.4 Mallinckrodt informed the Monitor of Mallinckrodt's completion of a multi-level review of approximately eight million pages of documents for redaction of information in accordance with Section V.B of the Operating Injunction and Mallinckrodt produced these documents and the associated redaction logs to the Minnesota Attorney General's Office on July 12, 2021, in accordance with the Operating Injunction.

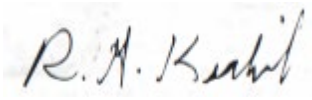
15.5 Mallinckrodt will move for the Bankruptcy Court's approval of the agreement and the payment to the universities to cover Mallinckrodt's allocable share of the costs of the repository to satisfy the requirement set forth in Section V.G.

16. CONCLUSION

16.1 Based upon the Monitor's work to date, Mallinckrodt continues to cooperate with the monitorship, and continues to provide helpful assistance to the Monitor in the exercise of his duties. The Monitor looks forward to continuing on this path in the next reporting period and beyond.

* * *

16.2 Wherefore, the undersigned Monitor respectfully submits this Second Monitor Report.



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

EXHIBIT 1

MALLINCKRODT INJUNCTIVE RELIEF
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. "OCC" shall mean the Official Committee of Opioid Related Claimants, appointed in the Debtors' Chapter 11 Cases.

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

Q. "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.

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

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

T. "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.

U. "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.

V. "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.

W. "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.

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

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

Z. "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. The provisions of this Agreement that apply to the OCC shall no longer apply upon the effectiveness of a Chapter 11 Plan.

E. **Term**

1. Unless addressed in Section II.E.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.

F. 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. Promptly after Mallinckrodt's receipt of any such written notice, Mallinckrodt shall provide such written notice to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC.

2. Upon receipt of written notice from such State Attorney General, Mallinckrodt shall provide a written response to the Settling States and to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC, 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 and Mallinckrodt shall promptly provide notice of any such additional response time to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC. 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.

7. Nothing herein shall compromise the OCC's right to enforce its specific information rights and consultation rights set forth in this Agreement in the Bankruptcy Court during the pendency of the Chapter 11 Cases.

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 the Monitor, 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 or the OCC, Mallinckrodt shall provide the requesting State Attorney General, or the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC, 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. A copy of each pool of candidates shall be shared with the OCC when such pools are exchanged between Mallinckrodt and the Settling States. The OCC may make suggestions for each side to consider.

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, provided, that the OCC may participate as an observer at any such interviews with the consent of the Settling States and Mallinckrodt. Mallinckrodt and the Settling States may veto any of the candidates, and must do so in writing (with a copy to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC) within 30 days of receiving the pool of candidates. If all three candidates within a pool are rejected by either Mallinckrodt or the Settling 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 (and shall provide a copy of such direction to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC). Notice of such additional qualified candidates shall be given to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC upon the names of such candidates being given to the other party.

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 (with a copy to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC) 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 Governmental Ad Hoc Committee (as such term is defined in the restructuring

support agreement) 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 and the OCC 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, the Settling States, and the OCC, either jointly or separately (in the discretion of the Monitor), 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, upon consultation with the OCC, shall agree with the Monitor on the Work Plan. If the Monitor, the Settling States, and Mallinckrodt (upon consultation with the OCC) 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 Pharmaceuticals

January 4, 2021

William T. McDermott
Assistant Administrator
Diversion Control Division
Drug Enforcement Administration
Washington, D.C. 20537

Attn: DEA Federal Register Representative [RIN 1117-AB47/Docket No. DEA-437]

Dear Mr. McDermott:

This letter constitutes comments from SpecGx LLC ("SpecGx") on the Notice of Proposed Rulemaking (NPRM) for Suspicious Orders of Controlled Substances, as published in the Federal Register on November 2, 2020, FR Vol. 85, No. 212, pages 69282-69299.

SpecGx appreciates this opportunity to comment on the NPRM, which is aimed at improving the process for detecting and reporting suspicious orders of controlled substances. As one of the nation's foremost manufacturers of controlled substances, we support the goals of this proposed rule.

We agree with the new approach established in the NPRM to create a "two-option framework" for handling orders received under suspicious circumstances (ORUSCs). One pathway permits a registrant to conduct due diligence to investigate each suspicious circumstance surrounding the ORUSC to determine whether each can be dispelled and the order released.[1] Those orders where the registrant is unable to dispel each suspicious circumstance surrounding the ORUSC are deemed to be a "suspicious order" and are to be reported to DEA within 7 calendar days after receiving the order. We appreciate that the two-option approach will improve visibility for DEA into orders truly deemed suspicious by the shipping registrant rather hiding within an ocean of orders that were cured and shipped, yet nonetheless reported to DEA as "suspicious" due to having been "flagged" at the start of an internal review process. We also believe this could help clarify for registrants with greater precision the agency's expectations for suspicious order reporting than was previous available in the Code of Federal Regulations and subsequent agency guidance.

We do, however, have two suggested changes to the proposed regulation

- 1301.78(a)(2)(i). Change the 7 calendar day reporting requirement to either 7 business days or 10 calendar days. Many orders are received and processed overnight meaning that the review process for an ORUSC may not start until the

[1] The other option is to immediately file a suspicious order report with DEA, decline to ship the order and maintain a record of any due diligence related to the suspicious order.

following day. In situations where the ORUSC is received late Friday or before a holiday weekend, the remaining time to review would be reduced by almost half or more.

- 1300.01(b) Order. We believe the definition of Order should read, "Order means any communication by a person to ***the*** registrant…" rather than "… a registrant…." The use of "the" makes it clear that the order communication belongs to the particular registrant receiving the communication.

Section II of the NPRM (Suspicious Orders and the Opioid Epidemic) lays out some of the agency's reasoning for the NPRM. It is clear that industry took inconsistent approaches with each registrant developing disparate strategies and procedures with various degrees of success. We believe this also highlights the need for better coordination of suspicious order systems between government and industry. Leveraging technological innovations could yield a significantly better, more advanced system to both improve registrant compliance as well as deliver actionable information to help improve DEA's ability to combat diversion in real time. Such a system could leverage big data processes, including systems capable of providing machine learning (*i.e.,* artificial intelligence).

As you point out in Section IV, your decision to provide access to limited ARCOS data through the ARCOS tool as part of your implementation of the SUPPORT Act gave industry visibility to 6 months of transactions for direct and to indirect downstream transactions. However, that data is somewhat limited as ARCOS reporters are only required to report on a quarterly basis, thereby creating a substantial lag. We believe that development of a data analysis system that provides industry with access to real-time drug distribution transactions (masked or blinded as to the identity of the "seller") would provide industry with a significant tool to detect and thereby prevent suspicious order from being filled. This is a serious data challenge that could be met by developing a system through a private-public partnership long advocated by SpecGx that would provide industry with the information necessary to make better real time "sell-don't sell" decisions while simultaneously providing DEA with unmasked data to aid the agency in exercising their oversight and investigative authority.

If you, or your staff, have any questions regarding our submission, please contact me at the email address or telephone number listed below. Thank you for the opportunity to comment on this proposed rule.

Sincerely,

S. Collier

Scott Collier
Director, Controlled Substances Compliance
SpecGx LLC
Office (314) 654-0147
Email scott.collier@mnk.com

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

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The following transaction was received from Amanda R. Steele entered on 7/23/2021 at 5:12 PM EDT and filed on 7/23/2021
Case Name: Mallinckrodt plc
Case Number: 20-12522-JTD
Document Number: 3409

Docket Text:
Exhibit(s) *//Second Report of R. Gil Kerlikowske, Independent Court-Appointed Monitor for Mallinckrodt LLC, Mallinckrodt Enterprises LLC, and SpecGx LLC* Filed by Mallinckrodt plc. (Steele, Amanda)

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

Document description: Main Document
Original filename:SECOND Mallinckrodt Monitor Report (with Exhibits 1 & 2).PDF
Electronic document Stamp:
[STAMP bkecfStamp_ID=983460418 [Date=7/23/2021] [FileNumber=17157282-0
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f3480b898804736395f6a0ae988342a769ba11951750bc0e15ba8ddca4684]]

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

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MIME-Version:1.0
From:DEBdb_ECF_Reply@deb.uscourts.gov
To:dummail@localhost.localdomain
Bcc: Amanda.Quick@atg.in.gov, Joseph.Larkin@skadden.com, aBehlmann@lowenstein.com, awalker@paulweiss.com, wclareman@paulweiss.com, asithian@paulweiss.com, b
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Message-Id:<17157296@deb.uscourts.gov>
Subject:Ch- 20-50850-JTD Mallinckrodt plc Exhibit(s)

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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: 223

Docket Text:
Exhibit(s) *//Second Report of R. Gil Kerlikowske, Independent Court-Appointed Monitor for Mallinckrodt LLC, Mallinckrodt Enterprises LLC, and SpecGx LLC* Filed by Mallinckrodt plc. (Steele, Amanda)

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

Document description: Main Document
Original filename:SECOND Mallinckrodt Monitor Report (with Exhibits 1 & 2).PDF
Electronic document Stamp:
[STAMP bkecfStamp_ID=983460418 [Date=7/23/2021] [FileNumber=17157294-0
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20-50850-JTD Notice will be electronically mailed to:

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