UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

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

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

October 21, 2021

Date Filed 10/21/21
Docket No. 4863

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THIRD 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 Third Monitor Report covers the period from the filing of the Second Monitor Report on July 23, 2021, to the present (the "Third Reporting Period"). The Third Monitor Report: (1) provides an update on Mallinckrodt's implementation of the Monitor's recommendations in the Second Monitor Report; (2) reviews the Monitor's actions during the Third Reporting Period, including the review of documents and data, and interviews or meetings with Mallinckrodt employees and third-party contractors; (3) summarizes observations from the

Monitor's fact-finding, and provides recommendations relating to those observations; and (4) describes anticipated next steps during the next reporting period.

1.2 Eight months into the monitorship, the Monitor has completed a substantial amount of "scoping" and assessment work, and expects that future reporting periods will increasingly involve auditing and monitoring of new compliance recommendations and their implementation.

1.3 In the last reporting period, the Monitor expressed his hope to engage in more in-person interactions with Mallinckrodt this Fall. Given the rise in the COVID-19 "Delta variant," however, there remains uncertainty regarding the course of the pandemic and what the Fall and flu season hold in store. Nonetheless, the Monitor has been able to continue remote interviews and meetings, including meetings with Mallinckrodt's employees, its outside legal counsel, and its consultant, Analysis Group, Inc. ("Analysis Group"). Additionally, the Monitor was able to observe a meeting of the Suspicious Order Monitoring Team. These meetings are discussed below in Section 11, *infra*. The Monitor remains hopeful that in time he will have greater opportunity to interact with Mallinckrodt personnel more directly.

1.4 The Monitor's recommendations are summarized in Section 4, and are elaborated upon in Sections 6 (Ban on Promotion) and 9 (Lobbying Restrictions) of this Report. Although the recommendations in the Second Reporting Period primarily related to Suspicious Order Monitoring ("SOM"), the recommendations in this Third Reporting Period relate principally to Mallinckrodt's compliance with the lobbying and promotion aspects of the Operating Injunction (as defined in Section 2, *infra*).

1.5 Mallinckrodt's employees, counsel, and outside consultants continue to be responsive, cooperative, and helpful to the Monitor. In the Third Reporting Period, Mallinckrodt

has provided over 180 files (consisting of 570 MB of documents and data), at the Monitor's request, in a timely and complete fashion in response to formal and informal requests for documents, and have assisted in arranging multiple interviews with key employees, Mallinckrodt's consultant, Analysis Group, and with the SOM team (the "SOMT"). The secure platform Mallinckrodt has established to share information with the Monitor continues to function effectively.

1.6 To date, the Monitor has received no reports related to Mallinckrodt's obligations under the Operating Injunction through the confidential hotline reporting system.

1.7 One notable event during the Third Reporting Period was Mallinckrodt's announcement of its settlements with the Official Committee of Opioid Related Claimants ("OCC"), the parties to the Restructuring Support Agreement, the Official Committee of Unsecured Creditors appointed in its Chapter 11 cases ("UCC"), and certain of its second lien noteholders, to support an amended Plan of Reorganization.

1.8 On September 3, 2021, Mallinckrodt filed a Notice of Filing of Settlement Term Sheets in Connection with the Joint Plan of Reorganization of Mallinckrodt PLC and its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code, attaching settlement term sheets with the aforementioned parties. *See* 20-12522, Dkt. No. 4121.

1.9 Thereafter, on September 29, 2021, Mallinckrodt filed its First Amended Joint Plan of Reorganization of Mallinckrodt PLC and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code. *Id.* at Dkt. No. 4508. The date currently proposed for the Bankruptcy Court's

hearing to consider approval of the plan is November 1, 2021. If the plan is approved, Mallinckrodt will file an examinership proceeding in Ireland to commence the reorganization.[1]

1.10 In sum, based on the information reviewed to date, Mallinckrodt continues to make a good faith effort 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. The Court adopted an amended and final Term Sheet on January 8, 2021 (referred to herein as the "Operating Injunction"). *See* 20-50850, Dkt. No. 196-1. A copy of the Operating Injunction is attached as **Exhibit One**.

2.2 In Section VI of the Operating Injunction, Mallinckrodt agreed to retain an independent Monitor, subject to this Court's approval, who would monitor Mallinckrodt's compliance with the Operating Injunction's terms. The Operating Injunction required the Monitor to 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, with subsequent reports to be submitted every 90 days thereafter, until the Effective Date. Following the Effective Date, the Monitor may decrease the frequency of such reports to every 180 days.

[1] The mechanics of the bankruptcy proceeding are beyond the scope of the Monitor's assessment of Mallinckrodt's compliance with the Operating Injunction. However, the proceedings are relevant to establish the "Effective Date" of the bankruptcy, as defined under the Operating Injunction, as that date – *i.e.*, the date on which the Chapter 11 Plan becomes effective – is a triggering event for other aspects of the Operating Injunction. *See* Operating Injunction § I.H (defining "effective date"); *id.* § II.C (noting Mallinckrodt's "consent[] to the entry of a final judgment or consent order upon the Effective Date imposing all of the provisions of [Operating Injunction] in state court in each of the Settling States"); *id.* § VI.B.2.b ("The frequency of Monitor Reports may decrease to every 180 days after the Effective Date.").

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 Monitor submitted the First Monitor Report 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 take.

3.2 ***The Second Monitor Report.*** The Monitor submitted the Second Monitor Report on July 23, 2021. *See* Case No. 20-12522, Dkt. No. 3409; Adv. Pro. No. 20-50850, Dkt. No. 223. The Second Monitor Report summarized the Monitor's ongoing efforts to audit Mallinckrodt's compliance with the Operating Injunction and provided a detailed analysis of Mallinckrodt's compliance with all Sections of the Operating injunction. That report also outlined the Monitor's efforts to better understand how Mallinckrodt monitors its direct and downstream customer's orders and set forth 21 recommendations, (a)-(u), related to various aspects of Mallinckrodt's SOM program, including the Monitor's overarching recommendation that Mallinckrodt further modernize and enhance its SOM capabilities using big data, artificial intelligence, and automated processes and algorithms. The Monitor also recommended, *inter alia*, changes to certain SOM policies, the direct order and chargeback review processes, and how Mallinckrodt conducts its due diligence for direct and downstream customers. Mallinckrodt agreed to implement each of these recommendations. The Second Monitor Report also described documents reviewed and requested, provided an overview of interviews conducted, and identified additional steps undertaken during the Third Reporting Period.

4. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Sections 6 and 9, *infra*, the Monitor has made the

following three recommendations to Mallinckrodt. Mallinckrodt has agreed to implement all of the following recommendations,[2] many of which are in the process of being addressed:

3(a) expand TrackWise, Mallinckrodt's internal system for logging unsolicited customer inquiries and complaints, to include results of the Product Monitoring Team's consultation with and referral of inquiries to other Mallinckrodt departments;

3(b) ensure that all external lobbyists performing work on Mallinckrodt's behalf have executed an Acknowledgment and Certification of Compliance with SpecGx Lobbying Restrictions ("Certification"), certifying compliance with the Operating Injunction; and

3(c) implement a process by which Mallinckrodt reviews and audits its external lobbyists' publicly filed state and federal activity reports to ensure that the information contained in the reports accurately reflects the lobbyists' communications with Mallinckrodt and the company's stated priorities.

5. THE INTEGRITY HOTLINE

5.1 As previously noted in prior Reports, 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. To date, the Monitor has received no reports to the hotline.

6. BAN ON PROMOTION (OI § III.A)

6.1 Section III.A of the Operating Injunction prohibits Mallinckrodt from engaging in certain activities relating to the Promotion of Opioids,[3] 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.

[2] These recommendations are prefaced by the number "3" to indicate they were made in the Third Monitor Report.

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

6.2 As noted in its Compliance Report submitted to this Court on November 30, 2020, 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 Departments, 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 As detailed in the Second Monitor Report, the Product Manager of Commercial, who chairs the PRC, initiated a process for Mallinckrodt to identify active items and materials that, while not yet scheduled for re-review, are opioid-related, and, as such, should be flagged and fast-tracked for submission to the PRC to assess compliance with the Operating Injunction.[4] That review was ongoing at the close of the last reporting period.

6.4 Mallinckrodt completed its review of the legacy items and provided the Monitor with a current list of active items and the items that were deactivated as part of the review. The

[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 for 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.

Monitor interviewed the Product Manager of Commercial to better understand the review process and to discuss specific deactivated items such as table top displays and other materials that the company previously deployed at conventions and similar events. These materials contain language advising customers to "encourage prescribers to use opioids sparingly" and will no longer be utilized. Similar references have also been removed from Mallinckrodt's corporate website following adoption of the Operating Injunction.

6.5 The Monitor's review of the currently active items, which include webpages for Mallinckrodt's products, is ongoing and the Monitor anticipates that additional follow-up discussions with PRC members will be needed. Based on review of the materials provided to date, however, it appears that the PRC is operating in a manner consistent with Section III.A of the Operating Injunction.

6.6 During the next reporting period, as part of his quarterly audit of data related to this subsection, the Monitor will review PRC meeting minutes and promotional materials submitted to and approved by the PRC since the filing of the Second Monitor Report. Additionally, the Monitor will conduct an independent review of these 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.

6.7 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.

6.8 As described in the Second Monitor Report, the Product Monitoring Team ("PMT") operates a call center for fielding and responding to customer inquiries and complaints. The calls are not recorded but are logged in an internal system called TrackWise.

6.9 During this reporting period, the Monitor reviewed the TrackWise log of customer inquiries from October 2020 through June 2021.[5] Each customer inquiry is assigned a unique number and is categorized by the type of customer initiating the call (consumer, healthcare facility, or government entity). The PMT member fielding the inquiry records the call date, the specific product referenced, a brief summary of the call, and the conclusion or answer provided. The inquiries included a substantial number of questions about potential allergens such as gluten in Mallinckrodt's products as well as a smattering of calls seeking information as to the bankruptcy proceeding's impact on Mallinckrodt's products. Based on the Monitor's review of the call-taker notes in TrackWise, it appears the PMT is handling customer inquiries in a manner consistent with the Operating Injunction and Mallinckrodt's policies relating to post-market communications.

Recommendation Related to the Product Monitoring Team and TrackWise

3(a) ***Expand TrackWise to include results of the Product Monitoring Team's consultation with and referral of inquiries to other Mallinckrodt departments.***

(i) **Observation:** In his review of the TrackWise call log, the Monitor observed a few instances in which the PMT member fielding the inquiry consulted someone outside their department to provide the appropriate response or referred the inquiry to another department, such as Global Security or Government Affairs. For instance, according to one

[5] The PMT records customer inquiries and complaints in TrackWise. The Monitor reviewed the log of customer inquiries during this reporting period but did not receive the complaints log. He anticipates review of customer complaints during the next reporting period.

TrackWise entry, a healthcare facility representative phoned the call center seeking to obtain Mallinckrodt brochures related to its "pain stewardship program." The PMT member consulted with the Senior Director of Government Affairs and Advocacy, who advised that the brochures were "a component of our discontinued CARES program" and, as such, were no longer available. The PMT member was advised to direct the caller to the Centers for Disease Control website. However, the TrackWise log does not include any additional notes confirming that the inquiry was closed in the manner proposed by the Government Affairs Department.

There were similar TrackWise entries detailing the PMT's referral of law enforcement questions to the Vice President of Global Security. In response to the Monitor's questions about these entries, the Director of Post-Market Surveillance was able to locate email exchanges detailing the communications between the Global Security and Product Monitoring Departments. These records confirm that Global Security responded to and ultimately closed the inquiries. However, that information was not reflected in TrackWise.

(ii) **Recommendation: Mallinckrodt should expand its TrackWise logs to include a section for Product Monitoring Team members to record the results of referrals to and consultations with other Mallinckrodt departments.**

Mallinckrodt has agreed to implement this recommendation.

6.10 In his Second Report, the Monitor noted the absence of a formalized process for periodic review and auditing of the TrackWise logs to confirm that the PMT's responses to customer questions and complaints are consistent with the Operating Injunction and Mallinckrodt's existing policies and procedures.

6.11 At the end of this reporting period, Mallinckrodt furnished the Monitor with its recently-developed review and auditing protocol, *Work Instruction for TrackWise Auditing*. The

protocol tasks the Director of Post-Market Surveillance, or her designee, with reviewing customer inquiries on a monthly basis and evaluating the PMT's responses for compliance with the Operating Injunction. Upon completion of her review, the Director of Post-Market Surveillance will isolate those responses identified as requiring corrective action and review any discrepancies with the Post-marketing Surveillance Team before the end of the month in which the audit was conducted. The *Work Instruction*'s effective date is November 2, 2021. Once it is fully implemented, the Monitor anticipates he will request and review completed audits on a quarterly basis.

7. NO FINANCIAL REWARD OR DISCIPLINE BASED ON VOLUME OF OPIOID SALES (OI § 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 As set forth in the Second Monitor Report, the Monitor verified Mallinckrodt's compliance with the above-quoted provisions of the Operating Injunction by reviewing its Field Sales Compensation Plan for 2021 ("FSCP") and an accompanying explanatory document, and conducting an interview with Mallinckrodt's Vice President of Commercial.

7.3 As a result of these efforts, the Monitor concluded that Mallinckrodt's compensation of qualified sales representatives based upon the performance of its SpecGx

business as a whole, including its sale of Opioid Products, complies with Section III.B of the Operating Injunction.

7.4 Mallinckrodt does not yet have an updated FSCP for 2022. Typically, Mallinckrodt's compensation plans take effect on January 1 each year, but the first payments under a new plan are not due until the first quarter, if payments are made quarterly, or the second quarter, if the payments are made semi-annually. Given the ongoing Chapter 11 confirmation proceedings, Mallinckrodt does not yet know when the 2022 FSCP will be finalized. Mallinckrodt will advise the Monitor when the plan is finalized.

7.5 As noted below in Paragraphs 11.14-11.15, on July 29, 2021, the Monitor met remotely with members of the OCC. OCC members suggested that the Monitor review materials relating to compensation paid to certain employees under Mallinckrodt's prior Key Employee Incentive Program ("KEIP"). As discussed below, at the request of the OCC, the Monitor reviewed documents relating to decisions by Mallinckrodt's key employees on opioid sales and distribution.

8. BAN ON FUNDING / GRANTS TO THIRD PARTIES (OI § 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" or "the Committee") 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 During the Second Reporting Period, the Monitor reviewed the SGGSAC's standard operating procedure ("SOP") and minutes of the March 2021 SGGSAC meeting. To better understand the SGGSAC's review process, the Monitor also interviewed key SGGSAC members, including the Committee Chair.

8.4 The Monitor's review of the March 2021 meeting minutes and related materials revealed that, in addition to six grant requests, 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.[6] *See* Mallinckrodt Compliance Report § 5.4.

8.5 The SGGSAC's SOP, in effect at the time of the March 2021 meeting, required that the SGGSAC send the requestor an email notifying them of the award and a Letter of Agreement ("LOA") detailing the terms applicable to Specialty Generics grants and sponsorships. 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. The LOA must be signed and returned to the SGGSAC before sponsorship funds are dispersed. In contrast to the SGGSAC SOP, the SGGSAC Request Form expressly states that an LOA is

[6] The Monitor intends to meet with AAM representatives to discuss whether, and to what extent, Mallinckrodt's recusal from certain AAM activities is documented and recorded.

not 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 $15,000 conference sponsorship.

8.6 In May 2021, Mallinckrodt revised the SGGSAC SOP to harmonize it with the Request Form so that both the SOP and the Request Form provide that the SGGSAC may, but is not required to, condition a sponsorship award on the recipient's execution of an LOA.

8.7 During this reporting period, the Monitor interviewed SGGSAC members, including the SpecGx Compliance Manager (the Committee's Secretary), about the SOP change to better understand how the Committee would determine 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.

8.8 According to the Compliance Manager, Mallinckrodt has taken additional steps to ensure that the Committee receives, in addition to the Sponsorship Request Form, supporting documents and other materials such as conference agendas and lists of proposed speakers, prior to approving any request. Where such materials are not available, or where the Committee feels that sufficient guardrails are not in place to ensure that Mallinckrodt funds are being used in a manner consistent with the Operating Injunction, the Committee will exercise its authority to request that the recipient execute a LOA.

8.9 The Monitor has requested minutes of SGGSAC meetings conducted in the wake of the SOP change and will continue to work with Mallinckrodt to ensure that the SGGSAC is operating in a manner consistent with Section III.C of the Operating Injunction as it relates to its awarding of sponsorships to third parties.

9. LOBBYING RESTRICTIONS (OI § 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 filing the Second Monitor Report, the Monitor has verified that all external state and federal lobbying firms engaged by Mallinckrodt received an Amendment to their Master Service Agreement ("Amendment") and a copy of the Operating Injunction, and that the principals of each firm executed the Amendment and an Acknowledgment and Certification of Compliance with SpecGx Lobbying Restrictions ("Certification"), certifying compliance with the Operating Injunction's relevant terms.

9.4 During this reporting period, the Monitor also reviewed publicly-filed activity reports of Mallinckrodt's state and federal external lobbyists, and interviewed the Vice President of Government Affairs and Patient Advocacy as well as the Associate Director of State Government Affairs and Advocacy, to discuss the lobbyists' activity reports and Mallinckrodt's efforts to assess its lobbyists' compliance with the Operating Injunction.

Recommendation Related to Mallinckrodt's Certifications for its External Lobbyists

3(b) ***Ensure that all external lobbyists performing work on Mallinckrodt's behalf have executed an Acknowledgment and Certification of Compliance with SpecGx Lobbying Restrictions ("Certification"), certifying compliance with the Operating Injunction.***

(i) **Observation:** The Monitor's review of publicly-filed state and federal activity reports for Mallinckrodt's external lobbying firms revealed that a number of firms identified multiple individuals (including the principal) conducting lobbying activities on Mallinckrodt's behalf. However, not all of these individuals executed a Certification. These included one federal firm where eight individuals were identified as lobbying on Mallinckrodt's behalf but only one, the firm's principal, was asked to and did execute a Certification. As for state lobbyists, the Monitor observed that, in some instances, multiple individuals within a single firm were asked to execute Certifications, but that additional lobbyists within those firms were identified in public reports as lobbying on Mallinckrodt's behalf.

(ii) **Recommendation: Mallinckrodt should review its roster of external lobbyists performing work on its behalf as reflected in publicly-filed activity reports and, where necessary, ensure that each lobbyist has executed an Acknowledgment and Certification of Compliance with SpecGx Lobbying Restrictions, certifying compliance with the Operating Injunction.**

Mallinckrodt has agreed to implement this recommendation.

9.5 During this reporting period, the Monitor interviewed the Vice President of Government Affairs and Patient Advocacy to further discuss Mallinckrodt's lobbying priorities and engagement with external lobbyists. The Monitor learned that Mallinckrodt convenes frequent meetings with its external lobbyists to communicate Mallinckrodt's priorities and to direct the lobbyists' activities. Mallinckrodt does not keep minutes of these meetings nor does it

document or summarize the issues discussed or directions given to each lobbyist. Rather, Mallinckrodt relies upon the publicly-filed state and federal activity reports to confirm that the lobbyists' activities conform to the company's directives and stated priorities.

Recommendation Related to Mallinckrodt's Review of its External Lobbyists' Activity Reports

3(c) ***Implement a process by which Mallinckrodt reviews and audits its external lobbyists' publicly filed state and federal activity reports to ensure accuracy in reporting.***

(i) **Observation:** The Monitor's review of publicly-filed federal lobbying disclosure reports ("LD-2s") for two of Mallinckrodt's external lobbying firms revealed entries describing lobbying activities related to "opioids" and "RX drug abuse and deterrence." No additional information was provided. When asked to explain (1) whether Mallinckrodt directed its lobbyists to perform work in these areas and (2) the specific directives given to the lobbyists, the Vice President of Government Affairs and Patient Advocacy opined that the "opioid" entry reflected past work performed by the lobbyist (pre-Operating Injunction) and that the lobbyist may have inadvertently carried the entry forward to more recent LD-2s. He could not discern the intended meaning of the "RX drug abuse and deterrence" entry, but surmised that it related to medication-assisted treatment or similar legislation related to addiction and recovery. However, there is no historical record of what was discussed during the relevant time period, and Mallinckrodt does not have a process for contemporaneous and regular review of its external lobbyists' publicly-filed state and federal disclosures to ensure that the reports accurately reflect Mallinckrodt's priorities and directives.

(ii) **Recommendation: Mallinckrodt should implement a process for reviewing and auditing its external lobbyists' publicly-filed state and federal activity**

reports to ensure that the information contained in the reports accurately reflects the lobbyist's communications with Mallinckrodt and the company's stated priorities.

Mallinckrodt has agreed to implement this recommendation.

9.6 During the next reporting period, the Monitor anticipates meeting with a number of Mallinckrodt's external lobbyists to better understand how these firms are conducting lobbying activities on the company's behalf in a manner consistent with the Operating Injunction as reflected in the contract Addenda and Certifications.

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

10.1 Some parts 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 As set forth in the Second Monitor report, Mallinckrodt provided certain certifications with respect to Sections III.E-I of the Operating Injunction on July 16, 2021, through Mallinckrodt's Specialty Generics Associate General Counsel for Compliance and Data Privacy. Additionally, Mallinckrodt has confirmed that it has not received any requests from the OCC 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 relate 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." § III.H.5.b. Mallinckrodt will promptly inform the Monitor if it receives any such request.

10.3 The Monitor will require Mallinckrodt's re-certification of the above-referenced statements annually, with the next annual certification anticipated in July 2022.

10.4 Additionally, regarding the ban on high dose Opioid Products, which Mallinckrodt has certified it does not currently manufacture or distribute, Mallinckrodt has confirmed it has not made any changes to its Specialty Generics Product Catalog[7] since the Second Monitor Report was filed. Mallinckrodt confirmed it will notify the Monitor if any changes are made to that catalog, and the Monitor will continue to review future product catalogs annually to ensure there is no change to Mallinckrodt's compliance with Section III.E of the Operating Injunction.

[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).

11. MONITORING AND REPORTING OF DIRECT AND DOWNSTREAM CUSTOMERS (OI § 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 During the Third Reporting Period, in order to continue to assess Mallinckrodt's compliance with Section III.G.1 of the Operating Injunction, the Monitor: (1) observed a monthly SOMT meeting and reviewed materials circulated in advance of that meeting; (2) participated in a meeting with the OCC; (3) attended a detailed (approximately three-hour) presentation by Analysis Group regarding its proposed creation of a Mallinckrodt/SpecGx direct and downstream SOM analytics platform; (4) reviewed voluminous additional data and documents provided in response to the Monitor's Second Document Request; (5) conducted a follow-up interview with the Director of Compliance; and (6) received an update from Mallinckrodt and its outside counsel regarding the status of the bankruptcy proceedings and of Mallinckrodt's implementation of the Monitor's 21 SOM-related recommendations set forth in the Second Monitor Report. A summary of each of these activities is provided below.

1. Monitor's Review of Materials Circulated prior to the SOMT's Meetings and His Observation of a SOMT meeting

11.3 The Monitor received and reviewed materials circulated to the SOMT prior to its July 27, 2021 meeting, and attended that meeting remotely with members of the Monitor Team.

11.4 The Monitor also reviewed two additional sets of materials the SOMT reviewed prior to chargeback restriction meetings, which included meeting agendas, chargeback review

"cover sheets"[8] that include excerpts of relevant media reports, a DEA memorandum of agreement, and a pharmacy's settlement agreement.

11.5 Based on the Monitor's review of these materials, and his attendance at the SOMT meeting, the Monitor will raise with Mallinckrodt the length of time of the chargeback review process, in particular when prompted by media search results. In one instance, almost two months passed between the date the SOMT discovered the relevant media report and its decision to restrict. To be sure, the decision to restrict, in that instance, does not seem to have been legally required, given the DEA's entry into a Memorandum of Agreement ("MOA") with the pharmacy that actually permitted the pharmacy to continue distributing controlled substances (while undertaking remedial and improved compliance measures). But restriction by Mallinckrodt was nonetheless wise, as DEA's MOA was based in part upon its view that the pharmacy, over a four-year period, "regularly filled and dispensed prescriptions written by a number of questionable prescribers knowing that said prescriptions were not issued for a legitimate medical purpose." Thus, given Mallinckrodt's appropriate decision to restrict, attention to the timeframe for review and implementation of restriction warrants examination, consistent with the Monitor's prior observations, and Mallinckrodt's agreement to evaluate this issue. *See* Second Monitor Report at 29-32.

11.6 A related issue of timeliness arises in the context of "ad hoc" reviews of chargeback restrictions. Such reviews presumably relate to more time sensitive cases that need not wait for the next regularly scheduled SOMT to take place. Indeed, Mallinckrodt's revised

[8] A "cover sheet" is the packet of materials (including a summary, documents, and data gathered from research and analysis), that together comprise the report shared with the SOMT regarding a potential chargeback decision.

Standard Operating Procedure ("SOP"), entitled *Suspicious Order Monitoring Program Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants*, states:

> The SOMT may hold ad hoc meetings or make the decision to restrict Chargebacks to the Downstream Registrant at any time upon determining the Downstream Registrant poses a potential risk of diversion, circulating materials to the SOMT and requiring the SOMT to vote on Chargeback Restriction utilizing the email program's voting buttons. Thus, the SOMT need not wait for a regular meeting of the SOMT to make such a decision.

SOP § 6.4.4.

11.7 The ability to vote by email should permit prompt resolution of ad hoc chargeback restriction issues. In one instance, however, it took four days (two business days) between the circulation of materials for an ad hoc vote on a proposed restriction and the SOMT's decision to restrict.

11.8 Similarly, Section 6.4.5 of the revised *Suspicious Order Monitoring Program Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants* SOP now requires the SOMT to "track the turnaround time for obtaining, analyzing and reporting Chargeback requests and restriction decisions" from the date the SOMT receives the chargeback data from the Finance Department. The Monitor's preliminary analysis reveals the SOP does not require the SOMT to track the time from the date the SOMT flags any media report as suspicious. The Monitor intends to discuss with Mallinckrodt the potential usefulness of tracking the turnaround time for chargeback reviews prompted by media reports.

11.9 Additionally, the Monitor is aware of one instance when Mallinckrodt learned incidentally that a restricted pharmacy was under co-ownership with another pharmacy, leading Mallinckrodt to restrict both. The Monitor will discuss with Mallinckrodt the feasibility of conducting a contemporaneous chargeback review of any co-owned pharmacies it can reasonably identify, particularly those within the same geographic area, through information

already available to it or by conducting additional research, or by requesting due diligence on pharmacies under common ownership from the relevant wholesaler.

11.10 Relatedly, the Monitor will discuss with Mallinckrodt the feasibility of modifying the chargeback review "cover sheet" (which accompanies chargeback review analyses and recommendations) to include a checkbox indicating whether the reviewer investigated the possible existence of other co-owned pharmacies that would warrant investigation.

11.11 To improve the media searches' effectiveness, the Monitor will discuss with Mallinckrodt the feasibility of amending the "cover sheet" to include a line for the reviewer to indicate whether there are any new terms that should be added to the SOMT's media search based on terms identified in the search result prompting the chargeback review.

11.12 Additionally, the Monitor will discuss with Mallinckrodt the feasibility of the SOMT obtaining notification from distributors when distributors restrict a pharmacy. It appears that, on one occasion, the SOMT discovered – after the fact, and only by happenstance (*i.e.*, through a patient emailing to complain about his pharmacy's lack of supply due to being "red flagged" and that the distributor "cut them off") – that one of Mallinckrodt's direct customers (a major wholesaler) had restricted a pharmacy, leading to Mallinckrodt's decision to restrict. The SOMT only learned on August 5, 2021, that the distributor had restricted sales to the pharmacy on May 21, 2021. As a result, Mallinckrodt decided to restrict the pharmacy on August 26, 2021, three months after the wholesaler had implemented its restriction, and three weeks after learning of that restriction. Similarly, in the case of the pharmacy noted above, *see supra* Paragraph 11.5, Mallinckrodt did not learn about a distributor's restriction of the pharmacy until more than a month after the restriction.

11.13 Finally, the Monitor will discuss with Mallinckrodt the feasibility of adopting additional due diligence measures when Mallinckrodt discovers a pharmacy's termination of a rogue employee for diversion of Opioid Products to determine why and how the employee was able to engage in illegal conduct and whether the pharmacy has adequately addressed any issues in its policies or procedures, such as insufficient controls.

2. Monitor's Meeting with the OCC

11.14 As noted above, on July 29, 2021, the Monitor met remotely with members of the OCC. During that meeting, OCC members suggested that the Monitor review materials relating to compensation paid to certain employees under its prior Key Employee Incentive Program ("KEIP"). The Monitor Team reviewed those documents.

11.15 To be sure, a number of the documents reviewed were troubling in their exhibition of a cavalier attitude towards the sale of opioids and an aggressive sales approach on the part of some individuals. At the same time, the documents are dated, and in many instances precede by several years Mallinckrodt's 2017 Memorandum of Agreement with the U.S. Drug Enforcement Administration, and are even further removed in time from the Operating Injunction that is the source of the Monitor's limited authority. Mallinckrodt's agreement to the Operating Injunction, and the Monitor's ongoing monitoring, auditing, and verification of Mallinckrodt's compliance with the Operating Injunction, is the mechanism all parties have accepted to address past practices that could potentially have resulted in diversion. While the Monitor has benefitted from having these documents called to his attention, and is mindful of the concerns they raise, he nonetheless believes that the historic conduct reflected in the documents is largely beyond the scope of the Monitor's authority, other than to the extent they inform the need for continued robust SOM compliance policies and procedures in the future, which

Mallinckrodt has agreed to undertake. Accordingly, these documents do not affect the Monitor's assessment of Mallinckrodt's present compliance with the Operating Injunction.

3. Monitor's Meeting with Analysis Group

11.16 On August 12, 2021, the Monitor and several members of the Monitor Team attended, in person, an informative three-hour meeting with the SpecGx General Counsel and Assistant General Counsel, Mallinckrodt's outside counsel, and Mallinckrodt's SOM consultant, Analysis Group.

11.17 In this meeting, Analysis Group and Mallinckrodt outlined their plan for implementing the Monitor's recommendation to use sophisticated data analytics in its SOM program, for both direct customers and indirect customers (through the chargeback review process). Specifically, Analysis Group is developing a proprietary mechanism to analyze direct customer order data and chargeback request data to identify irregular volumes, frequencies, and patterns of orders, as well as statistical outliers.

11.18 This data is to be presented in a "dashboard" for both direct customers and downstream registrants to enhance and streamline customer due diligence. These dashboards are designed to be user-friendly and to incorporate and display both a wide array of relevant data and the graphical representation of that data. For example, the direct customer dashboard will show, in one centralized location, key customer information, a description of the flagged order, why it was flagged, and historical customer data, with links to additional information directly from the dashboard, including but not limited to prior due diligence reviews, inventory reports, and additional ordering data.

11.19 Based on Analysis Group's suggested changes, Mallinckrodt will continue to monitor orders for unusual volume and frequency, but its direct customer review process will

also incorporate a statistical approach to outliers and implement risk-based parameters. Similarly, Mallinckrodt will track and analyze changes in its direct customers' share of Mallinckrodt's total orders by product, allowing Mallinckrodt to analyze unusual changes in a customer's monthly *share* of volume in addition to changes in that customer's gross volume.

11.20 For indirect customers (downstream registrants), Analysis Group's work focuses on how to appropriately prioritize Mallinckrodt's review of downstream registrants and the data Mallinckrodt uses to review them. In developing the downstream registrant dashboard, Analysis Group discovered there is a close alignment between Mallinckrodt's direct sales volume and the chargeback data it receives. For example, unlike the past, when Mallinckrodt's access to data was more limited, it now receives chargeback data for 100% of the oxycodone dosage units it sells. For hydrocodone, Mallinckrodt receives chargeback data for 99% of the dosage units it sells. Analysis Group's analysis further demonstrates why Mallinckrodt's timely access to and analysis of chargeback data is necessary to effectively monitor downstream registrants.

11.21 Analysis Group recommends that Mallinckrodt prioritize its review of downstream registrants by not only absolute chargeback growth, *i.e.* the increase in a downstream registrant's purchase volume over time, as it currently does, but with additional metrics that may be associated with diversion and are more likely to capture random, but significant, volume fluctuations for smaller customers.

11.22 Similarly, Analysis Group considered and identified a number of additional potential data sources to incorporate in Mallinckrodt's downstream registrant dashboard, including but not limited to pharmacy ordering trends, registrant geographic data, demographic information, industry trends, and licensing and regulatory information.

11.23 Like the dashboard for direct customers, Mallinckrodt's downstream customer dashboard will compile, among other information and data, the downstream registrant's customer information, purchasing history, a summary of its other distributors, and volume-related data for both the downstream customer and in comparison to other pharmacies serving as a benchmark.

11.24 Implementing both of the dashboards Analysis Group is designing will further automate Mallinckrodt's SOM, and the Monitor expects the dashboards will markedly improve the SOMT's ability to effectively analyze data from various sources and reduce the rate of automatic flags for low-risk orders or customers with limited purchasing history, necessitating time-consuming manual review and diverting valuable resources from higher risk orders.

11.25 Analysis Group's development of these dashboards is underway, and Mallinckrodt's IT and Business Departments are working to achieve the key milestones in this process. As of the date of this Report, Mallinckrodt expects to implement Analysis Group's new platform for direct customers by December 31, 2021, and for indirect customers in early 2022.

4. Monitor's Review of Voluminous Additional Data and Documents

11.26 The Monitor is continuing to review a voluminous amount of data in response to a request for approximately 18 document categories with detailed subparts, including but not limited to the following categories of information:

(a) customer data, including a list of all direct customers, order histories, annual sales data, customer segmentation data, 852 data, and 867 data;

(b) chargeback data and documents related to chargeback reviews and reinstatement requests, including all chargeback data for certain months; chargeback data for restricted but subsequently reinstated pharmacies; reports submitted by direct customers or independent consultants in connection with reinstatement requests; the list of independent consultants Mallinckrodt provides to downstream customers; lists of any pharmacies Mallinckrodt reviewed but decided not to restrict; documentary support for the SOMT's decisions not to restrict certain pharmacies; explanations for chargeback

reinstatements; and a list of any pharmacies Mallinckrodt needs to continue to monitor after the pharmacy's chargeback reinstatement request is approved or after SOMT decides not to restrict the pharmacy;

(c) correspondence with the DEA;

(d) daily SOM-related reports for flagged orders and correspondence related to the release of any flagged orders;

(e) materials circulated to the SOMT prior to meetings and SOMT meeting minutes;

(f) direct customer contracts;

(g) due diligence questionnaire responses;

(h) manufacturing and procurement quotas for certain years;

(i) documents related to the public-private "clearinghouse" concept;

(j) newly available ARCOS data; and

(k) the SOM file directory.

11.27 Mallinckrodt has agreed to provide the Monitor with a virtual tour of the ARCOS database, including the newly available data, so he can better understand its capabilities. Mallinckrodt and the Monitor will schedule this tour during the next monitoring period.

5. Monitor's Supplemental Interview of Director of Controlled Substances Compliance

11.28 The Monitor conducted a two-hour interview with the Director of Controlled Substances Compliance to discuss issues relating to the production of materials in response to the Monitor's Second Document Request. Together, the Monitor and the Director reviewed many of the documents produced during the Second Reporting Period, including chargeback review "cover sheets" and customer segmentation data.

11.29 The Monitor and Director discussed Mallinckrodt's onboarding of the two new SOMT members, discussed further *infra*, the manner in which SOMT members' responsibilities would be affected by those hires, and the newly implemented two-person approval process for

flagged orders. They also discussed the third-party consultants Mallinckrodt hired to assist in making revisions to its customer due diligence questionnaires, discussed *infra*.

11.30 The Director advised that, in addition to implementing the Monitor's recommendations, the SOMT is working on how to better assess the SOM programs utilized by its smaller customers, who may have less robust systems in place than the bigger wholesalers due to resource constraints, through onsite and virtual visits.

6. Status of Implementation of Monitor's Recommendations

11.31 The Monitor met remotely with SpecGx's Chief Financial Officer, General Counsel, and Associate General Counsel, along with Mallinckrodt's outside counsel, regarding the status of Mallinckrodt's implementation of the Monitor's 21 SOM recommendations outlined in the Second Monitor Report.

11.32 Those recommendations are identified in the Second Monitor Report by the letters (a)-(u),[9] and fall within the following six categories: (a) Mallinckrodt's enhancement of its SOM program with assistance from Analysis Group; (b) hiring additional SOMT members and implementing a two-level review process for any flagged orders; (c) improvements to the chargeback review process, including reducing the time a pharmacy is under review before a restriction decision is made and incorporating additional data sources in the SOMT's review of pharmacies; (d) the proposed industry "clearinghouse" concept; (e) Mallinckrodt's due diligence processes for direct and downstream customers; and (f) revisions to various policies.

[9] The status of Mallinckrodt's efforts to implement the Monitor's recommendations in the Second Monitor Report, lettered (a)-(u), are addressed herein by relevant category rather than sequentially and may therefore be listed out of order *infra*. These recommendations are also now prefaced by the number "2" to indicate they were made in the Second Monitor Report. The reasons for the recommendations are set forth in the Second Monitor Report.

Mallinckrodt's progress in implementing the Monitor's recommendation as to each of these categories is set forth below.

(a) Recommendations Related to Enhancing Mallinckrodt's SOM Program With the Support of Analysis Group

11.33 The Monitor made the following recommendations for enhancing Mallinckrodt's SOM program with assistance from Analysis Group:

2(a) modernize and enhance the SOM function with the use of big data, artificial intelligence, and automated processes and algorithms;

2(m) re-evaluate direct customer order thresholds with the assistance of Analysis Group;

2(n) re-evaluate chargeback thresholds with the assistance of Analysis Group; and

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

11.34 As set forth in detail above, Analysis Group and Mallinckrodt are currently implementing new dashboards to use in reviewing flagged orders by direct customers and monitoring downstream registrants, which they expect will streamline and enhance Mallinckrodt's SOM capabilities by further automating the SOMT's processes and incorporating additional data sources and metrics for comparison. As part of this effort, Analysis Group and Mallinckrodt are re-evaluating the thresholds for direct customer orders and chargeback thresholds and analyzing how to further refine the SOM process to accurately flag orders potentially resulting from suspicious activity, while clearing low-risk orders that should not necessitate time-consuming manual review. Mallinckrodt intends to have its dashboard for direct customers implemented by December 31, 2021, with its dashboard for indirect customers implemented in early 2022.

(b) Recommendations Related to Hiring Additional SOMT Members and Implementing a Two-Level Review Process for Any Flagged Orders

11.35 The Monitor made the following recommendations related to the SOMT's hiring process and two-level review process for direct orders:

> 2(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;
>
> 2(c) consider the sufficiency of both short-term and long-term human resource allocation in the SOM function; and
>
> 2(p) implement two-level review and approval for release of flagged orders.

11.36 In response to these recommendations, Mallinckrodt hired two new employees to replace its former Controlled Substances Compliance Auditor/Analyst. Mallinckrodt hired an Auditor/Analyst with a data-analytics background, including a Master of Science in Predictive Analytics and relevant prior work-experience, who will be located in Hobart, New York. Mallinckrodt also hired a Lead Controlled Substances Compliance Consultant, who has over sixteen-years of experience in the DEA, including applying pharmaceutical regulations related to suspicious order monitoring The Lead Controlled Substances Compliance Consultant will be located in St. Louis, Missouri. After a training period, the newly hired Auditor/Analyst and Lead Controlled Substances Compliance Consultant will conduct a two-level review and approval process for releasing flagged orders, escalating any issues to the Manager and Director of Controlled Substances Compliance as necessary. In fact, the recommendation of two-level review has already been implemented, and the new Lead Controlled Substances Compliance Consultant will continue it.

11.37 Mallinckrodt has revised its SOP entitled *Suspicious Order Monitoring Program Review of Direct Customer Orders* to reflect this new protocol, requiring both reviewers to "agree that the order is not suspicious" before releasing a flagged order. To ensure coverage

(*e.g.*, for vacations, other leave, or personnel changes), the SOP specifies that the first-level review may be completed by any of four individuals, and the second-level review process by any of three more senior SOMT members. However, "[i]n no instance shall the First and Second level reviews be completed by the same person."

11.38 As Mallinckrodt only recently onboarded the two new SOMT members, Mallinckrodt will re-evaluate the SOMT's needs and resources during the next monitoring periods. The Monitor will conduct interviews with these two new SOMT members in the next reporting period.

(c) Recommendations Related to the Chargeback Review Process

11.39 The Monitor made certain recommendations related to the chargeback review process, including that Mallinckrodt:

> 2(d) use best efforts to ensure chargeback restrictions restrict not only chargeback payments, but also the supply of Opioid Products to a restricted pharmacy;
>
> 2(e) use best efforts to obtain timely provision of chargeback data from direct customers;
>
> 2(f) evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data;
>
> 2(g) after analyzing turnaround times for chargeback reviews and restrictions, amend relevant SOPs to memorialize firm timelines; and
>
> 2(k) amend relevant SOPs to create a chargeback review task checklist, provide an audit trail, and ensure second-level review and approval.

11.40 Mallinckrodt has revised its chargeback review SOP to reflect that "[t]he effective date of a Chargeback Restriction related to a Downstream Registrant is the day the Direct Customer is notified of the Chargeback Restriction," eliminating Mallinckrodt's prior practice of providing its direct customers with a multi-day grace period to implement the restriction. Mallinckrodt has also advised the Monitor that the SOMT and Compliance Department will raise

this issue of restricting not just chargeback payments but the supply of Opioid Products to any restricted pharmacy with its distributors.

11.41 In implementing the Monitor's recommendations, Mallinckrodt determined that the lag time between a direct customer's purchase and when that customer makes a chargeback request was less than what it previously estimated; generally, Mallinckrodt's four largest customers, who comprised 95% of its sales by gross price between February and July 2021, make chargeback requests within roughly two to five days of purchase. Though Mallinckrodt will seek to negotiate provisions requiring timely chargeback requests as the direct customer's contracts come up for renewal, Mallinckrodt's analysis demonstrates that the chargeback data it receives for the overwhelming majority of its sales is more up to date than it previously thought. As set forth in Paragraph 11.20, *supra*, Mallinckrodt's timely receipt of chargeback data for almost all of its sales for Opioids containing products is unquestionably valuable and, by reducing the turnaround time for analyzing this data, Mallinckrodt can even more effectively monitor its downstream registrants. Mallinckrodt is now analyzing the timeliness of smaller customers' chargeback requests and will update the Monitor on its findings during the next reporting period.

11.42 In order to reduce the turnaround time for obtaining, analyzing, and making restriction decisions based on chargeback data, Mallinckrodt is revising its relevant SOPs to memorialize a shorter timeframe for obtaining chargeback data from the Finance Department and scheduling SOMT meetings. Mallinckrodt has already revised its SOP entitled *Suspicious Order Monitoring Program Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants* to incorporate the Monitor's recommendations. Mallinckrodt now requires that chargeback data be reviewed within fourteen days of receipt. Mallinckrodt has also

documented the SOMT's practice of holding ad hoc meetings to consider chargeback restrictions as necessary, and permitting chargeback restrictions to be made at any time (including by email if necessary), when the downstream registrant "poses a potential risk of diversion." Importantly, Mallinckrodt will now formally track how long the SOMT takes to complete a chargeback review in its meeting minutes, which the Monitor will review to determine whether Mallinckrodt is conducting those reviews in a timely manner.

11.43 The Monitor notes that, although the revised SOP eliminates the grace period Mallinckrodt previously extended to distributors when issuing a chargeback restriction, the SOP does not set a timeframe for Mallinckrodt to issue a chargeback restriction letter after the SOMT agrees to a restriction, which would ideally occur immediately after the SOMT meeting and no more than twenty-four hours after such a decision. As part of its efforts to track the turnaround time for completing chargeback reviews, based on both chargeback data and media reports, the Monitor intends to discuss with the appropriate SOMT members whether they should also track the date when restriction letters are issued following a decision, to the extent it does not do so already on the chargeback "cover sheets."

11.44 As to recommendation 2(k), Mallinckrodt advises that the Director of Controlled Substances Compliance has developed a checklist to further standardize and formalize the chargeback review process. The Monitor has requested a copy of this document for review.

11.45 The Monitor also made recommendations concerning the data Mallinckrodt incorporates in its chargeback review process:

> 2(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; and
>
> 2(i) assess the potential value of additional factors to consider in conducting chargeback reviews.

11.46 Mallinckrodt is addressing recommendations (h) and (i) through its work with Analysis Group, detailed in Paragraphs 11.16-11.25, *supra*. Mallinckrodt also plans to have the SOMT engage direct customers to discuss if, and how, Mallinckrodt can obtain retail-level data from them when Mallinckrodt is considering restricting a pharmacy.

11.47 Lastly, the Monitor recommended that Mallinckrodt "[e]xplore options for making media review more effective." For the month of September, Mallinckrodt's counsel is comparing the Google alerts it uses to identify potentially suspicious downstream registrants with two media companies' search results during the same time period. The Monitor expects to receive Mallinckrodt's comparative analysis of the different methods, and will make any further recommendations he believes are necessary to improve Mallinckrodt's media searches in light of that analysis.

(d) Recommendation Regarding an Industry "Clearinghouse"

11.48 The Monitor recommended that Mallinckrodt "[c]ontinue to actively pursue the opportunity for a public-private 'clearinghouse' concept, in collaboration with the U.S. Drug Enforcement Administration ("DEA") and industry partners." Mallinckrodt remains committed to supporting this endeavor, by lending its assistance to DEA and private third-parties.

(e) Recommendations Related to Mallinckrodt's Due Diligence for Direct and Downstream Customers

11.49 The Monitor recommended that Mallinckrodt enhance its customer due diligence by:

> 2(r) establishing minimum standards and criteria for conducting retail pharmacy due diligence, potentially with the advice and input of a third-party compliance consultant;
>
> 2(s) revising direct customer questionnaires to yield helpful, actionable, and verifiable information and determine a method for sampling or randomly auditing questionnaires; and

2(t) establishing regularly scheduled interactions with direct customers.

11.50 Since the Second Monitor Report, Mallinckrodt has engaged two third-party consultants to enhance its direct customer and downstream registrant due diligence processes. These consultants each worked for the DEA for over 30 years and have significant experience advising manufacturers and distributors on regulatory issues related to the sale of controlled substances. With these consultants, Mallinckrodt is revising and updating its due diligence questionnaire for direct customers and developing a more standardized recommendation form for downstream registrants who receive a chargeback restriction but wish to be reinstated, which will identify the information and practices Mallinckrodt will evaluate in connection with a chargeback reinstatement request. The Monitor intends to interview each of the consultants, and will review the updated questionnaire and any guidance provided to downstream registrants in connection with chargeback reinstatement requests when they are completed. Mallinckrodt expects to revise these materials, based upon input from the consultants.

11.51 In response to these recommendations, Mallinckrodt has also updated its SOP entitled *Suspicious Order Monitoring Program Review of Direct Customer Orders* to require the SOMT to "[c]onduct annual due diligence visits (in person or virtual) with one of the following Direct Customers: AmerisourceBergen, McKesson, and Cardinal. In addition, conduct due diligence visits with at least six other Direct Customers annually." During the next monitoring period, the Monitor will request Mallinckrodt's schedule for these due diligence visits in 2022, and, after those visits are completed, Mallinckrodt's findings, including any suggested improvements, related to those direct customers' SOM programs.

(f) Recommendations Related to Changes to Mallinckrodt's SOM Policies

11.52 The Monitor recommended that Mallinckrodt update its policies to:

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

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

11.53 Mallinckrodt has appropriately revised two of its SOM SOPs to incorporate the Monitor's recommendations.

12. COMPLIANCE DEADLINES (OI § III.J)

12.1 The Monitor concluded that Mallinckrodt was in full compliance with the provisions of the Operating Injunction As of the Petition Date – *i.e.*, on or about October 12, 2020 – with the exception of the provisions in Section V ("Public Access to Mallinckrodt Documents"). As of July 12, 2021, the Monitor concluded that Mallinckrodt was likewise in full compliance with Section V.

13. TRAINING (OI § III.K)

13.1 Section III.K requires Mallinckrodt to provide regular training (at least annually) to relevant employees on the obligations the Operating Injunction creates. Mallinckrodt's employee trainings comply with the Operating Injunction.

13.2 During the Third Monitoring Period, the Monitor reviewed the steps Mallinckrodt takes to test its employees' retained knowledge after completing the Operating Injunction training, which consists of the following three components: (1) reviewing and certifying compliance with the Operating Injunction for Opioid Business Policy; (2) attending a live training from an instructor via WebEx; and (3) completing a survey regarding any board service that may violate Section III.C.

13.3 As previously reported, Mallinckrodt uses the learning management system ComplianceWire for all employee trainings, including trainings related to the Operating

Injunction's obligations and any changes to SOPs implementing those obligations, and to track employees' completion of their trainings.

13.4 At the time of the filing of this Report, Mallinckrodt has confirmed that five newly hired or promoted employees are scheduled to take live Operating Injunction training on October 22, and have already completed an Operating Injunction Policy certification and board service survey. All other relevant employees, including the two new SOMT members, have completed all Operating Injunction-related trainings assigned to them for 2021.

13.5 Mallinckrodt advised that it tests Operating Injunction training's effectiveness during the annual live training sessions, which are held for specific business departments and consist of a PowerPoint presentation with hypothetical factual scenarios, related questions, and an open discussion amongst the group. During these instructor-led sessions, Mallinckrodt emphasizes why its employees need to learn about the Operating Injunction and how it impacts their specific job duties. To that end, Mallinckrodt advises that the training sessions are tailored to the needs of each business group that attends them.

13.6 Mallinckrodt also uses ComplianceWire to initiate and track trainings related to new and revised SOPs. As detailed in Section 8, *supra*, Mallinckrodt recently revised the SGGSAC operating policy to remove the requirement that third party recipients of funding for sponsorships execute a Letter of Agreement certifying that Mallinckrodt funds will not be used in a manner inconsistent with the Operating Injunction. SGGSAC Committee members were notified via ComplianceWire of a required training on the revised policy. To fulfill the training requirement, the Committee members were asked to certify that they had read and understood the policy. The policy included a Revision History directing the reader to the amended policy sections with a brief description of any changes.

13.7 The Monitor intends to attend a live training session to observe the extent to which live trainings sufficiently test and focus upon employees' retained knowledge of the Operating Injunction's provisions. The Monitor will also continue his discussions with Mallinckrodt about the potential need for additional measurement of employee comprehension and retention of new and revised Operating Injunction-related SOPs.

14. CLINICAL DATA TRANSPARENCY (OI § 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 As the Monitor previously reported, Mallinckrodt contracted with the company Vivli Inc. ("Vivli") to make such data available, and Mallinckrodt has advised the Monitor that all of the data required to be shared under Section IV is available through that platform.[10] Any research proposals submitted through Vivli will be reviewed for scientific merit by an independent review panel.

14.3 As of the filing of this Third 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.

14.4 Similarly, as of the filing of this Third 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.

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

15. PUBLIC ACCESS TO MALLINCKRODT'S DOCUMENTS (OI § 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). As noted in the Second Monitor Report, Mallinckrodt complied with this requirement by reviewing documents for redaction of information in accordance with Section V.B of the Operating Injunction and producing these documents and the associated redaction logs to the Minnesota Attorney General's Office on July 12, 2021.

15.2 After entering into 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, Mallinckrodt obtained the Bankruptcy Court's approval of the agreement and 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. Mallinckrodt has requested an invoice and is awaiting payment directions from the relevant Attorneys General Offices.

16. OTHER ISSUES OF NOTE

16.1 The DEA performed an audit of Mallinckrodt's Hobart, New York facility in July 2021. Mallinckrodt advised the Monitor of the audit and shared with the Monitor two findings of alleged regulatory violations by letters signed on September 2, 2021. The first alleged violation is that Mallinckrodt "failed to have power of attorney revocations that were issued by [a former employee] upon his departure from the firm," in violation of Title 21 C.F.R. § 1305.05(e). The second alleged violation is that Mallinckrodt "failed to include the exporter's contact information and DEA registration number on DEA Forms 161," in violation of Title 21 C.F.R. § 1312.22(c)(ii).

16.2 The letters informing Mallinckrodt of these allegations state that the "failure to comply with the aforementioned regulation[s] constitutes a violation of the Controlled Substances Act," and permits Mallinckrodt 30 days to comply with the regulations in lieu of judicial action. Mallinckrodt replied to these letters within 30 days and explained its remediation and compliance.

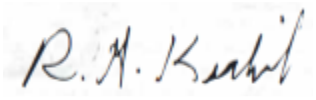
16.3 The Operating Injunction requires Mallinckrodt to "comply with all laws and regulations that relate to the sale, promotion, distribution, and disposal of any Opioid Product." Operating Injunction § III.I.2. Furthermore, the Operating Injunction does not differentiate between categories of violations based upon levels of degree or seriousness, and therefore would seem to include even *de minimis* technical violations of the sort noted in the DEA audit. Nonetheless, the Operating Injunction allows for a 30-day cure period in the event the Monitor discovers any violation of the Operating Injunction. *See* Operating Injunction § VI.B.2.d. Here, given Mallinckrodt's prompt remediation of these issues, the Monitor is satisfied that Mallinckrodt is not presently in violation of any applicable law or regulation, and therefore need not cure such violations within the 30-day period the Operating Injunction permits. Mallinckrodt agrees to continue to promptly notify the Monitor of any other government authority inspections or audits, and the remedial measures taken in response.

17. CONCLUSION

17.1 Based upon the Monitor's work to date, Mallinckrodt continues to provide helpful assistance to the Monitor in the exercise of his duties and, in the Monitor's view, is in compliance with the Operating Injunction. The Monitor looks forward to continuing on this path in the next reporting period and beyond.

* * *

17.2 Wherefore, the undersigned Monitor respectfully submits this Third 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.

Miscellaneous:

20-12522-JTD Mallinckrodt plc

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

U.S. Bankruptcy Court

District of Delaware

Notice of Electronic Filing

The following transaction was received from Amanda R. Steele entered on 10/21/2021 at 7:31 PM EDT and filed on 10/21/2021
Case Name: Mallinckrodt plc
Case Number: 20-12522-JTD
Document Number: 4863

Docket Text:
Periodic Report Regarding Value, Operations and Profitability of Entities in Which the Debtors' Estates Hold a Substantial or Controlling Interest *// Third 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:MNK - Third Monitor Report.PDF
Electronic document Stamp:
[STAMP bkecfStamp_ID=983460418 [Date=10/21/2021] [FileNumber=17297355-0] [443530b79e721dc660bad58e001f81331b99c83dba41d6bf9a7786b338e83e2735 3b8047c4ce6e80ea03ae528ae5b1009af223cf5347da804d64a2eede90d444]]

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

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

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

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

Sameer M. Alifarag on behalf of Interested Party Wilmington Savings Fund Society, FSB, as indenture trustee
SAlifarag@pryorcashman.com

Angela M. Allen on behalf of Interested Party Cotter Corporation (N.S.L.)
AAllen@jenner.com, thooker@jenner.com

Philip D. Anker on behalf of Interested Party Covidien Limited (f/k/a Covidien plc)
philip.anker@wilmerhale.com, whdocketing@wilmerhale.com;Yolande.Thompson@wilmerhale.com;Joel.Millar@wilmerhale.com;Allyson.Pierce@wilmerhale.com

David B. Anthony on behalf of Creditor Tribal Leadership Committee
danthony@bergerharris.com, mnicholls@bergerharris.com

Aaron S. Applebaum on behalf of Interested Party sanofi-aventis U.S. LLC
aaron.applebaum@us.dlapiper.com, carolyn.fox@us.dlapiper.com

Joseph N. Argentina, Jr. on behalf of Creditor Bridgeton Landfill, LLC
joseph.argentina@faegredrinker.com, rokeysha.ramos@faegredrinker.com

Joseph N. Argentina, Jr. on behalf of Interested Party VWR International, LLC
joseph.argentina@faegredrinker.com, rokeysha.ramos@faegredrinker.com

W. David Arnold on behalf of Creditor Nemera Buffalo Grove LLC
darnold@rcolaw.com

Bradley R. Aronstam on behalf of Interested Party Angus C. Russell
baronstam@ramllp.com,
hgibbons@ramllp.com;jlano@ramllp.com;jsullivan@ramllp.com;dkrech@ramllp.com;ckwiatkowski@ramllp.com;5031916420@filings.docketbird.com;jparry@ramllp.com

Bradley R. Aronstam on behalf of Interested Party Bryan M. Reasons
baronstam@ramllp.com,
hgibbons@ramllp.com;jlano@ramllp.com;jsullivan@ramllp.com;dkrech@ramllp.com;ckwiatkowski@ramllp.com;5031916420@filings.docketbird.com;jparry@ramllp.com

Bradley R. Aronstam on behalf of Interested Party George A. Kegler
baronstam@ramllp.com,
hgibbons@ramllp.com;jlano@ramllp.com;jsullivan@ramllp.com;dkrech@ramllp.com;ckwiatkowski@ramllp.com;5031916420@filings.docketbird.com;jparry@ramllp.com

Bradley R. Aronstam on behalf of Interested Party Joann A. Reed
baronstam@ramllp.com,
hgibbons@ramllp.com;jlano@ramllp.com;jsullivan@ramllp.com;dkrech@ramllp.com;ckwiatkowski@ramllp.com;5031916420@filings.docketbird.com;jparry@ramllp.com