UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

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

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

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In re:	)	
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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.	)	

FOURTH 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 Fourth Monitor Report covers the period from the filing of the Third Monitor Report on October 21, 2021, to the present (the "Fourth Reporting Period"). The Fourth Monitor Report: (1) provides an update on Mallinckrodt's implementation of the Monitor's recommendations in the Second and Third Monitor Reports; (2) reviews the Monitor's actions during the Fourth Reporting Period, including the review of documents and data, and interviews or meetings with Mallinckrodt employees and third-party consultants; (3) summarizes

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

1.2 A summary of all Monitor recommendations to date—including the additional recommendations set forth in this Report—appear in a summary chart attached as **Exhibit One**. The Monitor's new recommendations are summarized in Section 4, and are elaborated upon in Section 11 (Monitoring and Reporting of Direct and Downstream Customers) of this Report.

1.3 Having now completed the first year of "scoping" and assessment activities based upon an initial work plan agreed to with Mallinckrodt and state representatives from the Ad Hoc Committee of governmental entities (the "Ad Hoc Committee"), which has resulted in a total of 26 recommendations addressed in this and prior Reports, the monitorship will now involve a sustained period of auditing. This auditing phase will involve a regular cadence of data and document production by Mallinckrodt to enable the Monitor's assessment of Mallinckrodt's continued compliance with the Operating Injunction (as defined below, *see* Section 2, *infra*), and the status of the Monitor's recommendations and their implementation. To this end, the Monitor and Mallinckrodt have agreed in principle (subject to refinement) to a detailed Audit Plan that will involve the production of documents and data to the Monitor over an agreed-upon timeline, with deliverables triggered by particular milestones. The milestones are set at annual, quarterly, and monthly intervals or—depending upon the nature of the information sought—on an "as soon as reasonably possible" basis. These deliverables are discussed *infra*, in the relevant sections of this Report.

1.4 The Bankruptcy Court's confirmation hearing to consider approval of the reorganization plan began on November 1, 2021 and concluded on January 6, 2022. If the plan

is approved, Mallinckrodt will file an examinership proceeding in Ireland to commence the reorganization, which is estimated to take approximately 100 days.[1]

1.5 As previously noted, the Monitor has expressed the hope of engaging in more in-person interactions with Mallinckrodt's personnel. Regrettably, however, the rise in the COVID-19 "Delta" variant has given way to the "Omicron" variant, with continued uncertainty as to the course of the pandemic. Nonetheless, the Monitor's work remains uninterrupted—including meetings with Mallinckrodt personnel, as well as Mallinckrodt's consultants and outside counsel—thanks to the availability of remote meeting capabilities. The Monitor remains hopeful that in time he will have occasion to interact with Mallinckrodt personnel more directly.

1.6 Mallinckrodt's employees, counsel, and consultants continue to be responsive, cooperative, and helpful to the Monitor. In the Fourth Reporting Period, Mallinckrodt has provided over 44 files (consisting of 36.8 MB of documents and data), at the Monitor's request, in a timely and complete fashion, and has assisted in arranging multiple interviews with key employees and consultants (namely, those who provided advice to Mallinckrodt relating to the direct customer due diligence questionnaire and downstream registrant reinstatement checklist discussed in greater detail in Section 11, *infra*). The secure platform Mallinckrodt has established to share information with the Monitor continues to function effectively.

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[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. 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.").

1.7 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, as defined below.

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" or "OI"). *See* 20-50850, Dkt. No. 196-1. A copy of the Operating Injunction is attached as Exhibit One to the First, Second, and Third Monitor Reports.

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.

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* Case No. 20-12522, 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 customer's orders and downstream registrants and set forth 21 recommendations, (a)-(u), related to various aspects of Mallinckrodt's Suspicious Order Monitoring (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 customers and downstream registrants. 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 to be undertaken during the Third Reporting Period.

3.3 ***The Third Monitor Report.*** The Monitor submitted the Third Monitor Report on October 21, 2021. *See* Case No. 20-12522, Dkt. No. 4863; Adv. Pro. No. 20-50850, Dkt. No. 277. The Third Monitor Report made recommendations relating to the ban on promotion (Operating Injunction § III.A), as well as lobbying restrictions (*id.* § III.D). The Monitor also offered observations relating to SOM compliance (*id.* § III.G), which are addressed in further detail in this Report.

4. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Section 11, *infra*, the Monitor has made two additional recommendations to Mallinckrodt, which are in fact refinements to issues addressed in earlier Reports. Mallinckrodt has agreed to implement these recommendations.[2] They are:

4(a) Collect data regarding the time intervals at each stage of chargeback restriction review in order to permit both Mallinckrodt and the Monitor to analyze, in a more granular way, the sources of time lags and what, if anything, can (or should) be done to reduce them. *See* ¶ 11.27, *infra*.

4(b) Supplement the chargeback review checklist with a checkbox for the reviewer to confirm that research was conducted to determine whether a pharmacy subject to restriction is related to other co-owned pharmacies and incorporate that checklist into the chargeback review cover sheet. *See* ¶ 11.33, *infra*.

5. THE INTEGRITY HOTLINE

5.1 The Monitor has still not, to date, received any reports to the hotline—*i.e.*, the anonymous reporting procedure the Monitor and Mallinckrodt established to permit reporting of compliance concerns related to the Operating Injunction to the Monitor through his counsel.

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 "4" to indicate they were made in the Fourth 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 detailed in its Compliance Report, Mallinckrodt's Promotional Review Committee ("PRC") reviews and approves new and existing promotional materials for compliance with the terms of Operating Injunction. *See* Mallinckrodt Compliance Report, 20-50850-JTD, Dkt. No. 174-1 (hereafter, "Mallinckrodt Compliance Report") § 4.6.

6.3 In previous reporting periods, the Monitor interviewed several PRC members to develop a better understanding of the PRC's mission, processes, and work flow. Going forward, on a quarterly basis and as part of the agreed-upon Audit Plan referenced above (*see* ¶ 1.3, *supra*), the Monitor will request and review the minutes of all PRC meetings held during that quarter as well as any promotional materials / pieces discussed during those meetings.

6.4 During this Fourth Reporting Period, the Monitor reviewed the minutes of the June 1, 2021, July 11, 2021, August 5, 2021 and September 30, 2021 PRC meetings. The meetings, led by the Product Manager of Commercial, were held via video-conference and lasted approximately 20-30 minutes. The meetings included review and approval of proposed revisions to one or more of Mallinckrodt's product catalogs: International or outside the United States (OUS), Specialty Generics, and Addiction Treatment; as well as the review and approval of new promotional materials for an addiction treatment product, Methadose Oral Concentrate Raspberry. In the next reporting period, the Monitor will review these materials and, if warranted, meet with selected PRC members for further discussion.

6.5 ***Recommendation 3(a).*** In the Third Report, the Monitor detailed the results of his review of Trackwise, Mallinckrodt's internal system for logging customer inquiries and complaints fielded by its Product Monitoring Team ("PMT"). While the Monitor ultimately determined that PMT members were handling customer inquiries in a manner consistent with the Operating Injunction and Mallinckrodt's policies relating to post-market communications, he

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. The response, if any, to the PMT referral was not documented in Trackwise. To ensure the inquiries were appropriately closed by the PMT, the Monitor recommended that Mallinckrodt expand Trackwise to include the results of a PMT member's referral of an issue outside the PMT. Mallinckrodt accepted the Monitor's recommendation.

6.6 During the Fourth Reporting period, Mallinckrodt took significant steps towards implementing the Monitor's TrackWise recommendation. In addition to revising its existing *Generics Medical Information Request* standard operating procedure ("SOP") to include expectations for inclusion of responses from external departments to PMT referrals and any supporting documentation into Trackwise, Mallinckrodt also amended the *TrackWise Complaint Entry and Processing* work instruction to provide additional detail regarding the company's processes for the receipt, classification, and resolution of customer inquiries and complaints. The Monitor received both policies near the end of this reporting period and will complete his review of them in the next reporting period. The Monitor also renewed his request for historical Trackwise complaint data and anticipates reviewing same in the next reporting period.

6.7 As previously reported, Mallinckrodt has developed an auditing protocol for another Trackwise work instruction titled *Auditing Medical Information for Operating Injunction for Opioid Business*, to ensure that PMT members are responding to customer inquiries in a manner consistent with the Operating Injunction. During this reporting period, the Monitor received and reviewed the results of the first audits conducted under the new protocol, specifically, TrackWise Audit Reports for the months of October 2021, November 2021, and

December 2021. The Director of Post-Market Surveillance, who supervises the PMT, issued the reports based on a review of nearly 200 Trackwise entries. According to the reports, the audit revealed two instances in which the Director of Post-Market Surveillance recommended corrective action or refresher training for PMT members, including one case in which a PMT member improperly responded to a pharmacist's questions regarding whether a non-Mallinckrodt opioid product could be crushed. Based on the Monitor's review of these reports, it appears that the Trackwise audits are being conducted in a manner consistent with Mallinckrodt's work instruction and the Operating Injunction.

6.8 During the next reporting period, as part of the agreed-upon Audit Plan, the Monitor will continue to review PRC meeting minutes and promotional materials submitted to and approved by the PRC on a quarterly basis. Additionally, the Monitor will continue to independently review these materials for compliance with Section III.A of the Operating Injunction[4] and, where applicable, Centers for Disease Control and Prevention Guideline Recommendations on a quarterly basis. *See* Operating Injunction § III.A.6.a.

[4] The Monitor has independently confirmed that Mallinckrodt has not added any new items to its Specialty Generics Product Catalog since the last review of the catalog in February 2021. *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).

In doing this review, the Monitor also confirmed Mallinckrodt is in compliance with Section III.E of the Operating Injunction banning the manufacture, promotion, or distribution of "high dose opioids" (*i.e.*, "any Opioid Product that exceeds 30 milligrams of oxycodone per pill), which Mallinckrodt has certified that it does not currently manufacture or distribute. Section § 10, *infra*. The Monitor will continue to review future product catalogs as reviewed by the PRC and received on a quarterly basis according to the Audit Plan, to ensure there is no change to Mallinckrodt's compliance with Section III.E of the Operating Injunction.

6.9 Further, under the Audit Plan, the Monitor will continue to review Trackwise Audit Reports, in accordance with the *Auditing Medical Information for Operating Injunction for Opioid Business*, 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 ("FSCP") for 2021 and an accompanying explanatory document, and conducting an interview with Mallinckrodt's former Vice President of Commercial. As a result, 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, complied with Section III.B of the Operating Injunction in 2021.

7.3 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 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.

7.4 As part of the agreed-upon Audit Plan referenced above (*see* ¶ 1.3, *supra*), the Monitor has requested a copy of Mallinckrodt's 2022 Sales Incentive Compensation Plans, and notice as to any significant changes from the 2021 plans.

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 Under its operating policy, titled *Specialty Generics Grant & Sponsorship Approval Committee*, the SGGSAC meets annually and on an ad hoc basis as needed. During the Fourth Reporting period, the Monitor reviewed the minutes of two August 2021 ad hoc meetings, third-party funding Request Forms, and any related materials the Committee considered in determining whether to approve or deny a specific request.

8.4 On August 3, 2021, the Committee convened (over e-mail, as the SOP permits) and voted to approve a $7,500 bronze-level sponsorship for the 2021 Smith Drug Annual Sales and Performance Meeting. Smith Drug, an independent pharmacy distributor, is a Mallinckrodt

customer. Prior to the vote, the Compliance Manager, who serves as the SGGSAC Recording Secretary, circulated the Request Form and Smith Drug's sponsorship opportunities detail sheet to the Committee and asked the members to review it and register their vote by August 6, 2021. The following day, August 4, 2021, the Compliance Manager provided additional supporting information to the Committee,[5] including the Annual Meeting agenda, and advised that the deadline to vote on the request was extended to August 9, 2021. The request was ultimately approved by a majority of the SGGSAC voting members.[6] Based on the Monitor's review of the request and accompanying materials, it appears that this sponsorship was funded in a manner consistent with the terms of Operating Injunction and the SGGSAC SOP.

8.5 On August 31, 2021, the SGGSAC met via videoconference to consider three requests. While the requests were submitted via the SGGSAC's sponsorship Request Form, the requested funds appear to have been earmarked to cover registration fees for Mallinckrodt employees to attend certain events.

8.6 The SGGSAC considered three requests to fund registration fees during the August 31, 2021 meeting: the OptiSource 2021 Annual Meeting ($1,250), the Pharmacy Select October 2021 Business Summit ($10,000), and the ECRM 2022 Generic Rx Program ($23,250). Each event was described as offering opportunities for Mallinckrodt employees to network with industry leaders, pharmacy distributors, and other key decision-makers. According to the Request Form submitted for registration in the ECRM Generic Rx Program, the proposed Mallinckrodt attendees would have the opportunity to meet with a number of customers and

[5] The Compliance Manager reported that she had received independent confirmation from Smith Drug that there were no speakers scheduled to appear at the Annual Meeting.

[6] The Annual Meeting was ultimately cancelled due to COVID-19.

"would be" customers over a three-day period. At the conclusion of the approximately 20-minute meeting, all three requests were approved.

8.7 In this same meeting, the former Vice President of Commercial, who chairs the SGGSAC, noted that the addition of conference registration fees to the SGGSAC's approval authority would result in an increased frequency of Committee meetings. During the next reporting period, the Monitor anticipates that he will meet with a number of SGGSAC members to gain a better understanding of the Committee's expanded authority to consider and approve registration fees. In addition, the Monitor will seek to discern whether, and to what extent, such requests implicate the Operating Injunction's Ban on Promotion and what steps Mallinckrodt has taken or will take to ensure that its employees do not engage in prohibited activities while attending these events.

8.8 During the Fourth Reporting period, the Monitor also interviewed a senior representative of the Association of Accessible Medicines ("AAM") to better understand Mallinckrodt's relationship and interaction with AAM. This was warranted, given Mallinckrodt's obligations under the Operating Injunction and its disclosure, in its Compliance Report, that certain employees had taken steps to recuse themselves from participating in AAM meetings or deliberations related to Opioids or the Treatment of Pain, to the extent they arise. The AAM representative expressed that AAM would continue to be flexible and amenable in accommodating the needs of its member organizations, including those members who may request recusal or exclusion from certain discussions.

8.9 During the next reporting period, as part of the agreed-upon Audit Plan referenced above (*see* ¶ 1.3, *supra*), the Monitor will continue to review a list of any grants and sponsorships awarded or rejected by the SGGSAC, along with any accompanying Request

Forms and the minutes of any SGGSAC meetings on a quarterly basis. Further, under the Audit Plan, the Monitor will review any new or updated disclosures from Mallinckrodt's directors, officers, and management-level employees on an annual basis.

8.10 The Monitor 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 grants and 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 prescribing 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 Third Monitor Report, the Monitor has reviewed all of the Certifications of Compliance with SpecGx Lobbying Restrictions ("Certifications") produced by Mallinckrodt and executed by individual lobbyists who are members of state and federal lobbying firms engaged by Mallinckrodt.

9.4 The Monitor compared these Certifications with publicly-filed activity reports of Mallinckrodt's state and federal external lobbyists to confirm whether all individuals publicly listed as performing lobbying work on Mallinckrodt's behalf have executed a certification. From this review, the Monitor determined that all state and federal lobbyists identified as performing work on Mallinckrodt's behalf have executed Certifications.

9.5 ***Recommendation 3(b).*** During the Fourth Reporting period, the Monitor discussed with Mallinckrodt its progress in confirming that each of its external lobbyists had acknowledged receipt of the Operating Injunction and certified that they would comply with its requirements, as outlined in Recommendation 3(b) from the Third Monitor Report. In addition to collecting Certifications from the remaining external lobbyists who publicly reported having performed lobbying activities on the company's behalf, Mallinckrodt also indicated that it was reviewing its current roster of external lobbying firms and assessing whether to re-engage certain firms in 2022. Mallinckrodt agreed to provide the Monitor a list of those firms, so that the Monitor may determine whether representatives of those firms account for any outstanding certifications.

9.6 Mallinckrodt also sent its external state and federal lobbyists an Annual Acknowledgement Letter (the "Acknowledgment Letter") reinforcing the Operating Injunction requirements as set forth in the Certification and listing the employees of each firm from whom Mallinckrodt had received an executed Certification. The principal of each firm was asked to return a signed copy of the Acknowledgement Letter confirming that: (1) no other employees were engaged in lobbying on Mallinckrodt's behalf; (2) the firm would notify Mallinckrodt of any employees not listed and submit certifications from those lobbyists to Mallinckrodt's Vice President of Government Affairs; and (3) the firm would promptly notify Mallinckrodt if new resources / employees were added during the course of the new year. The Monitor has received and reviewed signed Acknowledgement Letters from Mallinckrodt's external lobbyists and believes that Mallinckrodt is working diligently to implement Recommendation 3(b).

9.7 ***Recommendation 3(c).*** In the Third Monitor Report, the Monitor detailed his review of Mallinckrodt's lobbying activities, as reflected in its external lobbyists' publicly-filed

disclosure reports, and identified two instances in which a lobbyist described having performed work that, absent additional detail or context, could potentially signal that the lobbyists were engaged in activity prohibited by the Operating Injunction.[7] While Mallinckrodt does meet regularly with its external lobbyists to direct their activities, these meetings are not formally documented and, as such, the company has no way to verify whether activities listed in its external lobbyists' disclosure reports accurately reflect the company's directives or priorities. The Monitor recommended that Mallinckrodt implement a process to ensure that its external lobbyists are accurately reporting their activities and that said activities are in compliance with the Operating Injunction.

9.8 In addition to meeting with Mallinckrodt to discuss the company's progress towards implementing Recommendation 3(c) from the Third Monitor Report, the Monitor also interviewed principals of two external lobbying firms to better understand how these firms were first made aware of the Operating Injunction and whether, and to what extent, their work on Mallinckrodt's behalf has been impacted. Both affirmed that Mallinckrodt has been open in its communications about the Operating Injunction and has provided them ample opportunity to ask any questions that may have arisen since its inception. Based on these discussions, the Monitor believes that Mallinckrodt is operating in a manner consistent with Section III.D of the Operating Injunction as it relates to its communications with its external federal lobbyists.

9.9 During this reporting period, Mallinckrodt's work towards implementing Recommendation 3(c) from the Third Monitor Report also included its initial drafting of a work

[7] During the Fourth Reporting Period, the Monitor interviewed the principals of these lobbying firms who echoed Mallinckrodt's belief that the identified entries were the result of transcription errors such as the cutting and pasting of information from pre-Operating Injunction disclosure reports. The Monitor accepts this explanation.

instruction designed to formalize the process by which the Vice President of Government Affairs will, on a quarterly basis, review drafts of external lobbyists' public disclosure reports, pre-filing, and record the results of that review contemporaneously. Mallinckrodt anticipates that the new protocol will be finalized in early 2022.[8] Based on this discussion, the Monitor believes that Mallinckrodt is working diligently to implement Recommendation 3(c).

9.10 During the next reporting period, the Monitor anticipates meeting with a number of Mallinckrodt's external state 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. Additionally, the Monitor will conduct further review of the Certifications received to date, in light of Mallinckrodt's decision not to re-engage certain firms.

9.11 During the next reporting period, as part of the agreed-upon Audit Plan referenced above (*see* ¶ 1.3, *supra*), the Monitor will also receive and review a list of any new bills lobbied for or against by internal and external lobbyists, as well as a list of any newly engaged lobbyists, on a quarterly basis. Further, under the Audit Plan, the Monitor will review a list of Mallinckrodt's prior year campaign contributions.

[8] Once the protocol is operational, the Monitor anticipates that he will review the results on an ongoing basis as part of his Audit Plan.

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.4), 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 sections 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);[9] 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's Specialty Generics Associate General Counsel for Compliance and Data Privacy (the "Associate General Counsel") provided certain certifications with respect to Sections III.E-I of the Operating Injunction on July 16, 2021. Those certifications are set forth in greater detail in Section 10.5 of the Second Monitor Report.

[9] *See supra* note 4, and accompanying text in ¶ 6.8.

10.3 As part of the agreed-upon Audit Plan referenced above (*see* ¶ 1.3, *supra*), Mallinckrodt will continue to update these certifications annually. In the event Mallinckrodt becomes aware of any violations of the above-referenced provisions of the Operating Injunction or the Associate General Counsel's representations in the most recent certification, Mallinckrodt has agreed to promptly inform the Monitor.

10.4 Mallinckrodt's Associate General Counsel executed the first updated annual certification under the Audit Plan on January 5, 2022.

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

11.1 During the Fourth Reporting Period, the Monitor continued to assess Mallinckrodt's compliance with Section III.G of the Operating Injunction by: (1) obtaining an update from Mallinckrodt and its outside counsel regarding the status of Mallinckrodt's implementation of the Monitor's SOM-related recommendations set forth in the Second Monitor Report and suggestions in the Third Monitor Report; (2) participating in a meeting with the OCC; (3) repeatedly conferring with Mallinckrodt regarding a unique situation involving an active pharmaceutical ingredient ("API") purchaser whom Mallinckrodt reported to the U.S. Drug Enforcement Administration ("DEA"); (4) drafting the Audit Plan, which includes numerous SOM-related items; and (5) continuing his review of the voluminous data and documents provided in response to the Monitor's Second Document Request and of other documents requested during the Fourth Monitoring Period. These efforts are described in further detail below.

1. Mallinckrodt's Implementation of the Monitor's Prior Recommendations

11.2 The Monitor met remotely with SpecGx's former General Counsel and Associate General Counsel, along with Mallinckrodt's outside counsel, to discuss the status of the

Monitor's recommendations in the Second Monitor Report. The implementation status of these recommendations is set forth below, by category.[10]

(a) Recommendations related to enhancing Mallinckrodt's SOM program with the support of Analysis Group

11.3 ***Recommendations 2(a), 2(i), and 2(m)-(o).*** The Monitor made Recommendations 2(a) (upgrading SOM system and architecture by making use of "big data" analytics); 2(i) (assessing, with Analysis Group, the value of additional criteria to include in chargeback restriction analysis) and 2(m)-(o) (re-evaluating direct order and indirect customer chargeback reviews) for enhancing Mallinckrodt's SOM program with assistance from Analysis Group. Mallinckrodt and its outside counsel have advised that Mallinckrodt and Analysis Group have implemented a new system for reviewing direct customer orders, and are on track to implement a parallel system for monitoring downstream registrants in the first quarter of 2022. Having already reviewed an early concept of the system at a meeting with Analysis Group in August 2021, the Monitor looks forward to the opportunity to see the system in action.

(b) Recommendations related to hiring additional SOMT members and implementing a two-level review process for any flagged orders

11.4 The Monitor made Recommendations 2(b)-(c) (hiring additional SOM staff with relevant data analytics qualifications) and 2(p) (requiring two-level review and approval of flagged direct customer orders). As noted in the Third Monitor Report, two new employees were hired to replace Mallinckrodt's former Controlled Substances Compliance Auditor / Analyst: (1) a Lead Controlled Substances Compliance Consultant (LCSCC) with over sixteen-years of experience in the DEA, including applying pharmaceutical regulations related to suspicious order

[10] The Recommendations in the Second Monitor Report, as well as subsequent additional recommendations from the Third and Fourth Monitor Reports, are summarized in attached **Exhibit One**.

monitoring, who is located in St. Louis, Missouri; and (2) a Compliance Consultant, filling the role of an auditor-analyst, with a data-analytics background, including a Master of Science in Predictive Analytics and relevant prior work-experience, who is located in Hobart, New York.

11.5 ***Recommendations 2(b)-(c).*** The Monitor conducted initial interviews with both the LCSCC and the Compliance Consultant. Both employees have now been onboarded, having undergone orientation and training.

11.6 The LCSCC's role primarily involves investigations related to chargeback and social media reviews and reinstatement requests for downstream registrants. Given the nature of the LCSCC's role and his prior DEA experience, the Monitor and the LCSCC discussed the LCSCC's ability to assist with strategic risk assessment for both direct customers and downstream registrants.

11.7 Under Mallinckrodt's revised *SOM Program Social Media Chargeback Review* SOP, the "LCSCC or designee will conduct a periodic review of Chargeback data for the prior twelve-month period and review media and publicly available information to identify Downstream Registrants which may pose a risk of diversion." The LCSCC recently completed this periodic review of Mallinckrodt's chargeback data for certain Opioid Products, by customer type and geographic location. Mallinckrodt provided a copy of the LCSCC's report on this review to the Monitor, which the Monitor will review during the next reporting period. The LCSCC expects to compile similar reports in the future, and Mallinckrodt has agreed to share such reports with the Monitor as soon as possible, under the Audit Plan referenced above (*see* ¶ 1.3, *supra*).

11.8 The Compliance Consultant's work largely focuses on reviewing and releasing direct customer orders, as well as assisting the LCSCC with reviewing chargeback data and

media reports. The Compliance Consultant also supports the Manager of Controlled Substances Compliance as needed.

11.9 ***Recommendation 2(p).*** Though the LCSCC's and Compliance Consultant's roles generally focus on different points in the supply chain, their responsibilities overlap to an extent. For example, the Monitor recommended, in Recommendation 2(p), that Mallinckrodt formalize and memorialize a two-level review process for releasing suspicious direct customer orders in its revised *Suspicious Order Monitoring Program Review of Direct Customer Orders* SOP. That revision has been made. Under the revised SOP, the LCSCC (or, potentially, an appropriate substitute of equal or higher rank, such as the Director or Manager of Controlled Substances Compliance) reviews and approves any direct customer orders the Compliance Consultant determines should be released. The Compliance Consultant reported this two-level review process is working well.

11.10 The LCSCC and Compliance Consultant are also both involved in developing Mallinckrodt's new direct customer and downstream registrant dashboards with Analysis Group.

11.11 The Monitor is pleased with Mallinckrodt's implementation of the Monitor's Recommendations 2(b)-(c), relating to the hiring of additional SOM staff with relevant data analytics qualifications. The new LCSCC and Compliance Consultant seem ideally suited to their roles, which they are clearly approaching with enthusiasm and commitment. Their statistics and data analytics backgrounds are precisely what are needed to guide Mallinckrodt's SOMT in a new era of predictive analytics, and will complement the changes Mallinckrodt is making with the assistance of Analysis Group.

(c) Recommendations related to the chargeback review process

11.12 The Monitor made Recommendations 2(d)-(h) and 2(k) 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) amend relevant SOPs to memorialize firm timelines, after analyzing turnaround times for chargeback reviews and restrictions;

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

11.13 ***Recommendations 2(d), 2(e), and 2(h).*** These recommendations require Mallinckrodt to use its best efforts to reach agreement with direct customers on various anti-diversion efforts. Mallinckrodt has implemented these recommendations by sharing with its three largest distributor customers—the so-called "big three" (namely, Amerisource Bergen, Cardinal Health, and McKesson)—a letter agreement proposing revisions to Mallinckrodt's existing supply agreements in order to obtain the distributors' agreement and cooperation on a number of issues. The letter agreement, a copy of which the Monitor has reviewed in draft form, requires distributors to use best efforts to cooperate in detecting and preventing the diversion of controlled substances by: (1) suspending or terminating the distribution of SpecGx's controlled substances to any recipient that SpecGx informs the distributor it is restricting (*per Recommendation 2(d)*); (2) responding promptly to SpecGx's requests for information related to the distributor's orders, sales, and distribution of SpecGx's products (*per Recommendation 2(h)*); and (3) notifying SpecGx if the distributor suspends or terminates the distribution of Controlled Substances to the recipient within five days after the suspension or termination.

11.14 Thus, as drafted, the letter agreement addresses (among other things) the concern the Monitor raised in paragraph 11.12 of the Third Monitor Report regarding direct customers' failure to timely inform Mallinckrodt when a downstream registrant is restricted. If agreed to,[11] the letter agreement's provision will help to avoid situations in which Mallinckrodt has learned of a direct customer's restriction of a downstream registrant sometimes months after the fact and, on at least one occasion, only by happenstance. Given the distributors' greater knowledge about their own direct customers (*i.e.*, the retail pharmacies), a direct customer's prompt communication of a restriction would be helpful to Mallinckrodt's own anti-diversion efforts.

11.15 ***Recommendation 2(e)***. The letter agreement also includes a provision requiring smaller direct customers to submit chargeback requests to SpecGx no later than five business days after the order is filled, and it requires the "big three" distributors to continue to promptly submit chargeback requests to Mallinckrodt. As previously reported, for Mallinckrodt's largest direct customers, the lag time between a customer's purchase and when that customer makes a chargeback request is short. For example, the three largest distributors, which account for approximately 93% of Mallinckrodt's Opioid sales by volume, make chargeback requests within roughly two to five days of purchase. Smaller direct customers account for a much smaller volume of opioid orders. Their lag time in submitting chargeback requests is also significantly longer. For example, of the approximately 27 smaller distributor direct customers accounting for about 1.28% of order volume, the range of average chargeback request times is from 9 to 102

[11] As a result of their entry into a global settlement agreement with a number of Settling States, *see infra* ¶¶ 11.36, 11.37, the "big three" distributors will soon be under monitorships, and therefore may have added incentive to agree to Mallinckrodt's proposal.

days. Reaching agreement with smaller distributors to shorten chargeback request times will assist Mallinckrodt in even more effectively monitoring downstream registrants.[12]

11.16 ***Recommendations 2(f)-2(g).*** In addition to the time lag in obtaining chargeback requests from direct customers, the Monitor has also focused, in prior reports, on Mallinckrodt's ***internal*** time lag from the time of receipt of chargeback data from its Finance Department to the time of executing a chargeback restriction. Thus, in Recommendation 2(f), the Monitor recommended a data collection process—*i.e.*, that Mallinckrodt evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data. And in Recommendation 2(g), the Monitor recommended a data analysis process—*i.e.*, that Mallinckrodt evaluate the data obtained in order to establish firm turnaround times for chargeback reviews and restrictions, and amend relevant SOPs to memorialize those timelines. While the Monitor believes that some progress has been made on both data collection and analysis, he nonetheless believes more can be done, and has shared his thoughts with Mallinckrodt in this regard, as explained further below.

11.17 As previously reported, Mallinckrodt revised its SOP entitled *Suspicious Order Monitoring Program Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants* to incorporate the Monitor's recommendations to: (1) require that chargeback data be reviewed within 14 days of receipt; and (2) formally track how long the SOMT takes to complete a chargeback review in its meeting minutes.

[12] A group of six distributors account for 4.9% of opioid orders, which is a small percentage of the total direct opioid orders that Mallinckrodt handles, but a relatively high percentage given this small number of distributors. This group does not participate in the chargeback program. Consequently, the valuable data that Mallinckrodt relies upon heavily to restrict chargeback payments is unavailable for these six direct customers. In the next reporting period, the Monitor will explore with Mallinckrodt whether other methods may assist in monitoring these particular customers, absent chargeback data.

11.18 As set forth in the Third Monitor Report, the Monitor continued to observe instances where the timeframe for completing the chargeback review process (particularly when prompted by media search results) as well as issuing restrictions seemed longer than necessary. In paragraph 11.5 of that Report, the Monitor suggested the timeframe for review and implementation of restrictions warranted Mallinckrodt's further examination.

11.19 During the Fourth Monitoring Period, the Monitor reviewed the SOMT's meeting materials and minutes for October and November 2021. That review revealed that relevant dates in the chargeback review process were not consistently identified in the meeting minutes, in accordance with the relevant SOP, and a key date—the date the chargeback restriction was issued—was not tracked in the minutes (presumably because the restriction is executed following the completion of the SOMT meeting and the drafting of the minutes). The Monitor also observed additional instances where it appears the review process could have been completed more expeditiously, perhaps due in large part to Mallinckrodt's necessary reliance on its distributors' due diligence. By collecting time lapse data from the chargeback review process in a more systematic way, the Monitor and Mallinckrodt will be able to fairly analyze the time lapses, the possible causes for them, and what if anything can (or should) be done to reduce them. Absent this data collection and analysis, the Monitor will have to speculate on whether seemingly unnecessary time lapses are appropriate under the circumstances, whether it is primarily due to delay by direct customers, and whether there is anything that can be done to reduce such delay. Furthermore, having such data available would permit Mallinckrodt's SOMT to have a useful discussion with key direct customers who may be at fault for slowing Mallinckrodt's internal chargeback review process, and perhaps help the direct customer to identify the reasons for delay on its end.

11.20 Under the revised *Suspicious Order Monitoring Program Social Media & Chargeback Reviews of Direct Customers and Downstream Registrants* SOP, the SOMT's meeting minutes are required to include the dates when: (1) the SOMT received the chargeback data from the Finance Department; (2) the SOMT (*i.e.*, the LCSCC) flagged the downstream registrant for further review; and (3) the SOMT's review was completed. But the Monitor observed that these dates were not consistently recorded in the meeting minutes for each pharmacy being considered for a chargeback restriction. For example, in the October meeting minutes, the date one pharmacy was flagged for review was included, but the date the SOMT's review was completed, which began in July 2021, was not. Although greater detail is provided in the chargeback cover sheets, without knowing when the SOMT's investigation was completed, the Monitor has difficulty assessing whether the investigation was completed "as promptly as possible" in accordance with the revised SOP.

11.21 The October minutes also referenced the SOMT's ad hoc restriction of three affiliated pharmacies, but the date the SOMT completed its review was not included. Without more information, it was unclear to the Monitor why the review took approximately five weeks. Although the Director of Controlled Substances Compliance later explained the unique circumstances involving an API purchaser described *infra* that prompted the SOMT's review of these pharmacies, the reason for the delay was not readily evident to the Monitor from either the minutes or the chargeback cover sheets.

11.22 Likewise, in the November meeting minutes, the dates when the SOMT's review was completed for two different pharmacies based on media reports were not included. Without knowing when the review process was completed for two of these pharmacies the Monitor infers that the review process took over two months.

11.23 As noted above, one undeniable reason for chargeback review time lapses is the delay, not by Mallinckrodt, but by its direct customers in responding to Mallinckrodt's SOMT's requests for due diligence during the course of a chargeback review. The Monitor's review of the October and November meeting materials and minutes reveals why—consistent with Recommendation 2(h) referenced *supra*—it is important for Mallinckrodt to use its best efforts to obtain access to direct customers' due diligence in a timely manner. For instance, for one of the pharmacies reviewed in October, the SOMT did not receive requested due diligence from its direct customer (a distributor) until almost two months after requesting it. Even worse, although the distributor explained why, from the distributor's perspective, there was a legitimate increase in the pharmacy's prescription volume, the distributor failed to inform the SOMT that there was a pending disciplinary proceeding against the pharmacy's owner and the pharmacist. The LCSCC only discovered this information through his own due diligence, which heavily factored into the SOMT's decision to restrict the pharmacy. Based in large part on the distributor's delay, the pharmacy was not restricted until almost three months after it was flagged for review. In the prior reporting period, the SOMT restricted a pharmacy on an ad hoc basis after its distributor did not provide the requested due diligence for almost three months. Similarly, for one of the pharmacies reviewed in October, the SOMT did not receive the due diligence it requested for four months, despite repeated follow up. Although in that particular circumstance Mallinckrodt ultimately decided not to restrict the pharmacy, this is not always the case, as the other examples referenced above make clear.

11.24 Delay in receiving requested due diligence from Mallinckrodt's direct customers is not uncommon. While the Monitor understands that the SOMT is dependent upon those direct customers to promptly respond to Mallinckrodt's requests for due diligence, and Mallinckrodt

may have good reasons (including contractual obligations) not to restrict downstream registrants without a strong basis for doing so, these delays negatively impact Mallinckrodt's ability to monitor downstream registrants, and in the worst case may perpetuate supply to a downstream registrant Mallinckrodt may be inclined to restrict.

11.25 The Monitor is not insensitive to the fact that Mallinckrodt does not operate in a vacuum and therefore does not exercise complete control over its direct customers. Those customers influence not only the timeliness of their own chargeback requests to Mallinckrodt, but also the provision of follow-up due diligence information to Mallinckrodt for purposes of the SOMT's chargeback review. Accordingly, it would be unfair and irrational to impose blind deadlines on the SOMT. But that is also not a reason to have no timelines at all. What those timelines can and should be, however, remains unclear. Presumably, they should be driven by an analysis of what the timelines have tended to be historically (at least during the onset of the monitorship), and by identification of unnecessary lags in the process that, through efficiency, could be shortened. While the Monitor believes the SOMT is continuing to make best efforts to conduct chargeback reviews and restrictions in a timely manner, the Monitor still does not believe Mallinckrodt is collecting sufficient data to inform the analysis of critical timelines in order to evaluate whether turnaround times are appropriate or could be more efficient.

11.26 The Monitor conducted two follow-up interviews with the Director of Controlled Substances Compliance regarding various SOM-related issues, including the most recent SOMT meetings and the benefits of tracking key dates in the chargeback review process, which, as described above, was not recorded consistently in the minutes despite the revision to the SOP.

Recommendation 4(a). Collecting data regarding time lags in the chargeback review process in a more detailed way.

11.27 **The Director of Controlled Substances Compliance informed the Monitor that the Director maintains an Excel spreadsheet for tracking the chargeback review process. After reviewing that spreadsheet, the Monitor recommended changes to include all relevant steps in the chargeback review process, identifying whether each instance of review is the result of a regular chargeback review, or due to an ad hoc review (prompted by, for example, a media alert), including the following significant events in the process: (1) the date the chargeback data was made accessible to the LCSCC for review; (2) the date the LCSCC began review; (3) the date of any due diligence request the LCSCC made to the distributor; (4) the date of the direct customer's response to the due diligence request; (5) the date of the SOMT's review of the LCSCC's analysis and / or recommendation; (6) the date of the SOMT's chargeback restriction decision; (7) the date the restriction decision is communicated and executed; and (8) the date of chargeback reinstatement (if applicable). The Monitor believes this spreadsheet, in addition to the chargeback review cover sheets and SOMT meeting minutes, will not only allow him to better audit Mallinckrodt's compliance with Section III.G of the Operating Injunction, but will provide an objective basis for Mallinckrodt to analyze its turnaround time for chargeback reviews at each critical point in the process, and therefore whether it is appropriate to memorialize additional, firm deadlines in this process. As part of the agreed-upon Audit Plan referenced above (*see* ¶ 1.3, *supra*), Mallinckrodt will produce an updated copy of the spreadsheet each month for the Monitor's review, and the Monitor will closely examine these turnaround times.**

11.28 This spreadsheet will also address the Monitor's suggestion in paragraph 11.8 of the Third Monitor Report that the SOMT track the turnaround time for both chargeback restrictions arising from chargeback data ***and*** social media reports, as it was unclear whether Mallinckrodt was required to track the latter under its revised SOP.

11.29 Mallinckrodt has agreed to this recommendation.

11.30 ***Recommendation 2(k).*** The Monitor also recommended that Mallinckrodt "amend relevant SOPs to create a chargeback review task checklist," to ensure a consistent approach to conducting chargeback reviews, as well as the availability of an audit trail to confirm what is checked in each review. During the Fourth Reporting Period, Mallinckrodt produced a copy of the *Suspicious Order Monitoring Program Indirect Customer Pharmacy Review Cover Sheet Checklist* (the "Chargeback Review Checklist") prepared by the LCSCC who is responsible for chargeback investigations.

11.31 This Checklist memorializes existing aspects of the SOMT's chargeback review process (*i.e.*, reviewing chargeback and ARCOS data for both the pharmacy under review and neighboring pharmacy), which are generally documented in the chargeback review cover sheets.

11.32 The Chargeback Review Checklist is intended to further standardize and formalize the chargeback review process. Given the SOMT's institutional knowledge, the Chargeback Review Checklist will be helpful in the event of vacation, personnel changes, and training new employees, if Mallinckrodt later determines additional resources are necessary in implementing Recommendation 2(c).

Recommendation 4(b). Formalizing the check for any co-owned pharmacies during the chargeback review process and incorporating the Chargeback Review Checklist into the chargeback review cover sheets.

11.33 **A worthwhile addition to the Chargeback Review Checklist would be a checkbox to confirm the reviewer's research for any co-owned pharmacies that can be reasonably identified. Given examples of co-owned pharmacies that have been restricted upon discovery, *see* Third Monitor Report ¶¶ 11.9-10, it makes sense to make research on co-ownership a standard practice in chargeback restriction reviews, and including this step on the Chargeback Review Checklist will help to ensure that this becomes a consistent practice. To that end, the Monitor recommends that Mallinckrodt attach the Chargeback Review Checklist to each chargeback review cover sheet. By doing so, Mallinckrodt will further standardize the chargeback review process, memorialize steps taken, and create a helpful audit trail for future review.**

11.34 Mallinckrodt agrees with this recommendation.

(d) Recommendation regarding an industry "Clearinghouse"

11.35 ***Recommendation 2(j).*** The Monitor has encouraged Mallinckrodt's support of, and involvement in efforts to create "a public-private 'clearinghouse' concept, in collaboration with the DEA and industry partners." Mallinckrodt remains committed to supporting this endeavor, by lending its assistance to DEA and private third-parties. There are now notable opportunities for Mallinckrodt to do so, as discussed below. These opportunities have coincided close in time with the Monitor's Recommendation 2(j), which was included in the Second Monitor Report.

(i) The Distributor Settlement Agreement's creation of a clearinghouse

11.36 As announced on the national opioid litigation settlement website (available at www.nationalopioidsettlement.com), on July 21, 2021 a global settlement agreement was announced between the "big three" distributors, on the one hand, and the National Prescription Opiate Litigation MDL Plaintiffs' Executive Committee and several State Attorneys General, on the other, to resolve opioid-related claims of states and subdivisions against the defendants (the "Distributor Settlement Agreement").[13] Notably, the Distributor Settlement Agreement includes the creation of a clearinghouse for the distributors to pool and share supply chain data relating to opioid distribution.[14] As described in the New York Attorney General's press release announcing a related settlement (whose terms are substantively identical to the global Distributor Settlement Agreement):

> . . . Attorney General James — in the context of an anticipated upcoming national settlement — negotiated for a change in the way information about opioid orders is collected and employed nationwide. Pursuant to that agreement, McKesson, Cardinal Health, and Amerisource Bergen will implement a new process for collecting and analyzing data about opioid orders received by the other companies through the creation of a groundbreaking clearinghouse, operating under the oversight of an independent third-party monitor. Specifically, this clearinghouse will pool data from the three distributors in order to allow consistent and aggregated data analysis — giving each distributor the ability to account for their own opioid shipments, while simultaneously accounting for the shipments of the other distributors. Additionally, the clearinghouse will use the distributors' collective data to establish pharmacy-specific opioid shipment limits that each distributor must follow.

[13] The Distributor Settlement Agreement, last updated on December 23, 2021, is available here: https://nationalopioidsettlement.com/wp-content/uploads/2021/12/Final-Distributor-Settlement-Agreement-12.23.21_Exhibit-Updates.pdf (last visited Jan. 16, 2022). Exhibit P to the Distributor Settlement Agreement contains Injunctive Terms, to which the parties have agreed.

[14] Section XVII of Exhibit P (at page P-24) relates to the creation of the clearinghouse.

> This system will enable, for the first time, a truer picture of overall opioids distribution across the nation and will require drug distributors to alter their shipments based on the shipments of other distributors.[15]

11.37 As the Settlement Agreement notes, it is the goal of the parties "for the Clearinghouse to obtain comprehensive data from all distributors, pharmacies, and other relevant data sources to provide maximum permissible transparency into the distribution and dispensing of Controlled Substances."[16] And, significantly, this endeavor envisions the expansion of the clearinghouse to include companies other than the parties to the Settlement Agreement. Specifically, in a second phase of the project, there will be a "focus on increasing data collection from non-[parties to the Settlement Agreement], pharmacies and other data sources . . . ."[17]

11.38 Industry-wide data aggregation offers great promise for more accurate, timely, and effective anti-diversion efforts, and presents an opportunity for both Mallinckrodt and its peers—at all stages of the supply chain—to collaborate in an unprecedented way to halt diversion. The Monitor encourages Mallinckrodt to actively explore such opportunities.

(ii) Academic studies of clearinghouse concepts

11.39 Mallinckrodt is also following with interest academic research developments into the use of "big data" analytics to enhance anti-diversion efforts. In fact, close to Mallinckrodt's St. Louis, Missouri headquarters, researchers at the John M. Olin School of Business at the Washington University in St. Louis are collaborating with the Brookings Institution to analyze

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[15] *See* Press Release, N.Y. Attorney General, "Attorney General James Reaches $1.1 Billion Agreement with Big Three Distributors to Treat and Prevent Opioid Use in NYS," July 10, 2021, *available at* https://ag.ny.gov/press-release/2021/attorney-general-james-reaches-11-billion-agreement-big-three-distributors-treat (last visited Dec. 31, 2021).

[16] *See* Settlement Agreement § XVII.C.2(a).

[17] *See* Settlement Agreement § XVII.D.

the DEA's ARCOS data in order to develop a predictive algorithm capable of identifying suspicious purchasers of opioids from innocuous purchasers.[18] That such cutting edge research, filled with so much promise, is taking place close to Mallinckrodt's headquarters offers a uniquely convenient opportunity for Mallinckrodt to share its expertise, as well as for Mallinckrodt to learn from the predictive data analytics research of this academic initiative. Mallinckrodt has responded to requests for assistance from the Olin School. The Monitor strongly encourages Mallinckrodt's contributions to these important efforts, from which both Mallinckrodt's and others' anti-diversion efforts are sure to benefit.

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

11.40 The Monitor's Recommendations 2(r), 2(s), and 2(t) addressed the need for enhanced direct customer and downstream registrant due diligence. This included both (1) enhancing direct customer questionnaires and (2) establishing clear "checklist" criteria for reinstatement of downstream registrants following chargeback restrictions.

11.41 ***Recommendations 2(r) and 2(s).*** In response to these recommendations, as previously reported in the Third Monitor Report, Mallinckrodt engaged two third-party consultants to assist with revising its direct customer questionnaires and developing a checklist of requirements for chargeback reinstatement for downstream registrants. After incorporating the due diligence consultants' independent recommendations, Mallinckrodt provided the Monitor

[18] *See* Blog Post, Kurt Greenbaum, "Olin researchers using machine-learning to flag suspicious opioid sales," Aug. 16, 2021, *available at* https://olinblog.wustl.edu/2021/08/olin-researchers-using-machine-learning-to-flag-suspicious-opioid-sales/ (last visited Dec. 31, 2021); *see also* Blog Post, Dean Mark Taylor, "Bellwether grant sparks new Olin-Brookings initiative focused on opioid epidemic," Apr. 7, 2021, *available at* https://olinblog.wustl.edu/2021/04/bellwether-grant-sparks-new-olin-brookings-initiative-focused-on-opioid-epidemic/ (last visited Dec. 31, 2021).

with a revised version of its *Suspicious Order Monitoring Questionnaire* for distributor direct customers (referred to here as the "Questionnaire") and its newly drafted *Requirements for 3rd Party Assessment for Chargeback Reinstatement Requests* (referred to here as the "Reinstatement Checklist").

11.42 ***The revised Questionnaire.*** The revised Questionnaire is significantly longer and more detailed than Mallinckrodt's prior version. The Questionnaire requests, among other things, information related to the distributor's business, generally, and a number of other areas of inquiry, including, but not limited to the distributor's: (1) DEA and government inspections; (2) court ordered or agreed-upon compliance obligations; (3) compliance with state and federal law; (4) suspicious order monitoring program; and (5) customers and customer due diligence. The revisions to the Questionnaire are designed to elicit more valuable information regarding not just the distributor and its practices and procedures, but also those of the distributor's customers.

11.43 The Monitor recommended—and Mallinckrodt agreed—that Mallinckrodt should revise the Questionnaire to: (1) request copies of any findings by the DEA or other government agency, instead of asking the customer to describe them; (2) inquire whether the customer has been the subject or target of a government investigation related to compliance with legal obligations involving controlled substances; and (3) include more targeted questions regarding the distributor's due diligence process for its customers, including due diligence visits and analysis of customer's dispensing data.

11.44 Mallinckrodt intends to carry through the changes to its distributor customer questionnaire to its questionnaires for other types of customers such as manufacturers, narcotic treatment programs, and laboratories.

11.45 Finally, the Monitor Team observed that in some instances direct customers responded "yes" to a question on the direct customer due diligence questionnaires regarding whether the DEA had made any findings as a result of the DEA's last inspection. While the *Suspicious Order Monitoring Program Review of Direct Customer Orders* SOP required Mallinckrodt's Customer Data Integrity Group ("CDIG") to escalate any "SOM Questionnaire response that contains a 'no' response or additional write-in information" to the SOMT, the SOP did not require a "yes" response to be forwarded to the SOMT for further review. In response to the Monitor Team's inquiry, Mallinckrodt determined that three questionnaires with a "yes" response to the DEA findings question had not been shared with Controlled Substances Compliance and that those questionnaires should be reviewed by the SOMT going forward. Upon further investigation, Mallinckrodt learned that one "yes" response was due to a misunderstanding of a question that may have created ambiguity. As a result, Mallinckrodt is taking four remedial steps: (1) determining the basis for the "yes" responses to the question regarding DEA findings; (2) requiring that all questionnaires be reviewed by the SOMT to identify any relevant issues or responses; (3) revising the questionnaires to remove any ambiguity; and (4) modifying the *Suspicious Order Monitoring Program Review of Direct Customer Orders* SOP to reflect the change in procedure.

11.46 ***The revised Reinstatement Checklist.*** Unlike the updated Questionnaire, the Reinstatement Checklist is an entirely new document drafted at the Monitor's recommendation, standardizing the information and practices Mallinckrodt will evaluate when considering a chargeback reinstatement request. Since Mallinckrodt did not previously have a standard list of factors that should be reviewed to analyze any downstream registrant's chargeback reinstatement request, the Monitor observed that this produced inconsistency in the degree of rigor observed in

those reports, and in both the breadth and depth of what they covered—*i.e.*, both in terms of topics covered, as well as the level of detail included. The Reinstatement Checklist will provide greater clarity to the independent consultants and pharmacies regarding Mallinckrodt's requirements for chargeback reinstatement. Moreover, more substantive diligence reports will provide Mallinckrodt with greater information regarding its downstream registrants, enhancing Mallinckrodt's SOM abilities.

11.47 The Reinstatement Checklist sets forth "minimum requirements" for any due diligence report submitted in connection with a chargeback reinstatement request, and it outlines, in detail: (1) a number of due diligence tasks that must be conducted; and (2) different categories of information Mallinckrodt requires the report to present and analyze. Specifically, the Reinstatement Checklist requires the report to include information related to licensing and registration, location, the pharmacy's customers and distributors, prescription / dispensing data, pharmacy guidance and training, and security and storage.

11.48 The Monitor recommended that Mallinckrodt revise the Reinstatement Checklist to: (1) identify certain due diligence tasks with greater specificity, such as the types of searches the consultant should review to ascertain whether there are any disciplinary or criminal proceedings against the pharmacy, the pharmacists, or the pharmacy technicians; (2) request certain information to be provided with the report, such as the pharmacy's on-boarding questionnaire from its distributor and any DEA findings; and (3) require the consultant to analyze additional "red flags" and prescription / dispensing data metrics.

11.49 ***Recommendation 2(t).*** The Monitor also recommended that Mallinckrodt "establish[] regularly scheduled interactions with direct customers." Accordingly, Mallinckrodt revised its *Suspicious Order Monitoring Program Review of Direct Customer Orders* SOP to

require the SOMT to conduct due diligence visits with one of the three largest distributors and at least six other direct customers every year.

11.50 The Director of Controlled Substances Compliance explained that the SOMT intends to prioritize visits with newer direct customers. Mallinckrodt shared with the Monitor a list of seven distributors it intends to visit in 2022. These include one of the three largest distributors and four new direct customers. While the Director would prefer to visit the distributors in person, the visits may take place virtually given the ongoing COVID-19 pandemic.

11.51 The Director also indicated Mallinckrodt is preparing a checklist the SOMT will use during these visits. The Monitor has requested a copy of the final version of that checklist and any reports the SOMT generates from those visits.

11.52 Finally, the Monitor discussed with the Director a topic raised in the Third Monitor Report, namely: "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." *See* Third Monitor Report ¶ 11.13. The Director noted that in the event of a second instance requiring the termination of another rogue employee, the SOMT would inevitably review the pharmacy's prior history, and at that time any systemic shortcomings in the pharmacy's procedures would be apparent. This has some persuasive force. Consequently, the Monitor does not see a need for further investigation of pharmacies with rogue employee issues at this time.

(f) Recommendations related to changes to Mallinckrodt's SOM policies

11.53 The Monitor's Recommendations 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) have been implemented with appropriate revisions.

(g) Recommendation related to changes to Mallinckrodt's social media review

(i) Results of media comparison analysis

11.54 In Recommendation 2(u), the Monitor recommended that Mallinckrodt "[e]xplore options for making media review more effective." Accordingly, Mallinckrodt's outside counsel retained the services of two media companies to analyze news "hits" generated in response to search terms provided by Mallinckrodt. The purpose of the analysis was to compare results generated by the two media companies with those of Mallinckrodt's current media search mechanism, which utilizes a free Google news search. Counsel's analysis determined that the two media companies, in addition to Mallinckrodt's current Google news search, produced a total of 1,425 media hits, covering print, radio, and television reports, in September 2021. Specifically, Google returned 840 results (59%), while the two media companies returned 483 (34%) and 102 (7%).

11.55 For purposes of the analysis, counsel defined "responsive" hits among the total 1,425 results as news results providing "actionable information about particular pharmacies or pharmacists that were reportedly engaged in suspicious or potentially unlawful drug-related activity." Of the 1,425 total results, 24 were deemed "responsive." Of the three providers, Google searches resulted in the most responsive hits, with 21 of the 24 responsive (88%).

11.56 The discovery of only 21 responsive Google hits among a group of 840 Google results (an accuracy rate of 2.5%) suggests that Mallinckrodt may be able to refine its Google search criteria in order to generate more accurate results. Mallinckrodt will seek to identify more refined and / or more complex search terms, along with more tailored natural language searches in order to improve the current 2.5% accuracy rate.

11.57 Given the overall more responsive hits of the Google search, however, Mallinckrodt is persuaded that its existing Google searches are currently the best available option to identify news reports likely to prompt a chargeback restriction review. Nonetheless, the Google search's failure to identify 3 of the 24 responsive articles has prompted Mallinckrodt to consider how its search can improve its responsiveness rate.[19]

11.58 The Monitor looks forward to receiving an update form Mallinckrodt regarding its efforts to improve both search accuracy and responsiveness, and the results of its refinements.

(ii) The Monitor's ad hoc testing of Mallinckrodt's media review

11.59 During the Fourth Reporting Period, the Monitor had an opportunity to test Mallinckrodt's media review, and was pleased to be able to confirm, on an ad hoc basis, that Mallinckrodt's search methods appear to be flagging notable media reports regarding suspicious downstream customers in real time. On November 2, 2021, the Monitor team identified a U.S. Department of Justice press release noting court action against WeCare pharmacy.[20] The

[19] Of the three articles the Google search failed to detect, Mallinckrodt's counsel viewed one as only marginally responsive, as it related to prior litigation involving a chain's retail pharmacies generally, not any new investigation or particular pharmacy location.

[20] *See* Press Release, U.S. Dep't of Justice, "Federal Court Orders Tampa Pharmacy to Close in Case Alleging Unlawful Opioid Distribution," Nov. 1, 2021, *available at* https://www.justice.gov/opa/pr/federal-court-orders-tampa-pharmacy-close-case-alleging-unlawful-opioid-distribution.

Monitor contacted the Director of Controlled Substances Compliance to determine whether the pharmacy was a downstream registrant. The Monitor received a prompt response from the Director noting that WeCare was a downstream registrant that Mallinckrodt had previously restricted based on chargeback review. The Director further noted—without prompting from the Monitor regarding the press release—that Mallinckrodt's routine media review had identified the press release. This prompt response to the Monitor's random inquiry gives the Monitor confidence that Mallinckrodt's processes and systems of review of relevant media items of relevance are working effectively.

11.60 The Monitor encourages the SOMT, and in particular the LCSCC, to remain vigilant in their reviews for additional potential search terms that could make the current search even more robust. This could be added to the Chargeback Review Checklist and / or to a checkbox on the "cover sheet" for chargeback reviews.

2. Monitor's Meeting with the OCC

11.61 As noted above, on November 1, 2021, the Monitor met remotely with members of the OCC. During that meeting, the Monitor provided his assessment of Mallinckrodt's cooperation and assistance to the Monitor to date. The Monitor's previous discussion of documents reviewed at the OCC's request appears in the Third Monitor Report. *See* Third Monitor Report ¶ 11.15.

3. Restriction (and subsequent reinstatement) of API Purchaser

11.62 Shortly before the Monitor filed the Third Monitor Report, Mallinckrodt informed the Monitor of Mallinckrodt's unusual restriction of a number of direct customers.[21]

[21] Unusual, because Mallinckrodt more typically imposes restrictions due to suspicious activity or media coverage related to ***indirect*** customers (*i.e.*, downstream registrants), which are most frequently pharmacies, not direct customers.

Mallinckrodt, through its Google news alert media review (discussed *supra*), had learned of immediate suspension orders the DEA issued to two of Mallinckrodt's direct customers on August 11, 2021.[22] Those included Woodfield Distribution, LLC and Woodfield Pharmaceuticals, LLC. On September 3, 2021, Mallinckrodt imposed chargeback restrictions for these direct customers (a manufacturer and distributor in Texas), as well as a related distributor in Florida that DEA had not suspended.

11.63 Subsequently, Mallinckrodt learned that a direct customer, which is a "virtual manufacturer" and API purchaser (the "Purchaser"), although not itself a DEA registrant, had previously arranged for the API to be delivered to a DEA registered dosage form manufacturer who distributed the finished product to a DEA registered third-party logistics firm for distribution to pharmacies. Among the manufacturers / distributors Purchaser supplied were the Woodfield companies.

11.64 After Purchaser made a series of requests to Mallinckrodt to supply Purchaser or others with Levorphanol 2 mg, a Schedule II controlled substance (including an unusually large quantity that Purchaser requested Mallinckrodt deliver directly to a pharmacy, which Mallinckrodt could not do under the terms of the Operating Injunction[23]), Mallinckrodt asked a series of probing questions of Purchaser's representatives regarding their SOM program.

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[22] Press Release, U.S. Drug Enforcement Admin., "DEA Houston Serves ISO on Woodfield Pharmaceuticals & Distribution," Aug. 11, 2021, *available at* https://www.dea.gov/press-releases/2021/08/11/dea-houston-serves-iso-woodfield-pharmaceuticals-distribution (last visited Dec. 30, 2021). The press release states that "DEA discovered that Woodfield Distribution, LLC., located in Sugar Land, Texas, violated several DEA regulations, by routinely storing millions of controlled substances in unsecured warehouse aisles, failing to report controlled substance thefts and losses, and falsifying records."

[23] *See* Operating Injunction § III.G.4 ("Mallinckrodt agrees that it will refrain from providing an Opioid Product directly to a retail pharmacy location or Health Care Provider.").

Ultimately, Mallinckrodt could not get comfortable with the state of Purchaser's due diligence or SOM protocols at that time. This, along with the fact that Purchaser sought Levorphanol to replace the supply DEA had seized from the Woodfield entities, led Mallinckrodt to restrict Purchaser's direct orders and report the restriction to DEA. Although the definition of Opioid Products in the Operating Injunction has a carveout for API that Mallinckrodt could arguably have applied to this situation,[24] Mallinckrodt instead acted to impose the restrictions.

11.65 More recently, Mallinckrodt has gained comfort from a number of steps taken to reassure Mallinckrodt of Purchaser's SOM standards. These include: (1) Purchaser's retention of experienced outside regulatory counsel; (2) Purchaser's retention of a third-party compliance consultant for a two-year period (during which time Mallinckrodt, and the Monitor, will be able to review quarterly compliance reports); (3) Purchaser's agreement to replace its prior third-party logistics vendor with one of the well-established "big three" distributors, who is well known to Mallinckrodt (and will itself be subject to injunctive terms and monitorship as a result of the distributor settlement discussed *supra*); and (4) Purchaser's agreement to these and other requirements in revised contract terms required by Mallinckrodt, which terms were shared with the Monitor (in draft form). The contract terms include, for example, significant anti-diversion obligations, including those the Monitor has previously recommended Mallinckrodt seek to establish with other direct customers, such as not directing Mallinckrodt product to restricted

[24] *See* Operating Injunction § I.Q ("The term 'Opioid Products(s)' shall not include . . . 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."). Here, the exclusion of API applies only when such API is "sold or marketed exclusively ***to DEA registrants***," and so the fact that Purchaser is not a DEA registrant suggests the exclusion would not apply. In any event, Mallinckrodt called this matter to the Monitor's attention and acted promptly to address it by imposing chargeback restrictions and notifying DEA.

pharmacies, advising Mallinckrodt when Purchaser itself restricts a downstream customer, and sharing information with Mallinckrodt that will be reviewable by the Monitor.

11.66 In sum, these are robust measures that, collectively, give the Monitor confidence in Mallinckrodt's ability to maintain oversight over its supply to Purchaser, and of the Monitor's ability to verify and monitor such compliance.

4. SOM-related Items in the Audit Plan

11.67 As noted above, the Monitor and Mallinckrodt have agreed in principle to an Audit Plan for the remainder of the monitorship, although the plan is subject to further refinement. This Plan requires Mallinckrodt to produce various documents and data sets at agreed-upon time intervals. As relevant to this section of the Report, several of these items relate to SOM issues.

11.68 The Monitor developed the SOM-related portion of the Audit Plan after reviewing and analyzing the voluminous SOM-related documents and data Mallinckrodt produced during the first four reporting periods. On the basis of this review and analysis, the Monitor has identified what he believes to be the most salient documents and data to focus the Monitor's auditing of Mallinckrodt's compliance with Section G of the Operating Injunction.

11.69 By way of example, among the SOM-related information the Monitor seeks under the Audit Plan, and the cadence for Mallinckrodt's production of that information, is the following:[25]

(a) ***On an annual basis.*** Annually, Mallinckrodt will provide: (1) a schedule of chargeback reinstatement reviews for the upcoming year; (2) sales data for SpecGx Opioid Products; (3) the schedule of Mallinckrodt's audits of its direct customers and any reports generated in connection therewith; (4) if changed or updated, the list of independent consultants Mallinckrodt

[25] As noted above, Mallinckrodt agrees to the Plan in principle, although it is subject to further refinement.

provides to direct customers and / or downstream registrants for use in connection with chargeback reinstatement requests; and (5) the list of search terms Mallinckrodt uses for its social media reviews of direct customers and downstream registrants. Mallinckrodt will also advise the Monitor of the results of its review of the SOM algorithms and any changes thereto.

(b) ***On a quarterly basis.*** Quarterly, Mallinckrodt will provide: (1) its government correspondence log; (2) a summary of all downstream customers that were reviewed by the LCSCC due to exceeding an order threshold but that were not reviewed by the SOMT in the prior quarter; (3) data related to direct customer orders; and (4) reports of the API Purchaser's compliance consultants. Mallinckrodt will also meet with the Monitor to discuss its progress on implementing his recommendations.

(c) ***On a monthly basis.*** Monthly, Mallinckrodt will provide: (1) the SOMT meeting materials and minutes; (2) materials related to, the reason for, and the outcome of any ad hoc reviews; (3) an updated version of the Excel spreadsheet tracking the length of time for the SOMT's completion of its chargeback restriction reviews.

(d) ***As soon as reasonably possible.*** As soon as reasonably possible, Mallinckrodt will provide: (1) any revised SOM-related SOPs; (2) the LCSCC's periodic chargeback reviews; and (3) any requests from a State Attorney General or State controlled substances regulatory agency concerning direct or downstream customers.

11.70 Of course, the Audit Plan does not limit the Monitor's ability to request additional documents and data within the scope of his work, as necessary, based on, among other things, his review of the documents obtained in each reporting period and other work of the monitorship.

5. Data and Documents Reviewed in the Fourth Monitoring Period

11.71 During the Fourth Monitoring Period, the Monitor continued his review of Mallinckrodt's voluminous production of documents in response to prior requests. Mallinckrodt supplemented its productions with up-to-date documents and data over the past 90 days, as the Monitor requested. The categories of information Mallinckrodt produced are summarized in ¶ 11.26 of the Third Monitoring Report.

11.72 In addition, Mallinckrodt also produced:

(a) its letter to the DEA concerning Purchaser, discussed *supra*;

(b) its proposed letter agreement for distributors, discussed *supra*;

(c) the list of seven distributors it intends to visit in 2022;

(d) the results of its media monitoring comparison analysis, explained *supra*;

(e) drafts of its revised SOM Questionnaire for distributor customers and its chargeback Reinstatement Checklist;

(f) an updated chart tracking its implementation of the Monitor's recommendations;

(g) an Excel spreadsheet tracking the timing of the SOMT's chargeback restriction reviews;

(h) the updated list of independent consultants Mallinckrodt provides to direct customers and downstream registrants in connection with chargeback reinstatement requests; and

(i) documents related to the initiative between Washington University in St. Louis and the Brookings Institution, the Olin-Brookings Commission, whose members will analyze how new technologies can curb opioid trafficking and issue policy recommendations based on their findings.

11.73 The Monitor will review and analyze the materials Mallinckrodt produces under the Audit Plan and share the results of that review in the next Report.

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 of the Operating Injunction requires Mallinckrodt to provide regular training (at least annually) to relevant employees on the obligations the Operating Injunction creates. As previously reported, Mallinckrodt's Operating Injunction training consists of three components: (1) reviewing and certifying compliance with the Operating Injunction for Opioid Business Policy; (2) completing a survey regarding any board service that may violate Section III.C; and (3) attending a live training from an instructor via WebEx.

13.2 As part of the agreed-upon Audit Plan referenced above (*see* ¶ 1.3, *supra*), on a quarterly basis Mallinckrodt will provide a list of: (1) any new employees in the groups identified in Section 5.10 of its Compliance Report; (2) the Operating Injunction-related trainings each employee is required to complete; and (3) the dates of completion.

13.3 As of January 5, 2022, Mallinckrodt identified three newly hired or promoted employees in the Fourth Reporting Period, all three of whom have completed the required Operating Injunction Policy certification and board service survey. Two of the three employees have completed the live Operating Injunction training. The remaining newly hired employee is scheduled to complete the live Operating Injunction training in February 2022.

13.4 Mallinckrodt advised that it tests the 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.

13.5 In order to observe the extent to which live trainings sufficiently test and focus upon employees' retained knowledge of the Operating Injunction, the Monitor is scheduled to attend three live trainings relating to: (1) Controlled Substances Compliance, Security, and Corporate Compliance; (2) Government Affairs; and (3) Commercial, Business Development and Licensing. After attending these live trainings, the Monitor will 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, making recommendations in the next Report, if necessary.

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.[26] 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 Fourth Monitor Report, there have still been no requests for access to this data. Mallinckrodt has agreed to inform the Monitor in the event of any such request.

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

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

15. PUBLIC ACCESS TO MALLINCKRODT'S DOCUMENTS (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 Office of Attorney General 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.

15.3 Mallinckrodt's outside counsel has advised the Monitor that Mallinckrodt has made payments to UCSF and Johns Hopkins consistent with the Bankruptcy Court order authorizing payment, and has worked with the universities and attorneys general to resolve technical and other issues related to the documents.

16. OTHER ISSUES OF NOTE

16.1 During the Fourth Monitoring Period, Mallinckrodt informed the Monitor of the terminations of a number of senior SpecGx executives as part of a reorganization and reduction in workforce. These include the termination of (1) the SpecGx Vice President and General Counsel; (2) the SpecGx Vice President of Global Security; (3) the SpecGx Vice President, Commercial; (4) the SpecGx Senior Director, Government Affairs; and (5) the SpecGx Director of Digital Communications and Community Relations. Each of these individuals have been interviewed by the Monitor, and two of them (SpecGx's Vice President and General Counsel, and its Vice President of Global Security) were senior and long-time members of the SOMT.

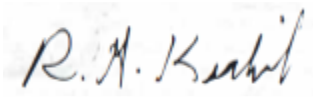
16.2 The Monitor looks forward to learning how the responsibilities of these individuals will be distributed, and will seek to confirm that sufficient resources are dedicated to continuing to manage their functions, and that none of these human resources changes will adversely affect Mallinckrodt's compliance with the Operating Injunction.

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 Fourth Monitor Report.



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

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EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE FOURTH MONITOR REPORT – FILED JANUARY 19, 2022)

I. FIRST MONITOR REPORT (4/26/2021)

No recommendations.

II. SECOND MONITOR REPORT (7/23/2021)

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)		
1.	**2(a)**	Modernize and enhance the SOM function using big data analytics, artificial intelligence, and automated processes and algorithms.
2.	**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.
3.	**2(c)**	Consider the sufficiency of both short-term and long-term human resource allocation in the SOM function.
4.	**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.
5.	**2(e)**	Use best efforts to obtain timely provision of chargeback data from direct customers.
6.	**2(f)**	Evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data.
7.	**2(g)**	After analyzing turnaround times for chargeback reviews and restrictions, amend relevant SOPs to memorialize firm timelines.
8.	**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.
9.	**2(i)**	Assess the potential value of additional factors to consider in conducting chargeback reviews.

10.	**2(j)**	Continue actively pursuing opportunity for a public-private "clearinghouse" concept, in collaboration with the U.S. Drug Enforcement Administration and industry partners.
11.	**2(k)**	Amend relevant SOPs to create a chargeback review task checklist, provide an audit trial, and ensure second-level review and approval.
12.	**2(l)**	Memorialize and routinize the periodic review of (1) pharmacies reviewed but not restricted, and (2) pharmacies that are reinstated.
13.	**2(m)**	Re-evaluate direct customer order thresholds with the assistance of Analysis Group, Inc. (AGI).
14.	**2(n)**	Re-evaluate chargeback thresholds with the assistance of AGI.
15.	**2(o)**	Determine whether flagging and releasing direct customer orders can be refined to better identify potentially suspicious orders, in collaboration with AGI.
16.	**2(p)**	Implement two-level review and approval for release of flagged orders.
17.	**2(q)**	Memorialize the confidentiality of thresholds, consistent with current practice.
18.	**2(r)**	Establish minimum standards and criteria for conducting retail pharmacy due diligence, potentially with the advice and input of a third-party compliance consultant.
19.	**2(s)**	Revise direct customer questionnaires to yield helpful, actionable, and verifiable information and determine a method for sampling or randomly auditing questionnaires.
20.	**2(t)**	Establish regularly scheduled interactions with direct customers.
21.	**2(u)**	Explore options for making media review more effective.

III. THIRD MONITOR REPORT (10/21/2021)

Section 6 – Ban on Promotion (OI § III.A)		
22.	**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.
Section 9 – Lobbying Restrictions (OI § III.D)		
23.	**3(b)**	Ensure all external lobbyists performing work on Mallinckrodt's behalf have executed an Acknowledgment and Certification of Compliance with SpecGx Lobbying Restrictions, certifying compliance with the Operating Injunction.
24.	**3(c)**	Implement a process by which Mallinckrodt reviews and audits its external lobbyists' publicly filed state and federal activity reports to ensure information contained in the reports accurately reflects the lobbyists' communications with Mallinckrodt and the company's stated priorities.

IV. FOURTH MONITOR REPORT (1/19/2022)

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)		
25.	**4(a)**	Collect data regarding time intervals at each stage of chargeback restriction review in order to permit both Mallinckrodt and the Monitor to analyze, in a more granular way, the sources of time lags and what, if anything, can (or should) be done to reduce them.
26.	**4(b)**	Supplement the chargeback review checklist with a checkbox for the reviewer to confirm that research was conducted to determine whether a pharmacy subject to restriction is related to other co-owned pharmacies and incorporate that checklist into the chargeback review cover sheet.

File a Court document:

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

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

U.S. Bankruptcy Court

District of Delaware

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Case Name: Mallinckrodt plc v. State of Connecticut et al
Case Number: 20-50850-JTD
Document Number: 307

Docket Text:
Exhibit(s) *(Fourth Report of R. Gil Kerlikowske, Independent Court-Appointed Monitor for Mallinckrodt LLC, Mallinckrodt Enterperises 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:W:\BJW\MNK - 4th Mallinckrodt Monitor Report (20-50850).PDF
Electronic document Stamp:
[STAMP bkecfStamp_ID=983460418 [Date=1/19/2022] [FileNumber=17408596-0
] [77db57a6de2621174a07c5eb522c5211db662fbbd273dcf8ef2bee7a77b081fe4da
d4961202b31c1be96cd75d7aeb364572a6e6b5474b4e76defa1d4ac344e0d]]

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

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