UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

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

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

April 19, 2022

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FIFTH 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 Fifth Monitor Report covers the period from the filing of the Fourth Monitor Report on January 19, 2022, to the present (the "Fifth Reporting Period"). The Fifth Monitor Report: (1) provides an update on Mallinckrodt's implementation of the Monitor's recommendations in prior Reports; (2) reviews the Monitor's actions during the Fifth 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—appears in the chart attached as **Exhibit 1**. 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).

1.3 During the Fifth Reporting Period, the Monitor reviewed Mallinckrodt's compliance with the Operating Injunction by reviewing documents Mallinckrodt produced in response to the Monitor's Audit Plan requests and conducting interviews. *See* Fourth Monitor Report ¶ 1.3. The Audit Plan includes requests for documents and data related to each section of the Operating Injunction and requires Mallinckrodt to produce documents at different time intervals (*i.e.*, annually, quarterly, monthly, and "as needed"). In response to the Audit Plan and the Monitor's ad hoc requests, Mallinckrodt provided over 129 files (consisting of 156 MB of documents and data), during the Fifth Reporting Period.

1.4 As previously reported, this Court's confirmation hearing to consider approval of the reorganization plan began on or about November 1, 2021 and concluded on or about January 6, 2022. The Court confirmed the plan in an opinion issued on or about February 3, 2022. *See* Dkt. No. 6347. As Mallinckrodt announced at the time of this Court's confirmation of the bankruptcy plan, the next step in Mallinckrodt's reorganization was for "the Directors of Mallinckrodt . . . to make certain filings to commence Examinership Proceedings in Ireland, which are required to implement certain Irish law aspects of the reorganization and allow for

emergence" from bankruptcy.[1] Mallinckrodt predicted "the Irish Examinership Proceedings to take approximately 100 days" and that Mallinckrodt would "formally emerge from Chapter 11 in the first half of 2022, following the completion of the Examinership Proceedings and once all conditions of the Plan are effective."[2]

1.5 During this time, there were a number of personnel terminations that occurred due to a reduction in force in connection with corporate restructuring. Some of those employee departures were identified in the Fourth Monitor Report (*see* ¶ 16.1), and changes in Mallinckrodt's personnel as a result of this restructuring are further discussed in Sections 6 (Ban on Promotion) and 14 (Other Issues of Note).

1.6 On January 20, 2022, the Monitor held a meeting with the Official Committee of Opioid Related Claimants (the "OCC") to discuss topics including the Fourth Monitor Report, recent departures from Mallinckrodt, and the ensuing personnel reorganization.

1.7 As previously noted, the Monitor has expressed the hope of engaging in more in-person interactions with Mallinckrodt's personnel. Following the delays caused by various Coronavirus ("COVID-19") variants, the Monitor has scheduled an initial site visit and meeting

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[1] *See* Press Release, "Mallinckrodt Plan of Reorganization Confirmed by U.S. Court," available at: https://www.mallinckrodt.com/about/news-and-media/news-detail/?id=28836. The bankruptcy 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.* § II.D ("The provisions of this Agreement that apply to the OCC shall no longer apply upon the effectiveness of a Chapter 11 Plan."); *id.* § VI.B.2.b ("The frequency of Monitor Reports may decrease to every 180 days after the Effective Date.").

[2] *See* Press Release, "Mallinckrodt Plan of Reorganization Confirmed by U.S. Court," available at: https://www.mallinckrodt.com/about/news-and-media/news-detail/?id=28836.

with Mallinckrodt personnel in May, at Mallinckrodt's St. Louis office. The Monitor intends to conduct a site visit at Mallinckrodt's Hobart, New York location in the late summer. In the meantime, the Monitor continues to benefit from the convenience of remote meetings with Mallinckrodt personnel and its consultants and outside counsel.

1.8 Mallinckrodt's employees, counsel, and consultants continue to be responsive, cooperative, and helpful to the Monitor. Based on the information reviewed to date, the Monitor believes that Mallinckrodt continues to make a good faith effort to comply with the terms and conditions of the Operating Injunction, as defined below. The Monitor is pleased with the progress Mallinckrodt has made on various fronts, with the improvements to Mallinckrodt's systems and processes, and with the tangible results these improvements have produced. Examples are discussed in further detail 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* Case No. 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* Adv. Pro. No. 20-50850, Dkt. No. 196-1. A copy of the Operating Injunction is attached as Exhibit 1 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 Court entered the order appointing the Monitor on February 8, 2021. 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 following the Monitor's appointment. *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 twenty-one 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),

3.4 ***The Fourth Monitor Report.*** The Monitor submitted the Fourth Monitor Report on January 19, 2022. *See* Case No. 20-12522, Dkt. No. 6185; Adv. Pro. No. 20-50850, Dkt. No. 307. There the Monitor provided an overview of his "scoping" and assessment activities during the first year of the Monitorship, which resulted in twenty-six recommendations in his first four reports, including his additional recommendations in the Fourth Monitor Report related to SOM compliance (*id.* § III.G). All of the Monitor's recommendations to date were detailed in an exhibit attached thereto. The Monitor also detailed the agreed-upon Audit Plan he developed after reviewing hundreds of documents and conducting dozens of interviews related to all categories of the Operating Injunction during the first four reporting periods. The Audit Plan requires Mallinckrodt to produce documents and data to the Monitor in future monitoring periods to facilitate the Monitor's continued auditing of Mallinckrodt's compliance with the Operating Injunction.

4. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Section 11, *infra*, the Monitor has made two additional recommendations to Mallinckrodt related to its direct customer due diligence and

SOM program. Mallinckrodt has agreed to implement these recommendations.[3] They are:

5(a) Revise the Due Diligence Questionnaire to inquire about relevant persons' criminal backgrounds. *See* ¶ 11.17, *infra*.

5(b) Require restricted direct customers to undertake substantial compliance reforms before reinstatement can occur. *See* ¶ 11.49, *infra*.

5. THE INTEGRITY HOTLINE

5.1 In the Fifth Reporting Period the Monitor received the first alert of a report to the hotline—*i.e.*, an existing anonymous reporting procedure that Mallinckrodt updated to permit the reporting of compliance concerns related to the Operating Injunction directly to the Monitor Team. Further examination revealed that the anonymous reporter withdrew the report without providing any substantive information. Consequently, there was no information to follow up on. Still, the Monitor is encouraged that the framework for such reports appears to be working.

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,[4] Opioid Products, products used for the treatment of Opioid-induced side effects, and the Treatment of Pain in a manner that directly or indirectly encourages the utilization of Opioids or Opioid Products.

6.2 As 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 the Operating Injunction. *See* Mallinckrodt Compliance Report, Adv. Pro. No. 20-50850, Dkt. No. 174-1 (hereafter, "Mallinckrodt Compliance Report") § 4.6.

[3] These recommendations are prefaced by the number "5" to indicate they were made in the Fifth Monitor Report.

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

6.3 Beginning in the last reporting period, and on an on-going basis as part of the agreed-upon Audit Plan, the Monitor receives PRC meeting minutes and promotional materials submitted and approved by the PRC on a quarterly basis. As detailed in the Fourth Report, the Monitor received PRC meeting minutes for the third quarter of 2021 but did not receive the promotional materials reviewed and approved during those meetings. During this Fifth Reporting Period, the Monitor received and reviewed those materials, which included updates to Mallinckrodt's existing product catalogs and a "sell sheet" for a new flavor profile of its Methadose Oral Concentrate product.[5] Based on the Monitor's review, these materials are consistent with Section III.A of the Operating Injunction.

6.4 The PRC met once in the fourth quarter of 2021. The Monitor received and reviewed the minutes of that October 26, 2021 meeting, as well as the promotional item reviewed and approved during the meeting. The meeting, led by the Product Manager of Commercial, was held via video-conference and lasted approximately fifteen minutes, during which time the PRC re-approved an active pharmaceutical ingredient promotional panel for display at the November 2021 CPhI Worldwide meeting in Milan, Italy.[6] Based on the Monitor's review, the convention panels are consistent with Section III.A of the Operating Injunction.[7]

[5] Upon approval by the PRC, the new product sell sheet and related materials are submitted to the FDA's Office of Prescription Drug Promotion pursuant to Mallinckrodt's *Filing Process for Advertising and Promotional Materials* SOP.

[6] A previous iteration of the panel was approved for display at the 2020 CPhI Worldwide meeting in India but the convention was canceled due to the COVID-19 pandemic.

[7] The Specialty Generics Grant & Sponsorship Approval Committee received and approved a separate request for funding of registration fees for the CPhI Worldwide Conference. The Monitor's analysis of those materials is detailed in Section 8 (Ban on Funding / Grants to Third Parties).

6.5 Near the end of the Fifth Reporting Period, the Monitor received PRC meeting minutes and promotional materials for the first quarter of 2022. The Monitor will detail his review and analysis of those materials in the next Report.

6.6 In his Second Monitor Report, the Monitor detailed his interviews of Mallinckrodt's Product Monitoring Team ("PMT") as well as his review of Mallinckrodt's policies related to post-market communications with patients and caregivers. The Monitor described the PMT's operation of a call center for fielding and responding to customer questions and complaints, and the logging of those calls in an internal system called TrackWise. He also noted the absence of a formalized process for periodic review and auditing of the TrackWise logs to confirm that the PMT's responses to customer questions and complaints are consistent with the Operating Injunction and Mallinckrodt's existing policies and procedures.

6.7 In response to this concern, Mallinckrodt developed and implemented a review and auditing protocol, *Auditing Medical Information for Opioid Business Work Instruction*, that tasked the Director of Post-Market Surveillance, or her designee, with reviewing customer inquiries on a monthly basis and evaluating the PMT's responses for compliance with the Operating Injunction. In the Fourth Monitor Report, the Monitor detailed his review and analysis of the first audits conducted pursuant to the new protocol, specifically TrackWise Audit Reports from the months of October, November, and December 2021. Pursuant to the Audit Plan, the Monitor will continue to receive and review these reports on a quarterly basis.

6.8 During the Fifth Reporting Period, Mallinckrodt informed the Monitor that the individual who conducted these initial audits, the Director of Post-Market Surveillance, was terminated as part of a reduction in force. Accordingly, the Monitor interviewed this individual, as well as the Compliance Manager, to: discuss how the Director of Post-Market Surveillance's

responsibilities were to be distributed; discuss what, if any, onboarding was done to prepare that employee's replacement to assume her responsibilities related to the Operating Injunction; and confirm that none of these recent personnel changes would adversely affect Mallinckrodt's compliance with the Operating Injunction. While the departed Director told the Monitor that no formal transfer of knowledge of the TrackWise audit process to her replacement had taken place, both she and the Compliance Manager expressed confidence in the designated replacement (an individual who was the Director's former supervisor) and her ability to take over the auditing process. The Monitor will continue to assess these transition efforts during the next reporting period.

6.9 In his interview with the former Director of Post Market Surveillance, the Monitor also discussed his review and analysis of the first set of TrackWise Audit Reports. In the meeting, the Monitor learned of a third-party vendor that Mallinckrodt utilizes (in addition to the PMT) to field customer inquiries and complaints on an as-needed basis due to high volume. The Director indicated that she reviewed this vendor's reports as part of her TrackWise audit process and documentation. However, the auditing protocol is silent as to the third-party vendor's role in Mallinckrodt's post-market communications. The Monitor has requested and anticipates reviewing the reports from this vendor, as well as any training related to the Operating Injunction provided to this vendor's employees, during the next reporting period, to ensure that these third-party employees also understand the Operating Injunction's terms and obligations when responding to customer inquiries and complaints.[8]

[8] As detailed in the Fourth Monitor Report, the TrackWise Audit Reports revealed two entries that warranted corrective action or refresher training including one instance in which the call-taker responded to a pharmacist's questions regarding whether a non-Mallinckrodt opioid product could be crushed. *See* Fourth Monitor Report ¶ 6.7. The Monitor has since learned that the call-taker was an employee of the third-party vendor and not a PMT member.

6.10 Mallinckrodt's newly-implemented auditing protocol is limited to the review and auditing of TrackWise customer inquiries and does not address the review and auditing of TrackWise customer complaint data, which the Monitor learned is logged separately from customer inquiries. During the Fifth Reporting Period, the Monitor reviewed historical TrackWise complaint data received by the PMT between October 2020 and December 2021.[9] The bulk of the complaint entries, which are categorized and coded according to type, related to defects in patch adhesives, broken tablets, and similar issues that were not pertinent to the duties and work of the Monitor.

6.11 The Monitor also reviewed the *TrackWise Complaint Entry and Processing Work Instruction* that "describe[s] expectations for entering data in the TrackWise Complaints Module including initiation, investigation, review, and closure." This work instruction references a number of SOPs and attachments pertaining to the handling of complaints, including two SOPs titled *Product Complaint Handling - Drug Products* and *Elevated Issue Management Notification Process - Product Monitoring* that detail the factors relied upon to determine whether a complaint, such as those related to suspected product tampering or counterfeiting, should be escalated.[10] The Monitor has requested these SOPs and attachments and anticipates reporting the results of his analysis during the next reporting period.

[9] Although the Monitor previously requested TrackWise inquiry and complaint data, he did not receive complaint data in time for substantive review during the Fourth Reporting Period.

[10] The Monitor's review of historical TrackWise complaint data revealed that less than one percent of the more than 7,000 product complaints received during that period were escalated to management for further review or action.

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." The Monitor previously reviewed Mallinckrodt's Field Sales Compensation Plan for 2021 ("FSCP"), and conducted an interview of Mallinckrodt's then-Vice President of Commercial to confirm that the FSCP was consistent with the Operating Injunction's requirements. *See* Second Monitor Report ¶¶ 7.2-7.5.

7.2 The Audit Plan requires Mallinckrodt, annually, to produce to the Monitor updates to its sales compensation plans. Mallinckrodt produced to the Monitor, on or about April 8, 2022 (when it was finalized by the company), updated sales compensation information for 2022. In the Sixth Reporting Period the Monitor will closely review these materials and conduct any necessary interviews to confirm Mallinckrodt's continued compliance with Section III.B.1 of the Operating Injunction.

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 Mallinckrodt's Compliance Report, the Specialty Generics Grant and Sponsorship Approval Committee ("SGGSAC" or "the Committee") reviews and approves

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 Fifth Reporting Period, the Monitor reviewed the minutes of two ad hoc meetings, which took place on November 3, 2021 and December 15, 2021, as well as the accompanying 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 November 3, 2021, the Committee convened via video conference and voted to approve an $88,000 attendance fee for the 2021 CPhI Worldwide Conference and a $15,000 sponsorship of the Coalition of Medication-Assisted Treatment Providers and Advocates of New York State.

8.5 The 2021 CPhI Worldwide Conference is a large global pharmaceutical trade show held annually in Europe, which attracts individuals and companies from across the industry. According to the Request Form (dated November 2, 2021) and accompanying materials, the conference was scheduled to occur from November 9-11, 2021 in Milan, Italy. The materials reviewed by the Monitor also indicated that Mallinckrodt had already paid the attendance fee before the Request was submitted to the Committee, with $44,000 paid in 2020, which was rolled over to 2021 when the Conference was canceled due to the ongoing COVID-19 pandemic, and an additional $44,000 paid in late August or early September 2021. Further, the materials indicated that Mallinckrodt would face a significant financial penalty for canceling its attendance so close to the event date, with a slide in a presentation to the Committee stating: "Cost of cancellation is high for SpecGX (approx. $88K of which $44K new spend)."

8.6 Based on his review of these materials, the Monitor is concerned as to the cancellation penalty's potential impact on the Committee's independent deliberative process. Although the SGGSAC's operating policy does not include a temporal requirement for submission of Request Forms, the SOP does require that decisions to cancel or change the scope of a funded activity be communicated to the Committee within 30 days of the activity. The request here, submitted for consideration one week before the conference began and months after the attendance fee was already paid, does not appear consistent with the policy's goal of ensuring compliance with Section III.C of the Operating Injunction. In the next reporting period, the Monitor will meet with SGGSAC members who approved the request to further discuss the process and the potential necessity of incorporating a timing requirement into the SGGSAC operating policy.

8.7 During its November 2021 meeting, the Committee also approved a corporate membership in the Coalition of Medication-Assisted Treatment Providers and Advocates of New York State ("COMPA"). COMPA is a non-profit membership organization dedicated to treating addiction through the use of pharmacotherapy. 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 the Operating Injunction and the SGGSAC SOP.

8.8 On December 15, 2021, the Committee convened via video conference and voted to approve a $3,295 sponsorship for an exhibit booth at the American Correctional Association 2022 Winter Conference. The sponsorship also covered registration for two Mallinckrodt employees. This conference was scheduled to take place in Phoenix, Arizona from January 6-9, 2022, and featured a variety of presentations on topics relevant to correctional institutions, including inmate healthcare. Mallinckrodt sought to attend the conference to bring awareness of

its addiction treatment products to potential customers in the correctional space. 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.

8.9 During the Fifth Reporting Period, the Monitor also spoke with the Compliance Manager, a member of the SGGSAC, to gain a better understanding of the Committee's expanded authority to consider and approve conference registration and attendance fees. The Compliance Manager explained that the SGGSAC determined that conference registration fees essentially "funded" a third-party, even if they did not constitute a formal sponsorship, and therefore decided to vet these fees for compliance with the Operating Injunction through the SGGSAC review process. The Monitor commends Mallinckrodt for this proactive step in maintaining compliance with its obligations under the Operating Injunction.

8.10 Through this interview, the Monitor also sought to discern whether, and to what extent, such conference registration requests implicate the Operating Injunction's Ban on Promotion and the steps Mallinckrodt has taken or will take to ensure that its employees do not engage in prohibited activities while attending these conferences and events. The Compliance Manager explained that employees attending these events are aware that they need to act in accordance with the Operating Injunction at all times, and are informally advised to exit the conference (ideally in a manner that garners the attention of others) if they observe something concerning, or if something that may be a violation of the Operating Injunction occurs at the event. Afterwards, they are required to inform the Compliance team about the incident. The Compliance Manager stated only one such instance has occurred, where an employee observed a banner displayed at an event that discussed the treatment of pain, and sent an image of the banner

to the Compliance team. The Monitor subsequently requested all materials relating to this incident and anticipates analyzing them during the next reporting period.

8.11 The Compliance Manager also described a second instance that prompted Mallinckrodt to make a proactive change to the SGGSAC review and approval process. The Compliance Manager informed the Monitor that a Mallinckrodt employee submitted a request to the SGGSAC to sponsor or attend an event. The title of one of the conference's agenda items clearly indicated that opioid prescriptions and pain management would be a discussion topic and, as such, Mallinckrodt's funding of the request would likely constitute a violation of the Operating Injunction. The request was ultimately rejected by the Committee, but as a result, the Compliance team decided to revise the SGGSAC SOP to incorporate a first-level review of all requests before they are submitted to the Committee. The Monitor received the SGGSAC meeting minutes pertaining to the denial of this specific request, and the revised SOP, near the conclusion of the Fifth Reporting Period, and anticipates reviewing both during the next reporting period. Upon receipt of those materials, the Monitor will also seek to discuss whether Mallinckrodt has considered remedial training or other corrective action for the employee(s) who submitted the original request.[11]

8.12 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. The Monitor will

[11] The SGGSAC SOP prohibits the Committee from providing a declination reason to the requestor because such articulation "could be viewed as coaching and/or influencing the content of revised or future applications." *See* § 7.5.1. The Monitor understands that Mallinckrodt has already initiated internal discussions between relevant employees, department heads, and others.

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 awarding 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 ***Recommendation 3(c).*** In the Third and Fourth Monitor Reports, the Monitor detailed his review of Mallinckrodt's lobbying activities, including his review of its external lobbyists' publicly-filed disclosure reports, and interviews with the principals of Mallinckrodt's two primary external federal lobbying firms. 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. As a result, the Monitor recommended that Mallinckrodt implement a process to ensure that its external lobbyists are accurately reporting their activities and that those activities comply with the Operating Injunction.

9.3 During the Fifth Reporting Period, the Monitor received and reviewed Mallinckrodt's *Lobbying Certification and Activity Review* SOP, the document designed to formalize the process by which the Government Affairs team will, on a quarterly basis, review drafts of external lobbyists' public disclosure reports, pre-filing, and record the results of that review contemporaneously, as recommended by the Monitor in Recommendation 3(c). The Monitor commends Mallinckrodt for codifying the Operating Injunction's lobbyist written

certification requirement in this SOP. *See* Operating Injunction § III.D.5. However, based on his initial review, the Monitor found the process for Mallinckrodt's audit of its lobbyists' disclosure reports to be lacking sufficient detail to be adequately assessed.

9.4 During the next reporting period, the Monitor anticipates receiving and reviewing the work product from the Vice President of Government Affairs' first quarter 2022 review under the *Lobbying Certification and Activity Review* SOP to determine whether Mallinckrodt has adequately implemented Recommendation 3(c), or whether the SOP may need to be revised to include further detail about the review process.

9.5 In addition to reviewing the *Lobbying Certification and Activity Review* SOP, the Monitor reviewed the publicly-filed 2021 disclosure reports for Mallinckrodt's external state lobbyists from four key states: California, New York, Missouri, and North Carolina. Following his review of these state lobbying disclosure reports, the Monitor interviewed two of Mallinckrodt's external state lobbyists to better understand the information included in the reports and the manner in which these firms conduct lobbying activities on the company's behalf to ensure compliance with the Operating Injunction.[12]

9.6 While the reports filed in Missouri, New York, and North Carolina did not contain significant substantive information, the reports filed by Mallinckrodt's California lobbying firm ("Lobbying Firm CA") revealed lobbying activity on Mallinckrodt's behalf related to controlled substances legislation in the first two quarters of 2021. Specifically, Lobbying Firm CA lobbied the state legislature regarding California's AB 1430, legislation that would require pharmacies to dispense oral dosages of controlled substances in a lockable vial, and

[12] Each of Mallinckrodt's external lobbyists is required to execute a contract addendum certifying their understanding and agreement to comply with the Operating Injunction's terms.

would require drug manufacturers to reimburse pharmacies for some or all of the cost of these lockable vials.

9.7 To gain a better understanding of Mallinckrodt's activities related to this proposed measure, the Monitor spoke with a partner of Lobbying Firm CA. Specifically, the Monitor inquired about Mallinckrodt's position on AB 1430, the lockable vial bill, and how lobbying on this proposed legislation interplayed with the Operating Injunction. The partner confirmed he had received the Operating Injunction, as well as a summary of its requirements, and that he understood those requirements to mean that he was not permitted to lobby on opioids, and that any action taken on legislation related to opioids would need to be approved in advance by Mallinckrodt's Director of Government Affairs and Advocacy. With regard to AB 1430, the partner told the Monitor that Mallinckrodt, upon being notified of the proposed measure, advised Lobbying Firm CA that it could not engage on the section of the bill addressing whether lockable vials should be utilized for controlled substances. However, the partner stated that Mallinckrodt advised that Lobbying Firm CA would be permitted to lobby on the narrow section of the bill pertaining to the drug manufacturers' reimbursement of the associated costs. The partner told the Monitor that this distinction was made clear in all written materials provided to California legislators on Mallinckrodt's behalf. The Monitor anticipates reviewing these materials during the next reporting period, but commends Mallinckrodt for their nuanced handling of this proposed legislation in light of its obligations under the Operating Injunction.

9.8 The Monitor also spoke with a partner from Mallinckrodt's New York lobbying firm ("Lobbying Firm NY"). The partner confirmed that he had received the Operating Injunction and certified his compliance with its lobbying requirements. He explained that he understood those requirements to mean that he was not permitted to lobby on legislation

pertaining to controlled substances, but he was permitted to track bills for Mallinckrodt concerning that issue. He also confirmed that Mallinckrodt provided adequate opportunities to address any questions about the Operating Injunction and its terms. Finally, he told the Monitor that Lobbying Firm NY had recently begun lobbying on Mallinckrodt's behalf on a bill, SB 7278/AB 8339, related to the proposed public release of information collected by the New York Department of Health through its opioid stewardship assessment. The Monitor anticipates reviewing this bill and Lobbying Firm NY's disclosures pertaining to this lobbying effort during the next reporting period.

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); 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 noted in the Fourth Monitor Report, Mallinckrodt's Associate General Counsel executed the first updated annual certification under the Audit Plan on January 5, 2022, providing certain certifications regarding Mallinckrodt's compliance with Section III.E.1. Those certifications are set forth in greater detail in Paragraph 10.5 of the Second Monitor Report.

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 During the Fifth Reporting Period, Mallinckrodt advised the Monitor of the addition of a number of Opioid Products to Mallinckrodt's product catalog. These include: (1) Amphetamine Sulfate Tablets, 5 mg and 10 mg; (2) Diphenoxylate Hydrochloride Tablets, 2.5 mg; (3) Atropine Sulfate Tablets, 2.5 mg; (4) Fentanyl Transdermal System, 37.5 mcg/hour and 62.5 mcg/hour; (5) Methadone Hydrochloride Oral Concentrate, USP (raspberry flavored), 10 mg/mL; (6) Methadone Hydrochloride Oral Solution, USP (raspberry flavored), 5 mg/5 mL and 10 mg/5 mL; and (7) Oxycodone Hydrochloride Tablets, USP, 10 mg and 20 mg. None of these products are High Dose Opioids within the meaning of the Operating Injunction—namely, "Opioid Product[s] that exceed[] 30 milligrams of oxycodone per pill." Operating Injunction § III.E.1. Thus, Mallinckrodt remains in compliance with Section III.E.1.[13]

[13] Materials related to these new products were submitted to Mallinckrodt's Promotional Review Committee ("PRC") during the Fifth Reporting Period. The Monitor has received those

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

11.1 During the Fifth 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 in prior reports; (2) continuing his review of the voluminous data and documents provided in response to the Audit Plan; (3) conducting follow up interviews with the Controlled Substances Compliance ("CSC") Director, the Lead CSC Consultant (the "LCSCC"), and the CSC Manager concerning, among other topics, the documents Mallinckrodt produced during the Fifth Reporting Period; and (4) receiving a virtual "tour" of the functionalities of Mallinckrodt's direct and indirect customer dashboards, developed through its work with Analysis Group, Inc. ("AGI"). This activity is described in further detail below.

1. Mallinckrodt's Updates on Implementation of Prior Recommendations[14]

11.2 During the Monitor's meetings with the CSC Director and the LCSCC, and in discussions with SpecGx's Associate General Counsel and Mallinckrodt's outside counsel, the Monitor received an update on Mallinckrodt's continued efforts to implement the recommendations in the Second and Fourth Monitor Reports. The implementation status of these outstanding recommendations is set forth below, by category.

materials and the minutes of the PRC meeting(s) in which the materials were discussed and anticipates reporting the results of his review in the next Report.

[14] Mallinckrodt's implementation of the Monitor's recommendations not specifically referenced herein are discussed in prior reports. All of the Monitor's recommendations to date are summarized in attached **Exhibit 1**.

(a) Recommendations Related to the Chargeback Review Process

11.3 ***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 shared with its three largest distributor customers—the so-called "big three" (namely, Amerisource Bergen, Cardinal Health, and McKesson)—a letter agreement amending Mallinckrodt's existing supply agreements in order to obtain the distributors' agreement and cooperation on a number of issues. As previously reported (*see* Fourth Monitor Report ¶¶ 11.13-11.14), the letter agreement Mallinckrodt proposed to each of these distributors requires them 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. 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 (per ***Recommendation 2(e)***).

11.4 To date, Mallinckrodt's attempts to reach an agreement with the "big three" distributors has not resulted in any agreement on the part of the distributors to use their best efforts to prevent the supply of Mallinckrodt's products to a downstream registrant that has been chargeback restricted. Mallinckrodt continues to negotiate the letter agreement with the "big three," and intends to propose the letter agreement to smaller distributors in the future.

(b) Recommendations Related to Tracking the Timeliness of Chargeback Reviews

11.5 ***Recommendations 2(f)-2(g) and 4(a).*** As detailed in prior reports, the Monitor has focused on the length of time the SOM Team ("SOMT") takes to complete chargeback reviews involving downstream registrants, including the lag time between various points in the process. Although collectively referred to as "chargeback reviews," the reviews may arise not only from the LCSCC's review of the chargeback data uploaded by the Finance Department, but also from Mallinckrodt's media searches, and now from the SOMT's analysis of flagged direct customer orders using the direct customer dashboard. Thus, in the Second Monitor Report, the Monitor recommended that Mallinckrodt evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data (***Recommendation 2(f)***), as well as amend relevant SOPs to memorialize firm timelines (***Recommendation 2(g)***). Subsequently, the Monitor more specifically recommended that Mallinckrodt 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 (***Recommendation 4(a)***). *See* Fourth Monitor Report ¶¶ 11.27-28.

11.6 The Monitor's recommendation arose from observations regarding widely varying lengths of time for the SOMT to complete chargeback reviews for downstream registrants, including some time lags that could be reduced. *See* Fourth Monitor Report ¶¶ 11.16-11.19 (discussing the Monitor's observations of the internal time lags in the chargeback review process based on his review of the SOMT's meeting materials and minutes); ¶ 11.23 (discussing lags of several months in the receipt of due diligence from direct customers, resulting in significant delay in Mallinckrodt's implementation of chargeback restrictions). Although the SOMT had recorded some of this data previously, it did not track the various steps of the chargeback review

process to the degree of detail that would permit an analysis of the typical turnaround time for each step in the review. This made it difficult or impossible for the SOMT and the Monitor to determine whether time delays (such as delays on the part of direct customers in responding to due diligence requests) were reasonable and appropriate, and what, if any, improvements could or should be made to standardize the process and ensure chargeback reviews were completed expeditiously.

11.7 Consistent with the Monitor's recommendation, Mallinckrodt now tracks the key phases of the chargeback review process in an Excel spreadsheet (the "Tracking Spreadsheet"), including: (1) the date the chargeback data was made accessible to the LCSCC for review; (2) the date the LCSCC began his 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 LCSCC's completion of his review; (6) the date of the SOMT's review of the LCSCC's analysis and / or recommendation and the SOMT's chargeback restriction decision; (7) the date the restriction decision is communicated to distributors and executed; (8) the date of any chargeback reinstatement; and (9) the date of any future required follow-up review. The Tracking Spreadsheet tracks the time intervals between these key phases in the chargeback review cycle, and includes any relevant comments regarding the review.

11.8 The Tracking Spreadsheet also helpfully records whether review of a distributor or pharmacy is prompted by Mallinckrodt's normal threshold flags, a distributor-initiated restriction of which the direct customer advises Mallinckrodt, a media alert, or a downstream registrant's reinstatement request (and the outcome of such a request).

11.9 As requested in the Audit Plan, Mallinckrodt has begun to produce to the Monitor, on a monthly basis, a copy of the Tracking Spreadsheet.

11.10 During the Fifth Reporting Period, the Monitor interviewed the CSC Director and the LCSCC regarding the Tracking Spreadsheet. This yielded additional helpful insight into the SOMT's review process and challenges in obtaining timely responses to due diligence requests from some direct customers.

11.11 In due course, the Monitor looks forward to assessing the accumulated data from the Tracking Spreadsheet, together with Mallinckrodt, in order to determine whether recommendations or guidelines regarding specific turnaround times may be appropriate. Accordingly, the Monitor will continue to analyze the Tracking Spreadsheet data in future reporting periods.

11.12 Even now, however, it seems that the Tracking Spreadsheet—and perhaps due to the very exercise of tracking such data—is already having a salutary effect. In a short time frame, the Monitor has observed that restriction decisions are being taken more promptly, and outstanding due diligence requests are less likely to linger for an extended time before Mallinckrodt implements a restriction. Additionally, as discussed below, Mallinckrodt's integration of the new direct customer and downstream registrant dashboards, developed with AGI, will provide the LCSCC and SOMT with even more helpful information regarding distributors' orders and distribution to downstream registrants in a more timely fashion, making the chargeback review process more efficient.

(c) Recommendations Related to Changes to the Chargeback Review Sheets

11.13 ***Recommendation 4(b).*** The Monitor also recommended that Mallinckrodt revise its *Suspicious Order Monitoring Program Indirect Customer Pharmacy Review Cover Sheet Checklist* to "[f]ormaliz[e] the check for any co-owned pharmacies during the chargeback review process and incorporate[] the Chargeback Review Checklist into the chargeback review cover sheets" to further standardize and document the LCSCC's review of downstream registrants.

The Monitor's review of the SOMT's materials for its January and February 2022 meetings confirmed Mallinckrodt has implemented Recommendation 4(b).

(d) Recommendations Related to Mallinckrodt's Due Diligence for Direct Customers

11.14 The Monitor also recommended enhanced direct customer due diligence. This included both (1) enhancing direct customer questionnaires (***Recommendation 2(s)***) and (2) establishing regularly scheduled interactions with direct customers (***Recommendation 2(t)***).

11.15 ***Recommendation 2(s).*** In the Fourth Monitor Report the Monitor discussed the Due Diligence Questionnaire that Mallinckrodt uses for distributor customers—either annually, or upon onboarding a new customer. The Monitor has reviewed an updated version of this questionnaire, which addresses the Monitor's recommendations in the Fourth Monitor Report. *See* Fourth Monitor Report ¶¶ 11.42-11.45.

11.16 At this time, however, Mallinckrodt has not yet shared with the Monitor copies of updated questionnaires for other direct customers, such as manufacturers, narcotic treatment programs, or laboratories, and will share them with the Monitor when finalized. *See id.* ¶ 11.44. The Monitor is also awaiting Mallinckrodt's revision of the *Suspicious Order Monitoring Program Review of Direct Customer Orders* SOP to reflect Mallinckrodt's now implemented change in its procedure to require all due diligence questionnaires to be reviewed by the SOMT rather than the Customer Data Integrity group. *See id.* ¶ 11.45.

Recommendation 5(a). Revise the Due Diligence Questionnaire to inquire about relevant persons' criminal backgrounds.

11.17 **In light of the LCSCC's findings in connection with a recent review of a distributor in Missouri, described more fully below in Paragraph 11.41, the Monitor has recommended that Mallinckrodt further amend the Due Diligence Questionnaire to inquire whether a direct customer's owners, officers, principals, or employees have ever been**

convicted of a federal, state, or local criminal offense. Mallinckrodt has agreed to this recommendation.

11.18 ***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 "big three" and at least six other direct customers every year.

11.19 During the Fifth Reporting Period, Mallinckrodt conducted three of its seven due diligence meetings and, on or about April 6, 2022, produced to the Monitor two documents that the SOMT is using in connection with these visits: the *CSC/Suspicious Order Monitoring Distributor Customer Audit Checklist* and the *SOM Distributor Review Security Questions*. These visits were conducted virtually (*i.e.*, remotely) rather than on-site, due to the ongoing global COVID-19 pandemic, but Mallinckrodt hopes to conduct future in-person visits.

11.20 Notably, as discussed in Paragraph 11.41-46, below, Mallinckrodt audited and suspended two of these direct customers in the Fifth Reporting Period, due to their inadequate SOM programs.

11.21 The Monitor discussed these meetings during his interviews with the CSC Director and the LCSCC, but without having yet received the *CSC/Suspicious Order Monitoring Distributor Customer Audit Checklist* or the *SOM Distributor Review Security Questions*. Accordingly, in the next reporting period the Monitor intends to follow up with Mallinckrodt regarding the substance of these visits, the SOMT's findings regarding the audited distributors and their SOM programs, and any reports generated from the meetings. The Monitor also

intends to closely examine the questionnaires and checklists the SOMT is using in connection with these visits.

11.22 Finally, as the Monitor noted in the Fourth Monitor Report, "[a] group of six distributors account for 4.9% of opioid orders" and "do[] not participate in the chargeback program." Fourth Monitor Report at 26 n.12. Given the value of chargeback data to Mallinckrodt's SOM program, the Monitor has asked Mallinckrodt to consider what other data, including potentially 867 distributor sales data, may be available to conduct a targeted review of these particular direct customers. Given the added diversion risk that these direct customers pose in the absence of chargeback data, the Monitor will continue to explore with Mallinckrodt whether other methods may assist in monitoring these customers in the absence of chargeback data. Mallinckrodt has also indicated its intent to conduct due diligence site visits for these customers, by conducting visits with two of them annually.

2. The Monitor's Review of Documents Produced During the Fifth Reporting Period and Related Interviews

11.23 During the Fifth Reporting Period the Monitor reviewed numerous categories of SOM-related documents, including but not limited to the following produced pursuant to the Audit Plan requests: (1) meeting minutes from the SOMT's December 2021 and January and February 2022 monthly meetings; (2) chargeback "review sheets" relating to downstream registrants discussed in those meetings, now updated with a checklist that has become part of the review sheet; (3) the SOMT's Tracking Spreadsheet; (4) the SOMT's government Communications Log; (5) the LCSCC's *Semi-Annual Controlled Substances Compliance Report: Analysis of Highly Diverted Controlled Substances Utilizing Chargeback Data*; (6) the revised SOM Questionnaire for Distributor Customers; (7) documents related to the direct customer dashboard developed with AGI; (8) direct customer order data by volume, segment,

and product; and (9) checklists for annual distributor reviews. Certain of these categories are discussed below.

(a) The LCSCC's Semi-Annual Controlled Substances Compliance Report: Analysis of Highly Diverted Controlled Substances Utilizing Chargeback Data

11.24 The Monitor met with the LCSCC on two occasions in February 2022 to discuss the LCSCC's periodic review of chargeback data. Prior to meeting, Mallinckrodt shared the LCSCC's 24-page report, titled *Semi-Annual Controlled Substances Compliance Report: Analysis of Highly Diverted Controlled Substances Utilizing Chargeback Data*, dated December 1, 2021, which the Monitor had received shortly before filing the Fourth Monitor Report.

11.25 The LCSCC's report fulfills the requirement of periodic reporting on chargeback data set forth in the *Suspicious Order Monitoring Program Social Media and Chargeback Review of Direct Customer and Downstream Registrant* SOP. That policy requires the "LCSCC or designee" to "conduct a periodic review of Chargeback data for the prior twelve-month period and review media and publicly available information to help identify Downstream Registrants which may pose a risk of diversion." *See* § 6.3.1. This review is separate from the chargeback review the LCSCC undertakes on an ad hoc basis in response to media alerts, and the regular monthly review the LCSCC undertakes of the pharmacies whose chargeback data exceeds relevant thresholds.

11.26 The LCSCC's review was useful in several respects discussed below. At the same time, the LCSCC recognizes that AGI's dashboard for monitoring downstream registrants will be even more valuable in identifying potential areas of concern.

11.27 For purposes of the LCSCC's initial report since taking his new position, the LCSCC analyzed Mallinckrodt's chargeback data to identify any trends, anomalies, and unusual patterns that could indicate red flags and possible downstream diversion. The report focused on

the chargeback data for five products: oxycodone 30 mg, oxycodone 15 mg, hydrocodone 10/325 mg, levorphanol 2 mg, and amphetamine salts. (Although the latter is not an Opioid Product, and therefore not within the scope of the Operating Injunction, the LCSCC is relying upon his DEA experience, and familiarity with frequently diverted substances, rather than focusing solely on prescription drugs within the scope of the Operating Injunction.) The Monitor Team noted that a number of Opioid Products identified in the Operating Injunction could be included in the LCSCC's future periodic reviews.[15] The LCSCC's analysis of the chargeback data for these products covered the twelve months prior to the LCSCC taking his new position at Mallinckrodt—*i.e.*, November 2020 through October 2021. The report included graphs and charts reflecting the top ten customers based on chargeback data, by volume, geographic location, and segment type, and provided a narrative analyzing the results of the review.

11.28 The LCSCC's analysis led to a number of useful findings. ***First***, the review identified some potentially suspicious downstream registrants, which in turn resulted in ad hoc reviews, some of which led to restrictions of some downstream registrants. Although some of these identified pharmacies would likely have been identified by the LCSCC in the normal course of monthly volume threshold reviews, some perhaps would not. For example, the LCSCC's review triggered ad hoc reviews of two pharmacies whose twelve-month order volumes were below the threshold that would ordinarily trigger a volume review. ***Second***, the report identified some ordering anomalies that prompted further due diligence, such as ordering

[15] The above-referenced policy requires the LCSCC to periodically review "[a]ll Opioid Products with heightened review of Oxycodone 15 mg, Oxycodone 30 mg, and Hydrocodone 10 mg products." *Suspicious Order Monitoring Program Social Media and Chargeback Review of Direct Customer and Downstream Registrant* § 6.2. The Operating Injunction defines "Opioid Products" as those "including but not limited to codeine, fentanyl, hydrocodone, hydromorphone, meperidine, morphine, oxycodone, oxymorphone, tapentadol, and tramadol." Operating Injunction § I.Q.

by one pharmacy in a large national chain that was purchasing three times the amount of oxycodone 15 mg as another pharmacy within the same town that is part of the same national chain. The LCSCC notified the relevant distributor and has requested a dispensing review for that particular pharmacy. ***Third***, the LCSCC identified an outlier pharmacy whose orders of levorphanol 2 mg dwarf those of the remaining top ten downstream registrants. The LCSCC has requested further due diligence from the distributor to understand this anomaly. Because levorphanol is not typically considered to be one of the products at greatest risk for diversion, Mallinckrodt had historically not had a simple volume threshold for levorphanol as it had for oxycodone 30 mg and 15 mg and hydrocodone 10 mg. Thus, but for the LCSCC's review, it is unclear whether the particular pharmacy ordering levorphanol would have triggered review.

11.29 The LCSCC agreed with the Monitor Team that certain enhancements to the analysis would be worthwhile in future periodic reviews. ***First***, further analysis of the independent retail pharmacy segment, which is the most likely area of diversion in the supply chain, would be valuable. "Drilling down" one level further in this segment may reveal additional insights about the nature of diversion risk in this segment among particular pharmacies. Knowing more about the identities of downstream registrants in that segment—even if they are not among the top ten downstream registrants by volume—could be enlightening. ***Second***, the report has revealed other areas for further investigation, such as the comparatively very high volume of oxycodone 30 mg sold in the state of Florida. Further research would be helpful, particularly given the historical diversion in Florida, and the prevalence of pain clinics there, in order to know whether the relatively higher volume in that jurisdiction is appropriate or raises diversion concerns. Similarly, an unusually large number of towns in a particular region of a single state—all in Southern New Jersey—account for as many

as five of the top ten zip codes by chargeback volume for oxycodone 15 mg. Further investigation of retail pharmacies within that region is warranted. ***Third***, the LCSCC could broaden his focus beyond the "top ten" chargeback customers in each product category, given that the top ten customers for the most highly diverted products (oxycodone 30 mg and 15 mg, and hydrocodone 10 mg) account for less than 2% of the total volume distributed. The Monitor understands that Mallinckrodt is continuing to analyze all chargeback data on a monthly (and sometimes ad hoc) basis, but for the narrower purposes of the LCSCC's annual chargeback review, it may be valuable for the LCSCC to consider a different or additional analysis to account for the large volume of chargeback orders not captured in the "top ten" analysis.

(b) The Government Communications Log

11.30 In accordance with the Audit Plan, during the Fifth Reporting Period Mallinckrodt produced a copy of the government communications log ("Communications Log") that the SOMT maintains. This log is required under the *SOM Program Review of Direct Customer Orders* SOP. The SOP requires that Mallinckrodt respond to routine shipping history requests from the DEA and other law enforcement agencies within 24 hours of receipt, and to document those requests. *See* § 6.1.3 ("Respond to routine shipping history requests from DEA within 24 hours of receipt and document in government correspondence log per Disclosure of Government Communications to Monitor.").

11.31 The Monitor Team reviewed the Communications Log for the fourth quarter of 2021 and the first quarter of 2022. The Monitor Team also interviewed the CSC Manager, who is principally responsible for maintaining the Communications Log and who, along with other SOMT members, receives and responds to government requests. Although the SOMT has maintained a log of such government requests for many years, for the Monitor's benefit the

SOMT has expanded the information contained in the Communications Log. The Communications Log includes not only communications regarding routine shipping verifications, but also other law enforcement requests for information primarily concerning Mallinckrodt's direct customers (although there are isolated instances of inquiries relating to downstream registrants).

11.32 The CSC Manager and the CSC Compliance Consultant II (formerly titled Analyst / Auditor) generally handle the majority of government inquiries, but any unusual requests are escalated, as appropriate, to the CSC Director and the LCSCC. All of the inquiries during the last two quarters have originated from the DEA, and almost all relate to sales of addiction treatment medication (*e.g.*, methadone, methadose, and buprenorphine) to addiction treatment centers. These medications are not "Opioid Products" as defined under the Operating Injunction. There have, however, been isolated instances of inquiries related to purchases of Opioid Products, such as oxycodone and hydrocodone. The Monitor has requested that Mallinckrodt provide copies of the underlying correspondence—from the law enforcement agency, and in response—relating to these Opioid Products. The Monitor requested that future productions of the Communications Log be accompanied by the correspondence relating to any Opioid Products. Mallinckrodt has agreed, and has begun to produce such correspondence.

11.33 The CSC Manager also explained her role in addressing customer complaints relating to potential diversion issues, such as missing tablets in bottles. Her investigation and the results of such investigations are recorded in TrackWise. The Monitor Team has previously reported on its review of TrackWise. *See* Fourth Monitor Report ¶¶ 6.5-6.9. That prior review, and related recommendation, focused upon the use of TrackWise by the Product Monitoring Team, rather than the SOMT. In the next reporting period the Monitor will review TrackWise

with a view to better understanding customer complaints relating to potential diversion, and the CSC's investigation and resolution of such complaints.

(c) The Revised SOM Program Review of Reinstatement Requests for Downstream Registrants SOP

11.34 In the Fourth Reporting Period, Mallinckrodt developed the *Requirements for 3rd Party Assessment for Chargeback Reinstatement Requests* (the "Reinstatement Checklist"). *See* Fourth Monitor Report ¶¶ 11.46-11.48. As noted in the Fourth Monitor Report, the Reinstatement Checklist was drafted at the Monitor's recommendation to standardize information and practices Mallinckrodt will evaluate when considering a chargeback reinstatement request. The creation of the Reinstatement Checklist necessitated some updates to *Mallinckrodt's SOM Program Review of Reinstatement Requests for Downstream Registrants* SOP.

11.35 In the Fifth Reporting Period, the Monitor reviewed the changes to this SOP, which now better reflects the SOMT's current practices and specifically requires that a restricted downstream registrant seeking reinstatement ensure completion of a comprehensive due diligence review and report as outlined in the Reinstatement Checklist. As revised, the SOP now states:

> If a Downstream Registrant requests reinstatement, it must ensure completion of a comprehensive due diligence review and report concerning the Downstream Registrant, as outlined in the Requirements for 3rd Party Pharmacy Assessment for Reinstatement Requests (rev. 12/21). This review/report is to be completed by an independent controlled substances compliance expert that is acceptable to the Company.[16] The expert shall provide that report directly to the Downstream Registrant.

[16] During the Fifth Reporting Period, Mallinckrodt advised the Monitor that there have been no changes to its list of independent consultants it provides to downstream registrants, which Mallinckrodt provided to the Monitor last year.

§ 5.2.1.

11.36 The SOP notes that "[t]he Company may also consider a comprehensive due diligence review completed by a Direct Customer of the Company, as outlined in the Requirements for 3rd Party Pharmacy Assessment for Reinstatement Requests (rev. 12/21)."

3. Mallinckrodt's Direct Customer Dashboard

11.37 In the Fourth Reporting Period, Mallinckrodt launched its direct customer surveillance dashboard. The direct customer dashboard—as used by Mallinckrodt's newly hired LCSCC—has already proven its value, by assisting the LCSCC in detecting high volume direct orders and associating them with suspicious downstream registrant orders. This has led to the restriction of three direct customers, as well as multiple downstream registrants associated with these distributors.

11.38 The Monitor met with a representative of AGI, along with Mallinckrodt's CSC Director, the LCSCC, and Mallinckrodt's outside counsel, in early March 2022. Mallinckrodt's counsel described the development and implementation of the direct customer dashboard as the largest project Mallinckrodt's Information Technology Department has undertaken in the last year, including all of Mallinckrodt's restructuring and bankruptcy efforts. This in part is due to the need for multiple systems to communicate and to be interoperable. For the reasons noted below, however, this appears to have been well worth the investment of resources and has already born fruit.

11.39 AGI provided an update on the launch of the direct customer surveillance dashboard and a live demonstration of the system. As detailed below, Mallinckrodt's LCSCC also shared a notable success story involving the SOMT's flagging of a particular direct customer (a distributor) that led to closer review of that customer's downstream registrants (*i.e.*,

Mallinckrodt's indirect customers). As a result, the SOMT decided to restrict the direct customer as well as four of that distributor's top customers within a mere ten days of flagging the direct order.

11.40 One benefit of the new direct customer dashboard is the ability of a reviewer to analyze related downstream registrant data. This improved interoperability permits the reviewer to access downstream registrant data in the course of direct customer surveillance.

11.41 For instance, the January 20, 2022 SOMT meeting minutes reflect that in late December 2021, the SOMT learned from a media alert of three pharmacies allegedly involved in a pill mill scheme. The LCSCC was able to identify a fourth pharmacy under common ownership, and also a common distributor among the four pharmacies ("Distributor A"). The LCSCC's review of ARCOS data revealed that at least ten other pharmacies were purchasing from Distributor A and only buying one, two, or three controlled substances. During the course of due diligence, the LCSCC discovered that the owner of Distributor A had a prior federal conviction for conspiracy to commit mail fraud and wire fraud. Requests for due diligence from the distributor did not allay Mallinckrodt's concerns. Consequently, the SOMT restricted direct sales to Distributor A.

11.42 In light of the LCSCC's discovery of an owner of a direct customer with a criminal record—*i.e.*, a prior federal conviction for mail and wire fraud—the Monitor issued Recommendation 5(a), set forth in Paragraph 11.17 *supra*, recommending that Mallinckrodt revise its Due Diligence Questionnaire to inquire about the criminal history of the officers, owners, and principals of all direct customers. Mallinckrodt has agreed to implement this recommendation.

11.43 Similarly, the February 17, 2022 SOMT meeting minutes reflect that on February 7, the direct customer dashboard identified a different distributor, "Distributor B," that ordered an unusually high volume of hydrocodone 10 mg. Mallinckrodt determined that it had insufficient information to explain the red flag, leading the SOMT to: (1) seek additional information from Distributor B; (2) examine chargeback data relating to Distributor B's top five customers; and (3) review ARCOS distribution data for these customers (which revealed several pharmacies were ordering quantities of oxycodone that were multiples of the volume purchased by their nearby competitors). The LCSCC identified Distributor B's top five downstream registrants and confirmed that the ordering patterns of four of those five downstream registrants were suspicious, leading to a restriction of both the direct customer (Distributor B) and the four downstream registrants (*i.e.*, pharmacies).

11.44 The SOMT deliberated as to whether to restrict some or all of Distributor B's orders, given that Mallinckrodt had a scheduled due diligence meeting with the distributor later in the month, and that some orders from Distributor B were for small volumes and could be important to hospice and long-term care. Ultimately, despite these countervailing considerations, the SOMT agreed to restrict Distributor B as well as four downstream registrants, all within just a ten-day period.

11.45 One of these restricted pharmacies was ordering hydrocodone from two suppliers and dispensing more than three to five times the volume of hydrocodone than other pharmacies in the area. The LCSCC also concluded that Distributor B's due diligence paperwork relating to the pharmacy was outdated and insufficiently detailed.

11.46 Two other pharmacies supplied by Distributor B were owned by the same individual, were located in close proximity (down the street), were purchasing only two products

(hydrocodone and oxycodone) in roughly equal quantities from at least two distributors, and in volumes four to six times larger than large chain pharmacies in the immediate area.

11.47 Disconcertingly, Mallinckrodt's LCSCC learned during the course of its due diligence on one of the pharmacies that one of the "big three" distributors, "Distributor C," had already restricted the downstream pharmacy more than six months before (*i.e.*, in June 2021) due to the pharmacy's high ratio of controlled to non-controlled substances dispensed, and the fact that the pharmacy's top three prescribers were nurse practitioners. However, Distributor C had not shared this information with Mallinckrodt until the SOMT's inquiry more than six months later, in February 2022. Although Mallinckrodt advises its direct customers of Mallinckrodt's restriction decisions (and, indeed, as noted above, is in the process of seeking a commitment from the "big three" to agree not to continue to supply such restricted downstream registrants), distributors do not necessarily reciprocate this information sharing. *See* Third Monitor Report ¶ 11.12 (describing two instances where distributors failed to inform Mallinckrodt when they restricted downstream customers). As this particular incident demonstrates, Mallinckrodt could have (and, the Monitor believes, almost certainly would have) restricted the pharmacy in question if Mallinckrodt had received a timely notification from Distributor C. Because Mallinckrodt did not receive this information in a timely fashion, however, it only discovered the unusually high volume ordering from the direct customer dashboard's identification of an unusually large hydrocodone order by an entirely ***different*** distributor.

11.48 The Monitor notes, once again, the importance of direct customers promptly informing Mallinckrodt of any restrictions that direct customers impose upon downstream registrants. *See* Fourth Monitor Report ¶ 11.14; Third Monitor Report ¶ 11.12. As previously noted, Mallinckrodt has attempted to secure the agreement of the "big three" distributors to

advise Mallinckrodt of such restrictions more promptly. The Monitor recognizes, of course, that Mallinckrodt's ability to influence its direct customers is limited. Nonetheless, in the next reporting period the Monitor will discuss with Mallinckrodt whether a continued lack of reciprocal information sharing warrants discussion at higher levels at Mallinckrodt (such as, for example, at the level of Vice President and General Counsel for SpecGx) and at a similarly senior level at the "big three."

Recommendation 5(b). Require restricted direct customers to undertake substantial compliance reforms before reinstatement can occur.

11.49 **The Monitor recommends that Mallinckrodt require restricted direct customers (such as Distributors A and B) to undertake substantial compliance reforms—of the sort Mallinckrodt has required of another distributor discussed in the Fourth Monitor Report, *see* Fourth Report ¶¶ 11.62-11.66—before Mallinckrodt resumes supplying these customers.** Mallinckrodt agrees with this recommendation.

* * *

11.50 The Monitor is encouraged that Mallinckrodt's increased SOM surveillance efforts—including its use of the direct dashboard, and its hiring of new staff such as the LCSCC—appear to be bearing fruit. As the CSC Director and the LCSCC have shared with the Monitor Team, some distributors have begun to notify Mallinckrodt of restrictions imposed by the distributors on their direct customers (*i.e.*, Mallinckrodt's indirect, downstream registrant customers), and they believe that the pace of pharmacy reviews and restrictions are up. Additionally, Mallinckrodt's restriction of three direct customers has stopped the supply of its potentially diverted Opioid Products to numerous other downstream registrants.

11.51 The Monitor views this as a success story. It reflects the implementation of sophisticated data analytics, combined with aggressive human analysis within a relatively short

time frame. Furthermore, this is the second time within as many reporting cycles that Mallinckrodt has restricted a direct customer—an event that, prior to the Operating Injunction, would have been a very rare occurrence. This is an encouraging sign of an SOM system that is more sophisticated than it was a year ago, and one that although matured is still improving.

11.52 The Monitor eagerly anticipates learning about the continuing effects of Mallinckrodt's implementation of its new indirect customer dashboard.

12. TRAINING (OI § III.K)

12.1 Mallinckrodt's training of employees on the Operating Injunction and related obligations and prohibitions is described in general terms in the Monitor's prior reports. *See, e.g.*, Fourth Monitor Report ¶ 13.1. Additionally, employees are now also required to pass a test following their live training.

12.2 In order to observe the extent to which live trainings sufficiently test employees' retained knowledge of the Operating Injunction, during the Fifth Reporting Period the Monitor Team attended three live trainings for the following subject areas: (1) Controlled Substances Compliance, Security, and Corporate Compliance; (2) Government Affairs; and (3) Commercial, Business Development and Licensing.

12.3 The SpecGx Compliance Manager led each of these live sessions, and the SpecGx General Manager (formerly, its Chief Financial Officer) and Associate General Counsel were present as well. The General Manager opened the sessions by emphasizing both his and Mallinckrodt's commitment to maintaining compliance with the Operating Injunction and the value of the Monitor's services. The General Manager's opening remarks appropriately conveyed a "tone from the top" consistent with Mallinckrodt's continued compliance with the Operating Injunction and its cooperation with the Monitor to date.

12.4 The Compliance Manager then guided the participants through the background of the Operating Injunction and the categories and key definitions set forth therein, focusing each presentation on the provisions most relevant to the department receiving training. Each presentation focused on what employees must, can, and cannot do consistent with the terms of the Operating Injunction, presenting between three and seven hypothetical scenarios to the participants. The Compliance Manager asked participants whether the conduct described was permissible or impermissible under the Operating Injunction. The sessions ended with an opportunity for the participants to ask questions.

12.5 The Monitor observed varying degrees of participation from the attendees in each remote WebEx session. Many had their video cameras turned off throughout the training, and participated by means of WebEx's "thumbs up" and "thumbs down" function. Though the Monitor acknowledges the difficulties in engaging participants during virtual trainings, he encourages Mallinckrodt to identify ways to enhance participation, whether through the use of polls or other incentives that encourage participants to actively respond to each hypothetical posed by the Compliance Manager and ask questions, when appropriate. Indeed, when participants took the opportunity to ask questions, the Monitor observed valuable exchanges between the Compliance Manager and the participants on the nuances of the Operating Injunction's terms.

12.6 The Monitor also reviewed the test questions, and accompanying answers, presented to employees in the form of a "quiz" following the live trainings. Employees were required to answer at least 80% of the questions correctly in order to pass the test. The test contained a mix of general questions posed to all employees, as well as tailored questions for specific company Departments, which sought to highlight some of the more nuanced areas of the

Operating Injunction pertaining to those Departments. The questions appeared to be sufficiently difficult and nuanced to accurately test employees' retention and understanding of the Operating Injunction terms and obligations. Furthermore, the questions took several forms, including "true/false," "fill in the blank," and multiple choice questions where there was more than one correct answer for employees to identify. During the Sixth Reporting Period, the Monitor anticipates requesting and reviewing additional documentation pertaining to employees' performance on these tests. The Monitor also anticipates discussing with Mallinckrodt how these tests will be developed in future years, and how, if at all, real life situations encountered during the course of the year may be incorporated into the training presentations and tests.

12.7 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. As of April 7, 2022, Mallinckrodt identified ten newly hired or promoted employees in the first quarter of 2022, all ten of whom have completed their live Operating Injunction training.

13. CLINICAL DATA TRANSPARENCY (OI § IV)

13.1 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.

13.2 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.[17] Any research proposals submitted through Vivli will be reviewed for scientific merit by an independent review panel.

13.3 During the Fifth Reporting Period, Mallinckrodt received its first request for access to certain clinical data hosted by Vivli. Mallinckrodt referred the inquiring doctoral candidate to Vivli, whose panel of independent reviewers will decide whether to share the data requested with the inquirer after determining if he or she is a "Qualified Researcher[] with a bona fide scientific research proposal." Operating Injunction § IV.B.1.

13.4 As discussed above, Mallinckrodt has developed the new Opioid Products identified in ¶ 10.4. Mallinckrodt has advised the Monitor that it will make the data for these products available through Vivli in the time required by Section IV.A.1.c. Operating Injunction § IV.A.1.c ("Mallinckrodt shall make available the above information for all studies for any new Mallinckrodt Opioid Product or new indications that are approved within 30 days after regulatory approval or 18 months after study comprehension, whichever occurs later.").

13.5 Mallinckrodt has agreed to inform the Monitor in the event of any further requests for access to its clinical data and additional new products or indications.

14. OTHER ISSUES OF NOTE

14.1 During the Fourth Reporting Period, Mallinckrodt informed the Monitor of the terminations of a number of senior SpecGx executives as part of a reduction in workforce. Similarly, during the Fifth Reporting Period, Mallinckrodt informed the Monitor of the termination of the Director of Post-Market Surveillance. As discussed above, the Monitor

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

interviewed the Director following her termination to ensure her responsibilities for implementing the Monitor's recommendations ~~were adequately~~ transitioned to her replacement.

14.2 Additionally, the Monitor conducted an introductory interview with the new SpecGx General Counsel, who assumed his role after the termination of the prior General Counsel during the last reporting period. The new General Counsel reiterated Mallinckrodt's commitment to the obligations of the Operating Injunction and the implementation of the Monitor's recommendations. The Monitor was impressed with the new General's Counsel background as a chemical engineer and intellectual property lawyer, as well as prior experience in the pharmaceutical industry, and looks forward to a cooperative working relationship.

14.3 The Monitor also scheduled a site visit to Mallinckrodt's facilities in St. Louis, Missouri for early May 2022. The Monitor plans to meet with various senior Mallinckrodt executives during this visit, and anticipates reporting on the same during the next reporting period.

15. CONCLUSION

15.1 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.

* * *

15.2 Wherefore, the undersigned Monitor respectfully submits this Fifth Monitor Report.

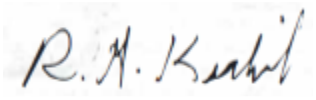

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EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE FIFTH MONITOR REPORT – FILED APRIL 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.

V. FIFTH MONITOR REPORT (4/19/2022)

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)		
27.	**5(a)**	Revise the Due Diligence Questionnaire to inquire about relevant persons' criminal backgrounds.
28.	**5(b)**	Require restricted direct customers to undertake substantial compliance reforms before reinstatement can occur.