SIXTH REPORT OF R. GIL KERLIKOWSKE, INDEPENDENT COURT-APPOINTED MONITOR FOR MALLINCKRODT LLC, MALLINCKRODT ENTERPRISES LLC, AND SPECGX LLC[1]

September 1, 2022

[1] As noted later in this Report, *see infra* at ¶ 1.7, although the United States Bankruptcy Court for the District of Delaware retains jurisdiction to adjudicate disputes related to enforcement of, or disputes concerning, the Operating Injunction, this Sixth Monitor Report and subsequent reports will not be filed with the Bankruptcy Court. Accordingly, the case caption appearing on the First through Fifth Monitor Reports has been removed.

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SIXTH 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 Sixth Monitor Report covers the period from the filing of the Fifth Monitor Report on April 19, 2022, to the present (the "Sixth Reporting Period"). The Sixth 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 Sixth Reporting Period, including the review of documents and data, and interviews or meetings with Mallinckrodt employees; (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 One**. The Monitor's new recommendations are summarized in Section 4, and are elaborated upon in Sections 7 (No Financial Reward or Discipline Based on Volume of Opioid Sales) and 11 (Monitoring and Reporting of Direct and Downstream Customers).

1.3 During the Sixth 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 ad hoc requests, visiting Mallinckrodt's headquarters and manufacturing facilities in the St. Louis area, and conducting interviews.

1.4 As described in the Fourth Monitor Report, *see* Fourth Monitor Report at 2 ¶ 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, during the Sixth Reporting Period Mallinckrodt provided over 150 files (consisting of 472 MB of documents and data).

1.5 ***Mallinckrodt's emergence from bankruptcy and resolution of opioid litigation.*** As previously reported, the Bankruptcy 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 that time, 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.[2] 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."[3] Mallinckrodt in

[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. The bankruptcy proceedings are relevant to establish the "Effective Date" of the bankruptcy, as defined under the Operating Injunction. *See* ¶ 1.7, *infra.*

[3] *See* Press Release, "Mallinckrodt Plan of Reorganization Confirmed by U.S. Court," Feb. 3, 2022, *available at* https://www.mallinckrodt.com/about/news-and-media/news-detail/?id=28836.

fact announced, on June 16, 2022, the completion of its reorganization plan and its emergence from the Chapter 11 bankruptcy process and Irish Examinership proceedings.[4]

1.6 The announcement also noted the appointment of a new global President and CEO, Mr. Sigurdur "Siggi" Olafsson (who replaced Mr. Mark Trudeau, who had served as President of Mallinckrodt for the past decade), the appointment of a new Chairman of the Board, Mr. Paul Bisaro, and a new board of independent directors. The press release noted that, as a result of its emergence from bankruptcy, "Mallinckrodt is now the first company that has permanently resolved opioid litigation on a global scale, including any future claims that might be brought for periods prior to emergence."[5] It further noted that "[t]he Company will continue operating its opioid business in a responsible manner, in compliance with an operating injunction agreed to with state Attorneys General that has been in place since the commencement of the Chapter 11 process, and under the oversight of an independent monitor."[6]

1.7 Mallinckrodt's emergence from bankruptcy established an Effective Date—*i.e.*, "the date on which the Chapter 11 Plan goes effective."[7] This has a number of practical impacts upon the monitorship: (1) it permits the settling states (*i.e.*, the 50 state signatories to the Restructuring Support Agreement[8]) to enforce the terms of the Operating Injunction in each of

[4] *See* Press Release, "Mallinckrodt Emerges from Chapter 11 with Strengthened Balance Sheet and Enhanced Financial Flexibility," June 16, 2022, *available at* https://www.mallinckrodt.com/about/news-and-media/news-detail/?id=29031.

[5] *Id.*

[6] *Id.*

[7] *See* Operating Injunction § I.H.

[8] The Restructuring Support Agreement is filed as Exhibit A to Docket No. 128 of Case No. 20-12522.

the states;[9] (2) it permits the Monitor to file reports at less frequent intervals (*i.e.*, quarterly, rather than semi-annually);[10] and (3) it means, practically, that this Sixth Report and subsequent reports of the Monitor will be shared with Mallinckrodt and the seven states on the Ad Hoc Committee of governmental entities (the "Ad Hoc Committee"),[11] but will not be filed with the Bankruptcy Court. Nonetheless, Mallinckrodt and the Ad Hoc Committee are in agreement that the Bankruptcy Court retains jurisdiction to adjudicate disputes the settling states may bring related to enforcement of, or disputes concerning, the Operating Injunction if the states have not obtained a state court order enforcing the injunctive terms.

1.8 As set forth above, under Section VI.B.2.b of the Operating Injunction the Monitor may now reduce the frequency of his reports to every 180 days. For now, the Monitor will continue to submit reports every 90 days. However, with Mallinckrodt's and the Ad Hoc Committee's approval, the Monitor has decided to shift the reporting timeframe to better align with Mallinckrodt's quarterly productions under the Audit Plan, which Mallinckrodt has agreed to produce on or about the 10th of the month following each quarter's close (*i.e.*, on or about January 10, April 10, July 10, and October 10), giving the Monitor more time to analyze the documents produced under the Audit Plan before preparing his report detailing his findings as to

[9] *See* Operating Injunction § II.C (stating that, "[a]fter the Effective Date, [the Operating Injunction's injunctive terms are] enforceable in state court in each of the Settling States").

[10] *See id.* VI.B.2.b ("The frequency of Monitor Reports may decrease to every 180 days after the Effective Date").

[11] As previously noted, *see* Second Monitor Report, Dkt. No. 3409 at 24 n.11, the Ad Hoc Committee consists of (1) seven States and (2) the court-appointed Plaintiffs' Executive Committee (the "PEC") in the multi-district litigation captioned *In re National Prescription Opiate Litigation*, Case No. 17-md-02804, MDL No. 2804 (N.D. Ohio) (the "MDL"). The seven states on the Ad Hoc Committee are part of a group of 50 states that are signatories to the Restructuring Support Agreement filed as Exhibit A to Docket No. 128 of Case No. 20-12522.

Mallinckrodt's compliance with the Operating Injunction in the preceding quarter. Under the modified schedule, the Monitor will provide his reports approximately every 90 days on the first day of every fourth month (*i.e.*, September 1, December 1, and so on).

1.9 ***The Monitor's final meeting with the Official Committee of Opioid Related Claimants (the "OCC").*** On April 28, 2022, the Monitor held a meeting with the Official Committee of Opioid Related Claimants (the "OCC") to discuss topics including the Fifth Monitor Report. OCC members inquired about the addition of new opioid products to Mallinckrodt's product catalogue. Specifically, they were interested in the reasons for the addition of the new products, a topic discussed below in connection with the interview of Mallinckrodt's Vice President of Sales and Commercial Operations, Generics. *See infra*, Section 7.

1.10 ***The Monitor's site visit to Mallinckrodt's St. Louis-area headquarters.*** As previously noted, the Monitor had expressed the hope of engaging in more in-person interactions with Mallinckrodt's personnel. Following delays caused by various Coronavirus ("COVID-19") variants, the Monitor and his team were able to conduct an initial site visit and meeting with Mallinckrodt personnel on May 9-10, 2022, at Mallinckrodt's St. Louis, Missouri-area headquarters, including two manufacturing facilities. This visit is discussed in more detail below. *See infra*, Section 11.

1.11 The Monitor intends to conduct a site visit at Mallinckrodt's Hobart, New York manufacturing facility later in the month of September 2022.

* * *

1.12 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 One to the First, Second, and Third Monitor Reports. Although Mallinckrodt recently emerged from bankruptcy, Mallinckrodt's confirmed and now operative Plan of Reorganization incorporates the Operating Injunction. *See* Case No. 20-12522, Dkt. No. 6660-2.

2.2 In Section VI of the Operating Injunction, Mallinckrodt agreed to retain an independent Monitor, subject to the Bankruptcy 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. As noted above, following the Effective Date, the Operating Injunction permits the Monitor to decrease the frequency of reports to every 180 days. *See* ¶ 1.8, *supra*. Although the Monitor has deferred, for now, a decision as to a change in

the frequency of future reports in the remainder of his term, the Monitor did extend the period of this Sixth Monitor Report in order to better align the production of additional documents and information sought from Mallinckrodt with the reporting schedule.

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.

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.

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.

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.

3.5 ***The Fifth Monitor Report.*** The Monitor submitted the Fifth Monitor Report on April 19, 2022. *See* Case No. 20-12522, Dkt. No. 6185; Adv. Pro. No. 20-50850, Dkt. No. 339.

4. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Sections 7 and 11, *infra*, the Monitor has made six new recommendations related to the Operating Injunction's ban on financial rewards and its requirement of monitoring and reporting of direct and downstream customers. Mallinckrodt has agreed to implement these recommendations.[12] They are to:

> 6(a) Mallinckrodt should include explicit references to the Operating Injunction in Sales Compensation Plans for future years.

[12] These recommendations are prefaced by the number "6" to indicate they were made in the Sixth Monitor Report.

6(b) Mallinckrodt should provide additional training to the Human Resources Department (by Mallinckrodt's legal counsel) to prevent consideration of improper incentives in bonus recommendations.

6(c) Mallinckrodt should ensure greater consistency among direct customer audit reports, and more fulsome follow-up where necessary to obtain compliance assurances.

6(d) The CSC Director should share with the SOMT, before each monthly meeting, his separate tracking list of pharmacies pending due diligence review to ensure tabled pharmacies do not evade future review.

6(e) Mallinckrodt should continue to raise with the "Big Three" distributors, the persistent issue of delayed provision of due diligence, which in turn delays Mallinckrodt's chargeback restrictions, potentially affecting the diversion of Opioid Products.

6(f) The CSC Director should ensure that evidence of diversion risks appearing in the TrackWise inquiry and complaint logs escalated by the Associate General Counsel (or designee) is reviewed and included in SOMT pharmacy reviews, as appropriate.

5. THE INTEGRITY HOTLINE

5.1 In the Sixth Reporting Period the Monitor still received no relevant substantive reports through the integrity hotline. The Monitor did, however, receive an errant report on an unrelated topic.

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,[13] 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.

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

6.2 As detailed in its Compliance Report, Mallinckrodt's Promotional Review Committee ("PRC") reviews and approves new and existing promotional materials for compliance with the terms of the Operating Injunction. *See* Mallinckrodt Compliance Report, Adv. Pro. No. 20-50850, Dkt. No. 174-1 (hereafter, "Mallinckrodt Compliance Report") § 4.6.

6.3 Beginning in the Fourth 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.

6.4 The PRC met six times in the first half of 2022.[14] The Product Manager of Commercial, who chairs the PRC, led the meetings. Each was conducted via videoconference and lasted between twelve and forty-two minutes. The Monitor reviewed the minutes of those meetings as well as the materials the PRC considered.

6.5 Among the items the PRC considered and approved were recently updated versions of the Specialty Generics Product Catalog which included the addition of 100-count bottles of Oxycodone Hydrochloride Tablets in 10 mg and 20 mg sizes. The PRC also reviewed and approved panels and other display materials designed for use at upcoming trade conferences and similar events. The materials touted the company's API manufacturing capabilities and advocated for broader access to Medication Assisted Treatment ("MAT") of opioid use disorder. Based on the Monitor's review, the content of these promotional items is consistent with Section III.A of the Operating Injunction.

6.6 At its January 20, 2022 meeting, the PRC reviewed a promotional flyer but ultimately determined that a vote for approval was unwarranted. The flyer, created by an outside

[14] Pursuant to its operating charter, the PRC meets on an as-needed basis. The 2022 meetings were held on January 20, February 10, February 24, March 10, March 24, and April 12.

advocacy group, promoted support for full access to MAT in prisons and jails. The Associate Director of Government Affairs, a PRC member, explained that Mallinckrodt's external lobbyists utilized the flyer in meetings with the Missouri state legislature and intended to continue doing so in Missouri and other jurisdictions such as Illinois. The PRC consulted its own standard operating procedure ("SOP") that excludes materials intended for use primarily for governmental or public policy matters and determined it would take no further action regarding the flyer. The Monitor reviewed the applicable sections of the SOP and concurs with the PRC's assessment.

6.7 At its February 24, 2022 meeting, the PRC considered a series of PowerPoint slides containing background information about Mallinckrodt in a number of areas, including its emergence from bankruptcy and the status of opioid tax legislation in several states. The meeting minutes reflect the PRC's discussion of the dynamic nature of certain subject areas, particularly those related to slides intended for use with external audiences. According to the Compliance Manager, a standing member of the PRC, the Commercial team submitted these specific slides for review because it occasionally incorporates the materials into its presentations to external groups. By approving the slides in advance of any potential future use, the PRC could ensure the Commercial team's ability to pull from them as needed, with the assurance that the materials had already been reviewed for compliance with the Operating Injunction.

6.8 The PRC's composition also changed during this reporting period. During the January 20, 2022 meeting, the PRC voted to approve its new operating charter which reflected two changes to its Standing Core Members list: the Associate Director of Regulatory Affairs and the Senior Director of Government Affairs were replaced, respectively, by the Director of Regulatory Affairs and the Associate Director of Government Affairs. The replacement of the

Senior Director of Government Affairs was due to personnel departures.[15] The second composition change was entirely administrative: the Associate Director of Regulatory Affairs was promoted to Director of Regulatory Affairs and remained on the PRC.

6.9 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.

6.10 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 ("PMS"), or her designee, with reviewing customer inquiries on a monthly basis and evaluating the PMT's responses for compliance with the Operating Injunction.

6.11 Beginning in the Fourth Reporting Period, and on an on-going basis as part of the agreed-upon Audit Plan, the Monitor receives and reviews TrackWise complaint and inquiry entries pertaining to opioids, as well as the results of this auditing process, on a quarterly basis. Many TrackWise inquiries pertain to the composition of Mallinckrodt's opioid products, such as

[15] In addition to the Senior Director of Government Affairs, the Director of Post-Market Surveillance, another Standing Core Member, was terminated as part of a reduction in force. The former Director of Post-Market Surveillance was one of two Product Monitoring team representatives on the PRC and, as such, Mallinckrodt does not intend to backfill her committee position given the continued membership of the Lead Medical Affairs Specialist.

whether the products contain allergens such as gluten, while TrackWise complaints generally encompass areas such as defects in patch adhesives, broken or missing tablets, or other product quality issues.

6.12 During this reporting period, the Monitor reviewed the TrackWise Audit Reports for the first six months of 2022. The former Director of Post-Market Surveillance conducted the first series of audits of TrackWise inquiries received between January 1, 2022 and March 4, 2022. In March, Mallinckrodt informed the Monitor that the Director of Post-Market Surveillance was terminated as part of a reduction in force. Subsequent audits were conducted by the Senior Director, Quality, and included reviews of both TrackWise inquiry and complaint data. According to the resulting audit reports, the process has not revealed any instances requiring remedial training or other corrective action thus far in calendar year 2022.[16]

6.13 Although the TrackWise work instruction does not contemplate auditing of complaint data, the Senior Director, Quality has taken the initiative in incorporating that process into her monthly auditing protocol. The Senior Director has spent thirty years at Mallinckrodt,

[16] As detailed in the Fourth and Fifth Monitor Reports, the December 21, 2021 TrackWise audit revealed that a call-taker, working for a third-party vendor, responded to a customer inquiry related to a non-Mallinckrodt opioid product. According to the former Director of Post Market Surveillance, who conducted the audit, Mallinckrodt provided the call-taker and the vendor's other employees with remedial training on the Operating Injunction to ensure that similar errors did not occur. The Monitor has requested, but has not received, the substance of the training provided to this third-party vendor, including the person or persons who led the training. However, the Monitor has met a number of times with the Senior Director of Quality to discuss the company's relationship with this vendor and the scope of its employees' duties. According to the Senior Director, the vendor's employees do not input inquiry data directly into TrackWise. Rather, they merely field calls and forward the appropriate information to a PMS team member who then handles any future outreach to the caller. The vendor generates its own call logs, which are reconciled internally with TrackWise. The Senior Director reviews this reconciliation as part of the TrackWise audit process.

the last sixteen in the Quality Department. She provided the Monitor with a detailed explanation of the coding process for inquiries and complaints received by the PMT and, with regard to complaints, the requirements for elevation to management and other departments pursuant to the *Elevated Issue Management Notification Process* SOP, which the Monitor also reviewed during this reporting period. Pursuant to the SOP, calls documented with specific product codes must be elevated to more senior management for further review. Using the product codes in TrackWise, the Senior Director is able to focus her audit process on those complaints to determine whether the PMT responded appropriately. She is also able to examine the underlying call details, as recorded in TrackWise, to assess how an elevated complaint was ultimately resolved. The Monitor commends Mallinckrodt and the Senior Director of Quality for voluntarily undertaking an audit process of TrackWise complaints, in addition to inquiries.

6.14 During one of his meetings with the Senior Director, the Monitor expressed concern that the TrackWise audits did not appear to reveal any shortcomings or deficiencies in the response to inquiries or the handling and elevation of complaints by the PMT. The Senior Director explained that the TrackWise audit's focus is the call-taker's compliance with the Operating Injunction and the company's policies for call handling. She noted, however, that there may be, and sometimes are, other quality issues raised by the call itself that are elevated pursuant to the complaint handling SOPs or that trigger Mallinckrodt's internal quality control processes and subsequent corrective action. Those events are reported elsewhere. For instance, a PMT member generates a monthly Post-Market Surveillance Executive Summary Report that enables the Senior Director to review and analyze product quality trends at a high-level, and implement Mallinckrodt's internal quality-control processes if necessary. The Monitor requested and reviewed the PMS Executive Summaries for the months of April and May 2022 during this

reporting period. These Summaries provided additional detail about the company's response to product quality complaints, including its compliance with the FDA's Drug Supply Chain Security Act, and allowed the Monitor to better understand Mallinckrodt's quality control process generally, and how it interplays with Mallinckrodt's obligations under the Operating Injunction.

6.15 Based on the Monitor's review of the underlying TrackWise data and the audit reports for the first two quarters of 2022, as well as his interviews with the Senior Director, Quality, it appears that the TrackWise entries and audits are being conducted in a manner consistent with Mallinckrodt's work instruction and the Operating Injunction.

6.16 The Monitor's review of TrackWise complaint data and the accompanying audit reports has raised one issue for further consideration. As discussed in the prior Report, the bulk of the complaint entries, which are categorized and coded according to type, relate to defects in patch adhesives, broken tablets, and similar issues that are not pertinent to the duties and work of the Monitor. Further, the number of opioid product complaints received on a quarterly basis is significantly higher[17] than the number of inquiries, making it challenging for the Monitor to assess compliance with the Operating Injunction for each complaint while also assessing the effectiveness of the audit process. As discussed further in Section 11, the Monitor believes that TrackWise is a potentially useful tool in Mallinckrodt's anti-diversion efforts and will explore with the company potential avenues to enhance the SOMT's use of TrackWise data.

[17] By way of limited example, 1,046 opioid product complaints were logged in TrackWise during the second quarter of 2022.

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

7.1 Section III.B.1 of the Operating Injunction states that "Mallinckrodt shall not provide financial incentives to its sales and marketing employees or discipline its sales and marketing employees based upon sales volume or sales quotas for Opioid Products." However, the same Section permits Mallinckrodt to create more holistic financial incentives, even if Opioid Products are included: "Notwithstanding the foregoing, this provision does not prohibit financial incentives (*e.g.*, customary raises or bonuses) based on the performance of the overall company or Mallinckrodt's generics business, as measured by EBITDA, revenue, cash flow or other similar financial metrics."

7.2 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 the FSCP was consistent with the Operating Injunction's requirements. *See* Second Monitor Report at 11 ¶ 7.2 to 12 ¶ 7.5. As noted below, in the Sixth Reporting Period the Monitor reviewed additional documents relating to the 2022 Sales Compensation Plan ("SCP") and interviewed Mallinckrodt's Vice President of Sales and Commercial Operations, Generics.

7.3 As described further below, the Monitor's review confirms Mallinckrodt's continued compliance with the above-quoted provisions of the Operating Injunction.

1. Review of SCP-related documents

7.4 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. This included, for the period January 1, 2022 through December 30, 2022: (1) general

Terms and Conditions for the SCP; (2) specific SCPs for Generics National Accounts, Addiction Treatment, and Active Pharmaceutical Ingredients ("API") salespersons and contractors; (3) a Discretionary Bonus plan for API employees and contractors; and (4) a Management By Objectives ("MBO") discretionary bonus plan for Generics National Accounts.

a. Generics National Accounts

7.5 The Monitor's primary interest was in the SCPs for the Generics National Accounts, as the Generics National Accounts Team is responsible for the sale of Opioid Products. Like Mallinckrodt's FSCP for 2021 for Generics National Accounts, SpecGx's performance remains a component of the SCP for 2022, although the weighting of SpecGx's contribution to performance has increased from 50% to 80%. The 2022 SCP consists of just two (instead of three) weighted metrics: (1) SpecGx achieving certain net sales and financial contribution margin targets (80%); and (2) the individual's rating under the MBO standards defined by the Vice President of Global Sales (20%).

7.6 Based upon the Monitor's review of the 2022 SCP for Generics National Accounts, it seems that the compensation of qualified sales representatives based upon the performance of the SpecGx business as a whole, including the sale of Opioid Products, and other factors unrelated to sales volume or sales quotas for Opioid Products, complies with Section III.B of the Operating Injunction. Additionally, the MBOs specific to Generics National Accounts, as explained to the Monitor by Mallinckrodt's Vice President of Sales and Commercial Operations, Generics (see discussion below), likewise assures the Monitor that the incentives are not designed to increase the volume of Opioid Sales.

b. Addiction Treatment National Accounts and API Sales Personnel

7.7 Mallinckrodt also shared with the Monitor the 2022 SCP for the Addiction Treatment National Account Manager and API U.S. and International Sales Personnel and independent contractors. Although Mallinckrodt's Addiction Treatment and API sales teams do not sell Opioid Products-- as defined in the Operating Injunction, and therefore would not be compensated based upon "sales volume or sales quotes for Opioid Products,"[18] the Monitor reviewed these plans for compliance with the Operating Injunction as well.

7.8 Like the 2022 SCP for Generics National Accounts, the 2022 SCP for the Addiction Treatment National Account Manager consists of two weighted components: (1) the addiction treatment team achieving certain net sales and contribution margin targets for the addiction treatment accounts (80%); and (2) the individual's MBO rating (20%). The same components and weightings apply to both the 2022 SCP for API U.S. and International Sales Personnel and independent contractors. Mallinckrodt also provided its guidelines for discretionary bonus awards to API sales team members and contractors, which may be awarded to individuals who contribute to Mallinckrodt's API business through either new development

[18] The Operating Injunction's definition of "Opioid Products" specifically excludes:

> medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage"; methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities; or raw materials, active pharmaceutical ingredients and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials, active pharmaceutical ingredients and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories.

See Operating Injunction § I.Q.

projects and increases in revenue from existing business. Based on the Monitor's review of these plans and guidelines, the Monitor concluded Mallinckrodt's compensation of the Addiction Treatment National Account Manager and the API sales team members and contractors comply with Section III.B of the Operating Injunction.

* * *

New Recommendation 6(a). Include explicit references to Operating Injunction in Sales Compensation Plans for future years.

7.9 **While the above-referenced SCPs do state that eligibility for certain incentives is dependent upon "[a]dherence to applicable laws, the Company Code of Conduct, policies, procedures and guidelines," the Monitor notes that the policies presently do not explicitly reference the Operating Injunction. The Monitor recommends that future iterations of the SCPs be modified to include more explicit references to the requirements of the Operating Injunction, and compliance with the Operating Injunction as a prerequisite for incentive compensation eligibility.** Mallinckrodt has agreed to this recommendation, which will be implemented for the 2023 SCPs.

2. <u>Interview of the Vice President of Sales and Commercial Operations, Generics</u>

7.10 As noted above, the Monitor interviewed the Vice President of Sales and Commercial Operations for Generics to discuss the 2022 SCP. The Vice President noted that completion of training (including training on the Operating Injunction) is a prerequisite for bonus eligibility.

7.11 Additionally, the Vice President reiterated that the MBOs are intended not to be product specific and cannot reward the sale of opioids. Indeed, out of an abundance of caution, the Vice President removed an incentive tied to a fentanyl patch product in a prior version of an MBO that was tied to assessing a foreign market outside of the United States, even though the

MBO was outside the scope of the Operating Injunction, which is directed to Mallinckrodt's activity within the United States, and not to foreign markets.[19] The Vice President determined that the reference to the specific Opioid Product should be removed even as to marketing activity outside the United States.

New Recommendation 6(b). Provide additional training to the Human Resources Department (by Mallinckrodt's legal counsel) to prevent consideration of improper incentives in bonus recommendations.

7.12 **The Vice President's discovery of an MBO that, in a prior iteration, contained a reference to an opioid product (albeit outside the United States, and therefore outside the scope of the Operating Injunction), suggests there would be value in additional oversight of sales compensation incentives. To support this effort, in-house counsel can train an appropriate Human Resources Department representative to conduct oversight of the MBOs for the Generics National Accounts Team. Since there are just four members of the Generics National Accounts Team, and the MBOs are brief, this recommended additional assurance and oversight can be accomplished with relatively little additional investment of time.** Mallinckrodt has agreed to this recommendation.

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

[19] *See, e.g.*, Operating Injunction § I.N (defining "Mallinckrodt's Opioid Business" as "Mallinckrodt's business operations relating to the manufacture and sale of Opioid Product(s) ***in the United States and its territories***" (emphasis added)); *id.* § I.T (defining, among other terms, "Promotion" as "dissemination of information or other practices intended or that could be reasonably anticipated to increase sales, prescriptions, the utilization of prescription products, or that attempt to influence prescribing practices or formulary decisions ***in the United States***" (emphasis added)).

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. During this reporting period, the Monitor reviewed the minutes of ten SGGSAC meetings, which took place from January 18, 2022 to June 17, 2022, 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.[20]

8.3 The Monitor also reviewed the newly-revised *Specialty Generics Grant & Sponsorship Approval Committee* SOP which went into effect on June 21, 2022, and includes several notable changes to the SGGSAC's composition and processes. First, to reduce the risk of the appearance of improper influence, the new SOP provides that sales, commercial, finance, and marketing team members may no longer serve as voting members of the Committee. Second, the Committee now meets biweekly and on an ad hoc basis as needed, rather than annually and on an ad hoc basis. Finally, the revised SOP implements a first-level review of sponsorship/grant requests by the Integrity & Compliance Team before SGGSAC Request Forms and supporting materials/documentation are submitted to the full Committee to ensure the

[20] In his review of the January 28, 2022 meeting minutes, the Monitor observed that the Committee approved a $2,490 sponsorship for registration and attendance fees for the Annual Meeting for the Association of Accessible Medicines ("AAM"). The Committee also discussed Mallinckrodt's decision not to renew its AAM membership for the current year. The company's relationship with AAM and its intersection with the Operating Injunction is detailed in both Mallinckrodt's Compliance Report and prior Monitor reports. As such, the company's decision not to renew its membership for the upcoming year due to cost considerations is notable.

request complies with the Operating Injunction. The Monitor commends Mallinckrodt on these changes, and believes that these revisions to the SOP enhance Mallinckrodt's compliance with Section III.C of the Operating Injunction.[21]

8.4 The Monitor met with the Compliance Manager, a member of the SGGSAC, to gain a better understanding of the revised *Specialty Generics Grant & Sponsorship Approval Committee* SOP and the Committee's operation under the new policy. The Compliance Manager explained that she and the Associate General Counsel comprise the Integrity & Compliance Team tasked with the responsibility of conducting the initial review of all Requests. As detailed in the Monitor's Fifth Report, the Integrity & Compliance Team's role in the SGGSAC's work was a partial response to a Mallinckrodt employee's submission of a conference registration request that, according to the conference agenda, would include events touching upon opioid prescriptions and pain management and, as such, Mallinckrodt's funding of the request would likely constitute a violation of the Operating Injunction. The full Committee ultimately rejected the request, but the Integrity & Compliance Team's review is designed to prevent potentially violative requests from ever reaching the full Committee. Since implementing the change, the Compliance Manager reported that the Integrity & Compliance Team has not denied any Requests at this first level of review. This may be due to applicants' increased understanding of the SGGSAC process and the prohibitions on third party funding as outlined in the Operating Injunction, but nevertheless, the Monitor will continue to closely assess all Requests.

8.5 The revised SOP also clarifies a question the Monitor raised in his Fifth Report regarding the Committee's outreach to employees whose funding requests are denied. Under the

[21] According to the meeting minutes, the SGGSAC also revised its operating charter. The Monitor received the updated charter at the end of this reporting period, and anticipates discussing his review and analysis in the next reporting period.

previous SOP, the Committee notified the employee via declination letter, but the SOP prohibited the SGGSAC from identifying the reason for the Committee's decision as providing this information "could be viewed as coaching and/or influencing the content of revised or future applications." The revised SOP contains no such prohibition. Rather, it permits the Committee to notify the internal requestor of the declination reason "so long as the integrity of the review is not compromised." The revised SOP does prohibit the SGGSAC from sharing the declination reason with the third party funding recipient. The Monitor appreciates Mallinckrodt's revised approach in that it preserves the SGGSAC's ability to provide remedial training or other corrective action for employees whose funding requests potentially run afoul of the Operating Injunction.

8.6 The revised SOP also allows the SGGSAC's approval of conference registration fees and sponsorships when the internal requestor is unable to submit a current agenda or other accompanying materials. Under the new SOP, the requestor can submit the prior year's agenda or other historical data, provided that the requestor supplements the request by submitting the current year's materials in a timely manner. The Monitor notes that the SGGSAC should close the loop on these conditional approvals by ensuring that the Committee's full approval upon receipt of the current year's materials is noted in the minutes of future meetings or, if deliberations took place over email, that such correspondence is appended to the original meeting minutes. For example, in its March 11, 2022 meeting, the Committee relied upon a prior year's agenda and other historical materials in approving a $12,000 attendance and exhibit fee for ThoughtSpot 2022, an annual tradeshow hosted by Mallinckrodt's customer AmeriSource Bergen. The Monitor was informed that the current year's event schedule and materials were ultimately approved by the Integrity & Compliance Team rather than the full SGGSAC.

However, the Integrity & Compliance Team's review is not reflected in the Committee's subsequent meeting minutes. The Monitor anticipates additional discussion with Mallinckrodt as to how best to document the review and approval of materials conducted outside of the customary SGGSAC meeting process.

8.7 Another issue raised in the Monitor's Fifth Report but left unaddressed in the revised SOP is the potential need for a temporal requirement for submission of third party funding Requests.[22] In response to the Monitor's concern, Mallinckrodt updated the funding Request Form, rather than the SOP, to incorporate a requirement that the internal requestor submit the form and any accompanying materials seven days prior to the next SGGSAC meeting. Any requests received after the required deadline will be moved to the next meeting for consideration. The revised form appears to address the Monitor's concern about the potential pitfalls of expedited or rushed review of third-party funding requests and the Monitor appreciates Mallinckrodt's response.

8.8 Another concern previously raised relates to the practice of SGGSAC members submitting and voting on their own funding requests. In his review of first and second quarter meeting minutes, the Monitor observed that the Associate Director of Government Affairs, a recent addition to the SGGSAC Standing Core Member list, submitted and voted to approve requests for funding of his own conference registration fees on two occasions. The first request, approved in the May 18, 2022 SGGSAC meeting, involved a $2,500 sponsorship of the North Carolina Biosciences Organization ("NCBIO") annual legislative reception. The second, at the June 17, 2022 SGGSAC meeting, concerned the approval of a $25,000 sponsorship of the

[22] As detailed in the Fifth Report, the SGGSAC approved a late-submitted sponsorship request where the accompanying materials noted that the company would face significant financial penalties for late cancellation. *See* Fifth Monitor Report at ¶ 8.5-8.6.

National Commission on Correctional Health Care ("NCCHC") Foundation for its National Conference. According to the Compliance Manager, the company discussed the question internally after the Monitor initially raised it but ultimately decided against prohibiting the practice. The Monitor anticipates further discussion with Mallinckrodt's leadership about the propriety of the practice, particularly in light of the recent SOP revision that removed commercial, finance, and sales employees from the SGGSAC to "reduce the risk of even the appearance of improper influence."

8.9 During the next reporting period, as part of the agreed-upon Audit Plan, 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 underlying materials, and the minutes of any SGGSAC meetings on a quarterly basis. The Monitor will continue to work with Mallinckrodt to ensure that the SGGSAC is operating in a manner consistent with Section III.C of the Operating Injunction as it relates to 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 ***Prior Recommendation 3(c).*** [23] 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

[23] All of the Monitor's recommendations to date are summarized in attached **Exhibit One**, along with implementation status. Implemented recommendations not specifically referenced in this report are discussed in prior reports.

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). At that time, the Monitor noted that the SOP was lacking sufficient detail about the review process to be adequately assessed. The Monitor anticipated a more fulsome review after Mallinckrodt's completion of one auditing cycle.

9.4 During this reporting period, the Monitor received and reviewed the results of the Government Affairs team's audit of Mallinckrodt's external state lobbyists' public disclosure reports under the *Lobbying Certification and Activity Review* SOP. The first quarter 2022 audit report consisted of an Excel spreadsheet, which listed the states encompassed in the review, the disclosure filing schedule for those states, links to the online filing location of the disclosure reports, and the audit results. However, information such as who conducted the audit, the date it was conducted, and the specific process for reviewing the disclosure reports was not included in the spreadsheet. Instead, the auditor inserted "no concerns noted," to reflect the results of the review of each state's disclosure reports. Similar to his review of the operating SOP, the

Monitor finds that the documentation of the process, as reflected in the audit report, lacks sufficient detail to be adequately assessed.

9.5 Given these concerns, the Monitor spoke with the Associate Director of Government Affairs who conducted the first quarter 2022 audit, to better understand the specifics of his review process, as well as other documents produced during this reporting period. The Associate Director provided a thoughtful and substantive explanation of the factors he considered in his review, such as whether the disclosures included prohibited activity and were in line with his direction to the lobbyists, and whether anything was reported erroneously. His review also confirmed that any work the lobbyists were doing for a trade organization or other entity did not spill over into or otherwise overlap with their work for Mallinckrodt. The Monitor commends the Associate Director on his detailed review process, and believes this level of scrutiny is consistent with Recommendation 3(c).[24] However, the Monitor notes that he was only able to accurately assess the adequacy of the review by speaking with the Associate Director, as both the audit work product and SOP lacked sufficient detail. The Monitor suggests that the audit report itself be amended in future quarters to include the missing details noted above so that the resulting report can exist as a standalone record to be assessed on its own merits.[25]

9.6 As detailed in the Fifth Report, the Monitor met with a partner of Lobbying Firm CA, one of Mallinckrodt's state lobbyists, to gain a better understanding of Mallinckrodt's

[24] The Monitor notes that he has not yet received the audit results for the disclosure reports of Mallinckrodt's federal lobbyists, and looks forward to receiving those documents as soon as they are available.

[25] The Monitor suggests utilizing the detailed TrackWise audit report records created by the Post-Market Surveillance team as a starting template.

activities related to legislation that would require pharmacies to dispense oral dosages of controlled substances in a lockable vial, and would require drug manufacturers to reimburse pharmacies for some or all of the cost of these lockable vials. During this reporting period, the Monitor received and reviewed the materials provided to California legislators, which outlined Mallinckrodt's nuanced position on this bill – specifically the cabining of its opposition solely to the bill's reimbursement provision. Based on the Monitor's review of this correspondence, Mallinckrodt's position and lobbying efforts related to this legislation[26] are consistent with Section III.D of the Operating Injunction.

9.7 Pursuant to the Audit Plan, the Monitor also received and reviewed a list of bills that Mallinckrodt lobbied either for or against during the first quarter of 2022. This list included the California lockable vial bill discussed above, as well as a New York bill which would require the Department of Health to publish certain reports on the Department's website detailing sales of opioids in the state, and a Missouri bill relating to naltrexone hydrochloride. The Monitor previously discussed the New York bill with a representative of Lobbying Firm NY, Mallinckrodt's New York lobbying firm. During his discussion of this list with the Associate Director, the Monitor raised the suggestion that Mallinckrodt include additional detail such as the company's position on each bill in its reporting of this activity to the Monitor pursuant to the Audit Plan, as such information would permit the Monitor to better assess whether Mallinckrodt's advocacy on these items complies with the Operating Injunction. The Monitor looks forward to reviewing more detailed disclosures in the coming quarters.

[26] During his interview with the Monitor, the Associate Director explained that this legislation was "effectively killed" for the year 2022, after the Appropriations Committee of the California legislature declined to advance it further. Therefore, the Monitor does not anticipate review of Mallinckrodt's advocacy efforts on this bill in future Reports.

9.8 During this reporting period, Mallinckrodt revised its Guide to Business Conduct, which outlined the company's rules and expectations for interacting with government officials. The previous Guide was drafted prior to the implementation of the Operating Injunction, and therefore did not mention any of its prohibitions or obligations. The new document, now titled the Code of Conduct, has been re-worked into an interactive webpage, which allows Mallinckrodt employees to navigate to specific sections based on overarching headings. The Code contains a link to the Operating Injunction in the final section, but does not reference the Operating Injunction in the preceding sections. Nonetheless, based on the Monitor's review of the revised Code of Conduct, Mallinckrodt's general policies pertaining to interaction with government officials are consistent with Section III.D of the Operating Injunction.

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 Pursuant to the Audit Plan, *see* ¶ 1.4, *supra*, the Monitor will request that Mallinckrodt's Associate General Counsel re-certify its representations regarding these provisions of the Operating Injunction in January 2023.

10.4 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 in the interim, Mallinckrodt has agreed to promptly inform the Monitor.

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

11.1 In the Sixth Reporting Period, the Monitor continued his assessment of Mallinckrodt's compliance with Section III.G of the Operating Injunction. Specifically, the Monitor: (a) obtained 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; (b) continued his review of data and documents provided in response to the Audit Plan; (c) conducted follow-up interviews with the Controlled Substances Compliance ("CSC") Director, the Lead CSC Consultant (the "LCSCC"), the CSC Auditor / Data Analyst, the CSC

Senior Manager, and the Vice President of Sales and Commercial Operations, Generics; and (d) met with Mallinckrodt employees at the company's St. Louis manufacturing facilities.

11.2 The Monitor's findings from this activity are described in the following sections: (1) documents the Monitor reviewed during the Sixth Reporting Period; (2) direct customer due diligence; (3) downstream registrant due diligence; and (4) other SOM-related issues.

1. Documents the Monitor Reviewed During the Sixth Monitoring Period

11.3 Mallinckrodt made a timely production of all SOM-related documents requested under the Audit Plan for the second quarter and in response to the Monitor's ad hoc requests.

11.4 In auditing Mallinckrodt's compliance with the Operating Injunction's SOM-related provisions, the Monitor reviewed the following documents or categories of documents: (1) the SOMT meeting materials and minutes for April, May, June, and July 2022; (2) the Tracking Spreadsheet; (3) the Government Communications log and related correspondence; (4) Mallinckrodt's updated list of media search terms; (5) sales data for highly diverted Opioid Products; (6) Mallinckrodt's letter agreement with one of the "Big Three" distributors; (7) direct customer flagged order data; (8) audit reports for four direct customers; (9) security audit reports; (10) data related to the SOMT's chargeback review process; and (11) TrackWise inquiries and complaints raising potential diversion concerns.

2. Direct Customer Due Diligence

a. *Direct customer flagged orders in Q2 2022*

11.5 At the Monitor's request, Mallinckrodt produced lists of flagged direct orders of opioid products for the first and second quarters of 2022. These lists separate orders by "lines," each of which represents a separate product a direct customer ordered. Thus, orders for multiple products contain multiple lines corresponding to each product ordered.

11.6 In the second quarter of 2022, out of a total of 26,293 lines of opioid products orders, 8,046 lines were flagged (31%). None of these flagged lines were withheld from shipment. By way of comparison, in the first quarter of 2022, out of a total 22,444 lines of opioid product orders, 7,596 lines were flagged (34%). Of these flagged orders, just ten (0.13%) were withheld from shipment. All of these held orders were orders from the direct customer referred to as Distributor B in the Fifth Monitor Report. *See* Fifth Monitor Report at 39 ¶ 11.43; *see also infra* at 40 ¶ 11.29.[27] The small number of held orders stands out. At the same time, this may not be particularly surprising, given the vast majority of direct orders come from the "Big Three" distributors (namely, Amerisource Bergen, Cardinal Health, and McKesson). Given the comparative advantages of the "Big Three" in terms of size, resources, and personnel, it is likely their SOM systems are more developed than the comparable SOM systems of smaller distributors.

11.7 The Monitor conducted an interview with the LCSCC and the CSC Auditor / Data Analyst, who provided additional background on Mallinckrodt's current practices with respect to review of direct customer orders. When a direct customer places an order, Mallinckrodt's direct customer dashboard applies algorithms to detect potentially suspicious orders. The algorithm flags orders based on unusual volume, frequency, or pattern.

11.8 The LCSCC and the CSC Auditor / Data Analyst review and flag the count of lines multiple times each day. The flagged lines are compiled in a report called the Unusual Order Report ("UOR").

[27] The LCSCC and CSC Auditor / Data Analyst explained that two other direct customers Mallinckrodt restricted were not flagged in the direct customer orders prior to being restricted because they were identified through a media alert. *See* Fifth Monitor Report at 38 ¶ 11.41 to 40 ¶ 11.46; Fourth Monitor Report at 43 ¶ 11.62 to 45 ¶ 11.64.

11.9 If the reviewers identify an order flagged for volume, pattern or frequency for a given direct customer, they often go to Mallinckrodt's Customer Service Department to ask if there are any new contracts with that customer or any market disruptions affecting order volumes. For example, if a competing supplier for a particular product exits the market, Mallinckrodt can anticipate increased order volumes for that product. In some instances, the reviewers contact the direct customer to inquire further about the order.

11.10 If the LCSCC and the CSC Auditor / Data Analyst are unable to resolve their concerns about an order after considering that customer's contract awards, market factors, the information provided by the customer, and the LCSCC's own due diligence, they consult with the CSC Director and the CSC Senior Manager. In the event this four-person team is unable to resolve their concerns regarding a particular order, the team prevents the order from being shipped and files a report with the United States Drug Enforcement Administration ("DEA") using the prescribed DEA online form. The Mallinckrodt team resolves questions arising from flagged orders within ten days and reports the outcome of their decision-making process to the SOMT, as appropriate.

11.11 The LCSCC and the CSC Auditor / Data Analyst reported that they have sufficient time and resources to resolve issues arising from the flagging algorithm. They reported that it was typical for a relatively low percentage of flagged orders to be withheld from shipment because most instances of flagging can be explained by market factors or input from customers. In the Monitor's view, the Mallinckrodt team appears to be taking appropriate steps to validate the orders the direct customer dashboard is flagging.

11.12 The Monitor requested backup documentation for flagged orders that were ultimately shipped and will review and analyze this documentation during the next reporting period.

b. *Operating Injunction hold list*

11.13 At the Monitor's request, Mallinckrodt produced a list of orders flagged and held because they did not comply with the requirements of the Operating Injunction. The reasons for such a hold could include, for example, an order of Opioid Products placed by a pharmacy, rather than a distributor, which Mallinckrodt is generally prohibited from shipping under the terms of the Operating Injunction.[28]

11.14 In the next reporting period the Monitor will seek additional information regarding Operating Injunction order holds, and the reasons for them.

c. *Due diligence of direct customers not enrolled in chargeback program*

11.15 As the Monitor has previously noted, six distributors (accounting for just under 5% of opioid orders) do not participate in the chargeback program. *See* Fourth Monitor Report at 26 n.12; Fifth Monitor Report at 30 ¶ 11.22. Given the value of chargeback data to Mallinckrodt's SOM program, the Monitor 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. Based on the Monitor's discussions with Mallinckrodt, the

[28] Under the terms of the Operating Injunction, with some exceptions, Mallinckrodt may not directly supply pharmacies. *See* Operating Injunction § III.G.4 ("Mallinckrodt agrees that it will refrain from providing an Opioid Product directly to a retail pharmacy location or Health Care Provider. Nothing in this provision, however, prevents Mallinckrodt from . . . providing an Opioid Product directly to a mail order pharmacy, distribution center serving a chain pharmacy, or pharmacy provider that exclusively serves long-term care or hospice providers and their patients.").

SOMT intends to prioritize visiting these distributors as part of the annual direct customer audit process.

11.16 The CSC Director has explained why some of the six distributors are not part of the chargeback program due to idiosyncrasies regarding the purchasing contracts for various categories of these direct customers. For example, one distributor receives a different pricing model as part of a buying group, rendering the chargeback discount unnecessary. Others purchase product for shipment directly to hospice care providers or nursing homes and do not get a chargeback because there is no intermediary (like a distributor) selling the product to them at a discounted price. Another distributor is a large grocery retail chain that has negotiated a particular pricing option with Mallinckrodt, and therefore does not need a chargeback price.

d. *Prior recommendations relating to agreements with direct customers on coordinated anti-diversion efforts*

11.17 ***Prior Recommendations 2(d), 2(e), and 2(h).*** The Monitor recommended that Mallinckrodt use its best efforts to reach agreement with direct customers on various anti-diversion efforts. To that end, Mallinckrodt shared with its three largest distributor customers—the so-called "Big Three"—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 at 24 ¶ 11.13 to 25 ¶ 11.14, the proposed letter agreement would require distributors to use best efforts to cooperate in detecting and preventing the diversion of controlled substances by: (1) suspending or terminating the distribution of SpecGx's controlled substances to any recipient that SpecGx informs the distributor it is restricting (per ***Recommendation 2(d)***); (2) responding promptly to SpecGx's requests for information related to the distributor's orders, sales, and distribution of SpecGx's products (per ***Recommendation 2(h)***); and (3) notifying SpecGx if the distributor suspends or

terminates the distribution of controlled substances to the recipient within five days after the suspension or termination. 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)***).

11.18 To date, Mallinckrodt's attempts to reach an agreement with the "Big Three" distributors have been only partially successful, with agreement reached with just one of the "Big Three" distributors in a letter dated February 28, 2022, and executed on April 26, 2022. The agreement memorializes the parties' steps "to cooperate in the detection and prevention of diversion of controlled substances from legitimate channels." Specifically: (1) the distributor agrees to suspend or terminate (as agreed by the parties) the supply of SpecGx product "to any recipient that SpecGx informs Distributor, in writing, raises a substantial risk of diversion of controlled substances from legitimate channels"; (2) if either SpecGx or the distributor suspend or terminate the supply of product to a recipient under circumstances other than those just described above, they agree to promptly notify the other of the termination; (3) both SpecGx and the distributor "agree[] to respond promptly to reasonable requests" for information, including due diligence relating to customers; and (4) the distributor agrees to submit chargeback requests promptly, consistent with its current agreement with SpecGx. The Monitor continues to believe that these are commonsense measures that serve the interests of the entire supply chain in addressing diversion effectively and efficiently. The Monitor is hopeful that this agreement will serve as a model for other direct customers of Mallinckrodt in time.

11.19 Mallinckrodt has been unable to reach agreement with the other two of the "Big Three" distributors and has not yet proposed the terms contained in the letter agreement to any of

its other smaller distributors, though the company intends to do so in the future. The Monitor will include any update on Mallinckrodt's progress in reaching such agreements with additional distributors in future reports.

e. *Prior recommendations relating to direct customer due diligence*

11.20 The Monitor previously recommended that Mallinckrodt enhance direct customer due diligence by (1) enhancing direct customer questionnaires (***Recommendation 2(s)*** and ***Recommendation 5(a)***) and (2) establishing regularly scheduled interactions with direct customers (***Recommendation 2(t)***).

11.21 ***Prior Recommendation 2(s).*** As previously noted, the Monitor has reviewed an updated version of the direct customer questionnaire for distributors. *See* Fifth Monitor Report ¶¶ 11.14-11.16; Fourth Monitor Report at 37 ¶ 11.42 to 38 ¶ 11.45. The Monitor also received and reviewed Mallinckrodt's revised *Suspicious Order Monitoring Program Review of Direct Customer Orders* SOP, which now reflects Mallinckrodt's current practice of requiring all due diligence questionnaires to be reviewed by the SOMT rather than the Customer Data Integrity group. *See* Fifth Monitor Report at 28 ¶ 11.16. To date, Mallinckrodt has not yet shared with the Monitor copies of updated questionnaires for other direct customers, including manufacturers, narcotic treatment programs, and laboratories, and will share them with the Monitor when finalized.

11.22 ***Prior Recommendation 5(a).*** The Monitor previously recommended that Mallinckrodt amend its Direct Customer 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 implemented the recommendation on the Distributor Due Diligence Questionnaire by inquiring whether "any individual employed or

contracted by [the Distributor] (or, in the case of a corporation, association, partnership,—any owners, officers, principals and employees)" has "ever been convicted of a crime in connection with controlled substance(s) or health care fraud under state or federal law." The questionnaire also inquires about relevant exclusions from state or federal healthcare programs, and revocations or suspensions of professional licenses and controlled substances licenses.

11.23 ***Prior 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.

11.24 To date, Mallinckrodt has conducted four due diligence visits (all of them virtual) in 2022—on January 7, February 22, March 28, and April 14. These visits have included participation by Mallinckrodt's CSC Director, Director of Security and Plant Protection, LCSCC, CSC Auditor / Data Analyst, and sometimes the CSC Senior Manager. The audit reports are typically completed by the CSC Auditor / Data Analyst, however some ad hoc reports were completed by the LCSCC.

11.25 The four visits to date are not all those that were initially planned. This is because of unanticipated events that required Mallinckrodt, on an ad hoc basis, to review a number of different direct customers where Mallinckrodt developed suspicions and ultimately took the unusual step of restricting some direct customers. The reasons for those restrictions are discussed in the Fifth and Fourth Monitor Reports. *See* Fifth Monitor Report at 38-40 ¶¶ 11.41-11.46; Fourth Monitor Report at 43-45 ¶¶ 11.62-11.64.

11.26 Previously, Mallinckrodt shared with the Monitor templates of the *CSC/Suspicious Order Monitoring Distributor Customer Audit Checklist* and the *SOM Distributor Review Security Questions* used in these visits. Mallinckrodt more recently produced copies of the audit reports created following the visits.

11.27 The audit reports appear to be thorough. The Monitor has, however, observed some inconsistency among the reports. For example, the audit checklist asks all direct customers under review whether they (1) "use a customer questionnaire to evaluate the controlled substances compliance programs of [their] customers"; and (2) if so, whether the questionnaire explicitly addresses a number of common "red flags" pharmacies should identify. In one instance, the direct customer agreed to add questions relating to such red flags to their standard due diligence screening. However, in another instance there is no indication whether or not the direct customer agreed to this step, or whether it was requested to do so. Similarly, while one report contains concluding observations, including an agreement on the part of the direct customer to notify Mallinckrodt of any restriction of a downstream customer, another audit report contained no observations at all.

11.28 Additionally, the Monitor has observed some instances where the information derived from the audit seems to warrant follow-up, but additional information is not provided. For example, in response to questions regarding whether the direct customer sells controlled substances to "mail order pharmacies," or "pursuant to a telemedicine patient-prescriber relationship," the answers were "yes," but the audit report does not reflect additional inquiry into either business practice to determine whether the direct customer is undertaking any specific due diligence measures to address potential concerns. Similarly, in one instance the direct customer answered "No," in response to this question: "Does the distributor audit pharmacy customers

and review Rx data to check for patterns of excessive prescribing by physicians?" The audit report does not explain what if any further steps were requested of the direct customer, or whether no further steps were deemed necessary despite the response. Furthermore, one direct customer noted that it had reported three or four suspicious customers to state authorities in the past two years. However, the audit report does not identify these downstream customers, which could have permitted Mallinckrodt to conduct a chargeback review or other check of its systems for these customers. Finally, the same direct customer answered "Yes," in response to a question regarding whether it sells "controlled substances to any customer that identifies as a specialty pharmacy distributing/dispensing to service chronic pain patients," but no additional details were provided.

New Recommendation 6(c). Ensure greater consistency among direct customer audit reports, and more fulsome follow-up where necessary to obtain compliance assurances.

11.29 **For the reasons set forth above, the Monitor recommends that auditing of direct customers is more consistent in the questions posed to direct customers, and also documents more fulsome follow-up questions where appropriate.** Mallinckrodt has agreed to this recommendation.

f. ***Prior recommendation relating to reinstatement of restricted direct customers***

11.30 ***Prior Recommendation 5(b).*** In the Fifth Monitor Report, the Monitor recommended that restricted direct customers undertake substantial compliance reforms before Mallinckrodt reinstates them. By way of example, the Monitor identified two distributors (referenced in the Fifth Monitor Report as Distributors A and B), who had been restricted. Distributor A was restricted after a media alert identified multiple pharmacies that Distributor A had supplied, but which were only purchasing a few kinds of controlled substances from

Distributor A. *See* Fifth Monitor Report at 38 ¶ 11.41. Additionally, after the LCSCC discovered an unusually high volume order of Hydrocodone 10 mg by Distributor B, and suspicious ordering by Distributor B's top five customers, Mallinckrodt restricted Distributor B. *See* Fifth Monitor Report at 39 ¶ 11.43. Thus, the Monitor recommended that Mallinckrodt require similarly restricted direct customers to undertake substantial compliance reforms—of the sort Mallinckrodt required of another distributor discussed in the Fourth Monitor Report, *see* Fourth Report at 43 ¶ 11.62 to 46 ¶ 11.66—before Mallinckrodt resumes supplying these customers.

11.31 Mallinckrodt informed the Monitor that the API Purchaser referred to in the Fourth Monitor Report began manufacturing again, and the SOMT expects to receive the first compliance report from the API Purchaser's third-party consultant in September. The Monitor intends to review this report, including the API Purchaser's sales data, when available.

11.32 Since agreeing to adopt ***Prior Recommendation 5(b)***, Mallinckrodt has not reinstated any additional direct customers, so the Monitor cannot offer any observations on the SOMT's implementation of this recommendation.

3. Downstream Registrant Due Diligence

11.33 In parallel with its direct customer due diligence efforts, Mallinckrodt is continuing to conduct due diligence on its downstream registrants, also referred to as indirect customers. A summary of updates on these efforts is provided below.

a. *The indirect customer dashboard*

11.34 Shortly before the submission of the Fifth Monitor Report, the Monitor met with Analysis Group, Inc. ("AGI"), Mallinckrodt's third-party vendor, for an update regarding the launch of Mallinckrodt's indirect customer dashboard. In that presentation, AGI shared the

metrics used to prioritize the review of downstream registrants. These metrics are based upon the regulatory requirement to conduct SOM based upon suspicious order volumes, frequencies, and patterns.[29]

11.35 AGI also shared sample screenshot images from the indirect customer dashboard. Much like an Excel document with multiple tabs, the indirect customer dashboard has numerous tabs, including among them: (1) a summarized "Prioritization" tab; (2) a "Selected registrant summary" tab; (3) a "Geographic analyses" tab; and (4) explanatory tabs providing definitions and a summary of methodology.

11.36 The implementation of the indirect customer dashboard (along with the direct customer dashboard) has had a dramatic effect on the volume and effectiveness of Mallinckrodt's indirect customer surveillance. As depicted in the chart below, the volume of chargeback reviews conducted, volume of resulting restrictions, and volume of reinstatements, increased significantly in the first half of 2022 as compared to 2021:

	Q1-Q2 2021	Q1-Q2 2022	% Change
Chargeback reviews	46	126	173%
Chargeback restrictions	28	91	225%
Reinstatements	2	4	100%

11.37 Mallinckrodt's increased volume of chargeback reviews and restrictions is a positive development. Such increased surveillance activity translates, in practical terms, to fewer diverted Opioid Products on the streets. Improved big data analytics, shorter turnaround times

[29] *See* 21 C.F.R. 1301.74(b) ("Suspicious orders include orders of unusual ***size***, orders deviating substantially from a normal ***pattern***, and orders of unusual ***frequency***." (emphasis added)).

for chargeback reviews, and a substantial investment in the direct and indirect customer dashboards, as well as the investment in human talent capable of managing and analyzing the big data available, have all played a part in these results. Anecdotally, Mallinckrodt also appears to be benefitting from improved response times from its direct customers to requests for due diligence (with some notable exceptions discussed below).

11.38 The Monitor wished to clarify whether the increased volume of suspicious chargeback reviews meant that a significant number of flagged downstream registrants would be left unreviewed. The LCSCC has confirmed that the highest risk category of downstream registrants—*i.e.*, independent pharmacies—are being reviewed in full. In the next reporting period the Monitor will gain a better understanding for what volume of flagged downstream registrants (other than independent pharmacies) are nonetheless not being reviewed.

b. *Chargeback review and timeliness*

11.39 In the Sixth Reporting Period, the Monitor reviewed SOMT meeting materials and minutes for April, May, June, and July 2022. The results of that review are summarized below. Additionally, the Monitor has analyzed the results of a tracking exercise, with the benefit of six months of data, to assess the timeliness of chargeback reviews, and the turnaround time at key phases of the chargeback review process. The results of that review are also summarized below.

i. SOMT meeting materials and minutes for April and May 2022

11.40 ***LCSCC review of flagged orders resulting in prompt ad hoc restrictions.*** The SOMT meeting materials and minutes for April 27 and May 19, 2022 describe a number of instances of prompt ad hoc restrictions generated by the indirect customer dashboard. For example, on Thursday, March 31, 2022, the LCSCC utilized the dashboard to identify nine

pharmacies in Houston, Texas, that were obtaining Oxycodone or Hydrocodone from a large number of suppliers (*i.e.*, between four and eight) and no other products. Further review determined that the pharmacies were all purchasing substantially larger quantities of Oxycodone than surrounding pharmacies. On Monday, April 4, 2022, the SOMT voted to restrict all nine pharmacies.

11.41 Similarly, on April 4, 2022, the LCSCC identified five additional pharmacies in Houston, Texas, that were obtaining Oxycodone or Hydrocodone from between four and eight suppliers, and no other products. Once again, further review determined the pharmacies were all purchasing substantially larger quantities of Oxycodone than surrounding pharmacies. The SOMT voted to restrict these five pharmacies on April 6, 2022.

11.42 On May 3, 2022 the LCSCC initiated a review due to a flagged metric related to Oxycodone 30 mg purchases. The ARCOS database revealed that the pharmacy purchased this product from as many as three distributors, and in a quantity more than three times the volume of two Walgreens stores, and more than five times the volume of another independent pharmacy. Receipt of due diligence from one distributor, including dispensing data, revealed that two physicians had written a large number of prescriptions filled at the pharmacy and had been previously arrested for operating a pill mill. The LCSCC identified state medical board orders seeking to revoke the medical licenses of these practitioners. Within 24 hours—*i.e.*, on May 4, 2022—the SOMT voted to restrict the pharmacy.

11.43 The more typical ad hoc review is prompted by a media article. The above reviews, however, were generated internally by Mallinckrodt, and are encouraging success stories. These stories also present an opportunity for Mallinckrodt to train and educate the distributor who shared the dispensing report that made it possible for the LCSCC to identify the

physicians. In this instance, Mallinckrodt had previously conducted a due diligence visit with the distributor in February 2022. Nonetheless, this event presents a perfect "teachable moment" that can helpfully improve the due diligence of that distributor and potentially others. Mallinckrodt may wish to use this example—anonymized as needed—in order to share its experience with other distributors. This would directly benefit the distributors themselves, by strengthening their own SOM programs, and indirectly benefit Mallinckrodt as well.

11.44 ***Deferred decision on a pharmacy possibly supplying hospice (but nonetheless raising concerns) without follow-up initially apparent to the Monitor.*** The SOMT meeting materials and minutes for May 19, 2022 reveal a particular pharmacy in Los Angeles reviewed on March 17, 2022 due to flagged metrics related to purchases of Oxycodone 30 mg. The ARCOS database revealed that the pharmacy purchased an annual quantity of dosage units of Oxycodone three times more than a Walgreens store and four times more than another independent pharmacy in the same zip code. Mallinckrodt's distributor provided information on May 11, 2022 that 95 percent of the pharmacy's business related to hospice care, which could explain the high volume of oxycodone purchases, but a member of the SOMT wondered why such a large volume of tablets (as opposed to liquid form) would be purchased for a hospice customer. In light of the SOMT's concerns, the group agreed to pose follow-up questions to the distributor and to table further discussion and decision pending obtaining additional information from the distributor. There was, accordingly, no restriction decision at the May 2022 SOMT meeting, and no restriction decision at the June or July 2022 SOMT meetings either. According to the minutes of these later SOMT meetings, the pharmacy was not discussed, nor is it listed for follow-up review in the Tracking Spreadsheet, *see infra* ¶ 11.45.

11.45 However, the Monitor later learned the CSC Director continued to investigate this pharmacy. The CSC Director maintains a separate list tracking pharmacies still under review and, as such, his efforts were not readily evident to the Monitor. The Monitor has since requested a copy of this list, which he will review during the next monitoring period.

> ***New Recommendation 6(d). The CSC Director should share with the SOMT, before each monthly meeting, his separate tracking list of pharmacies pending due diligence review to ensure tabled pharmacies do not evade future review.***

11.46 **As an additional safeguard, the Monitor recommends the CSC Director circulate his separate tracking list to all members of the SOMT before each monthly meeting. By including this list in the monthly meeting materials, it is more likely that any pharmacy (or other entity) tabled for future discussion at a SOMT meeting will be the subject of follow-up discussions at each subsequent SOMT meeting until the team reaches a final decision on the resolution of the review.** Mallinckrodt agrees with this recommendation.

ii. SOMT meeting materials and minutes for June 2022

11.47 ***Deferred decision on a pharmacy relating to a non-Opioid Product, without follow-up.*** The SOMT meeting materials and minutes for June 16, 2022 reflect discussion of a particular pharmacy in Utah with flagged metrics related to a non-Opioid Product. Although not an Opioid Product, and therefore beyond the scope of the Monitor's review, the Monitor notes that the SOMT voted to table further discussion of this pharmacy, pending receipt of due diligence from a distributor. However, review of the subsequent July 21, 2022 SOMT minutes reveals no discussion of this pharmacy.[30] Despite the fact that this product is not an Opioid

[30] There is a reference at the end of the July SOMT meeting minutes to comments by an SOMT member that may relate to this pharmacy, although it is unclear. The SOMT member "stated that it may be helpful to go back and revisit a pharmacy that we reviewed a couple of months ago that flagged for [the non-Opioid Product] that we had wanted to review again to

Product, the Monitor makes this observation because it is relevant to, and consistent with, the observation made above regarding a different pharmacy flagged for an Opioid Product. *See* ¶ 11.44, *supra*. Thus, this second observation, in a different month, reinforces the Monitor's recommendation that the SOMT carefully catalogue all "tabled" pharmacies to ensure that they are reviewed at the next opportunity, and that final restriction decisions are eventually made.

11.48 ***Continued delay in the sharing of due diligence information by distributors impacting timeliness of Mallinckrodt's restriction decisions.*** The SOMT meeting materials and minutes for June 16, 2022 reflect discussion of a particular pharmacy in Oklahoma previously reviewed on April 22, 2022 due to flagged metrics related to purchases of Hydrocodone and Morphine. The LCSCC's review revealed that the pharmacy had purchased over 360,000 dosage units of Hydrocodone in a 12-month period—*i.e.*, over 100,000 more dosage units than the combined purchases by the Walgreens, Walmart, and CVS in the area. The LCSCC also determined that the pharmacy is purchasing more than seven times the quantity of Morphine purchased by the same three chains of pharmacies combined. Additionally, the LCSCC determined that the pharmacy's Oxycodone purchasing outpaced, by more than four times, the quantity purchased by the same chain pharmacies. A due diligence request was sent to the distributor on April 22. However, no response was received, and no restriction decision was made at the May 19 SOMT meeting discussed above. The SOMT voted to restrict the pharmacy at the June 16 SOMT meeting.

11.49 The same SOMT meeting minutes from June 16 reveal two other instances of similar delay, involving a pharmacy in Kentucky and another in Georgia. The LCSCC began his

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understand more about it." However, the pharmacy is not identified in the minutes, and the resolution of this issue remains unclear.

review on April 25 and April 26, 2022, respectively, and made requests for due diligence to one of the "Big Three" distributors on the same days. No responses were received by the time of the May 19 SOMT meeting, or the subsequent June 16 SOMT meeting. The SOMT voted to restrict both pharmacies at the June 16 SOMT meeting.

11.50 Unfortunately, the Monitor has found that the wait for due diligence that ultimately never arrives is a regrettable but not infrequent occurrence. It results in even further delay and, of course, the potential for more diversion. The delays referenced above, of approximately one month beyond when a restriction decision could reasonably have been made, are illustrative and not isolated. Under the circumstances—*i.e.*, extremely high order volumes of three Opioid Products at high risk of diversion—the delayed restriction by even one month can mean a significant difference in terms of the diversion of dangerous controlled substances. On the other hand, restricting direct customers based on incomplete information can result in cutting off patients' access to pain treatment medications legitimately prescribed to them and necessary for them to effectively manage their pain.

11.51 The Monitor of course appreciates that distributor due diligence delays present a complicated problem for Mallinckrodt, as Mallinckrodt does not exercise control over its direct customers, or the timeliness of their provision of due diligence. This compels Mallinckrodt to make important decisions with imperfect information. And this necessarily creates risk for Mallinckrodt. There is risk in making a restriction decision too soon, just as there is risk in waiting too long. In the Monitor's view, an approximately 30-day period for a distributor to respond to an initial due diligence request—*i.e.*, in essence, "is this pharmacy a supplier of a long-term care ("LTC") facility, or a hospice or hospital?"—should be more than sufficient for Mallinckrodt to comfortably restrict a pharmacy if the distributor fails to provide a response

within that time frame. Ultimately, however, it is not for the Monitor to say where Mallinckrodt should draw this line. Mallinckrodt itself, and its experienced SOMT, is best positioned to assess its risk and to determine how best to mitigate it, with all the consequences those decisions entail.

iii. SOMT meeting materials and minutes for July 2022

11.52 ***Continued delay in the sharing of due diligence information by distributors impacting timeliness of Mallinckrodt's restriction decisions.*** The SOMT meeting materials and minutes for July 21, 2022 exhibit a pattern consistent with that observed in June. As was the case with the June meeting minutes described above, in July the SOMT made restriction decisions that—but for the delay in the provision of due diligence information—could have been made at least one month earlier. For example, the LCSCC began a review of a pharmacy in Oklahoma on May 9, 2022[31] in connection with its purchases of Hydrocodone 10 mg. The LCSCC's description of the volume ordered is startling: "This pharmacy is dispensing enough Hydrocodone for every man, woman, and child in the county to have 20 dosage units per year. A comparison with other pharmacies in the county has this pharmacy purchasing more than 50,000 dosage units over the next largest pharmacy." But more disconcerting is what comes next: "A request was sent to [Big Three Distributor 1] for better understanding of this pharmacy's utilization of Hydrocodone 10 MG. As of the date of this report, [Big Three Distributor 1] has not responded to requests for due diligence." At the July 21, 2022 SOMT meeting, the SOMT decided to restrict the pharmacy anyway, not having yet received the requested distributor due diligence.

[31] SOMT meeting minutes from May and June do not reflect any discussion of this pharmacy.

11.53 Once again, this incident is not isolated. The SOMT meeting materials and minutes for July 21, 2022 also discuss a pharmacy in Illinois for which the LCSCC began his review on May 10, 2022[32] in connection with its purchases of Hydrocodone. The LCSCC observed that the volume purchased by this pharmacy in a low population density area "equates with dispensing 245 dosage units for every resident of the city and 68 dosage units to every resident of the county." Once again, the LCSCC noted: "A request for due diligence to [Big Three Distributor 1] was sent to understand the Hydrocodone utilization. As of this meeting, [Big Three Distributor 1] has not responded to requests for due diligence." Having still not received the requested due diligence, the SOMT voted to restrict the pharmacy on July 21, 2022.

11.54 In sum, as was observed in the case of the June meeting minutes, a recurring problem is the delay between Mallinckrodt's request for distributor due diligence and its receipt of due diligence. In each of the four instances observed above (two in June; two in July) it was clearly possible to halt the flow of narcotics to pharmacies at least one month earlier than the eventual restriction. But this problem is not just recurring within the Sixth Reporting Period. Indeed, the Monitor has repeatedly called attention to the persistent delays in the "Big Three" distributors' provision of due diligence information to Mallinckrodt. *See, e.g.*, Fifth Monitor Report at 40-41 ¶ 11.48; Fourth Monitor Report at 25 ¶ 11.14; Third Monitor Report at 24 ¶ 11.12. The Monitor hopes Mallinckrodt will continue to raise these delays with the "Big Three" distributors.

> ***New Recommendation 6(e). Mallinckrodt should continue to raise with the "Big Three" distributors the persistent issue of delayed provision of due diligence, which in turn delays Mallinckrodt's chargeback restrictions, potentially affecting the diversion of Opioid Products.***

[32] SOMT meeting minutes from May and June do not reflect any discussion of this pharmacy.

11.55 **The Monitor recommends that Mallinckrodt raise with each of the "Big Three" distributors the issue of Mallinckrodt not receiving timely responses to due diligence requests, or the provision of other due diligence information (such as a distributor's own restriction decision).** Mallinckrodt agrees with this recommendation.

iv. Tracking the timeliness of chargeback reviews

11.56 In prior reports, the Monitor recommended evaluating the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data (***Recommendation 2(f)***), amending relevant SOPs to memorialize firm timelines (***Recommendation 2(g)***), and collecting data regarding time intervals at each stage of the chargeback restriction review process 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, could (or should) be done to reduce them (***Recommendation 4(a)***). Mallinckrodt agreed to and has implemented these recommendations.

11.57 As detailed in prior reports, the Monitor has focused on the length of time the 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 and chargebacks using the direct and indirect customer dashboards.

11.58 The Monitor's recommendation arose from observing widely varying lengths of time for the SOMT to complete chargeback reviews for downstream registrants, including some time lags that seemed reducible. *See* Fourth Monitor Report at 26 ¶ 11.16 to 27 ¶ 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); *id.* at 29 ¶ 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). The lack of sufficiently granular data made it difficult or impossible for the SOMT and the Monitor to determine whether time lags (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.

11.59 Accordingly, the SOMT expanded the existing Excel spreadsheet it was using to track chargeback restrictions to include the key phases of the chargeback review process the Monitor identified (referred to herein as the "Tracking Spreadsheet"), beginning in January 2022. *See* Fourth Monitor Report at 31 ¶ 11.27 (describing phases of chargeback review that are tracked in the Tracking Spreadsheet). Consistent with the request outlined in the Monitor's Audit Plan, Mallinckrodt produces this Tracking Spreadsheet to the Monitor monthly.

11.60 In the Sixth Reporting Period, the Monitor reviewed the accumulated data in the Tracking Spreadsheet in an effort to determine whether recommendations or guidelines regarding specific turnaround times may be appropriate.

11.61 At this time, based on the Monitor's review of the data, his interviews with the CSC Director and the LCSCC, and the increased efficiency the Monitor has already observed in the SOMT's ability to implement chargeback restrictions as a result of the launch of the direct and indirect customer dashboards, *see* ¶ 11.35, *supra*, the Monitor is not recommending that Mallinckrodt adopt strict timelines for the completion of chargeback reviews or, for that matter,

timelines for the steps in the chargeback review process. As noted above, *see* ¶¶ 11.50-11.51, *supra*, the Monitor recognizes Mallinckrodt's need to balance two competing considerations: on the one hand, preventing the unlawful diversion of Opioid Products; on the other hand, avoiding unnecessarily restricting the supply of such products to legitimate downstream registrants and their customers. Where to draw the line must be for Mallinckrodt to decide. Nonetheless, below the Monitor offers some observations regarding the Tracking Spreadsheet and reasonable timeframes for certain steps in the chargeback review process.

i. Ad hoc reviews based on media reports

11.62 Based upon the data reflected in the June 2022 Tracking Spreadsheet (which covers preceding months dating back to October 2021), the Monitor was able to observe certain trends. For the one direct customer and the 19 downstream registrants the SOMT reviewed between December 2021 and May 2022 based on media reports (resulting in ad hoc restrictions), the length of time between the LCSCC's completion of his review and the date of the SOMT's review ranged from 0-1 days. Likewise, the SOMT implemented the chargeback restriction for all of those customers within no more than one day. With the exception of the one direct customer the SOMT restricted, the total review time for each of these restrictions was no more than 5 days. In these instances, the LCSCC and SOMT were able to review, vote on, and restrict expeditiously.

ii. Total time for the review and decision process generally

11.63 As for more general reviews, in the 17 instances where the SOMT restricted a direct customer or downstream registrant for any reason (*e.g.*, chargeback data, media report, etc.), excluding ad hoc reviews,[33] the total time from the date the review was initiated to the

[33] Although most media reports result in ad hoc reviews, that is not always the case. Some are reviewed during regularly scheduled SOMT meetings.

issuance of the restriction ranged from 3-62 days, with 11 of those customers (65% of them) reviewed and restricted in under 45 days.

11.64 In 19 of the 21 instances where the SOMT reviewed a direct customer or downstream registrant for any reason but did ***not*** restrict, the time from the initiation of the review process to the SOMT's review ranged from 23 to 90 days. However, for 8 of those customers (38%), the SOMT completed its review process but decided not to restrict within 45 days.

11.65 With the indirect customer dashboard, the LCSCC's review of direct and indirect customers is now more likely to continue throughout the month because the indirect customer dashboard is dynamic, constantly incorporating newly available data from various sources. Accordingly, imposing specific deadlines tied to the uploading of chargeback data and the SOMT meetings is impractical at this time. Nonetheless, the SOMT may wish to note the 45-day "sweet spot" for resolving a large percentage of reviews—either through a restriction or decision not to restrict—and may wish to factor this timeline in internal goals and decision-making.

iii. The SOMT's requests for and receipt of due diligence

11.66 As the Monitor has previously reported, the distributors' delay in providing the SOMT with requested due diligence is a significant cause of delay in the chargeback review process. Based upon Tracking Spreadsheet data available thus far, it is clear to the Monitor that the delay in receiving due diligence from distributors is a significant (if not the leading) cause of delay in the SOMT's ability to expeditiously complete chargeback reviews.

11.67 There were 27 instances when the SOMT initiated review of a direct customer or downstream registrant based on chargeback data, requested due diligence from the downstream registrant's distributor, and ultimately received that due diligence from the distributor. In 24 of

those instances (89%), the distributors provided the information within 15 days. The 3 instances when Mallinckrodt did ***not*** receive due diligence within 15 days involved two of the "Big Three" distributors. In 19 of the 27 instances when the SOMT received the requested due diligence, it restricted the direct customer or downstream registrant, and for 16 of those 19 customers (84%), the total time for the review and restriction process ranged from 0-10 days.

11.68 However, in the 18 instances where the SOMT reviewed downstream registrants based on chargeback data and requested due diligence but did not receive it, the total length of time for the review process was much longer than in the instances when Mallinckrodt promptly received due diligence from the distributors. The SOMT ultimately restricted 13 of those 18 downstream registrants (72%) anyway, and, with the exception of one ad hoc review completed in 1 day, the total review time from when the review was initiated to when the restriction was issued ranged between 28 and 62 days. In other words, extensive delay still results in restriction in the vast majority (72%) of instances. This should give Mallinckrodt comfort in erring on the side of restriction when a distributor's response to a due diligence request exceeds a reasonable time frame for response.

11.69 The Monitor's observations were further validated during his interviews of the CSC Director and the LCSCC, who explained that the distributors are likely to respond promptly or not at all. For these reasons, and based on the examples of the distributors' delays in responding to requests for information detailed in prior reports and above, *see* ¶¶ 11.48-54, *supra*, the Monitor has made ***New Recommendation 6(e).***

* * *

11.70 The Monitor is sure both Mallinckrodt and the Monitor will continue to see value in the data the Tracking Spreadsheet collects, and will routinely review and revisit the observations summarized above, as appropriate.

c. *Media reviews*

11.71 Shortly before the submission of the Fifth Monitor Report, Mallinckrodt shared with the Monitor an updated list of Media Monitoring Search Terms, dated April 15, 2022. This list is now more robust and comprehensive than a similar list of search terms shared with the Monitor in or about May 2021.

11.72 On April 14, 2022, Mallinckrodt's outside counsel updated the Google search terms so as to reduce "false positives" through the use of Boolean search terms. Having run this new search, Mallinckrodt's counsel compared the new results to the results previously returned using different search terms, and was able to confirm that the same media results were produced in response to the new terms.

11.73 When possible, the Monitor has continued to test the effectiveness of the Google searches on an ad hoc basis by inquiring with Mallinckrodt regarding media coverage that the Monitor learns about independently. For example, on August 4, 2021, the U.S. Department of Justice issued a press release regarding criminal and civil resolutions with a New Jersey pharmacy, Dunn Meadow LLC.[34] According to the press release and related charging documents, Dunn Meadow "pleaded guilty . . . to an information charging it with conspiring to illegally distribute prescription fentanyl and giving kickbacks to healthcare providers," and "also signed a civil settlement with the United States for violations of the False Claims Act and the Controlled Substances Act." The press release further noted that, "[d]espite warnings from third parties, ***including some of its suppliers***, Dunn Meadow continued to fill prescriptions for TIRF

[34] Press Release, U.S. Dep't of Justice, "New Jersey Pharmacy Admits Illegal Distribution of Prescription Opioids and Kickback Scheme and Agrees to Criminal and Civil Penalties" (Aug. 4, 2022), *available at* https://www.justice.gov/usao-nj/pr/new-jersey-pharmacy-admits-illegal-distribution-prescription-opioids-and-kickback-scheme.

medications and other opioids written by doctors with suspicious and problematic prescribing habits, sometimes without receiving an original prescription," and "[a]fter ***two different pharmaceutical suppliers terminated supply agreements*** with Dunn Meadow, Dunn Meadow submitted applications to other suppliers stating that no supplier had ever suspended, ceased, or restricted controlled substance sales to Dunn Meadow." (Emphasis added.)

11.74 The Monitor inquired with Mallinckrodt whether (a) Mallinckrodt's Google media search had captured the press release, and (b) whether Mallinckrodt's chargeback data reflect chargeback requests related to either Dunn Meadow LLC, or its parent company, Allegheny Pharma LLC.

11.75 Mallinckrodt's CSC Director informed the Monitor that Mallinckrodt's Google search terms did successfully return the information relating to the press release. The CSC Director further noted that Mallinckrodt actually first became aware of Dunn Meadow Pharmacy in September 2021, as a result of the SOMT's review of a particular API purchaser's orders of Levorphanol. *See* Fourth Monitor Report at 43 ¶ 11.62 to 46 ¶ 11.66. (Mallinckrodt had no information regarding Dunn Meadow Pharmacy before September 2021.) Dunn Meadow Pharmacy had purchased Levorphanol products from that API purchaser. However, when the SOMT conducted its review Dunn Meadow Pharmacy's DEA registration was already inactive and Mallinckrodt had no chargeback data for Dunn Meadow Pharmacy. Consequently, Mallinckrodt cannot determine the identify of Dunn Meadow Pharmacy's suppliers.

11.76 The Monitor is reassured, in light of this response from Mallinckrodt, that the Google media searches continue to be effective in capturing relevant information for review.

d. *Review of TrackWise Complaints*

11.77 As noted in the Fifth Monitor Report, the Monitor undertook, in the Sixth Reporting Period, to review TrackWise with a view to better understanding customer complaints relating to potential diversion, and the CSC Manager's investigation and resolution of such complaints. *See* Fifth Monitor Report at 35-36 ¶ 11.33. As discussed below, the Monitor has now had an opportunity to review recent inquiries and complaints recorded in TrackWise and their disposition, where relevant to the SOMT.

i. Reports of tablet counts over or under the correct count

11.78 The Product Complaint logs reflect a common complaint regarding bottles of tablets that are under or over the listed tablet count. More often than not these variances are minor—such as a 100-count bottle containing one or two tablets less or too many. Mallinckrodt has shared with the Monitor the tablet thresholds it uses to determine whether a variance is within a tolerable range or not, consistent with a Quality Specification and FDA guidance. If the variance is within the tolerance (*i.e.*, +/- a certain tablet variance depending on the bottle size), the variance need not be escalated for further review. Variances outside the tolerance range do require escalation. For example, the following complaints relate to significant variances that are outside the tolerance and triggered further investigation:

(a) April 12, 2022 – A pharmacy reported a sealed 100-count bottle missing Oxycodone tablets.

(b) April 22, 2022 - A pharmacy reported a sealed 100-count bottle missing Oxycodone tablets.

(c) May 25, 2022 – A pharmacy reported a sealed 100-count bottle missing Oxycodone tablets.

(d) May 27, 2022 – A pharmacy reported a sealed 100-count bottle missing Hydromorphone tablets.

(e) May 31, 2022 – A pharmacy reported a sealed 100-count bottle missing Oxycodone tablets.

11.79 In the next reporting period, the Monitor will discuss with the CSC Senior Manager the above variances and the investigations related to them.

11.80 Another investigation involved a series of 10 Colorado-based pharmacies (from a single chain) reporting shortages in Oxycodone 5 mg bottles despite the seal on the bottles being intact. The shortages were reported in March 2022. Based upon the bottle serial numbers, Mallinckrodt was able to determine the timing of the labelling of the bottle. Review of a closed circuit television ("CCTV") video recording by the Packaging SME, Security Director, and CSC Senior Manager revealed mechanical problems with the bottle line filler, and possible mishandling. Mallinckrodt records confirmed that bottles from this packaging line were shipped to a distributor in Colorado in February 2022. The CSC Senior Manager ultimately concluded there was no evidence of diversion or tampering in connection with this incident.

ii. Report of inappropriate intravenous use of immediate release Hydromorphone 2 mg tablets (April 11, 2022)

11.81 The Inquiry Log summarizes an April 11, 2022 call from a consumer regarding Hydromorphone 2 mg tablets. According to the report, the caller "stated that []he had mixed the tablet with water, filtered it and injected the mixture and was requesting to know if any of the buffers were dangerous if injected." Additionally, "[h]e said that []he was relaxed and also wanted to know if it was an immediate or extended release tablet." The Mallinckrodt employee handling the call advised the caller to immediately call 911 or poison control. The employee noted that this is an immediate-release product, and that the dosing varies between intravenous and oral routes of administration, and that intravenous use could lead to an overdose. Although perhaps not a diversion issue over which Mallinckrodt has any control, the nature of this downstream customer interaction is revealing in what intelligence it may potentially provide.

iii. Pharmacy inquiry regarding chargeback restriction (June 9, 2022)

11.82 The Inquiry Log summarizes a June 9, 2022 call from a pharmacy regarding a letter to the pharmacy's distributor restricting chargeback payments. The Mallinckrodt employee handling the call advised the CSC Director. According to the SOMT meeting minutes and materials from the May 19, 2022 meeting—and consistent with the Inquiry Log—the LCSCC spoke with the pharmacist on June 9, 2022, and shared information regarding the reinstatement process.

11.83 This episode reflects good and timely coordination between the Post-Market Team ("PMT") and the SOMT. However it is not clear the SOMT generally fully leverages the available information in the TrackWise logs. Indeed, the CSC Director confirmed that the SOMT does not routinely consult TrackWise as a source for suspicious order monitoring. The Monitor views the TrackWise logs as one additional potentially helpful source of intelligence regarding the end use of Mallinckrodt's products, and the dispensing of those products by pharmacies for which it otherwise has limited data. Accordingly, TrackWise logs could perhaps be more effectively be used to identify additional diversion risk.

11.84 The Associate General Counsel recently informed the Monitor that she (or her designee) will now be completing a quarterly review of the TrackWise logs and escalating any relevant inquiries to the CSC Director for his review.

> ***New Recommendation 6(f). The CSC Director should ensure that evidence of diversion risks appearing in the TrackWise inquiry and complaint logs escalated by the Associate General Counsel (or designee) is reviewed and included in SOMT pharmacy reviews, as appropriate.***

11.85 **In light of the Associate General Counsel's new quarterly review process, any relevant evidence regarding diversion risks will be readily available to the SOMT for use in connection with chargeback reviews. Accordingly, the Monitor recommends the CSC**

Director review the entries the Associate General Counsel escalates to him and work with the LCSCC to incorporate them in the chargeback review process, as appropriate. Mallinckrodt agrees with this recommendation.

e. *Government communications log*

11.86 As previously reported, *see* Fifth Monitor Report at 34 ¶ 11.30 to 36 ¶ 11.33, the Audit Plan requires the production of the government communications log ("Communications Log") the SOMT maintains 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."). The CSC Auditor / Data Analyst is the keeper of the Communications Log.

11.87 In the Sixth Reporting Period, Mallinckrodt produced a copy of the Communications Log covering the time period from January 3, 2022 through June 30, 2022, reflecting a total of 136 government communications. Almost all of the inquiries in this period (134) originated from the DEA, and a significant majority (117) related to shipping verifications for drug addiction treatment medications (*e.g.*, Methadone, Methadose, and Buprenorphine) to addiction treatment centers. These medications are not "Opioid Products" as defined under the Operating Injunction. Only one inquiry was a state board of pharmacy and one was a grand jury subpoena relating to a restricted customer.

11.88 During the Sixth Reporting Period there were only three instances of inquiries related to purchases of Opioid Products. Mallinckrodt provided copies of the underlying inquiry from the law enforcement agency.

f. *Downstream registrant reinstatement reviews*

11.89 As previously noted, Mallinckrodt developed the *Requirements for 3rd Party Assessment for Chargeback Reinstatement Requests* at the Monitor's recommendation. *See* Fourth Monitor Report at 38 ¶ 11.46 to 39 ¶ 11.48. As initially conceived, based upon Recommendation 2(r), this document was intended to serve as a checklist that would set a floor (*i.e.*, "minimum" requirements) for pharmacy compliance prior to reinstatement, and so was therefore referred to in the Fourth and Fifth Monitor Reports as the "Reinstatement Checklist." It was drafted to standardize information and practices Mallinckrodt will evaluate when considering a chargeback reinstatement request.

11.90 In practice, however, although Mallinckrodt accepted the recommendation and initial characterization of the document as a "checklist," Mallinckrodt pointed out that not all of the checklist factors would necessarily apply to every pharmacy under review. Accordingly, Mallinckrodt believes that the document should instead function as a guide to potentially relevant factors, not all of which will necessarily apply in every instance. Accordingly, the Reinstatement Checklist, as modified, should be thought of as the "Reinstatement Guide."

11.91 The creation of the Reinstatement Guide necessitated some updates to *Mallinckrodt's SOM Program Review of Reinstatement Requests for Downstream Registrants* SOP. 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 Guide. The SOP also 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)."

4. <u>Other SOM-related issues</u>

a. *The Ad Hoc Committee alert regarding a suspicious distributor*

11.92 During the Fifth Reporting Period, a representative of the Ad Hoc Committee notified the Monitor that a sales representative of a small distributor appeared to be highlighting to prospective customers that the injunction against the "Big Three" distributors would adversely affect the supply of controlled substances. The sales representative's pitch was that customers should instead seek their supply through the sales representative, since the sales representative's business "is a secondary wholesaler, with no contracts!" The sales representative also mentioned that the representative's business carries "many generic Medications."

11.93 The Ad Hoc Committee's representative advised the Monitor of this email, and was interested—particularly given the reference to generic medications—in whether the small distributor is a Mallinckrodt customer. Mallinckrodt's CSC Director informed the Monitor that this particular distributor was located in Mallinckrodt's system, but may only have been purchasing non-controlled substances from Mallinckrodt since the distributor has no DEA number and no chargeback data.

b. *Internal audits*

11.94 The CSC Auditor / Data Analyst described her role, since January 2022, in participating in various internal audits. Specifically, the CSC Auditor described lab audits performed to ensure that lab documentation is correct. For example, the audit team will

randomly check whether the number of tablets removed from a vault for a lab test matches the number of tablets consumed and returned to a vault. Audits also review access permissions to cages and vaults containing restricted products to ensure access is not granted too broadly. The CSC Auditor described this as a "mini DEA audit" to proactively identify any problems in advance of a potential DEA audit. In the next reporting period the Monitor will request copies of documentation from recently completed lab audits.

11.95 Another category of internal audits is security audits arising from any security incident that is compliance related. Security audits involve confirming appropriate protocols and procedures are followed regarding the retrieval and storage of controlled substances in vaults and cages. In the Sixth Reporting Period, Mallinckrodt shared two sample security audit reports with the Monitor. However, these reports are dated January 2020 and December 2019, respectively, and therefore predate the more recent work of the new CSC Auditor / Data Analyst, and the start of the monitorship. Accordingly, in the next reporting period the Monitor will work with Mallinckrodt to obtain more recently completed security audits.

12. TRAINING (OI § III.K)

12.1 Mallinckrodt's training of employees on the Operating Injunction and related obligations and prohibitions is described generally in the Monitor's prior reports. *See e.g.*, Fourth Monitor Report at 49 ¶ 13.1. Additionally, employees are now also required to pass a quiz following their live training. *See* Fifth Monitor Report at 42 ¶ 12.1 and 43-44 ¶ 12.6.

12.2 During the Sixth Reporting Period, the Monitor audited Mallinckrodt's compliance with the Operating Injunction's training requirements by: (1) interviewing the SpecGx Compliance Manager to discuss, among other things, the live trainings the Monitor

observed virtually during the Fifth Reporting Period; and (2) reviewing the list of newly hired employees and the trainings they completed, which Mallinckrodt produced under the Audit Plan.

1. <u>Interview with the Compliance Manager</u>

a. *The live Operating Injunction trainings Through WebEx*

i. Encouraging greater employee engagement during trainings

12.3 After attending three live trainings during the Fifth Reporting Period, the Monitor interviewed the Compliance Manager to share his observations and suggestions to encourage employee participation. As detailed in the Fifth Monitor Report, *see* Fifth Monitor Report at 43 ¶ 12.5, when employees took the opportunity to ask questions during the trainings, as opposed to more passively responding to the hypothetical scenarios the compliance Manager posed by using the "thumbs down" and "thumbs up" feature in WebEx, the Monitor observed valuable exchanges between the Compliance Manager and the participants regarding the nuances of the Operating Injunction.

12.4 As Mallinckrodt recognizes, although the remote trainings pose certain challenges (including the degree of employees' engagement), by conducting the required Operating Injunction trainings through WebEx Mallinckrodt can efficiently train employees across the company's footprint in many geographic locations. The Compliance Manager indicated that, prior to the COVID-19 pandemic, Mallinckrodt conducted trainings both in person and remotely, and the company is still discussing how it will conduct the Operating Injunction trainings in the future once employees can more safely travel.

12.5 In addition to the use of the "thumbs up" and "thumbs down" feature in WebEx, the Monitor and the Compliance Manager discussed the use of polls and other tools to make the

trainings even more interactive, and the Compliance Manager agreed to explore incorporating additional features available in WebEx with the Training Department.

12.6 In order to encourage greater employee engagement, the Compliance Manager also agreed to work with the Information Technology Department to determine whether Mallinckrodt can disable employees' ability to participate by audio only, requiring them to sign on through a computer with video and audio capabilities instead, which would ensure employees are both listening to the information provided by the Compliance Manager and viewing the valuable information presented in the accompanying PowerPoint.

12.7 The Compliance Manager confirmed Mallinckrodt tracks the duration each participant is logged into the WebEx to ensure the participants are not signing on late or leaving the sessions early. But, of course, participation is not the same as engagement, and so Mallinckrodt's efforts to ensure not merely high levels of participation but also employee engagement and information retention are important.

12.8 The Monitor recognizes that Mallinckrodt's multi-component Operating Injunction training demonstrates its commitment to ensuring employees understand the requirements relevant to their departments, and the company's approach to training appears to be successful, given that all employees pass the quizzes. The Monitor is still determining, with Mallinckrodt's assistance, the percentage of employees who pass the quizzes on their first try.

ii. The live training hypothetical scenarios

12.9 As part of the live trainings, employees are presented with a series of hypothetical scenarios related to issues relevant to the department receiving training and asked to identify whether the proposed conduct is "permissible" or "impermissible" under the Operating Injunction. During her interview, the Compliance Manager confirmed the Legal and Compliance

Departments collaborate to review these hypotheticals each year and revise them to incorporate scenarios raising concerns regarding compliance with the Operating Injunction that occurred during the prior year, when relevant.

12.10 Based on this discussion, the Monitor updated the Audit Plan to request copies of the PowerPoint training presentations, including the revised hypothetical scenarios, before they are finalized each year. Mallinckrodt has agreed to this request.

b. *The Operating Injunction quizzes*

12.11 As the Monitor previously reported, Mallinckrodt now requires its employees to complete quizzes following their Operating Injunction training in order to test their retention of information relayed during those trainings and understanding of the Operating Injunction's requirements generally. *See* Fifth Monitor Report at 43 ¶ 12.6. The Compliance Manager informed the Monitor that the quizzes are developed by legal counsel and reviewed by the Compliance Department and administered through ComplianceWire.

12.12 To test their retention of the relevant information, participants must take a quiz within 14 days of the live training. To earn a passing grade, participants are given three chances to answer 8 out of 10 questions correctly. The participant must complete the quiz within 28 days of the live training.

12.13 The Compliance Manager indicated that all employees have passed the quizzes, but she agreed to identify for the Monitor the percentage of employees who are successful on their first attempt, so the Monitor can work with Mallinckrodt to identify a baseline initial pass rate the company should strive to meet or exceed each year.

12.14 The Compliance Manager also confirmed the quizzes will be evaluated for any necessary updates every year, including updates to reflect real life scenarios that arise, and she agreed to provide copies of the quizzes to the Monitor before Mallinckrodt finalizes them.

2. Employee Trainings During the Second Quarter

12.15 As part of the agreed-upon Audit Plan referenced above, *see* ¶ 1.4, *supra*, on a quarterly basis Mallinckrodt has agreed to 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 July 7, 2022, Mallinckrodt identified six newly hired or promoted employees in the second quarter of 2022, all of whom have completed each component of their 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.[35] Any research proposals submitted through Vivli will be reviewed for scientific merit by an independent review panel.

13.3 In response to the Monitor's request in the Audit Plan, *see* ¶ 1.4, *supra*, Mallinckrodt's Associate General Counsel confirmed there were no requests for access to this

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

clinical data during the second quarter of 2022. Mallinckrodt's outside counsel also confirmed there were no clinical studies for any of the new Opioid Products identified in the Fifth Monitor Report. *See* Fifth Monitor Report at 22 ¶ 10.4. No new clinical studies were conducted because all of the products are merely different flavors or dosages of existing products.

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

14.1 Section V of the Operating Injunction required Mallinckrodt to produce certain documents to the Settling States within nine months of October 12, 2020 (*i.e.*, on or before July 12, 2021). As noted in the Second and Fourth Monitor Reports, Mallinckrodt complied with this requirement by reviewing documents for redaction of information in accordance with Section V.B of the Operating Injunction and producing these documents and the associated redaction logs to the Minnesota Attorney General's Office on July 12, 2021.

14.2 After entering into a "Mutual Letter of Understanding" with the University of California San Francisco, Johns Hopkins University, and the Minnesota Office of Attorney General to transfer Mallinckrodt's documents to the Opioid Industry Documents Archive (the "Archive"), Mallinckrodt obtained the Bankruptcy Court's approval of the agreement and payment to the universities to cover Mallinckrodt's allocable share of the costs of the repository to satisfy the requirement set forth in Section V.G.

14.3 On May 10, 2022, the University of California, San Francisco and Johns Hopkins University announced the addition of 1.4 million Mallinckrodt documents to the Archive, which

had previously contained roughly 15,000 documents.[36] This large addition of documents generated media attention, including coverage in the *Washington Post*, which published a lengthy analysis of selected documents.[37]

14.4 The Archive is publicly available,[38] and the documents are full-text searchable. They include Mallinckrodt emails, memos, presentations, sales reports, budgets, audit reports, DEA briefings, meeting agendas and minutes, expert witness reports, and depositions of Mallinckrodt executives.

14.5 According to Johns Hopkins University, the Archive is expected to compile new documents from future settlements or judgments as part of opioid litigation.

15. OTHER ISSUES OF NOTE

15.1 In the Sixth Reporting Period the Monitor learned of Mallinckrodt's entry into a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") relating to Mallinckrodt's sales of H.P. Acthar Gel ("Acthar"). Acthar is not an Opioid Product, and is indicated for treatment of, among other things, rheumatoid arthritis, sarcoidosis, and certain ophthalmic, renal, and neurologic conditions. The Monitor discussed with Mallinckrodt's Global Chief Compliance Officer and outside counsel whether certain reporting requirements under the Acthar CIA may have

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[36] *See* Robin Scullin and Carly Kempler, *Opioid Industry Archive Releases 1.4 Million Documents from Leading Opioid Maker Implicated in Drug Crisis*, Johns Hopkins University HUB, May 10, 2021, *available at* https://hub.jhu.edu/2022/05/10/opioid-industry-archive-releases-documents-drug-crisis/.

[37] Meryl Kornfield, Scott Higham and Steven Rich, *Inside the Sales Machine of the 'Kingpin' of Opioid Makers, Washington Post*, May 10, 2022, *available at* https://www.washingtonpost.com/investigations/interactive/2022/mallinckrodt-documents-doctors-sales/.

[38] *See* https://www.industrydocuments.ucsf.edu/opioids/

relevance for the Monitorship. The answer is, not very much. Indeed, the CIA quite purposefully carves out the Operating Injunction from its scope. At the same time, however, the CIA requests that Mallinckrodt provide copies of the Monitor's reports, suggesting that the HHS-OIG does apparently believe there is some relationship between the parallel oversight. And, since the Acthar CIA will require both Mallinckrodt and an Independent Review Organization ("IRO") (Ernst & Young) to assess, among other things, Mallinckrodt's promotional practices, which could have some relevance to the Operating Injunction's ban on the promotion of Opioid Products, the Monitor has requested—and Mallinckrodt has agreed to provide—an opportunity to review the initial IRO "report card" anticipated in May 2023. Additionally, the Monitor has requested that Mallinckrodt's in-house counsel share a copy of an annual risk assessment prepared for the SpecGx business, which the Monitor learned about in the course of his discussions regarding the Acthar settlement.

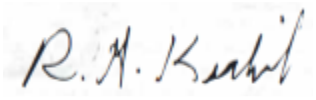
15.2 The Monitor has scheduled a site visit to Mallinckrodt's facilities in Hobart, New York, later in September 2022. The Monitor plans to meet with various senior Mallinckrodt executives during this visit, and anticipates reporting on the same during the next reporting period.

16. CONCLUSION

16.1 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.

* * *

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



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

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EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE SIXTH MONITOR REPORT DATED SEPTEMBER 1, 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.

VI. SIXTH MONITOR REPORT (9/1/2022)

Section 7 – No Financial Reward or Discipline Based on Volume of Opioid Sales (OI § III.B)		
29.	**6(a)**	Include explicit references to the Operating Injunction in Sales Compensation Plans for future years.
30.	**6(b)**	Provide additional training to the Human Resources Department (by Mallinckrodt's legal counsel) to prevent consideration of improper incentives in bonus recommendations.
Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)		
31.	**6(c)**	Ensure greater consistency among direct customer audit reports, and more fulsome follow-up where necessary to obtain compliance assurances.
32.	**6(d)**	Share with the SOMT, before each monthly meeting, the CSC Director's separate tracking list of pharmacies pending due diligence review to ensure tabled pharmacies do not evade future review.
33.	**6(e)**	Continue to raise with the "Big Three" distributors, the persistent issue of delayed provision of due diligence, which in turn delays Mallinckrodt's chargeback restrictions, potentially affecting the diversion of Opioid Products.
34.	**6(f)**	Ensure evidence of diversion risks appearing in the TrackWise inquiry and complaint logs escalated by the Associate General Counsel (or designee) is reviewed and included in SOMT pharmacy reviews, as appropriate.