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

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TWELFTH 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:

I. EXECUTIVE SUMMARY

1.1 This Twelfth Monitor Report covers the period from the filing of the Eleventh Monitor Report on November 20, 2024, to the present (the "Twelfth Reporting Period").[1] The Twelfth Monitor Report: (1) provides an update on Mallinckrodt's implementation of the Monitor's recommendations in prior reports; (2) reviews the Monitor's work during the Twelfth Reporting Period, including the Monitor Team's review of documents and data, and interviews and meetings with Mallinckrodt's employees; (3) summarizes observations from the Monitor's fact-finding; (4) includes five new recommendations; and (5) describes anticipated next steps in the Thirteenth Reporting Period.

1.2 During the Twelfth Reporting Period, the Monitor once again assessed Mallinckrodt's compliance with the Operating Injunction by reviewing documents Mallinckrodt produced in response to the Monitor's Audit Plan[2] requests and ad hoc requests, reviewing publicly available information pertaining to Mallinckrodt and the topics addressed in the Operating Injunction, and conducting interviews. In response to the Audit Plan and the

[1] In the Seventh Reporting Period, the Monitor, Mallinckrodt, and the Ad Hoc Committee agreed that the Monitor would submit future reports, effective January 1, 2023, every 180 days.

[2] As described in the Fourth Monitor Report, 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 soon as reasonably possible"). *See* Fourth Monitor Report at 2 ¶ 1.3.

Monitor's ad hoc requests, during the Twelfth Reporting Period Mallinckrodt provided approximately 783 files (consisting of approximately 1.43 GB of documents and data).

1.3 Among the more notable developments in the Twelfth Reporting Period was the announcement, on March 13, 2025, of a merger agreement between Mallinckrodt plc and Endo, Inc. ("Endo"). The planned merger, and its implications for the Mallinckrodt monitorship, are discussed below, in Section 15.

1.4 A summary of the Monitor's recommendations to date, and the status of implementation of the recommendations, appears in the chart attached as **Exhibit 1**.

1.5 This Report, along with the Monitor's prior reports, will be publicly accessible on Mallinckrodt's website.[3]

* * *

1.6 Mallinckrodt's employees and counsel 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 discussed below.

[3] *See* Mallinckrodt's "Corporate Compliance" webpage, *available at* https://www.mallinckrodt.com/corporate-sustainability/corporate-compliance/ (last visited May 1, 2025) (listed under "Operating Injunction" drop-down). As previously discussed, the Monitor's reports are no longer filed with the Bankruptcy Court. Nonetheless, Mallinckrodt and the Ad Hoc Committee agree 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 Settling States have not obtained a state court order enforcing the injunctive terms.

II. THE OPERATING INJUNCTION

2.1 On October 12, 2020, Mallinckrodt and the Settling States[4] agreed to the Mallinckrodt Injunctive Relief Draft Term Sheet. *See* Case No. 20-12522, Dkt. No. 128, Ex. 2 (Bankr. D. Del.). 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 (Bankr. D. Del.). A copy of the Operating Injunction is attached as Exhibit 1 to the First, Second, and Third Monitor Reports.

2.2 In Section VI of the Operating Injunction, Mallinckrodt agreed to retain an Independent Monitor, subject to the Bankruptcy Court's approval, who would monitor Mallinckrodt's compliance with the Operating Injunction's terms. The Bankruptcy Court entered the order appointing the Monitor on February 8, 2021.

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

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

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).

III. 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 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 212 (Bankr. D. Del.).

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 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 223 (Bankr. D. Del.).

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 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 277 (Bankr. D. Del.).

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 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 307 (Bankr. D. Del.).

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 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 339 (Bankr. D. Del.).

3.6 ***The Sixth Monitor Report.*** The Monitor submitted the Sixth Monitor Report on September 1, 2022.[5]

3.7 ***The Seventh Monitor Report.*** The Monitor submitted the Seventh Monitor Report on December 1, 2022.

3.8 ***The Eighth Monitor Report***. The Monitor submitted the Eighth Monitor Report on May 30, 2023.

3.9 ***The Ninth Monitor Report***. The Monitor submitted the Ninth Monitor Report on November 27, 2023.

3.10 ***The Tenth Monitor Report***. The Monitor submitted the Tenth Monitor Report on May 24, 2024.

3.11 ***The Eleventh Monitor Report***. The Monitor submitted the Eleventh Monitor Report on November 20, 2024.

IV. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Section 11, the Monitor has made five new recommendations related to the Operating Injunction's requirement to monitor and report direct and downstream customers. Mallinckrodt has agreed to implement these recommendations,

[5] As noted above, *supra* at 2 ¶ 1.5 n.3, the Sixth Monitor Report and subsequent reports were not filed with the Bankruptcy Court, but are available on the Mallinckrodt website.

which are that Mallinckrodt should:

12(a)[6] Ensure the SOMT minutes (a) better reflect the SOMT's analysis by providing greater support and context for the decisions of the CSC Director and SOMT, and (b) are reviewed carefully to ensure the minutes reflect an accurate historical record of the SOMT's decisions and reasoning for future reference.

12(b) Adopt a defined time for reporting suspended direct customers and restricted indirect customers to the DEA.

12(c) Ensure the Director of CSC Analytics (with assistance if needed) undertakes an annual analysis to determine what findings from the Annual Report may be applied to enhance Mallinckrodt's SOM program.

12(d) Use best efforts to negotiate with direct customers that do not submit chargeback requests for all of their controlled substances orders, in order to obtain chargeback data for every such purchase (or substantially equivalent transactional data to the data accompanying chargeback requests for those purchases).

12(e) Conduct a due diligence visit for every direct customer that does not submit chargeback requests for controlled substances (or that does not provide substantially equivalent transactional data to the data accompanying chargeback requests for such substances), if the customer has not had a due diligence visit in the past three years, with periodic follow-up visits as appropriate.

V. THE INTEGRITY HOTLINE

5.1 The Monitor and Mallinckrodt established a process by which compliance concerns related to the Operating Injunction can be reported to the Monitor, through his counsel, utilizing a system known as the Integrity Hotline. Specifically, Mallinckrodt modified this reporting system to enable reporters to select "Operating Injunction" from a menu of reported issue types. Mallinckrodt has agreed to share any such reports with the Monitor Team.

5.2 Mallinckrodt performs quarterly tests of the Integrity Hotline to ensure any report with the issue type "Operating Injunction" is received by the Monitor Team. *See* Tenth Monitor Report at 6 ¶ 5.2. During the Twelfth Reporting Period, Mallinckrodt conducted Integrity

[6] Each of these recommendations is prefaced by the number "12" to indicate they were made in the Twelfth Monitor Report.

Hotline tests in the fourth quarter of 2024 and the first quarter of 2025. The Monitor Team received proper notice of both tests when they were submitted to the Integrity Hotline, and Mallinckrodt promptly produced the underlying test reports at the Monitor Team's request.

5.3 As of the date of this Report, the Monitor has still not received any relevant substantive reports relating to the Operating Injunction through the Integrity Hotline. Nonetheless, in the next reporting period, the Monitor intends to confirm that Mallinckrodt will continue to make the Integrity Hotline available after the expected conclusion of the monitorship and discuss how Mallinckrodt plans to review and respond to any concerns that are reported.

VI. 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, Opioid Products, products used for the treatment of Opioid-induced side effects, and the Treatment of Pain in a manner directly or indirectly encouraging the utilization of Opioids or Opioid Products.

1. The Promotional Review Committee

6.2 Mallinckrodt's Promotional Review Committee ("PRC") reviews and approves new and existing promotional materials for compliance with 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 ongoing basis as part of the agreed-upon Audit Plan, the Monitor has received PRC meeting minutes and promotional materials submitted to, and approved by, the PRC on a quarterly basis.

6.4 During the fourth quarter of 2024, the PRC did not meet. Accordingly, there were no meeting minutes or materials for the Monitor to review.

6.5 During the first quarter of 2025, the PRC met twice. At the first meeting, on February 6, 2025, the PRC reviewed the interactive version of the Addiction Treatment Catalog for Mallinckrodt's website (the "Catalog"), which was created based upon a printed version of the catalog. Among other things, the PRC discussed two products included in the Catalog, buprenorphine and naloxone sublingual film for sublingual or buccal use. The Catalog's pages for these products linked to an external website for the prescribing information and medication guide because those two products are manufactured by another company, and Mallinckrodt only acts as a distributor. The PRC also discussed whether Mallinckrodt's own subject matter experts reviewed some of the content and language used to describe enhancements in daily shipping efficiency and the addresses used in the catalog for Sales and Marketing Support.

6.6 As a follow-up to that meeting, on February 13, 2025, an updated Catalog was circulated for continued review by the PRC. One additional question was raised regarding photographs used on the catalog's cover, in response to which the PRC was informed that alternative photographs could be applied to the next version. A further addendum to the meeting minutes, circulated on March 3, 2025, addressed an update to the MetricStream number for the catalog. The Monitor Team reviewed the meeting minutes and a PDF version of the Addiction Treatment Catalog as updated, and had no concerns the online Catalog implicated the Operating Injunction's Ban on Promotion.

6.7 The PRC met again, on February 20, 2025, to review the Efficient Collaborative Retail Marketing ("ECRM") Customer Slides, which were prepared for use at an upcoming ECRM conference, and discussed Mallinckrodt's capabilities and market share regarding certain products. During the conversation, it was noted that subject matter experts had conducted technical reviews for quality-related and quota-related information prior to the PRC's meeting.

The PRC provided feedback regarding certain figures and wording, and other product-specific or location-specific content. The Monitor Team reviewed the meeting minutes and the ECRM Customer Slides, and had no concerns the slides implicated the Operating Injunction's Ban on Promotion.

2. Conference Attendance

6.8 During the Eleventh Reporting Period, while reviewing the meeting minutes and materials for the Specialty Generics Grant and Sponsorship Approval Committee ("SGGSAC" or the "Committee"), *see* Eleventh Monitor Report at 9-10 ¶ 6.10, the Monitor Team learned that Mallinckrodt employees occasionally take notes while attending conferences, which are then reviewed internally by the appropriate team or department. The Monitor Team requested production of any of these conference notes pertaining to Opioids. Mallinckrodt agreed to determine whether any of these conference notes have been maintained, and if so, whether they relate to Opioids or to other topics related to the Operating Injunction, and produce those notes as appropriate.

6.9 During the Twelfth Reporting Period, the Monitor Team received a summary of notes from Mallinckrodt's attendees at the ECRM Health System / Institutional Pharmacy Session held on June 10-13, 2024 in Tucson, Arizona. The Monitor Team reviewed the notes, which were thorough and discussed a number of issues relevant to the Company's business and industry, and determined that none of the notes appeared to reflect conversations that violated the Operating Injunction.

3. TrackWise

6.10 As previously noted, *see* Second Monitor Report at 9-10 ¶ 6.9, Mallinckrodt's Product Monitoring Team ("PMT") operates a call center for customer inquiries and complaints. These calls are logged in an internal database called "TrackWise."

a. TrackWise inquiry and complaint entries pertaining to Opioids

6.11 Beginning in the Fourth Reporting Period, and on an ongoing basis as part of the agreed-upon Audit Plan, the Monitor has received and reviewed quarterly TrackWise inquiry and complaint entries pertaining to Opioids, as well as the results of the Mallinckrodt's auditing process. During the Twelfth Reporting Period, the Monitor Team reviewed TrackWise Opioid-related data for the fourth quarter of 2024, as well as the corresponding audit reports.

6.12 Consistent with prior reviews, many TrackWise inquiries pertained to the availability and content of Mallinckrodt's products (such as whether they contained gluten or animal byproducts). Similarly, TrackWise complaints were comparable to prior reviews, and primarily concerned low quantities of missing tablets, broken tablets, and issues with adhesion of overlays for Mallinckrodt's fentanyl patches. Complaints raising other issues, such as suspected product tampering or diversion, were appropriately escalated. Based on the Monitor Team's review of the underlying TrackWise data and the audit reports for the fourth quarter of 2024, it appears the TrackWise entries and audits are being conducted in a manner consistent with the Work Instruction and the Operating Injunction.

b. TrackWise Policies and Work Instructions

6.13 The Monitor Team also reviewed the latest versions of the Mallinckrodt's policies and Work Instructions pertaining to TrackWise. One such updated policy was the *Medical Information Request* Standard Operating Procedure ("SOP"). The purpose of the document is to describe Mallinckrodt's policy and process for responding to unsolicited requests for medical

information, which are documented in TrackWise. The Monitor Team compared the updated policy to the December 2021 version it previously reviewed, and determined that no significant material changes had been made.

6.14 The Monitor Team also reviewed Mallinckrodt's changes to the *Elevated Issue Management and Notification Process – Product Monitoring* SOP, which was updated to include reference to a more informative *TrackWise Complaint Entry and Processing* Work Instruction (which the Monitor Team reviewed and compared as well), as well as a more fulsome Management Notification Matrix attached as Exhibit A to the SOP.

6.15 Finally, the Monitor Team reviewed the *Guidance for Frequently Asked Product Questions – Pharmaceuticals.* This guidance document provides template responses for PMT employees to use when confronted with customers' frequently asked questions about Mallinckrodt and specific products, in order to maintain consistency in the Company's responses. In sum, the Monitor Team believes these updates will be helpful to Mallinckrodt's PMT, and ensure that product inquiries and complaints continue to be appropriately handled, documented, and elevated in a consistent manner.

4. Mallinckrodt's Website and Social Media Pages

6.16 As part of the latest update to the Audit Plan, Mallinckrodt agreed to provide the Monitor Team with a quarterly summary of any substantive changes to Mallinckrodt's website and public social media pages that concern or relate to topics relevant to the Operating Injunction. During the fourth quarter of 2024 and the first quarter of 2025, Mallinckrodt confirmed that no such changes had been made.

5. Departure of Mallinckrodt's Vice President of Communications

6.17 During the first quarter of 2025, Mallinckrodt informed the Monitor that the Vice President of Communications, whom the Monitor had interviewed during the Tenth Reporting

Period, *see* Tenth Monitor Report at 12 ¶ 7.16 – 15 ¶ 7.23, was leaving Mallinckrodt. The Monitor and the Monitor Team interviewed the Vice President of Communications prior to her departure. During that interview, she confirmed that there had been no changes to Mallinckrodt's internal and external communications that affected any of the topics covered by the Operating Injunction, including its restriction on promotion. In addition, she informed the Monitor that Mallinckrodt was reviewing the Global Social Media Guidelines as part of the normal cadence of its business and intended to make minor, non-substantive changes as necessary. The Vice President of Communications expressed her belief that Mallinckrodt's Communications Department is diligent in complying with the Operating Injunction, and recommended that no changes to its approach be made. However, she opined that additional resources, including additional employees, should be provided to the Communications Department so that it can continue to perform its functions properly, as it did under her tenure.

6. Marketing Budget for Opioid Products

6.18 The Monitor receives Mallinckrodt's annual marketing budget for Opioid Products on an annual basis and, when necessary, requests that Mallinckrodt identify and explain significant changes from the budget for the prior year.

6.19 In the Twelfth Reporting Period, the Monitor Team reviewed the annual marketing budget for 2025. The Monitor Team observed increases in the amounts budgeted for a handful of categories as compared to the amounts budgeted for 2024. All but one of those categories related to travel and meals. The Monitor Team confirmed with Mallinckrodt that the amounts budgeted reflected an anticipated return to pre-Covid spending for in-person meetings and attendance at industry events, as was the case with the 2024 budget, as well as an overall increase in travel expenses. The remaining category for which the amount budgeted for 2025 increased meaningfully over the amount budgeted for 2024 pertained to subscriptions. Again, as

was the case with the 2024 budget, Mallinckrodt confirmed that one reason for the difference was an increase in outside organizations' membership dues or fees, and that Mallinckrodt anticipated that the actual amount to be spent would be less than what was budgeted. Additionally, Mallinckrodt informed the Monitor Team that it decided to gather more external market data through use of a third-party analytics platform for the pharmaceutical market, and through other sources, in order to understand better the U.S. market supply chain.

6.20 Relatedly, the Monitor requested that Mallinckrodt provide a list of outside organizations in which Mallinckrodt participates or to which Mallinckrodt pays dues, in order to confirm that participation in or paying dues to any of those organizations does not violate the Operating Injunction's restrictions. In response, Mallinckrodt provided the Monitor Team with a list of organizations to which it had (and had not) paid membership fees as of March 2025. The Monitor Team reviewed the list and was satisfied with its contents.

7. Marketing Budget for API Products

6.21 The Monitor Team also reviewed Mallinckrodt's 2025 marketing budget for API products. There were modest increases, if any, to the projected expenses as compared to the 2024 budget. The Monitor determined that no follow up with Mallinckrodt was necessary.

VII. 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."

7.2 The Monitor's Audit Plan requires Mallinckrodt to produce to the Monitor on an annual basis updates to Mallinckrodt's sales compensation plans. As noted in the Eleventh Monitor Report, the Monitor Team received the updated sales compensation plans for 2024 at

the end of the Tenth Reporting Period, in May 2024. *See* Eleventh Monitor Report at 12-13 ¶ 7.2. As such, the Monitor Team expects to receive, and review, the 2025 sales compensation plans during the next reporting period.

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

8.1 Section III.C of the Operating Injunction restricts Mallinckrodt's ability to provide financial support or In-Kind Support to any Third Party that Promotes or educates about Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects. Section III.C also restricts Mallinckrodt's directors, officers, and management-level employees from serving on boards of entities engaging in Opioid Promotion.

1. The Monitor Team's Interview of the New SGGSAC Chair

8.2 As detailed in Mallinckrodt's Compliance Report, the SGGSAC reviews and approves third-party requests for grants and sponsorships to ensure compliance with the Operating Injunction. *See* Mallinckrodt Compliance Report § 5.4.

8.3 During the Twelfth Reporting Period, the Monitor Team interviewed the new Chair of the SGGSAC, who also serves as the Senior Director, Integrity & Compliance for SpecGx. The Monitor Team sought to learn more about her plans for the Committee as its new Chair and her thought process when reviewing a funding request.

8.4 Regarding the Chair's background, the Senior Director joined Mallinckrodt in 2017 in an accounting role, following a decade of experience in various accounting and financial reporting roles. In 2022, she transitioned within Mallinckrodt to a role in corporate development, and in early 2024, moved to the Integrity & Compliance Department. She began serving as the Chair of SGGSAC in November 2024.

8.5 When asked for her understanding of the purpose of the Committee, the Chair explained that the goal is to be good stewards of Company funds, and ensure all funding

complies with applicable laws and regulations, as well as the Operating Injunction. To do so, the Committee reviews all materials submitted with the funding request, including using keyword searches on conference agendas and other lengthy materials. She also noted that her review goes beyond the materials submitted to the Committee, and includes reviewing external websites as well as having conversations with the funding requestor in Committee meetings to better understand the proposed event and the kinds of discussions Mallinckrodt employees might have while in attendance.

8.6 When asked whether the Committee has denied any requests during her tenure as Chair, she noted two. The first request was for funding to sponsor a conference hosted by the American Correctional Association that included a workshop which focused on alternatives for the treatment of pain. The second request was for funding to sponsor an event hosted by the Canadian Society of Addiction Medicines, in which "references to treatment of pain were glaring and permeated throughout" the conference agenda; the Integrity & Compliance Department denied that request before it was presented to the Committee. The Monitor Team's review of these requests is discussed below. *See infra* at 16-17 ¶ 8.9.

8.7 In sum, the Monitor Team is satisfied that the Senior Director will be a thorough and diligent Chair of the Committee, and encourages the combination of these in-depth reviews and discussions of funding requests.

2. <u>The Monitor Team's Review of SGGSAC Meeting Minutes and Materials</u>

8.8 During the Twelfth Reporting Period, the Monitor Team reviewed the minutes of all SGGSAC meetings that took place in the fourth quarter of 2024 and the first quarter of 2025. Additionally, the Monitor Team reviewed the accompanying third-party funding Request Forms,

and any related materials the Committee considered in determining whether to approve or deny a request.

8.9 Given the volume of meeting minutes and accompanying request materials reviewed during the Twelfth Reporting Period, what follows is a brief summary of some of the more noteworthy SGGSAC meetings and materials the Monitor Team reviewed:

(1) During the fourth quarter of 2024, three members of the Commercial Department submitted a funding request to sponsor a conference hosted by the Canadian Society of Addiction Medicine. As discussed with the new Committee Chair, *supra* at 14 ¶ 8.2 – 15 ¶ 8.7, the Integrity & Compliance Department reviewed this request prior to submission to the Committee, and declined it before it reached the Committee, because "references to treatment of pain were glaring and permeated throughout" the conference agenda. By way of limited example, the conference agenda listed a session entitled "Pain medicine review for the health care practitioner: An interactive, case-based workshop" and in the description: ***"We now know that the forced tapering of opioids was also harmful to these same patients. We also know that many people with substance use disorders have under-diagnosed and under-treated pain conditions . . . ."*** (emphasis added). In another session, entitled "Safer Supply, Opioid Agonist Therapy, and decriminalization: Practical solutions and effective policies," the overview for the session stated: ***"The public debate over Safer Supply (SS) has been intense. Safer Supply advocates claim that SS reduces overdose death in fentanyl users who have rejected or failed at Opioid Agonist Treatment (OAT). They also claim that diversion of hydromorphone tablets benefits people who use fentanyl, and there is no evidence that diversion has caused significant harm to the public . . . ."*** (emphasis added). Both of these topics clearly violate the Operating Injunction's provisions regarding the Treatment of Pain, as well as the funding and promotion of Opioids generally. The Monitor Team agrees with Mallinckrodt's decision to decline the request without submitting it to the Committee. Nonetheless, the Monitor Team recommends some sort of corrective training for the Commercial Department employees who submitted the request, given the clearly concerning language used in the conference agenda.

(2) On November 6, 2024, the Committee discussed a request for a sponsorship and exhibit fee to attend the American Correctional Association Winter Conference. The request was conditionally approved pending receipt of the final agenda. However, as the Senior Director, Integrity & Compliance mentioned, when the final agenda was received in January 2025, it included a workshop entitled "Clinical Updates in Correctional Medicine" which included pain management and learning

objectives such as "a working knowledge of the different medications that are available for pain." Given the implications on the Operating Injunction's provisions regarding the Treatment of Pain, the Integrity & Compliance Department decided to revoke the conditional approval and decline this request without sending it back to the Committee. The Monitor Team agrees with this assessment.

(3) On January 22, 2025, the Committee reviewed a funding request to sponsor and attend the National Commission on Correctional Healthcare's ("NCCHC") Spring Conference. The Committee discussed an agenda topic entitled "Managing Wound Pain and Inflammation to Promote Healing" and whether it implicated the Treatment of Pain. To do so, the Committee referred back to the Monitor's Seventh Report, when a similar conference agenda topic was analyzed for a prior NCCHC funding request. *See* Seventh Monitor Report at 13 ¶¶ 8.6-8.7. Based on the Monitor's prior analysis, the Committee decided to approve the request. The Monitor Team encourages the Committee to continue this kind of discussion and analysis, particularly in light of the monitorship's anticipated conclusion.

(4) Additionally, during the same January 22, 2025 meeting, the Committee reviewed a request for a corporate membership in the North Carolina Life Sciences Organization ("NCLifeSci"). The goal of this group is to promote the growth and development of North Carolina's life sciences industry through advocacy at the state and federal levels. The Committee's meeting minutes confirmed that the Chair had reviewed the website for NCLifeSci, and shared with the Committee that the website contained a link to something called a "BIO Advocacy Toolkit" that contained information on advocating for different positions related to opioids and other life sciences topics. Following this discussion, the Committee vote resulted in a 2-2 tie, due to one member abstaining. Therefore, the request was declined because the Committee's procedures require a majority vote in favor to approve a request.

8.10 Near the end of the Twelfth Reporting Period, Mallinckrodt and its external counsel requested a meeting with the Monitor Team, to seek the Monitor's guidance regarding the propriety of the NCLifeSci funding request discussed *supra* at 17 ¶ 8.9, as well as one additional funding request to sponsor the ThoughtSpot 2025 conference co-hosted by Cencora and Good Neighbor Pharmacy. Mallinckrodt provided relevant links for the Monitor Team to review relating to each organization.

8.11 Following its review, the Monitor Team concluded that it agreed with the SGGSAC's decision to deny the NCLifeSci funding request. The Monitor Team noted that the Bio Advocacy Toolkit was prominently linked on NCLifeSci's homepage, under the Public Policy tab, and the one-page advocacy reference guides under the Opioids category seemed to violate the Operating Injunction. The Monitor Team also considered the purpose of the NCLifeSci group, which appeared to be aimed towards lobbying at the state and federal levels for different policies that touch the life sciences industry.

8.12 Regarding the ThoughtSpot 2025 Conference co-hosted by Cencora and Good Neighbor Pharmacy ("GNP"), the Monitor Team concluded that sponsoring this event would not violate the Operating Injunction. Mallinckrodt brought to the attention of the Monitor Team certain 2019 / 2020 blog posts on GNP's website that discussed the Treatment of Pain. The Monitor Team considered the age and content of the blog posts and determined that based upon the content and the fact that the posts were older and pre-dated the Operating Injunction, the Monitor Team did not think these posts alone were enough to deny the request. Mallinckrodt also flagged a "Comprehensive Pain Management" training course offered through GNP's website. This course was provided by the American Pharmacists Association, appeared to be aimed toward healthcare providers, and was not offered at the ThoughtSpot 2025 Conference itself. Finally, Mallinckrodt explained that the fees paid by the Company would be going towards the ThoughtSpot 2025 event, rather than any sort of ongoing sponsorship of Cencora or GNP themselves. In light of these factors, the Monitor Team did not think that conditionally approving this funding request would violate the Operating Injunction. However, the Monitor Team encouraged the SGGSAC to review the Continuing Education courses offered at

ThoughtSpot 2025 when that information becomes available. The Monitor Team appreciates Mallinckrodt proactively soliciting its guidance regarding these requests.

8.13 The Monitor will continue to audit the SGGSAC to ensure it 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.

3. Mallinckrodt's Community Charitable Giving Program

8.14 As previously reported, the Monitor Team reviewed Mallinckrodt's Community Charitable Giving Program ("CCGP"), through which individuals or entities seeking donations from Mallinckrodt may submit requests for funding through its website. *See* Ninth Monitor Report at 16 ¶ 7.9 – 18 ¶ 7.12. As a result of discussions with the Monitor Team, the webpage for the CCGP, as well as the application portal page, were updated to reference the Operating Injunction and provide a link to the document. *See* Tenth Monitor Report at 22 ¶ 9.9 – 24 ¶ 9.10.

8.15 Based upon a revision to the Audit Plan, any funding requests and accompanying materials received through the portal that concern or relate to topics the Operating Injunction addresses are provided to the Monitor Team on a quarterly basis. Mallinckrodt informed the Monitor Team that during the fourth quarter of 2024, no such requests were submitted. However, during the first quarter of 2025, Mallinckrodt informed the Monitor Team that the CCGP has been discontinued, because Mallinckrodt is no longer accepting unsolicited requests for charitable contributions.

4. The Monitor Team's Review of CMS Open Payments Data and Interview of the Senior Director of Regulatory Affairs

8.16 As indicated in the Eleventh Monitor Report, the Monitor Team reviewed publicly available data through the Centers for Medicare & Medicaid Services ("CMS") Open Payments website, which collects and publishes information about financial relationships

between, on one hand, drug and medical device companies, and, on the other hand, certain health care providers.[7] *See* Eleventh Monitor Report at 19 ¶ 8.13 – 20 ¶ 8.15. This data showed that Mallinckrodt LLC, an entity subject to the Operating Injunction, paid: (1) $432,248.36 in consulting fees to Medical Center A in 2023; (2) $497,667.74 in consulting fees to Medical Center A in 2022; and (3) $9,125.00 in consulting fees to Dr. A in 2021. After reviewing that data, the Monitor Team sought further information from Mallinckrodt about the purpose of the consulting fee payments to Medical Center A and Dr. A. The Monitor Team spoke with Mallinckrodt's Associate General Counsel and external counsel about these questions. They explained that in order to comply with Risk Evaluation and Mitigation Strategy ("REMS") requirements,[8] Mallinckrodt typically pays into a consortium that hires a third-party vendor to handle the mandatory monitoring and reporting. In this case, that vendor was Reporting Vendor A, a division of Medical Center A. Further, Dr. A is an employee of Reporting Vendor A.

8.17 However, the Monitor Team had additional questions about the Consulting Agreement between the Company and Dr. A. Mallinckrodt identified the Senior Director of Regulatory Affairs as the person most knowledgeable about that arrangement, and the Monitor Team interviewed her during the Twelfth Reporting Period. The Senior Director previously worked at Mallinckrodt from 2002 to 2006, and rejoined the Company in 2018 in the Regulatory Affairs Department. Her job duties include managing submissions to the FDA for potential new

[7] *See* Mallinckrodt Llc – OpenPaymentsData.CMS.gov, *available at* https://openpaymentsdata.cms.gov/company/100000005429 (last visited Apr. 29, 2025).

[8] As discussed in the Eleventh Monitor Report, *see* Eleventh Monitor Report at 19-20 ¶ 8.14, the U.S. Food & Drug Administration ("FDA") requires pharmaceutical companies to create drug safety programs for certain medications with serious safety concerns, such as a opioids, to help ensure the benefits of the medication outweigh its risks. *See* Risk Evaluation and Mitigation Strategies | REMS, *available at* https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last visited Apr. 29, 2025).

products to ensure the submissions meet regulatory requirements and are eventually approved. She is also a member of the PRC, and a prior member of the SGGSAC, and is therefore familiar with the Operating Injunction's provisions relating to promotion and funding.

8.18 Regarding the consulting fees paid to Dr. A, the Senior Director explained that Mallinckrodt was previously seeking approval from the FDA for a new drug product—an immediate release, abuse deterrent form of oxycodone. The process began in November 2018, when the Company hired Dr. A as a consultant to assist with a presentation regarding the new drug to a Joint Meeting of two different FDA Advisory Committees (the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Committee).

8.19 The Senior Director explained that, generally, FDA Advisory Committee meetings are open to the public and held to review potential new drugs and evaluate whether the benefits of the product outweigh the potential risks. To prepare for these presentations, Mallinckrodt utilizes consultants to serve as mock panelists, one of whom was Dr. A. Following the live presentation to the FDA Advisory Committees in November 2018, the FDA did not approve the product and instead asked Mallinckrodt to conduct additional clinical studies regarding potential risks concerning injection of the product. After those studies were conducted, Mallinckrodt rehired Dr. A as a consultant in August 2020 to review the materials from the prior submission, and to help prepare an updated presentation for the next Advisory Committee meeting, which was the arrangement documented in the Consulting Agreement produced to the Monitor Team.

8.20 However, after receiving an additional deficiency letter from the FDA, Mallinckrodt decided not to move forward with the new drug and did not attend another

Advisory Committee meeting. As a result, Dr. A was only paid part of his consulting fee, as reflected by the $9,125.00 payment to Dr. A on the Open Payments website.

8.21 Additionally, the Senior Director confirmed that the payments to Medical Center A were related to Mallinckrodt's REMS program, as previously explained by Mallinckrodt's internal and external counsel, and not related to this FDA approval process. Following this discussion, the Monitor Team was satisfied that the payments reflected on the Open Payments website had a proper purpose and did not violate the Operating Injunction's restrictions.

IX. 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 In the Third Monitor Report, the Monitor recommended Mallinckrodt implement a process to ensure that its external lobbyists are accurately reporting their activities and that those activities comply with the Operating Injunction. *See* Prior Recommendation 3(c). In the Fifth Reporting Period, Mallinckrodt implemented the *Lobbying Certification and Activity Review* SOP, which formalizes the process by which the Government Affairs Team reviews, on a quarterly basis, external lobbyists' public disclosure reports and contemporaneously records the results of that review.

1. External Lobbyists' Efforts

9.3 During the Twelfth Reporting Period, under the Audit Plan, the Monitor Team received and reviewed the results of the Government Affairs Department's audits of Mallinckrodt's external state and federal lobbyists' public disclosure reports under the *Lobbying Certification and Activity Review* SOP for the fourth quarter of 2024. The report, which the Director, Government Affairs & Patient Advocacy prepared, details the states covered by the

external lobbying firms encompassed in the review, the applicable state or federal disclosure report filing schedule, and an assessment of whether the activities reported comply with the Operating Injunction. It also provides links to the online filing location of the disclosure reports. As with the last several audit reports, this audit report did not identify any concerns or potentially violative activity. However, the report disclosed that for the State of Washington, none of the monthly reports for the months following September 2024 were available online at the time of review, due to a redesign of the State's website. Mallinckrodt was able to provide the information pertaining to the State of Washington, as well as to all other applicable states, in the audit report for the first quarter of 2025.

9.4 Under the Audit Plan, the Monitor also receives a list of bills that Mallinckrodt's external lobbyists reported lobbying for or against on the Company's behalf during the reporting period. The disclosure for the fourth quarter of 2024 revealed no lobbying activity at the federal or state levels on Mallinckrodt's behalf. Similarly, the disclosure for the first quarter of 2025 showed that no lobbying activity was undertaken on Mallinckrodt's behalf at the federal level or in five states (California, Maine, Massachusetts, New York, and North Carolina). The lobby activity undertaken in Illinois, Missouri, and Washington is discussed further below.

9.5 In Illinois, lobbying efforts were undertaken on Mallinckrodt's behalf in support of SB 2185, which was introduced on February 7, 2025 and which—as amended on March 5, 2025 and on April 4, 2025—would amend the Illinois Unified Code of Corrections to provide that, "if at any time a committed person screens positive as having or being at risk for an opioid use disorder, is diagnosed with an opioid use disorder or is exhibiting symptoms of withdrawal from an opioid use disorder, and medication for opioid use disorder or medication assisted treatment (rather than just medication assisted treatment) is clinically indicated by a licensed

physician, a licensed physician assistant, or a licensed nurse practitioner, then the individual may consent to commence medications for opioid use disorder, which shall be provided by the Department of Corrections."

9.6 Lobbying was undertaken on Mallinckrodt's behalf in Illinois in support of SB 2330. This bill, which was introduced on February 7, 2025, would amend the Illinois Unified Code of Corrections to provide as follows, effective January 1, 2026:

> Provides that the Department of Corrections shall be required to ensure all persons under its care are assessed for substance use disorder, as defined in the Substance Use Disorder Act. Provides that this process includes screening and assessment for opioid use disorders. Provides that for a committed person diagnosed with opioid use disorder, the Department shall offer, or facilitate access to, all medication-assisted treatment options deemed appropriate by an authorized health care professional. Provides that the Department shall not impose limitations on the types of medication assisted treatment that may be recommended by an authorized health care professional as part of a treatment plan. Provides that an individual receiving medication-assisted treatment prior to being committed to a Department of Corrections facility shall be entitled to, upon request, continue such treatment in the medication assisted treatment program for any period of time deemed medically necessary by an authorized health care professional. Provides that no person shall be denied participation in medication-assisted treatment program on the basis of a positive drug screening upon entering the Department's custody; nor shall any person receive a disciplinary infraction for such positive drug screen. Provides that no person shall be denied participation in medication-assisted treatment based on prior success or failure of any medication-assisted treatment program. Provides that for each Parole District, the Department shall develop a plan to facilitate access to medication-assisted treatment for persons diagnosed with opioid use disorder in the community following release. Provides that the Department may adopt rules for the implementation of these provisions.

9.7 In Missouri, lobbying efforts were undertaken on Mallinckrodt's behalf in support of HB 7, HB 9, and HB 10, which were each introduced on February 19, 2025 and each of which

is an appropriations bill for the fiscal period of July 1, 2025 to June 30, 2026. The bills provide as follows:

(1) Section 7.040 of HB 7 would appropriate $9,600,000 from the General Revenue Fund to the Department of Economic Development, Business and Community Solutions Division, for "a grant to a public university with an established partnership with a not-for-profit organization that has received a similar state-funded grant for establishing Missouri in re-shoring active pharmaceutical ingredient (API) manufacturing[.]"

(2) Section 9.195 of HB 9 would appropriate $7,900,000 from the Opioid Addiction Treatment and Recovery Fund to the Department of Corrections for "a pilot program to ensure the availability and use of all medication assisted treatment products approved by the FDA to treat opioid use disorder, including but not limited to those specified in Section 191.1165, RSMo, in conjunction with treatment for incarcerated offenders[.]"

(3) HB 10 would appropriate funds from the Opioid Addiction Treatment and Recovery Fund to the Department of Mental Health, Division of Behavioral Health, in varying amounts for a number of purposes, including but not limited to the following:

- $2,510,730 for "distribution to a non-profit located in a city with more than four hundred thousand inhabitants and located in more than one county, founded in 1982 to prevent and treat opioid substance use by detoxification, temporary housing, treatment programs for sobriety, and fentanyl epidemic recovery, provided that local matching funds must be provided on a 50/50 state/local basis" under Section 10.105;

- $1,000,000 for "distribution to a fire department located in a city with more than one hundred five thousand but fewer than one hundred twenty-five thousand inhabitants that engages in partnerships between social work resources, mental health resources, and emergency responders to connect community members to essential services" under Section 10.105;

- $6,900,000 for "community grants to local governments impacted by the opioid epidemic" under Section 10.105;

- $1,000,000 for "grants no less than $250,000 distributed to Prevention Resource Centers for primary care substance-use prevention" under Section 10.106;

- $1,200,000 (in addition to $4,402,527 from the General Revenue Fund) for "Recovery Community Centers" under Section 10.109;

- $1,835,879 for "Recovery Support Services" under Section 10.110;
- $1,304,370 for "Addiction Medicine Fellowships" under Section 10.111;
- $6,040,316 for "treatment of alcohol and drug abuse" under Section 10.115;
- $5,100,000 for "statewide distribution of opioid antagonists approved by the [FDA]" with a limited carveout for "a pilot project to distribute fentanyl test strips to community-based organization" under Section 10.115;
- $8,000,000 for "statewide distribution of opioid antagonists approved by the [FDA] to law enforcement agencies and first responders" under Section 10.115;
- $1,113,000 for "an organization serving a city not within a county and the surrounding region to support prevention of opioid overdose" under Section 10.115;
- $1,000,000 for "a substance abuse initiative that focuses on providing medication assisted treatment to treat substance abuse disorders" under Section 10.145; and
- $4,512,500 for "graduate medical program grants for specialty areas which provide specific training for physicians to prevent, diagnose, and manage substance abuse disorder/opioid use disorder" and other related uses under Section 10.765.

9.8 In Washington, lobbying efforts were undertaken on Mallinckrodt's behalf in opposition to HB 1422, which was first introduced on January 17, 2025 and which would modify the fee and enforcement regulations of the state's drug take-back program, address program operator performance parity, and create a new statutory requirement regarding the state legislature's review of the Department of Health's fee-setting authority for the drug take-back program.

9.9 The Monitor Team reviewed all of the foregoing bills in order to assess whether the lobbying activities undertaken on Mallinckrodt's behalf in support of or in opposition to the

bills complied with the restrictions of the Operating Injunction. The Monitor Team was satisfied that Mallinckrodt's external lobbyists' efforts did not violate those restrictions.

9.10 During the Twelfth Reporting Period, the Monitor Team also conducted a "spot check" of recent public lobbying disclosure reports that Mallinckrodt's external lobbyists filed. The Monitor Team reviewed this information to confirm that: (1) Mallinckrodt's external lobbyists were not engaging on legislative topics that concerned increased access to Opioids or the Treatment of Pain as prohibited by the Operating Injunction; (2) the work Mallinckrodt's external lobbyists were reporting to their respective states aligned with the quarterly list of bills provided to the Monitor by the Company; and (3) Mallinckrodt had obtained a Certification and Operating Injunction Acknowledgement from each lobbyist and lobbying firm publicly listed as performing advocacy work on Mallinckrodt's behalf.

9.11 In connection with that review, Mallinckrodt confirmed that it received the requisite executed certifications, including one for a newly engaged external lobbyist. In addition, Mallinckrodt informed the Monitor that an individual who had been employed by the external lobbyist for Washington, D.C. was no longer employed by that lobbyist.

2. Implementation of Prior Recommendation 8(a)

9.12 In the Eighth Monitor Report, the Monitor recommended that Mallinckrodt provide annual training to its external lobbyists, focusing on the Operating Injunction's lobbying-related provisions. As noted in the Ninth Monitor Report, Mallinckrodt adopted the recommendation and implemented the training. *See* Ninth Monitor Report at 22 ¶ 8.11.

9.13 During the Twelfth Reporting Period, none of the registered lobbyists for Mallinckrodt participated in any training sessions because the annual training was held during the prior reporting period. The Monitor Team anticipates that the lobbyists will complete their

next annual training during the next reporting period, and will report as such in the next Monitor Report.

3. The Monitor Team's Review of Mallinckrodt's Political Donations

9.14 Mallinckrodt contributes to political candidates and other political groups through the Mallinckrodt LLC Political Action Committee ("MNKPAC"), which is a federally registered political action committee. The Monitor Team reviewed MNKPAC's federal lobbying expenditures during the fourth quarter of 2024 and the first quarter of 2025.

9.15 During the fourth quarter of 2024, MNKPAC donated $2,500 to the campaign of a U.S. Senator who will be seeking reelection in 2028. The Monitor Team reviewed the Senator's campaign website, which appeared not to have been updated since 2021—prior to the Senator having been elected to the Senate—and learned that it contained only a passing reference to efforts that the Senator took while serving as a state Attorney General to address the opioid crisis. The Monitor Team also reviewed the Senator's official website, which referred generally to the Senator's efforts to address the opioid crisis prior to joining the Senate. As such, they did not appear to refer to or advocate for positions implicating the Operating Injunction's lobbying-related prohibitions.

9.16 Against that backdrop, the Monitor Team conducted additional research, which revealed that prior to being elected to the Senate and while serving as a state Attorney General, the Senator supported efforts that the predecessor state Attorney General took to hold pharmaceutical manufacturers and distributors liable, through litigation brought with other states' Attorneys General, for causing or contributing to the opioid crisis. In addition, the Senator wrote opinion pieces that were published in different newspapers that articulated the Senator's view of that crisis and its effects on the Senator's state. Other articles discussed the $500 million settlement of the litigation referenced above. Subsequently published opinion

pieces discussed the Senator's continuing opposition to what is colloquially known as "Big Pharma" while serving in the Senate.

9.17 Also during the fourth quarter of 2024, MNKPAC donated $2,500 to the 2024 reelection campaign of a member of the U.S. House of Representatives. The Monitor Team reviewed the campaign's website and determined that none of its contents appeared to advocate for positions implicating the Operating Injunction's lobbying-related prohibitions. The Monitor Team also reviewed the Representative's official website, which contained a press release from September 2023 discussing the Representative's introduction of legislation aimed at preventing opioid overdoses and increasing access to overdose reversal medications such as naloxone.

9.18 During the first quarter of 2025, MNKPAC donated $5,000 each to two political action committees. From the Monitor Team's review of the websites of those recipients, neither appeared to advocate for positions implicating the Operating Injunction's lobbying-related prohibitions.

4. Stateside Associates, Inc. Reports

9.19 As part of a recent update to the Audit Plan, Mallinckrodt agreed to provide to the Monitor Team, on a quarterly basis, copies of any legislative reports or summaries that Stateside Associates, Inc. ("Stateside") produced for Mallinckrodt. In accordance with that agreement, Mallinckrodt provided the Monitor Team with the reports that Stateside prepared for the fourth quarter of 2024 and the first quarter of 2025. The Monitor Team reviewed those reports, which provided overviews of certain 2024 state gubernatorial and legislative elections, with a focus on issues pertaining to healthcare generally, and on pending and enacted state legislation addressing

issues surrounding prescription drug prices (such as matters to be addressed by prescription drug affordability boards and measures to impose price caps and reporting requirements).

9.20 The reports also addressed legislation introduced in a handful of states seeking to prohibit those states' agencies from purchasing opioid antagonists from any company that was a party to any settlement with any state due to either (1) its role as a manufacturer or distributor of opioids or (2) its having played a role in or having contributed to the opioid epidemic. They also addressed the efforts in certain states to establish drug affordability boards and to enact legislation to address other issues that pertain to the pharmaceutical industry generally but not Mallinckrodt specifically, such as price gouging and price transparency, and to ensure that non-opioid pain treatments are not given less favorable treatment than opioids or other narcotics by health insurers regarding coverage, pricing, or recommended or prescribed utilization.[9] The reports were factual in nature and contained links to the referenced legislation or other materials, and the Monitor Team had no concerns regarding the reports' contents.

X. 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

[9] The reports also dealt with legislation proposed in a number of states relating to issues that do not directly pertain to Mallinckrodt's Opioid business, such as legislation relating to: the prohibition of or support for programs or laws that further diversity, equity, and inclusion; the expansion of what constitutes discrimination on the basis of sex or other characteristics; mandating the use of digital currencies; and the establishment of minimum hourly wages.

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 its requirement that Mallinckrodt comply with all laws and regulations relating to the "sale, promotion, distribution, and disposal of any Opioid Product" (*id.* § III.I).

10.2 Accordingly, it has been the Monitor's practice to request an annual certification from a Mallinckrodt representative as to Mallinckrodt's compliance with these provisions of the Operating Injunction. Consistent with the Audit Plan, in January 2025, the Associate General Counsel re-certified Mallinckrodt's compliance with these provisions of the Operating Injunction.

10.3 In the event Mallinckrodt becomes aware of any violations of the above-referenced provisions of the Operating Injunction or the Associate General Counsel is aware of a need to amend the representations in the most recent certification in the interim, Mallinckrodt has agreed to promptly inform the Monitor. Mallinckrodt has provided no such notice of any needed amendment during the Twelfth Reporting Period.

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

11.1 In the Twelfth Reporting Period, the Monitor continued his assessment of Mallinckrodt's compliance with Section III.G of the Operating Injunction. Specifically, the Monitor Team: (1) continued its review of documents and data Mallinckrodt provided under the

Audit Plan and in response to the Monitor Team's ad hoc requests, as well as publicly available materials; (2) conducted interviews with the Director of Controlled Substances Compliance ("CSC"), Director of CSC Analytics, both CSC Managers ("CSC Manager B" and "CSC Manager C"), the CSC Senior Manager, and the Senior Vice President of Commercial & Strategy; and (3) obtained updates from Mallinckrodt and its outside counsel regarding the grand jury subpoenas discussed below, *see infra* at 112 ¶ 11.205 – 114 ¶ 11.209, and the status of Mallinckrodt's implementation of the Monitor's recommendations related to suspicious order monitoring ("SOM") in prior reports and other SOM-related issues, including the "working group's"[10] observations.

11.2 The Monitor's findings are described in the following sections: (1) documents the Monitor Team reviewed during the Twelfth Reporting Period; (2) Opioid sales and market dynamics; (3) direct customer due diligence; (4) indirect customer due diligence; (5) SOM Team ("SOMT")[11] meeting minutes and materials; (6) the Director of CSC Analytics' Annual Report;

[10] During the Eleventh Reporting Period, Mallinckrodt's counsel shared with the Monitor that a number of areas of interest to the Monitor are under review by an informal working group (the "Working Group") in the Company comprised of various in-house and outside counsel and subject matter experts. *See* Eleventh Monitor Report at 61 ¶ 11.92.

[11] The SOMT, which meets monthly to review potential suspensions and restrictions of direct and downstream customers, is comprised of employee representatives of various departments, including the CSC Department. The CSC Team is comprised of employees in the CSC Department who report to the Legal Department. Some members of the CSC Team (who also participate in the SOMT) perform a variety of SOM-related roles, including but not limited to performing internal audits, reviewing flagged orders, conducting chargeback reviews, and performing direct customer due diligence visits. These employees include the following: the CSC Director, the Director of CSC Analytics, the CSC Senior Manager, the CSC Managers, and the CSC Specialist. However, the CSC Team also includes other employees with CSC compliance responsibilities who are not members of the SOMT, such as security personnel, and those involved with quota management. Thus, to avoid confusion, the Monitor refers herein to either the SOMT (or members of the SOMT) when discussing core functions of the SOMT, *i.e.*, indirect customer reviews and the SOMT's suspension and restriction decisions, and the CSC Team (or members of the CSC Team) when discussing other CSC compliance responsibilities.

(7) Mallinckrodt's Working Group to consider SOM-related topics; and (8) other SOM-related issues.

1. Documents Reviewed During the Twelfth Reporting Period

11.3 Mallinckrodt timely produced all SOM-related documents requested—on a quarterly basis for the fourth quarter of 2024 and the first quarter of 2025; on an annual basis for 2024; and on a monthly basis. The Monitor Team also made requests for documents and information on an ad hoc basis, and Mallinckrodt continued to provide timely responses to those requests.

11.4 In auditing Mallinckrodt's compliance with the Operating Injunction's SOM-related provisions, the Monitor Team reviewed documents, including the following:

(1) SOMT meeting materials and minutes for October, November, and December 2024, and for January and February 2025;

(2) a spreadsheet of all indirect customers the SOMT has evaluated for restriction and / or reinstatement;

(3) correspondence with the U.S. Drug Enforcement Agency ("DEA") regarding restriction and reinstatement of downstream registrants;

(4) the Opioid Product-related inquiries in the Government Communications log for the fourth quarter of 2024 and the first quarter of 2025, as well as related correspondence;

(5) sales data for Opioid Products, including highly diverted Opioid Products;

(6) direct customer flagged order data;

(7) certain suspicious order reports ("SORs") and related correspondence for flagged direct customer orders in October, November, and December 2024 and in January and February 2025;

Unless the Monitor is referring to actions or decisions by the SOMT or CSC Team as a whole, the Monitor is referring to a sub-set of each group's members.

(8) a sampling of SOM questionnaires direct customers submitted to Mallinckrodt in 2024;

(9) revised SOM questionnaires;

(10) various revised SOM policies;

(11) TrackWise data for inquiries and complaints raising potential diversion concerns for the third and fourth quarters of 2024;

(12) the Director of CSC Analytics' 2024 Annual Controlled Substances Compliance Report, Analysis of Highly Diverted Controlled Substances Utilizing Chargeback & ARCOS[12] Data;

(13) the list of distributor customers the CSC Team intends to visit, either virtually or in person, to conduct due diligence visits in 2025;

(14) reports from direct customer due diligence visits in 2024 and 2025, as well as other documents obtained by the CSC Team related to those visits;

(15) data regarding distributor customers that do not submit chargeback requests;

(16) agreements with distributor customers;

(17) a summary of changes to the indirect customer dashboard;

(18) the aggregate production quota DEA issued for hydrocodone and oxycodone from 1995 to 2025;

(19) Mallinckrodt's manufacturing and procurement quotas for both oxycodone and hydrocodone in recent years, including 2024;

[12] "ARCOS," the acronym for the DEA's "Automation of Reports and Consolidated Orders System," is a data collection system which manufacturers and distributors use to report controlled substances transactions to the DEA, consistent with those registrants' regulatory reporting obligations. *See* U.S. Dep't of Justice, Drug Enforcement Admin., Diversion Control Division, "ARCOS Retail Drug Summary Reports," *available at* https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/arcos-drug-summary-reports.html (hereafter, "ARCOS Retail Drug Summary Reports") (last visited on May 1, 2025); *see also* 21 U.S.C. § 827(d)(1); 21 C.F.R. 1304.33. The DEA—and manufacturers and distributors—can utilize this information "for determining quota, distribution trends, internal audits, and other analyses." *See* ARCOS Retail Drug Summary Reports.

(20) Internal Audit Reports and Internal Process Reports;

(21) Mallinckrodt's 8-K, 10-K, and 10-Q filings with the U.S. Securities and Exchange Commission ("SEC"), including those reporting on Mallinckrodt's receipt of the federal grand jury subpoenas from the U.S. Attorney's Office for the Western District of Virginia and the U.S. Attorney's Office for the Eastern District of Pennsylvania; and

(22) Mallinckrodt's cover letters accompanying productions of documents subpoenaed by the U.S. Attorney's Office for the Western District of Virginia and the U.S. Attorney's Office for the Eastern District of Pennsylvania.

11.5 The Monitor also reviewed other publicly available documents as discussed below, including but not limited to: reports published by the independent Monitor of Purdue Pharma, L.P., Steven C. Bullock (the "Purdue Monitor"); a U.S. Department of Justice press release and related complaint; and relevant news articles.

2. Opioid Sales and Market Dynamics

a. Mallinckrodt's SEC filings

11.6 As in prior reporting periods, the Monitor Team reviewed Mallinckrodt's filings with the SEC, including Mallinckrodt's reported net sales of Opioids. The Monitor previously reported on Mallinckrodt's disclosure of a large increase in net sales of Opioids in 2023. *See* Eleventh Monitor Report at 43 ¶ 11.49; *see also* Tenth Monitor Report at 33 ¶ 12.6 – 35 ¶ 12.11; *id.* at 35 ¶ 12.12 – 37 ¶ 12.20. Specifically, Mallinckrodt's total 2023 net sales of Opioids were $262.3 million, as compared to $206.7 million in 2022, reflecting a 26.9% increase. *See* Tenth Monitor Report at 38 ¶ 12.22. The Senior Vice President of Commercial & Strategy attributed that growth to market dynamics resulting in both higher sales volume and pricing. *Id.* at 34 ¶ 12.11 – 37 ¶ 12.20.

11.7 In the Twelfth Reporting Period, the Monitor Team reviewed Mallinckrodt's 10-Q filing (quarterly report) for the quarterly period ending September 27, 2024, as well as its 10-K

filing (annual report) for the fiscal year ending December 27, 2024. These reports reflect continued increases in net sales of Opioids. For example, as reported in the 10-Q, Mallinckrodt reported third quarter 2024 net sales of Opioids of $85.9 million, as compared to $65.9 million in the same quarter of 2023—*i.e.*, an increase of 30.3%. Similarly, Mallinckrodt's 10-K reported $349.9 million in total net sales of Opioids in 2024 as compared to $262.3 million in 2023—*i.e.*, an increase of 33.4%. These reported year-over-year increases are larger than the 26.9% increase reported from 2022 to 2023.

11.8 To better understand Mallinckrodt's growth in net sales of Opioids from 2023 to 2024, the Monitor Team reviewed: (1) Mallinckrodt's 2024 annual sales data for all Opioid Products, as well as for the three most highly diverted Opioid Products (*i.e.*, hydrocodone / APAP 10/325 mg, oxycodone 15 mg, and oxycodone 30 mg); (2) Mallinckrodt's fourth quarter 2024 sales data for those three Opioid Products; (3) Mallinckrodt's manufacturing and procurement quotas for oxycodone and hydrocodone in 2022, 2023, and 2024; (4) the DEA's aggregate production quotas for hydrocodone and oxycodone in 2024 and 2025; and (4) certain IQVIA[13] market data. The Monitor Team also conducted two interviews with the Senior Vice President of Commercial & Strategy. The Monitor's observations regarding Mallinckrodt's 2024 Opioid sales, based upon the above sources of information, are provided below.

b. The U.S. market for Opioids continues to decline, as the DEA decreases the aggregate production quota for both hydrocodone and oxycodone

11.9 The Senior Vice President of Commercial & Strategy confirmed the fact that the U.S. market for Opioids has continued to decline, including for hydrocodone and oxycodone

[13] IQVIA provides data aggregation and analytics services for the pharmaceutical industry. *See* Prescription Information, IQVIA, *available at* https://www.iqvia.com/locations/united-states/solutions/life-sciences/information-solutions/essential-information/prescription-information (last visited May 1, 2025).

products, and informed the Monitor Team that he expects sales of Opioids to further decline in 2025. His impressions are consistent with the DEA's decreasing aggregate production quota for oxycodone and hydrocodone and with well-known broader market dynamics, such as decreased prescribing and greater awareness of the risk of opioid addiction. As for quota, from 2019 to 2024, the DEA decreased the aggregate production quota for both hydrocodone and oxycodone molecules every year, a downward trend that continued in 2025.[14] From 2024 to 2025, the DEA decreased the aggregate production quota for oxycodone and hydrocodone slightly (by 0.1% and 0.08% respectively).

c. Mallinckrodt's 2024 increase in net Opioid sales was driven primarily by price, not volume, and Mallinckrodt maintains a significant share of the markets for both oxycodone and hydrocodone

11.10 Net sales is the product of volume and price. As for volume, Mallinckrodt's Opioid sales measured by volume (*i.e.*, dosage units) continued to increase in 2024, but only slightly. In other words, Mallinckrodt's sales volume of Opioid products (measured by dosage units), grew—but at a significantly lower rate between 2023 and 2024 than between 2022 and 2023. Between 2022 and 2023, the volume of Mallinckrodt's sales of Opioids grew 48%. However, between 2023 and 2024, the volume of Mallinckrodt's sales of Opioids grew by less than 1% (*i.e.*, by 0.47%).

11.11 Since the growth in the volume of Mallinckrodt's Opioid sales between 2023 and 2024 was minimal, the 33.4% increase in Mallinckrodt's net Opioid sales during the same period can be attributed largely to price increases (which Mallinckrodt attributes to factors including increasing costs and inflationary pressure), rather than volume. Indeed, Mallinckrodt's Senior

[14] Under the Audit Plan, Mallinckrodt provided the Monitor Team with the DEA's aggregate industry production quota, by molecule, for hydrocodone and oxycodone.

Vice President of Commercial & Strategy confirmed that the increase in net sales in 2024 was due primarily to Mallinckrodt's increase in price for both primary and secondary (*i.e.*, "backup" supply) contracts.

11.12 Notwithstanding the low rate of growth in Mallinckrodt's Opioid sales, Mallinckrodt's sales of hydrocodone / APAP tablets of all strengths still reflected a relatively high market share. As of December 2024, Mallinckrodt had the largest share of both the hydrocodone / APAP tablet market and the hydrocodone / APAP 10/325 mg tablet market.

11.13 The Senior Vice President of Commercial & Strategy attributes Mallinckrodt's high hydrocodone / APAP tablet market share (in an otherwise declining opioid market) in part to Mallinckrodt's vertically-integrated supply chain. For example, since Mallinckrodt makes its own hydrocodone, which it then uses to manufacture finished dosage products, Mallinckrodt knows how much manufacturing and procurement quota to request from the DEA and is less likely to experience quota-related delays. Additionally, Mallinckrodt's Hobart, New York facility, where the tablets are produced, is very efficient, as a result of having the experience of producing hydrocodone / APAP over a long period of time. Finally, the market has relatively few players, including those who have either not returned after exiting the market or whose output remains modest.

11.14 In December 2024, Mallinckrodt had lower market shares for oxycodone immediate release tablets and oxycodone / APAP tablets, compared to its market share for hydrocodone / APAP tablets, but Mallinckrodt is still a significant presence in both of those oxycodone markets. The Senior Vice President of Commercial & Strategy attributed Mallinckrodt's lower market share for oxycodone products to greater competition. However, he

acknowledged that Mallinckrodt's market share for oxycodone immediate release tablets increased slightly in 2024 as competitors struggled to meet market demand.[15]

11.15 Despite maintaining a high market share for hydrocodone / APAP tablets, immediate release tablets, and oxycodone / APAP tablets, Mallinckrodt's manufacturing and procurement quotas for oxycodone and hydrocodone molecules decreased, with one exception, discussed below.

d. Mallinckrodt's DEA-approved manufacturing and procurement quotas for hydrocodone and oxycodone decreased, with one exception

11.16 From 2023 to 2024, Mallinckrodt's manufacturing and procurement quotas for oxycodone and its procurement quota for hydrocodone decreased, while its manufacturing quota for hydrocodone increased slightly. The percentage changes in Mallinckrodt's manufacturing and procurement quotas for hydrocodone and oxycodone between 2022 and 2023, and between 2023 and 2024, are set forth below:

Mallinckrodt's DEA-Approved Manufacturing Quota Change 2022-2024		
Molecule	**% Change 2022-2023**	**% Change 2023-2024**
Hydrocodone	23%	3.50%
Oxycodone	27%	-2.10%
Mallinckrodt's DEA-Approved Procurement Quota Change 2022-2024		
Molecule	**% Change 2022-2023**	**% Change 2023-2024**
Hydrocodone	46%	-0.12%
Oxycodone	11%	-14%

[15] As discussed in the Tenth Monitor Report, the now Senior Vice President of Commercial & Strategy previously explained the reasons for Mallinckrodt's increased market share for oxycodone immediate release tablets (and oxycodone / APAP) in 2023, including competitors' exits from those markets (sometimes arising from compliance-related issues and the challenges of government regulatory enforcement) and supply constraints on Mallinckrodt's remaining competitors. *See* Tenth Monitor Report at 36 ¶ 12.15.

11.17 With the exception of Mallinckrodt's manufacturing quota for hydrocodone, which increased slightly from 2023 to 2024, Mallinckrodt's otherwise declining quotas for hydrocodone and oxycodone are consistent with the DEA's decreases in quotas for both molecules. The slight increase in Mallinckrodt's manufacturing quota for hydrocodone is perhaps explained by the high market demand for its hydrocodone tablet products given the lack of competition in that market.

11.18 Finally, Mallinckrodt and the Monitor Team discussed the DEA's recent changes to the procurement quota application process, namely whether the CSC Team has sufficient resources to (1) apply for procurement quota allotments on a semi-annual, rather than annual, basis and (2) comply with the DEA's new quota monitoring requirements. *See* Eleventh Monitor Report at 73 ¶ 11.128 – 75 ¶ 11.131. The CSC Director believes Mallinckrodt has sufficient resources to apply for and manage quota, although the DEA's changes to the prior quota system still pose certain challenges for the Company.

e. Although the increase in the volume of Mallinckrodt's sale of all Opioid Products was minimal, its sales of two of the most highly diverted products increased

11.19 Notwithstanding the shrinking market for Opioids generally, and the minimal increase in the volume of Mallinckrodt's sale of all Opioids, the volume of Mallinckrodt's sales of two of the most highly diverted products increased from 2023 to 2024: (1) hydrocodone / APAP 10/325 mg; and (2) oxycodone 15 mg. The Monitor Team discussed the increased sales of these two products with the Senior Vice President of Commercial & Strategy.

i. Mallinckrodt's sales of hydrocodone / APAP 10/325 mg increased by 5.1% from 2023 to 2024

11.20 The volume of Mallinckrodt's sales of hydrocodone / APAP 10/325 mg increased by 5.1% from 2023 to 2024. The Senior Vice President of Commercial & Strategy could not

identify a specific reason for Mallinckrodt's marginal increase in hydrocodone / APAP 10/325 mg sales, but he (and the data he shared with the Monitor Team) confirmed that Mallinckrodt's share of the hydrocodone / APAP 10/325 market has declined since July 2024. In approximately July 2024, Mallinckrodt's market share of the hydrocodone / APAP 10/325 mg peaked, reaching its highest level in about five years. Since then, it has continued to decrease through the end of December 2024.

ii. Mallinckrodt's sales of oxycodone 15 mg increased by 14.7% from 2023 to 2024

11.21 The volume of Mallinckrodt's sales of oxycodone 15 mg increased by 14.7% from 2023 to 2024. The Senior Vice President of Commercial & Strategy attributed Mallinckrodt's increased volume of sales of oxycodone 15 mg to the corresponding decrease in its volume of sales of the higher strength oxycodone 30 mg.

* * *

11.22 In sum, Mallinckrodt's increased net sales of Opioids in 2024 were almost entirely due to price, unlike its increased net Opioid sales in 2023, which were due to a combination of both price and volume. Further, the significantly decreased growth of the volume of Mallinckrodt's Opioid sales and its decreased manufacturing and procurement quotas for oxycodone and procurement quota for hydrocodone are consistent with the shrinking Opioid market and the DEA's decreased quotas for the industry. However, the market data shows that Mallinckrodt still commands a large market share for hydrocodone / APAP tablets, and a significant portion of the market share for both oxycodone immediate release tablets and oxycodone / APAP tablets due to lack of competition, quota constraints, and other market dynamics. Thus, Mallinckrodt's position in the market necessitates its continued attention to potential diversion by both direct and indirect customers.

3. Direct Customer Due Diligence

11.23 Mallinckrodt's two systems for monitoring potentially suspicious direct customer orders are: (1) an algorithm that monitors direct customer orders for unusual quantity, pattern, or frequency (the "Algorithm"), and (2) the "OI Hold system," which monitors direct customer orders for potential violations of the Operation Injunction's provisions. If the Algorithm or the OI Hold system flags an order, Mallinckrodt will not ship the order until CSC Team members release the hold—*i.e.*, by addressing or ruling out the suspicion. Each quarter, the Monitor Team reviews: (1) a report of all orders for Opioid Products the Algorithm flagged in that period, by product; and (2) a report of all orders flagged by the OI Hold system.

11.24 Additionally, the Monitor Team reviews a SOR for a randomly chosen week each month to confirm that two appropriate CSC Team members[16] reviewed the flagged direct customer orders before determining whether to release them. The Monitor Team also reviews supporting documentation Mallinckrodt produces related to the released flagged orders. In the Twelfth Reporting Period, the Monitor Team reviewed SORs for October, November, and December 2024 and for January and February 2025.

a. The flagged direct customer order reports for the fourth quarter of 2024 and the first quarter of 2025

11.25 As the Monitor has previously reported, the CSC Specialist, or her designee (who must be another member of the CSC Team), conducts the first-level review of all direct customer orders the Algorithm flags. The first-level reviewer determines whether to release each order

[16] The CSC Specialist and a CSC Manager have typically performed the first and second-level review of flagged orders, respectively. At times, other members of the CSC Team may assist with the review process due to vacation, illness, and capacity. During the fourth quarter of 2024 and the first quarter of 2025, the Senior CSC Manager and CSC Manager C largely conducted the flagged order reviews.

after consulting the direct customer dashboard and reviewing the customer's order history and other relevant documentation. *See infra* at 44 ¶ 11.32 – 45 ¶ 11.33. If necessary, the first-level reviewer will confer with the Customer Service Department regarding any changes in the customer's contracts or product needs and contact the customer for additional information. A flagged order is only released after review and approval by both (1) the first-level reviewer and (2) either a CSC Manager, the Director of CSC Analytics, or the CSC Director.[17]

11.26 While almost all of the flagged direct customer orders are released after the two-level review process, that review process is still a necessary part of Mallinckrodt's efforts to prevent diversion.

11.27 In the fourth quarter of 2024, two CSC Team members released all of the flagged direct customer orders.

11.28 In the first quarter of 2025, two CSC Team members released all but three flagged direct customer orders. Two of the three orders were for addiction treatment products, and the customers cancelled their orders. However, regarding the third order, Distributor O[18] placed an order for Opioid Products after its suspension in January. *See infra* at 54 ¶ 11.58. The Algorithm appropriately flagged Distributor O's order, and Mallinckrodt cancelled the order before shipment.

[17] The *SOM Program Review of Direct Customer Orders* SOP was recently revised to require that the second-level review be conducted by ***the CSC Senior Manager*** (instead of one of the two CSC Managers), the Director of CSC Analytics, or the CSC Director. *See SOM Program Review of Direct Customer Orders* § 6.10.6.

[18] For Distributors A through N, the references in the Twelfth Monitor Report correspond to the anonymized references in the Tenth and Eleventh Monitor Reports.

b. Orders flagged by the OI Hold system during the fourth quarter of 2024 and the first quarter of 2025

11.29 Mallinckrodt's OI Hold system places an automatic hold on an order if the customer placing the controlled substance sales order: (1) is not a DEA registrant; (2) is in an industry segment (*e.g.*, retail pharmacy) not authorized to purchase an Opioid Product under the Operating Injunction (*see* OI § III.G.4); or (3) is only authorized to place orders for addiction-treatment Opioids but places an order for a non-addiction treatment Opioid.

11.30 In the fourth quarter of 2024, the OI-Hold System flagged a county jail customer's order for addiction treatment opioids. Mallinckrodt confirmed that the customer could purchase such products, but its account was not set up correctly in Mallinckrodt's system, resulting in the flagged order. After Mallinckrodt's Data Integrity Department corrected the customer's account information, the order was appropriately released.

11.31 Mallinckrodt confirmed there were no orders flagged for potential violations of the Operating Injunction in the first quarter of 2025.

c. The SORs for select weeks in October, November, and December 2024 and in January and February 2025

11.32 As noted above, the Monitor Team also reviews the SOR for a randomly selected week each month to confirm all flagged orders for Opioid Products are only released after two CSC Team members review them and conclude the orders are not potentially suspicious per the relevant SOP. The Monitor Team also reviews the supporting documentation for the flagged orders that are released where the reviewer indicates in the SOR such documentation exists.[19]

11.33 With certain exceptions identified below, the SORs for selected weeks in the Twelfth Reporting Period show two members of the CSC Team released each order after

[19] In order to determine whether an order is not potentially suspicious, the first-level reviewer may review documents related to the customer's ordering history and practices and

determining the customer's aggregate monthly orders did not represent an unusual: (1) quantity compared to orders by similar customers within the same industry segment; (2) share compared to orders by similar customers within the same industry segment; (3) volume compared to orders by similar customers within the same industry segment; or (4) quantity for the customer, and the number / frequency of the customer's orders was not unusual compared to those placed by similar customers within the same industry segment.

11.34 During the Twelfth Reporting Period, the Monitor Team observed limited additional bases for the CSC Team's release of flagged orders, all of which arose from errors that occurred in either the placement or processing of the direct customers' orders. However, to avoid a scenario where a direct customer cancels a flagged order to evade scrutiny by the CSC Team: (1) the Algorithm screens every order, even if the order is placed or processed in error; (2) all flagged orders are reported to DEA on a SOR and subject to the CSC Team's standard review process; and (3) two members of the CSC Team must review each flagged order and determine whether it can be "released."[20] The Monitor is satisfied that in each instance when an order was cancelled, the reviewers determined that the order was appropriately cancelled and not suspicious.

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relevant market dynamics. Indeed, the CSC Specialist (who has typically performed the first-level review for flagged orders) has informed the Monitor Team that, as a matter of course, she maintains documentation provided by the Commercial Department concerning customers' contract awards, issues with customers' primary suppliers, product shortages, and other information that may bear on whether an order flagged by the direct customer dashboard as potentially suspicious can be released. At times, the reviewer will require additional information from the Commercial Department or the direct customer to release an order. When the reviewer already possesses, or compiles as part of its review, supporting documentation that is specific to the released flagged order, the reviewer indicates this in the SOR by marking "Yes" in the "Supporting Documentation" column.

[20] Such orders were not actually "released," because as described here, they were cancelled.

11.35 In addition to the Monitor Team's review detailed above, the Monitor Team interviewed the CSC Senior Manager and CSC Manager C regarding certain SORs and accompanying documentation produced during the Twelfth Reporting Period.

11.36 Based on the Monitor Team's review and interview, regarding the released flagged orders for which the SOR indicated "Supporting Documentation" existed, it appears the CSC Team members properly obtained and maintained backup documentation before releasing those orders.

11.37 However, as previously noted, the SORs do not contain the data available to the CSC Team on the direct customer dashboard, including the values of certain metrics the reviewers analyze when determining if a flagged order should be released, because they largely contain only the information Mallinckrodt is required to provide to the DEA for potentially suspicious orders, in the format DEA requires. *See* Eleventh Monitor Report at 33-34 ¶ 11.24; Tenth Monitor Report at 46 ¶ 12.49 – 47 ¶ 12.53. As a result, the Monitor requested that Mallinckrodt consider whether additional documentation could be provided to the Monitor Team to better reflect the information the CSC Team reviews, and relies on, when deciding to release a particular order. *See* Eleventh Monitor Report at 61 ¶ 11.92 – 66 ¶ 11.104. The CSC Director agreed to do so and, subsequently, Mallinckrodt informed the Monitor Team that request is a subject of the ongoing Working Group, which has not yet provided an update on this issue. The Monitor will continue to discuss this request with the CSC Team and Mallinckrodt's outside counsel (who has relayed the Working Group's observations to the Monitor Team) and provide an update in the next report.

d. Direct customer questionnaires

11.38 As the Monitor previously reported, and as noted *infra* at 89 ¶ 11.131, Mallinckrodt requires direct customers to complete various questionnaires, which include questions about the customers' SOM programs. *See* Seventh Monitor Report at 22 ¶ 11.15.

i. The Monitor Team's review of direct customer questionnaires

11.39 Under the Audit Plan, Mallinckrodt produces a sampling of direct customer questionnaires for the Monitor Team's review each year. During the Twelfth Reporting Period, the Monitor Team reviewed 2024 questionnaires for five existing direct customers, including three distributor customers and two narcotic treatment program customers. Those customers provided answers to all of the "yes" or "no" questions and filled in the information the questionnaires request. With one exception discussed below, all of the customers also "attached" other information sought by the questionnaires.

11.40 ***Distributor O's questionnaire and subsequent restriction.*** As the Monitor previously reported, when the Monitor Team reviewed a sampling of direct customer questionnaires ***for 2023***, the Monitor Team observed that none of the direct customers provided Mallinckrodt with "a brief written description" of their SOM program, which the questionnaire directed each customer to attach. *See* Eleventh Monitor Report at 48 ¶ 11.62. The Monitor therefore recommended that Mallinckrodt "require every distributor customer to provide a brief written description of its SOM program with its completed questionnaire, consistent with the questionnaire's request." *See* Recommendation 10(b). Mallinckrodt has since implemented that recommendation.

11.41 In reviewing the direct customer questionnaires ***for 2024***, the Monitor Team observed that one distributor customer, Distributor O, provided a one-line, high-level summary

of its SOM program below the prompt ("We utilize a 3rd party, algorithm based, automated som system"), but did not include a more detailed description with its questionnaire response.

11.42 During an interview with the CSC Director and other members of the SOMT, the Monitor Team asked whether the CSC Team sought additional information from Distributor O regarding its SOM program after reviewing the questionnaire in September.[21] The CSC Director indicated the CSC Team did not do so because Distributor O was already scheduled for a due diligence visit later that year, which took place in December. Following that visit, the SOMT suspended Distributor O after learning Distributor O did not incorporate ARCOS data in its SOM program to the extent Mallinckrodt expects. The CSC Team's due diligence visit to Distributor O and its resulting suspension are discussed *infra* at 53 ¶ 11.55 – 55 ¶ 11.60.

11.43 While in this instance the CSC Team appropriately determined it had sufficient information regarding Distributor O's SOM program to consider the questionnaire complete, the Monitor reiterates the spirit of Prior Recommendation 10(b): in reviewing direct customer questionnaires, the CSC Team should determine whether the customer has fully and appropriately responded to the questionnaire at the time of review, and promptly request additional information from the customer as necessary, regardless what other information the CSC Team may already have about that customer or whether the direct customer is already scheduled for a due diligence visit. And it is particularly important that Mallinckrodt do so when a customer provides less than fulsome responses to the requests that go to the heart of the CSC Team's ability to assess the adequacy of the customer's SOM program, like the customer's description of its SOM program.

[21] Distributor O's questionnaire was provided to Mallinckrodt in September 2024, after the Monitor's recommendation in the Tenth Monitor Report.

11.44 On that point, it appears the CSC Team shared the Monitor's concern about the fulsomeness of certain direct customers' questionnaire responses, as they proactively updated two of the questionnaires to seek additional information regarding the specifics of a customer's SOM program. Specifically, in the updated versions of the Distributor SOM Questionnaire and the Manufacturer SOM Questionnaire, which were provided to the Monitor Team in the Twelfth Reporting Period, Mallinckrodt expanded on its request that the customer attach "a brief written description" of its SOM program. Now, below the question "Does the company or facility have a documented suspicious order monitoring ("SOM") program that complies with 21 CFR 1301.74(b)," those Questionnaires state:

> If "Yes, please attach a written description of the company or facility's SOM program that includes information sufficient to understand and confirm that the company or facility has effective controls to prevent, detect, and investigate the diversion of controlled substances, including a description of the company or facility's:
>
> - Efforts to comply with the Controlled Substances Act and related DEA regulations;
> - Security controls to prevent theft and diversion of controlled substances;
> - Record-keeping practices related to controlled substances;
> - Procedure for reporting thefts, significant loss, and suspicious orders of controlled substances to the DEA;
> - Process for restricting its customers for failure to prevent diversion of controlled substances;
> - Direct order review of the volume, pattern, and frequency of controlled substances purchases by its customers;
> - Customer due diligence process, including information and documentation it obtains from new customers upon onboarding;
> - Process for reviewing existing customers and the frequency of such reviews, including whether the company or facility uses a customer questionnaire to evaluate the controlled substances compliance and SOM programs of its customers.

11.45 This revision provides greater direction to distributors and manufacturers regarding the description of their SOM programs that must be attached, and establishes objective criteria for the CSC Team to analyze the sufficiency of the customers' responses.

ii. Updates to the direct customer questionnaires

11.46 Towards the end of the Twelfth Reporting Period, Mallinckrodt provided the Monitor Team with revised questionnaires for each type of direct customer, *i.e.*, distributor, analytical lab / researcher, manufacturer, narcotic treatment program, and pharmacy. As discussed below, the questionnaires were updated to, among other things, incorporate: (1) the Monitor's Prior Recommendation 11(a); and (2) additional questions regarding ARCOS data, which members of the SOMT determined were prudent after the SOMT suspended six distributors for failing to incorporate ARCOS data into their SOM programs to the extent Mallinckrodt expects.

11.47 ***Prior Recommendation 11(a).*** In the Eleventh Reporting Period, based on the Monitor Team's review of publicly available information related to the U.S. Department of Justice's prosecution of a pharmacy distributor executive who owned the former-Mallinckrodt distributor customer referred to as "EB" in the government's indictment, the Monitor recommended Mallinckrodt "revise every customer questionnaire to ask whether any supplier has previously (1) requested the customer undertake SOM-compliance reforms or (2) suspended sales to the customer, and request further information from the customer as appropriate." *See* Prior Recommendation 11(a); Eleventh Monitor Report at 46 ¶ 11.59 – 47 ¶ 11.60.

11.48 Mallinckrodt implemented Prior Recommendation 11(a), and the Distributor, Analytical Lab / Researcher, and Narcotic Treatment Program SOM Questionnaires were each updated to ask the customer:

Has any supplier previously:

a. Suspended or restricted controlled substance sales to the company or facility? ☐ YES ☐ NO

b. Requested the company or facility undertake any reforms of its controlled substances compliance or SOM program? ☐ YES ☐ NO

If "Yes" to either question, please attach a description of the suspension, restriction, or requested reforms and the whether the reforms have been completed.

11.49 ***The questionnaires now include more questions about use of ARCOS data.***

Also during the Eleventh Reporting Period, the CSC Director informed the Monitor Team that Mallinckrodt was considering revising the distributor questionnaire to seek additional information on distributors' utilization of ARCOS data. Mallinckrodt considered such a revision after the SOMT suspended six distributors upon finding they failed to adequately incorporate ARCOS data into their SOM programs, despite many (if not all) of them responding to Mallinckrodt's questionnaire by answering "Yes" to the question: "Does your company utilize the DEA Online ARCOS Tool to monitor customer purchases from all suppliers?" *See* Eleventh Monitor Report at 55 ¶ 11.78 – 59 ¶ 11.87.

11.50 As reflected in the updated Distributor SOM Questionnaire, Mallinckrodt no longer asks whether a distributor simply utilizes ARCOS data, but rather inquires more specifically about the way in which the distributor uses and evaluates ARCOS data. The revised Questionnaire states as follows:

32. Does the company or facility download and utilize the ARCOS data file made available via the DEA ARCOS-Online website as part of its SOM program?	☐ YES ☐ NO
If "Yes," does the company or facility utilize the ARCOS data download to evaluate: • the ratio of high strength formulations of controlled substances as compared to lower strengths purchased by its direct customers? ☐ YES ☐ NO • its direct customer's dispensing data as compared to local, regional, or national, averages (where applicable)? ☐ YES ☐ NO • any geographic dispensing anomalies of its direct customer's controlled substances purchases? ☐ YES ☐ NO Does the company or facility utilize the DEA ARCOS-Online: Retail Buyers Statistics Lookup tool to monitor direct customer purchases from all suppliers? ☐ YES ☐ NO	

* * *

11.51 The Monitor Team will analyze the additional changes to the direct customer questionnaires, and discuss those changes with Mallinckrodt, as appropriate, in the next reporting period.

e. Direct customer due diligence visits

11.52 As the Monitor previously reported, until Mallinckrodt's *SOM Review of Direct Customer Orders* SOP was updated in April 2025, *see infra* at 90 ¶ 11.143 – 91 ¶ 11.144, the CSC Team was required to conduct annual due diligence visits (either in-person or virtually) with one of the "Big Three" distributors and six other direct customers. *See* Sixth Monitor Report at 38 ¶ 11.23. During the Twelfth Reporting Period, the Monitor Team reviewed: (1) the CSC Team's reports for three due diligence visits in 2024; (2) a list of seven distributors the CSC Team intends to visit in 2025; and (3) the CSC Director's report for the due diligence visit with Distributor D in 2025.

iii. The CSC Team's due diligence visits in 2024

11.53 In the Eleventh Reporting Period, the Monitor Team reviewed the reports the CSC Team prepared for three direct customer due diligence visits conducted in 2024: Distributor O, Distributor P, and Distributor Q.

11.54 All three of the reports reflect that, among other things, the CSC Team representatives attending each visit reviewed the distributors' SOM procedures, including but not limited to whether those distributors: (1) had various written policies regarding onsite due diligence visits to customers; (2) evaluated relevant metrics related to their customers (*i.e.*, the ratio of controlled substance to non-controlled substances dispensed by the customer); and (3) monitored customers' purchases for common "red flags" (*e.g.*, ordering excessive quantities of a limited variety of controlled substances while ordering few, if any, other controlled or non-controlled substances). The CSC Team's findings in connection with the visits to Distributor O and Distributor P are discussed further below (there were not any noteworthy findings in connection with the CSC Team's visit to Distributor Q).

11.55 ***The CSC Team's Visit to Distributor O.*** The SOMT suspended Distributor O following the CSC Team's due diligence visit in December 2024. As discussed *infra* at 98 ¶ 11.165 – 100 ¶ 11.172, Distributor O is one of the distributors that purchases Opioid Products but does not submit chargeback requests. As a result, Mallinckrodt had a "blind spot" for sales of its products to Distributor O's customers, *i.e.*, Mallinckrodt's indirect customers, which the CSC Team representatives raised with Distributor O, among other issues, during that visit.

11.56 As reflected by the CSC Team's report, the CSC Team representatives explained the significance of chargeback data to Distributor O, and inquired whether Distributor O would be willing to provide chargeback data or provide equivalent information regarding its sales of Mallinckrodt products. While Distributor O was amenable to providing that information, the

lack of chargeback data became less relevant in light of Distributor O's failure to incorporate ARCOS data into its SOM program to the extent Mallinckrodt expects, which resulted in its restriction.

11.57 During the visit, Distributor O informed the CSC Team representatives that it was using the ARCOS "lookup tool" but not downloading, and analyzing, such data. The Director of CSC Analytics informed Distributor O that Mallinckrodt had suspended other distributors for failing to do so, and Distributor O agreed to incorporate ARCOS data into its SOM program—but did not do so.

11.58 Indeed, the following month (in January 2025), the CSC Team sent Distributor O a due diligence request concerning one of its pharmacy customers and asked Distributor O to identify why it had not flagged that customer because its purchases of hydrocodone 10 mg constituted 100% of its hydrocodone purchases—a significant red flag. After Distributor O's response to the CSC Team's request made clear Distributor O was still not incorporating ARCOS data into its SOM program to the extent Mallinckrodt expects, the SOMT decided to suspend sales.

11.59 Like some, if not all, of the six distributors the SOMT suspended in the Eleventh Reporting Period for the same reason, Distributor O's direct customer questionnaire (submitted less than three months before the due diligence visit) answered "Yes" to the question: "Does your company utilize the DEA Online ARCOS Tool to monitor customer purchases from all suppliers?" As discussed *supra* at 51-52 ¶ 11.50, Mallinckrodt has now revised the distributor and manufacturer questionnaires, and now no longer asks whether those customers simply utilize ARCOS data, but rather inquires about the customers' use and evaluation of specific ARCOS data. The Monitor anticipates the revised questionnaire will help avoid repetition of what has

now become a common scenario, by enabling the CSC Team to identify a clear deficiency in a distributor's (or manufacturer's) SOM program through its annual questionnaire, without having to expend valuable resources conducting a due diligence visit.

11.60 That said, Mallinckrodt's experience with Distributor O helps to illustrates the basis for the Monitor's recommendation 12(e), which is that the CSC Team conduct annual due diligence visits with distributors that do not submit chargeback requests for any products, given Mallinckrodt's lack of visibility into those distributors' sales. *See infra* at 98 ¶ 11.165 – 100 ¶ 11.172. While the CSC Team could not have necessarily discerned the ARCOS-related deficiency in Distributor O's SOM program without a due diligence visit, distributors like Distributor O pose a unique challenge to the CSC Team's ability to monitor its direct customers, and extra attention to the sufficiency of these smaller distributors' efforts to prevent diversion is warranted.

11.61 ***The CSC Team's Visit to Distributor P.*** The CSC Team representatives who conducted Distributor P's due diligence visit did not specifically identify any concerns regarding the sufficiency of its SOM program. However, the Monitor Team conveyed a request to the CSC Team regarding Distributor P's use of ARCOS Data.

11.62 Specifically, Distributor P informed the CSC Team representatives that, while its SOM program incorporated ARCOS data, Distributor P did not realize that ARCOS data could be downloaded. Distributor P indicated that it would "immediately start trying to figure out a way to leverage that data" to "fill in gaps, validate metrics, and use for comparison reviews." Distributor P informed the CSC Team representatives that it had already "started development to incorporate the ARCOS data file into" its SOM process and expected that work to be finished by the end of October 2024. Thus, the Monitor requested that the CSC Team inquire about the

status of Distributor P's incorporation of the ARCOS download, and the CSC Team agreed to do so. The Monitor will provide an update on this request in the next reporting period.

iv. The CSC Team's due diligence visits in 2025

11.63 In the Twelfth Reporting Period, the CSC Team provided a list of the seven direct customers it intends to visit in 2025.[22] The CSC Team informed the Monitor that one of those customers, Grocery Chain A,[23] was selected because Mallinckrodt does not receive chargeback data from that customer, although Grocery Chain A has expressed an encouraging openness to sharing downstream transaction data akin to chargeback data, provided it is technologically feasible to do so.[24]

11.64 Mallinckrodt conducted two of those seven visits in the Twelfth Reporting Period, and the Monitor Team reviewed the resulting report for "Big Three" Distributor D. The Monitor Team has not yet received the report from the second visit but will review that report in the next reporting period.

11.65 ***The CSC Director's due diligence visit to Distributor D***. The CSC Director's report for his due diligence visit to Distributor D reflects that he reviewed various aspects of Distributor D's SOM process and did not identify any concerns regarding its sufficiency. Additionally, the CSC Director gave a presentation to Distributor D's compliance team

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[22] Since Mallinckrodt only recently revised the *SOM Review of Direct Customer Orders* SOP to require the CSC Team (or a third-party selected by the CSC Team) to conduct due diligence visits for no fewer than ten direct customers per year, the Monitor and the CSC Team have not yet discussed whether the CSC Team intends to visit additional distributors this year and, if so, which distributors. *See infra* at 90 ¶ 11.143 – 91 ¶ 11.144.

[23] Grocery Chain A purchases products from Mallinckrodt, which are shipped to Grocery Chain A's warehouses. Grocery Chain A then distributes those products to its retail locations.

[24] As discussed in greater detail *infra*, Mallinckrodt is engaged in continued discussions with Grocery Chain A regarding obtaining that data. *See infra* at 101-02 ¶ 11.175.

leadership regarding Mallinckrodt's compliance program, after which they discussed "issues of mutual concern."

11.66 Distributor D noted Mallinckrodt's inquiries about pharmacies under review account for the vast majority of Distributor D's investigation of its customers. To that end, Distributor D asked the CSC Director why Mallinckrodt's CSC Team does not make such inquiries with the pharmacies directly. As the Monitor Team and the CSC Director have previously discussed, and as the CSC Director informed Distributor D in response, the CSC Team takes the position that, because Mallinckrodt does not have a contractual relationship with the pharmacies under review, such inquiries are typically best directed to the pharmacies' distributors, rather than the pharmacies themselves. As the CSC Director has explained to the Monitor Team, due diligence requests are best directed to distributors because: (1) the distributors, like Mallinckrodt, have an obligation to monitor their customers and are therefore a more reliable and credible source of information than the pharmacies under review that do not want to be restricted; and (2) the distributors receive additional information from their customers, like dispensing data, that is available to them but not to Mallinckrodt. However, on limited occasions when the CSC Team determined it was appropriate to do so, the CSC Team has contacted pharmacies and requested due diligence information.

11.67 The Monitor understands the basis for Mallinckrodt's position on this issue, and that its SOM resources are not infinite and must be deployed in the most efficient way possible. The Monitor anticipates the CSC Team will continue to direct inquiries to the pharmacies under review directly, when appropriate.

f. Tracking distributors that the CSC Team believes warrant further monitoring

11.68 In the Eleventh Monitor Report, the Monitor discussed Distributor G, which was suspended after the CSC Team obtained information from several disparate sources that raised concerns about Distributor G's SOM program. One such source was Distributor G's response to the CSC Team's request for additional information about a flagged order. While Distributor G's order was released by the CSC Team after review, based on Distributor G's response to the CSC Team's due diligence request, the Senior CSC Manager recommended close monitoring of Distributor G. Around that time, other members of the CSC Team became concerned about the adequacy of Distributor G's SOM program based on: (1) Distributor G's unsatisfactory answers to the customer questionnaire; and (2) its responses to the CSC Team's requests for due diligence about Distributor G's pharmacy customers that were under review. Although the SOMT ultimately suspended Distributor G, it was not clear to the Monitor Team to what extent (and when) different information was shared between the members of the CSC Team who reviewed Distributor G's flagged orders and the members who reviewed Distributor G's questionnaire and conducted reviews of Distributor G's pharmacy customers. Although the various CSC Team members who reviewed these different sources of information are all members of the SOMT and are present for the SOMT meetings and review of SOMT materials, and customarily share information regarding direct and indirect customers, neither the CSC Senior Manager nor the CSC Director could specifically recall having a conversation about Distributor G before Distributor G's responses to certain due diligence requests in August 2024 prompted Mallinckrodt's visit with Distributor G.

11.69 As a result, the Monitor Team discussed with Mallinckrodt: (1) whether the CSC Team can track distributors that CSC Team members believe warrant further monitoring in a

way that is evident to the entire Team; and (2) whether there is a way to improve the evaluation of direct customer flagged orders with more contemporaneous reference to the indirect customer dashboard, or to the SOMT's "Tracking Spreadsheet" of restrictions in order to assess whether a direct customer's flagged orders should receive heightened scrutiny in light of the pattern of downstream pharmacy customer restrictions associated with that distributor.

11.70 In the Twelfth Reporting Period, Mallinckrodt's outside counsel informed the Monitor Team that the Working Group, discussed *infra* at 88 ¶ 11.136 – 107 ¶ 11.190, is exploring potential changes to the direct and indirect customer dashboards. The Working Group expects those changes to include indicators of some kind to track information like the intelligence referenced above that is not evident from the information currently contained in the dashboards. The Monitor will provide an update on any changes to the dashboards in the Thirteenth Monitor Report.

g. The SOMT's review of distributors based on its analysis of restrictions of the distributors' customers

11.71 As discussed in the Eleventh Monitor Report, the SOMT suspended six distributors after identifying deficiencies in their SOM programs based on the SOMT's restriction of those distributors' customers. *See* Eleventh Monitor Report at 54 ¶ 11.76 – 59 ¶ 11.87. Specifically, members of the CSC Team looked at the distributors for which a high percentage of customers were restricted and then reviewed the basis for its restrictions of those customers to discern any patterns. In each case, the distributors' customers were restricted based on analysis of ARCOS data. As a result, the SOMT was able to quickly conclude that the distributors failed to incorporate or analyze ARCOS data to the extent Mallinckrodt expects and suspended them.

11.72 The Monitor and the CSC Director agreed it would be beneficial for Mallinckrodt to periodically repeat this analysis in the future, as it is yet another important tool the CSC Team can use to detect potential diversion. Examining distributors' SOM programs from different angles that incorporate additional data points can reveal deficiencies in the distributors' SOM programs that may not have been detectable from other sources of information—as no single source of information can offer a complete picture of a distributor's SOM program. Indeed, in this case, the ARCOS deficiency in the distributors' SOM programs was not apparent from the distributors' questionnaire responses, but rather from information the SOMT obtained through its own due diligence.

11.73 During the Twelfth Reporting Period, the Monitor Team asked the CSC Director whether he had determined how frequently that analysis would be conducted. The CSC Director re-iterated that he expects the CSC Team to conduct this analysis at regular intervals but has not yet determined how frequently. He also informed the Monitor Team that Mallinckrodt is currently determining whether aspects the analysis can be automated. In the next reporting period, the Monitor Team will provide an update on how frequently the CSC Team will conduct this analysis and whether the analysis can be conducted more efficiently using technology.

4. Indirect Customer Due Diligence

11.74 As the Monitor has previously reported, *see* Eleventh Monitor Report at 51 ¶ 11.71; Tenth Monitor Report at 58 ¶ 12.85 – 59 ¶ 12.88, Mallinckrodt monitors its downstream customers using: (1) the indirect dashboard, which analyzes purchase data for changes in volume, growth, and per capita usage, and "flags" customers with potentially suspicious ordering patterns for the SOMT members' review; and (2) the ARCOS dashboard, which allows members

of the SOMT to locate, and then review, downstream registrants with statistically anomalous ordering patterns based on all reportable ARCOS purchases.

11.75 Under the Audit Plan, in the Twelfth Reporting Period Mallinckrodt provided the Monitor Team with a summary of all changes to the indirect dashboard in 2024. As set forth in that summary, Mallinckrodt made two updates to the indirect customer dashboard:

(1) added colorization to indicate whether a pharmacy was restricted, under review, or had been reviewed but not restricted; and

(2) fixed an IT-related issue with the zip codes used to calculate the per capita flag.[25]

The Monitor Team anticipates that the colorization enhancement will allow the SOMT members to even more easily prioritize reviewing the indirect customers "flagged" for review.

11.76 Mallinckrodt also informed the Monitor Team that the ARCOS dashboard now includes a "Long Term Growth" metric so that the ARCOS dashboard can measure both short-term and long-term growth (one year versus two years). Mallinckrodt was able to add this additional metric as a result of downloading and storing monthly ARCOS reports over time.

11.77 The Monitor Team encourages Mallinckrodt to continue enhancing the dashboards as Mallinckrodt has done throughout the monitorship to further streamline review of flagged indirect customers and to incorporate additional information as it becomes available.

5. <u>SOMT Meeting Minutes and Materials</u>

11.78 In the Twelfth Reporting Period, the Monitor Team reviewed SOMT meeting minutes and materials for October, November, and December 2024, and for January and February 2025. The results of that review, the Monitor's related findings from interviews with

[25] The CSC Team indicated that the issue with the zip codes in DEA registration file not syncing with the zip codes in the U.S. census file was quickly identified and resolved.

the SOMT's members (including the CSC Director, the Director of CSC Analytics, and CSC Managers B and C), and any resulting recommendations, are discussed below.

11.79 As discussed in further detail below, the Monitor Team and Mallinckrodt's outside counsel had detailed discussions about the Monitor Team's impressions from review of the SOMT meeting minutes. Specifically, the Monitor Team's initial impression from reviewing those minutes was that: (1) the minutes reflected insufficient analysis to support the minutes' "No Action Recommendations"[26] the CSC Director had approved; and (2) the minutes required more careful review to avoid error, and to ensure they create an accurate record of the SOMT's decisions and reasoning for future reference. In further discussion with Mallinckrodt and its outside counsel, and based upon additional documentation and information shared with the Monitor Team, it became clear that the deficiencies the Monitor Team observed in the minutes were a product of incomplete ***documentation***, not deficient ***analysis***. Specifically, Mallinckrodt provided additional "Review Sheets,"[27] which the Monitor Team had an opportunity to review.

[26] A "No Action Recommendation" refers to a SOMT member's recommendation that "no action" is necessary regarding a pharmacy under review because the information obtained explains the indirect customer dashboard's "flag" for that pharmacy, assuring the reviewer that there is no risk of diversion. The then-operative version of the *SOM Program Media & Chargeback Reviews of Direct Customers and Downstream Registrant* SOP required the Director of CSC Analytics to review and investigate flagged indirect customers and present his findings to the SOMT for a final decision as to whether to restrict the indirect customer. § 6.4.1. However, the SOP also permitted the Director of CSC Analytics to make a "no action necessary recommendation" regarding an indirect customer under review. *Id.* § 6.4.2. The SOP required the CSC Director to approve all No Action Recommendations. *Id.* Further, any No Action Recommendations approved by the CSC Director were also reviewed by the SOMT, which has typically concurred with the CSC Director's approval. That SOP has been recently revised (as discussed *infra* at 79-80 ¶ 11.122), to permit other members of the SOMT to make such recommendations.

[27] As discussed in prior reports, when a pharmacy is under review, the SOMT member conducting the review creates a Review Sheet documenting his or her findings, which is circulated (or otherwise made available) to the entire SOMT for its review before the meeting at

Based upon that review, the Monitor revised his initial recommendations to address issues of poor documentation, rather than deficient analysis.[28]

11.80 Accordingly, the Monitor's revised recommendation from review of the SOMT meeting minutes and materials is as follows: the minutes should better reflect the SOMT's analysis by providing greater support and context for the decisions of both the CSC Director and the SOMT, and be reviewed to eliminate errors, in order to ensure the minutes create an accurate record of the bases for those decisions for future reference.

11.81 Additionally, the Monitor recommends that, to avoid potential failures to report suspicious pharmacies to the DEA (as Mallinckrodt's policies require), Mallinckrodt should adopt internal deadlines to define the time for reporting suspended direct and restricted indirect customers to the DEA.

11.82 Finally, for the reasons discussed below, outdated references to the former "LCSCC" (now, the Director of CSC Analytics) led the Monitor Team to discuss with Mallinckrodt's outside counsel the need for a Management of Change ("MOC") policy. The Monitor Team subsequently shared its existing MOC policy with the Monitor Team and

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which the pharmacy will be discussed. *See, e.g.*, Eleventh Monitor Report at 55 ¶ 11.78; Fifth Monitor Report at 30-31 ¶ 11.23.

[28] Mallinckrodt's CSC Director confirmed that the Review Sheets preexisted the SOMT meetings, and were made accessible to members of the SOMT for review in advance of those meetings—*i.e.*, that the Review Sheets were not a post-hoc creation of the SOMT in reaction to the Monitor Team's observations. Indeed, upon review of the supplemental materials, the Monitor Team is persuaded by the dates of the documents that the materials preexisted the SOMT meetings. In one instance, there was an update (in January 2025) to reflect enhanced analysis to a Review Sheet that had initially been drafted in October 2024. The enhancement was made to reflect additional support for the decision the SOMT had already made, and also to train the SOMT on the need for greater detail in these summaries, consistent with feedback from the Monitor Team.

confirmed that, notwithstanding these dated references to the former title of the Director of CSC Analytics, Mallinckrodt is complying with that MOC policy.

a. SOMT meeting minutes and Review Sheets should better document the analysis and material bases for recommendations and decisions, and eliminate errors to create an accurate record for future reference

i. The "Comments / Analysis" section of the Review Sheets (which are copied into the meeting minutes) do not sufficiently document the analysis or material bases for recommendations and decisions

11.83 Review of the October and November 2024 SOMT meeting minutes revealed a need for a number of enhancements to the summaries supporting the SOMT's "No Action Recommendations" for pharmacies under review, as well as the Review Sheets from which portions of the minutes' summaries are drawn. This is important for at least two reasons: (1) a relatively large number of pharmacies reviewed resulted in No Action Recommendations in those months (32 in October 2024; 47 in November 2024), and each recommendation was approved by the CSC Director, with the SOMT concurring; and (2) naturally, a decision by the SOMT to take no action on direct or indirect customers under review necessarily means that Mallinckrodt (and others) will continue to supply those customers with controlled substances. Consequently, the need for accuracy and support for these decisions is critical.

11.84 As explained below, the Monitor Team's initial impressions from the minutes were based upon the fact that the Review Sheets provided to the SOMT in support of "No Action Recommendations" had not been shared with the Monitor Team. Mallinckrodt subsequently shared those Review Sheets with the Monitor Team, but some still failed to demonstrate that more rigorous analysis had been conducted, or was available to the deliberating SOMT. Consequently, review of the Review Sheets emphasized, once more, the need for clearly

documented and well-reasoned records—*i.e.*, both minutes ***and*** Review Sheets. The issues the Monitor Team observed in the minutes are discussed in greater detail immediately below.

11.85 ***First,*** based on the minutes as drafted, the Monitor Team observed many instances of what appeared to be reviewers clearing pharmacies with No Action Recommendations when the comparison of the subject pharmacy's ARCOS data to that of comparable pharmacies seemed to suggest a restriction may have been warranted. In other words, the pharmacy comparisons, as reflected in the minutes, should ***not*** have dispelled the SOMT's suspicion regarding the pharmacies at issue, but nonetheless resulted in No Action Recommendations.

11.86 One typical example, from the November 2024 SOMT minutes, was the review of a pharmacy, Pharmacy A, based upon the growth of Pharmacy A's morphine purchases. The review provides the following analysis:

> ARCOS 6-month data noted Morphine purchases of ***16,300 d/u***. [Pharmacy A] was compared to two other pharmacies in its zip code/competition zone, and it was noted that those two chain pharmacies[’] . . . purchases for Morphine [were] ***8,100 d/u*** and ***4,500 d/u***, respectively. [Pharmacy A] showed an ***ARCOS growth rate of 26%*** for Morphine in a one-year time-period from 12,900 d/u to 16,300 d/u, a 3,400 d/u increase. ***Based on this review, MCSC is recommending no further action with CS Director concurring.***

November 2024 SOMT Minutes (emphasis added). At first blush, this is a troubling comparison. The analysis suggests the pharmacy under review ordered substantially ***more*** morphine than the two pharmacies the reviewer selected as comparators—in one instance, more than twice the dosage units ordered; in another instance, more than three times the dosage units ordered. Furthermore, the reviewer noted that the ARCOS growth rate for the subject pharmacy had increased substantially over a one-year period—*i.e.*, by as much as 26%. Of course, without the

benefit of the accompanying Review Sheets Mallinckrodt subsequently produced for the Monitor Team's review discussed below, none of these facts are reassuring. If anything—without more—they deepen, rather than lessen the concern for potential diversion. Without more information or analysis, the conclusion certainly seemed at least unsupported by—and, indeed, even contradicted by—the reviewer's summary.

11.87 However, as reflected in the accompanying Review Sheet—which had not been provided to the Monitor Team at the time of its review—the pharmacy in question was larger than its comparable pharmacies across multiple different categories, and not only regarding morphine. As the Review Sheet makes clear, "[t]he comparison chains were 55% and 62% smaller ***overall for all ARCOS reportable drug items***." (emphasis added) Thus, the initially surprising conclusion in the minutes seems attributable to a defect in documentation rather than in analysis.

11.88 The November 2024 minutes are not an isolated instance of this issue. Similar examples exist in subsequent SOMT meeting minutes for the months of December 2024 and January 2025. The "Comments/Analysis" section of some of the corresponding Review Sheets, which are copied into the meeting minutes, were not much of an improvement over the minutes because they contained no additional analysis (although there is more extensive analysis and data in other sections of the Review Sheets that are not always summarized in the "Comments/Analysis" section). Nonetheless, Mallinckrodt's CSC Director has confirmed the Review Sheets were made available to the SOMT, and that he (or the Director of CSC Analytics) personally reviewed them, prior to making a decision on the No Action Recommendations, even if the basis for the decision was not clearly noted in the "Comments/Analysis" section of the

Review Sheets. The Monitor accepts this representation, while expecting to see more robust contemporaneous documentation in the next reporting period.

11.89 ***Second,*** certain decisions to clear pharmacies flagged for "growth" appeared, similarly, to have been poorly reasoned—*i.e.*, based solely upon the pharmacies' increased purchases of Mallinckrodt product. Specifically, the Monitor Team observed several instances where the indirect dashboard flagged a pharmacy for growth in its purchases of a particular Mallinckrodt product, but the resulting No Action Recommendation essentially reached a circular conclusion—*i.e.*, the growth flag was explained, and justified, based solely upon the pharmacy's increase in purchases of Mallinckrodt's product. In one such instance, given the lack of available ARCOS data for analysis, the reviewer noted that "Chargeback data showed that [the pharmacy] had a previous 6-month purchase of [the product] of 3,000 d/u as compared to the current volume of 4,400." Apparently without more, the reviewer then offered this conclusion: the CSC Manager "attributed this growth flag for this product ***to the purchase increase in MNK/SpecGx product***." (emphasis added)

11.90 But, of course, the fact that there are increased purchases of Mallinckrodt's product is already clear from the growth flag on the indirect dashboard that prompted this review. Since the indirect customer dashboard flags pharmacies for review based on their chargeback data, *i.e.*, data that reflects the volume of Mallinckrodt's product(s) purchased by a particular pharmacy, it follows that every growth flag will necessarily be due to increased purchases. So, without more, that explanation would not help to explain the increase in purchases that triggered the flag. Nor would the above-quoted conclusion provide any assurance that the growth was appropriate. By merely stating, in essence, that the growth flagged by the indirect customer dashboard based upon available chargeback data was attributable to growth in

the pharmacies' purchases, the summary states an obvious and circular conclusion, leaving the reader with the impression that the CSC Director based his approval of the No Action Recommendation, and the SOMT based its decision to concur with the CSC Director's approval, on insufficient information, and insufficiently rigorous analysis.

11.91 In response to the Monitor Team's observations, Mallinckrodt shared additional documentation—namely, Review Sheets—that the Monitor Team had not previously received. Those Review Sheets provide additional evidence to support the No Action Recommendations, and provide additional context to what otherwise would seem to be circular conclusions. Thus, once again, it seems the problem is one of insufficient documentation and description in the minutes, rather than insufficient analysis. In one instance, however, the Monitor Team identified a January 2025 updated narrative that supplemented the original October 2024 narrative, providing an additional basis for the No Action Recommendation that was not apparent from the Review Sheet at the time it was shared with the SOMT.

11.92 In subsequent SOMT meeting minutes the circular conclusions appear to have been addressed with supplemental information. For example, in the revised October 2024 minutes, the SOMT provided more robust explanations for the approved No Action Recommendations, including that the increase amounted to a relatively small number of prescriptions on average, based upon typical usage. Additionally, in the SOMT meeting minutes for December 2024, and for January and February 2025, the language reflecting a conclusion that the CSC Manager "attributed this growth flag for this product to the purchase increase in MNK/SpecGx product" is absent from the minutes.

11.93 ***Third,*** reviews of pharmacies initiated based on purchases of certain non-Opioid controlled substances that were non-ARCOS-reportable products appeared to be routinely

resolved with only the explanation that there was no ARCOS data available for such products. To be sure, products not reported to ARCOS will typically not be Opioids as defined in the Operating Injunction, as is the case with the Schedule IV controlled substance temazepam (a non-Opioid primarily prescribed for insomnia) discussed below. Nonetheless, since the indirect customer dashboard analyzes pharmacies' purchases of those products, and the CSC Team's resolution of the flags for those products is not described sufficiently in the Monitor Team's opinion, the Monitor Team has taken the opportunity to recommend more fulsome documentation of the review and analysis of these flags, as explained in the recommendation below.

11.94 Specifically, the Monitor Team observed multiple instances where a pharmacy's purchase of a Schedule IV controlled substance triggered a "flag" on the indirect customer dashboard, such as for unusual volume or growth in the pharmacy's purchases of that product.[29] But, without further elaboration, the minutes routinely suggested that the reason for the No Action Recommendation was due to the absence of ARCOS data for the product triggering the flag.[30] In one typical example relating to temazepam, the minutes first observed that the

[29] In future meeting minutes, the SOMT may wish to identify the schedule of the product at issue as additional support for the explanation that ARCOS data is not available for such products, as higher scheduled products are less likely to be abused.

[30] Not all controlled substances are reportable to ARCOS. As the DEA website explains, "[i]ncluded in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only)." *See* U.S. Dep't of Justice, Drug Enforcement Admin., Diversion Control Division, "Automation of Reports and Consolidated Orders System (ARCOS)," *available at* https://www.deadiversion.usdoj.gov/arcos/arcos.html (last visited May 3, 2025). Accordingly, some Schedule IV controlled substances, like temazepam, are not reported to ARCOS.

The U.S. Department of Justice Office of Inspector General ("OIG") noted this limitation of ARCOS data even regarding certain opioid products in a 2019 report on the DEA. *See* U.S.

reviewer "initiated this review based on SOM indirect flag for Volume" of the product. The minutes then stated the "product … could not be analyzed or compared as this drug product is not ARCOS reportable. [The CSC Manager] is recommending no further action with concurrence from the Director of controlled substance compliance." Of course, if the lack of ARCOS data had been the sole reason for clearing the pharmacy, the SOMT's analysis would be unsatisfying because all pharmacies purchasing such products would be cleared routinely, without the need for further review, making the summary unnecessary. For that reason, both Mallinckrodt and the Monitor Team agree that a lack of ARCOS data—without more—would be an insufficient basis to clear a pharmacy whose purchases triggered a chargeback review due to a "flag" of some kind. Yet, regarding the examples described above, to the extent these No Action Recommendations, and the CSC Director's decision to approve them, involved considerations other than the absence of ARCOS data, such considerations were not apparent from the SOMT meeting minutes.

11.95 However, the Review Sheets that had not originally been shared with the Monitor Team illustrate the existence of deeper analysis behind the No Action Recommendations and additional grounds for the Recommendations. Specifically, the Review Sheet for this pharmacy states that, "[b]ased on ARCOS data, [Pharmacy B] is purchasing similar quantities of ARCO[S]

Dep't of Justice Office of Inspector General, Review of the Drug Enforcement Admin.'s Regulatory and Enforcement Efforts to Control the Diversion of Opioids (Sept. 2019) at 29 ("We also found that ARCOS does not contain all of the information necessary to detect the diversion of all pharmaceutical opioids. Some manufacturers and distributors of certain pharmaceutical opioids on Schedules III, IV, and V are not required to report ordering information to DEA."), *available at* https://oig.justice.gov/reports/2019/e1905.pdf (last visited Apr. 24, 2025). The Report expressed "concern[] that the nine opioid compounds not reported in ARCOS are just as dangerous to public safety as those on Schedules I and II. For example, a 2016 Florida Medical Examiners Commission report found that tramadol, a Schedule IV controlled substance used to treat moderate to severe pain, was detected in 949 overdose fatalities in Florida since 2015." *Id.*

reportable products compared to it[s] competitors." Consequently, once again, the problem appears to relate to an issue of documentation, not analysis.

11.96 In subsequent SOMT meeting minutes, this issue appears to have been addressed. As noted above, in the revised October 2024 minutes, the SOMT provided more robust explanations for the No Action Recommendations approved by the CSC Director, beyond the mere fact that the product was not ARCOS-reportable, including, for example, that the increase amounted to a relatively small number of prescriptions on average, based upon typical usage.

ii. SOMT meeting minutes must be carefully reviewed to avoid errors, in order to ensure the documentation reflects a complete and accurate historical record

11.97 As explained below, the Monitor Team observed a number of cut-and-paste errors in the October 2024 meeting minutes that resulted in word-for-word duplication of a prior review for a different pharmacy 1, in the summary review for pharmacy 2, and called this to the attention of the SOMT. Thus, for instance, the review of pharmacy 1 in the October minutes appears to have been duplicated identically in the immediately following reviews of pharmacies 2, 3, and 4. (The names, DEA numbers, and cities and states of pharmacies 2, 3, and 4 are different, but their narrative summaries are identical to the summary for pharmacy 1.)

11.98 The Monitor Team requested, and Mallinckrodt provided, a corrected set of October 2024 SOMT minutes.[31] The revision indicated the correction of the cut-and-paste errors. However, the revised minutes show a total of 29 pharmacies with No Action Recommendations approved by the CSC Director, with the SOMT concurring, reflecting the

[31] The revised minutes could have been more clearly identified as such, not only in the blue font Mallinckrodt uses for updated sections of the minutes, but also in the title of the minutes on the first page. Mallinckrodt has agreed, in future, to make the revised version of the minutes clearly designated as such, and to continue to indicate any modifications in blue font.

removal of three of the original 32 pharmacies previously designated as such in the uncorrected October 2024 minutes. As of the February 2025 SOMT minutes, these three pharmacies appeared to remain in an indeterminate state, with no decision by the SOMT yet made, and therefore exceeding the 90-day period the SOMT is using as a "rule of thumb" to restrict still pending restriction decisions. Thus, while the error might appear to be insignificant—and may ultimately be insignificant if the pharmacies in question are not restricted anyway—the error at a minimum resulted in delayed resolution of those pharmacies' reviews, despite the possible need for restriction.

11.99 The Monitor Team inquired about the timing and final decision on these pharmacies. Mallinckrodt, through its outside counsel, advised that a decision on one of the pharmacies was made in the March SOMT meeting (which minutes the Monitor Team has not reviewed in this Twelfth Review Period), but has acknowledged that the review of the remaining two of these pharmacies will now take longer than the 90-day period Mallinckrodt has established as the default period for completion of pharmacy reviews. *See infra* at 91 ¶ 11.147 – 92 ¶ 11.149 (discussing new policy). Additionally, Mallinckrodt has acknowledged the oversight resulting in the No Action Recommendation for these two pharmacies, but has pointed to the relatively small error rate when viewed in the context of the large number of pharmacies the SOMT has reviewed for restriction over time.

> ***Recommendation 12(a). Ensure the SOMT minutes (a) better reflect the SOMT's analysis by providing greater support and context for the decisions of the CSC Director and SOMT, and (b) are reviewed carefully to ensure the minutes reflect an accurate historical record of the SOMT's decisions and reasoning for future reference.***

11.100 **As the above discussion makes clear, the Monitor identified three areas of the SOMT meeting minutes that were insufficiently detailed, making it difficult for the Monitor Team to evaluate the reasonableness and justification for the SOMT members' No**

Action Recommendations, and the CSC Director's approval of them. Without the supporting detail that Mallinckrodt subsequently provided, the three flaws appeared to be: (1) comparisons between pharmacies that raised suspicion and seemed to support restriction of the subject pharmacies but instead resulted in No Action Recommendations; (2) explanations for No Action Recommendations that seemed circular, in that they explained chargeback growth as the result of growth in purchases of Mallinckrodt product, helping little to understand the reasons for the flag; and (3) the routine clearing of pharmacies whose purchases of non-ARCOS-reportable products triggered flags merely because there was no ARCOS data available to evaluate purchases of these products, even though the products are controlled substances and there was some unexplained flag based on the pharmacies' purchase of those products.

11.101 **Additionally, given the nature of the mistakes identified above—including three pharmacies for which there were originally No Action Recommendations that were approved but then revised, on further review—there is a need for much closer and more careful review of the minutes.**

11.102 **For the above reasons, the Monitor recommended Mallinckrodt (1) improve and enhance the analysis documented in SOMT meeting minutes to support No Action Recommendations, including by providing all material reasons for the SOMT's decisions; and (2) because of the importance of these minutes in creating a record for future reference, that the SOMT adopt a mechanism for careful review, including perhaps consideration of a second editor on the SOMT.** ***Mallinckrodt has agreed to implement this recommendation.***

11.103 The CSC Director agreed to spend more time reviewing the SOMT meeting minutes to identify errors. Further, Mallinckrodt is considering which personnel with the appropriate training and experience may be best suited to conducting an additional review of the minutes.

b. Correspondence with DEA regarding restriction and reinstatement of downstream registrants

11.104 As in prior reporting periods, the Monitor Team reviewed Mallinckrodt's correspondence with the DEA regarding restriction and reinstatement of downstream registrants because Mallinckrodt's SOPs require the SOMT to notify the DEA of such restrictions and reinstatements. *See SOM Program Media Searches & Chargeback Reviews of Direct Customers and Downstream Registrants* SOP § 6.4.5; *SOM Program Review of Reinstatement Requests from Downstream Registrants* SOP § 6.3.5.2.

11.105 Specifically, during the Twelfth Reporting Period, the Monitor Team reviewed the SOMT's correspondence with the DEA from November 2024 to March 2025. In general, the Monitor Team found that the SOMT's communications completely and accurately conveyed the SOMT's restrictions and reinstatements of downstream registrants. However, the Monitor Team observed limited instances where certain restrictions were not conveyed to the DEA because the customers were reinstated shortly after restriction, or they were not conveyed until months after the restriction occurred—and only after the Monitor Team called this to the SOMT's attention. These instances are described further below.

i. The SOMT did not report restrictions to the DEA when the indirect customers were quickly reinstated based on receipt of information obviating the bases for restriction

11.106 In the Twelfth Reporting Period, the SOMT restricted two pharmacies but reinstated both of them within a matter of days, without informing the DEA of those restrictions.

When the Monitor Team inquired into the reason Pharmacy C's and Pharmacy D's restrictions were not reported to the DEA, Mallinckrodt responded that, because the Pharmacies were promptly reinstated after the SOMT received information obviating the bases for the restrictions, the CSC Team did not report those short-lived restrictions.

11.107 Specifically, the SOMT restricted (on an ad hoc basis) Pharmacy C, following notification of a distributor restriction from Distributor N, and Pharmacy D, following a review initiated because of a media alert announcing the indictment of a pharmacist for the theft of controlled substances from the pharmacy. The SOMT promptly reinstated the pharmacies after one day and three days, respectively.

11.108 ***Reinstatement of Pharmacy C.*** The SOMT's decision to reinstate Pharmacy C was based on information received directly from Pharmacy C, independent confirmation of that information with the Pharmacy's distributor, Distributor S, and re-review of the Pharmacy's metrics. Specifically, Pharmacy C explained that it exclusively purchased controlled substances from Distributor S and had always complied with its requirements. However, Pharmacy C began re-onboarding[32] with another distributor, Distributor N, because of Distributor N's pricing. For business reasons, Pharmacy C did not complete re-onboarding with Distributor N, and Distributor N preemptively restricted Pharmacy C for failing to provide a dispensing report (which Distributor N interpreted as a failure to comply with its requirements). The SOMT independently confirmed with Distributor S that Pharmacy C raised no diversion concerns and noted no unusual patterns, ratios, or volumes upon reviewing Pharmacy C's metrics, and the SOMT reinstated Pharmacy C.

[32] Pharmacy C had not purchased products from Distributor S in years and, thus, its account was inactive.

11.109 ***Reinstatement of Pharmacy D***. The SOMT's decision to reinstate Pharmacy D was based on the SOMT's discussions with Pharmacy D's Director of Pharmacy and review of supplemental documentation, which revealed that the accused individual was terminated, Pharmacy D implemented a series of enhanced security protocols, and Pharmacy D entered into a memorandum of agreement to improve inventory security.

*** * ***

11.110 The Monitor is satisfied that the information the SOMT subsequently received did obviate the need for the restrictions of Pharmacies C and D, and that they were appropriately reinstated. The Monitor is also satisfied with Mallinckrodt's explanation as to why those restrictions did not warrant notification to DEA. Indeed, in these instances, the restrictions were premised upon insufficient information that, if made available sooner, would have avoided the need for restriction in the first place. Accordingly, the reinstatement effectively functions as a "correction" of the initial restriction, and therefore makes notification to the DEA seem less helpful and important. The Monitor approves of the SOMT's approach in this regard—*i.e.*, should the SOMT initially restrict, but promptly reinstate based on similar circumstances in the future.

ii. The CSC Team did not report certain restrictions to the DEA until the Monitor informed it that the DEA had not yet been notified of those restrictions

11.111 The Monitor Team discovered four instances when the SOMT had restricted a pharmacy and the restriction was not reported to the DEA, although Mallinckrodt's policy requires such reporting. Upon raising the observation with Mallinckrodt, the SOMT subsequently reported those restrictions to the DEA.

11.112 Specifically, in December 2024, the SOMT restricted (on an ad hoc basis) Pharmacy E, Pharmacy F, and Pharmacy G. The SOMT's February 7, 2025 correspondence to

the DEA, which conveyed all other December 2024 restrictions, did not include or reference those three pharmacies.

11.113 Similarly, in February 2025, the SOMT restricted Pharmacy H. However, the SOMT's March 24, 2025 correspondence to the DEA, which conveyed all other February 2025 restrictions, did not include or reference Pharmacy H.

11.114 When the Monitor Team inquired (on April 18, 2025) into the reason these four restricted pharmacies were not reported to the DEA, Mallinckrodt responded that these pharmacies were inadvertently excluded from the routine correspondence. Mallinckrodt confirmed that each inadvertently excluded pharmacy was subsequently reported to the DEA on April 25, 2025, following the Monitor Team's notice to Mallinckrodt.

11.115 Unlike suspicious ***direct customers'*** orders from Mallinckrodt, which Mallinckrodt must report to the DEA "when discovered," under the DEA's regulations concerning distribution of controlled substances, *see* 21 C.F.R. § 1301.74(b) ("The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders ***when discovered*** by the registrant.") (emphasis added), Mallinckrodt does not view ***indirect customers'*** purchases from Mallinckrodt's distributors (or distributors' chargeback requests relating to those purchases) as "orders" within the meaning of those regulations. Thus, Mallinckrodt has not established a deadline for reporting to the DEA indirect customer restrictions, although Mallinckrodt's policy requires such disclosures, without specifying any particular timeframe for reporting. *See SOM Program Media Searches & Chargeback Reviews of Direct Customers and Downstream Registrants* SOP § 5.4.1.

11.116 For that matter, the direct customer order policy also does not explicitly establish a reporting timeline. *Compare SOM Program Review of Direct Customer Orders* § 6.13.2. It

does, however, state that such reporting should occur "as required." *See id.* § 6.10.8 ("If the review determines that the order is suspicious, it shall be cancelled and reported to DEA as required."). Based upon the Monitor's observations noted above, without established reporting timelines there is risk that the restrictions may not be reported at all.

11.117 Mallinckrodt acknowledged its delayed reporting, but notes that Mallinckrodt's policy requires more than the law does. The Monitor concurs that the oversight is relatively insignificant in context for several reasons: (1) the delayed reporting relates to a very small number of the 357 pharmacies that were restricted and reported to DEA in 2024, making the error rate itself very small; (2) no law or regulation required Mallinckrodt to report these restrictions to the DEA; and (3) the Operating Injunction requires providing information to the DEA only upon request, *see* § III.G.1.d. In sum, while Mallinckrodt accepts that it must comply with its own policy's reporting requirement, it characterizes the oversight in this instance as a failure to do what it was otherwise not required to do by law, regulation, or the Operating Injunction. While that is true, the Monitor believes that establishing a defined time for reporting to the DEA will help Mallinckrodt to comply with its reporting policy, which—unlike the law, regulation, and Operating Injunction—does require the reporting of these instances to the DEA.

Recommendation 12(b). Adopt a defined time for reporting suspended direct customers and restricted indirect customers to the DEA.

11.118 **Given the lack of any specific reporting deadline in the current SOM policy for chargeback reviews—or, for that matter, for the restriction of direct customers—and the risk that such restrictions could potentially evade reporting to the DEA entirely, the Monitor has recommended that Mallinckrodt adopt clear internal deadlines for the reporting of any suspensions for direct customers or restrictions for indirect customers to the DEA.** ***Mallinckrodt agreed to implement this recommendation.***

c. Management of Change

11.119 As noted above, the October and November 2024 SOMT meeting minutes included a relatively large number of pharmacies that fell into the category of No Action Recommendations. That section of the minutes is typically introduced by the following paragraph:

> Per Section 6.4.3 of the Suspicious Order Monitoring Program Media & Chargeback Reviews of Direct Customers and Downstream Registrants SOP a "no action necessary recommendation" by the LCSCC must be approved by the Director, Controlled Substance Compliance or their designee and documented in the investigation summary sheet. The following pharmacies were reviewed by the LCSCC and the Director, Controlled Substance Compliance and no action is recommended. SOMT reviewed each and concurred.

11.120 The then-current version of Section 6.4.3 of the SOP, titled *Suspicious Order Monitoring Program Media & Chargeback Reviews of Direct Customers and Downstream Registrants* stated, accordingly:

> A "no action necessary recommendation" by the LCSCC must be approved by the Director, Controlled Substance Compliance or their designee and documented in the investigation summary sheet. If the SOMT determines that the Downstream Registrant should not be restricted, the reason will be notated.

§ 6.4.3.

11.121 The No Action Recommendation paragraph in the SOMT meeting minutes and Section 6.4.3 of the SOP are consistent in their reference to the LCSCC, but both are also consistently incorrect and outdated, because the title of the LCSCC has now changed. The title "LCSCC" (or, "Lead Controlled Substance Compliance Consultant") was updated and superseded by the title Director of CSC Analytics in August 2024.

11.122 In addition, these No Action Recommendations are now being made (initially, prior to CSC Director approval), by at least four separate SOMT members: the Director of CSC

Analytics, CSC Managers B and C, and CSC Specialist. Thus, lingering references to an outdated "LCSCC" title does not accurately reflect who is responsible for conducting these reviews. Although a relatively insignificant issue, this observation suggested to the Monitor Team the need for a MOC policy and procedure to ensure timely corresponding updates to all relevant implicated policies and procedures, specifically in the area of CSC. Mallinckrodt, through its counsel, advised that a MOC policy does exist and requires updates every two years.

11.123 Mallinckrodt shared a copy of a detailed and extensive policy titled *Document Management - Quality*Stream DMS Module*, which sets forth, in Section 6.12, the Company's policy on periodic reviews of procedural documents, including SOPs and Work Instructions. Specifically, the SOP states: "Procedural documents (*e.g.*, SOP, WI, FRM, GD, and POL) will be reviewed at least once every two years from the effective date of the document." *Document Management - Quality*Stream DMS Module* § 6.12.1. Accordingly, the Monitor is reassured that there is a document review policy in place to regularly update outdated policies.

11.124 Separately, Mallinckrodt and its outside counsel advised the Monitor Team of the Working Group's decision to update and revise relevant CSC policies, as discussed elsewhere in this Report. An updated policy now addresses the current title ("Director of CSC Analytics") of the former LCSCC and provides that the aforementioned members of the CSC Team may make No Action Recommendations. *See supra* at 79-80 ¶ 11.122.

6. The Director of CSC Analytics' Annual Report

11.125 In March 2025, the Director of CSC Analytics once again produced an annual report (the "Annual Report") based upon his review and analysis of highly diverted controlled substances.[33] The most recent Annual Report, dated March 24, 2025, is a 41-page report titled

[33] The Director of CSC Analytics has reported similarly on prior occasions, as required by the *SOM Program Media Searches & Chargeback Reviews of Direct Customers and*

Annual Controlled Substances Compliance Report Analysis of Highly Diverted Controlled Substances Utilizing Chargeback & ARCOS Data – FY 2024, which covers the timeframe from October 1, 2023 through September 30, 2024. The Annual Report analyzes five products: (1) hydrocodone / APAP 10/325 mg; (2) oxycodone 30 mg; (3) oxycodone 15 mg; (4) oxycodone 20 mg; and (5) hydromorphone 8 mg.

11.126 As indicated in its updated title (*i.e.*, "***& ARCOS Data***"), the Annual Reports now reflect the SOMT's greater use of ARCOS data in addition to the chargeback requests submitted by Mallinckrodt's direct customers.[34] Specifically, the latest Annual Report utilizes ARCOS data from March 1, 2024 through August 31, 2024.[35]

Downstream Registrants SOP. *See* Tenth Monitor Report at 72 ¶ 12.124 – 75 ¶ 12.131; Eighth Monitor Report at 40 ¶ 11.36 – 43 ¶ 11.43; Fifth Monitor Report at 31 ¶ 11.24 – 34 ¶ 11.29. The then-operative version of that policy requires the "LCSCC or designee" to "conduct a periodic review of Chargeback data for the prior twelve-month period and review media and publicly available information to help identify Downstream Registrants which may pose a risk of diversion." *See* § 6.3.1.

[34] Report 11, for example, was titled *Annual Controlled Substances Compliance Report Analysis of Highly-Diverted Controlled Substances Utilizing Chargeback Data—FY 2023*.

[35] As noted in the Tenth Monitor Report, Mallinckrodt's CSC efforts have benefitted greatly from the availability of additional ARCOS data, which has improved the CSC function's ability to identify "red flags" to a degree chargeback data alone previously did not allow. *See* Tenth Monitor Report at 73 ¶ 12.128 – 75 ¶ 12.129. (Expanded ARCOS data only became available as of May 2021).

11.127 The Annual Report also provides helpful statistics regarding the SOMT's productivity during the period of review, such as numbers of pharmacies reviewed as compared to the prior year and percentages of pharmacies reviewed that were restricted. This data is summarized below (supplemented by data the Monitor Team requested, and which Mallinckrodt provided, from outside the Annual Report):

Reviews and Restrictions, By Year, from 2021 to Present							
	2019	***2020***	***2021***	***2022***	***2023***	***2024***	***Q1 2025***
Number of Pharmacies Reviewed for Restriction	124	98	76	231	403	742	185
Total # of Restrictions	52	55	50	133	200	357	98

Figure 1.

Percent Change in Restrictions, By Year, from 2021 to Present					
	2019 - 2020	***2020 - 2021***	***2021 - 2022***	***2022 - 2023***	***2023 - 2024***
Number Reviewed for Restriction – Percentage Change	(21%)	(22.4%)	203.9%	74.5%	84.1%
Total Restrictions – Percent Change	5.7%	(9.1%)	166%	50.4%	78.5%

Figure 2.

11.128 The Annual Report also provides helpful statistics regarding the SOMT's review of reinstatement requests, and the percentages of reinstatement requests that were granted (again, supplemented by data the Monitor Team requested, and which Mallinckrodt provided, from outside the Annual Report):

Reinstatement Requests,[36] By Year, from 2021 to Present					
	2021	***2022***	***2023***	***2024***	***Q1 2025***
Number of Pharmacies Reviewed for Reinstatement	8	18	45	157	55
Number of those Pharmacies Reinstated	5	11	30	100	36

Figure 3.

[36] Reinstatement includes reinstatement of both direct and indirect customers. Indirect customer requests and reinstatements occur far more frequently than direct customer requests and reinstatements.

11.129 Finally, the Annual Report reveals the percentages of various "triggers" that prompted reviews and restrictions (*e.g.*, Media Alerts, distributor notifications to Mallinckrodt, chargeback flags, and ARCOS flags):[37]

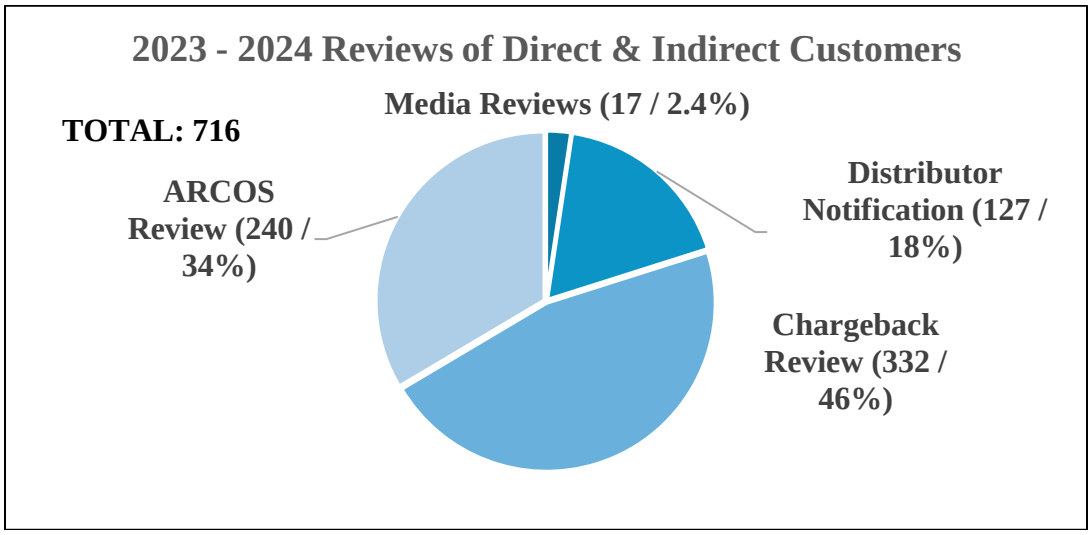

Figure 4.

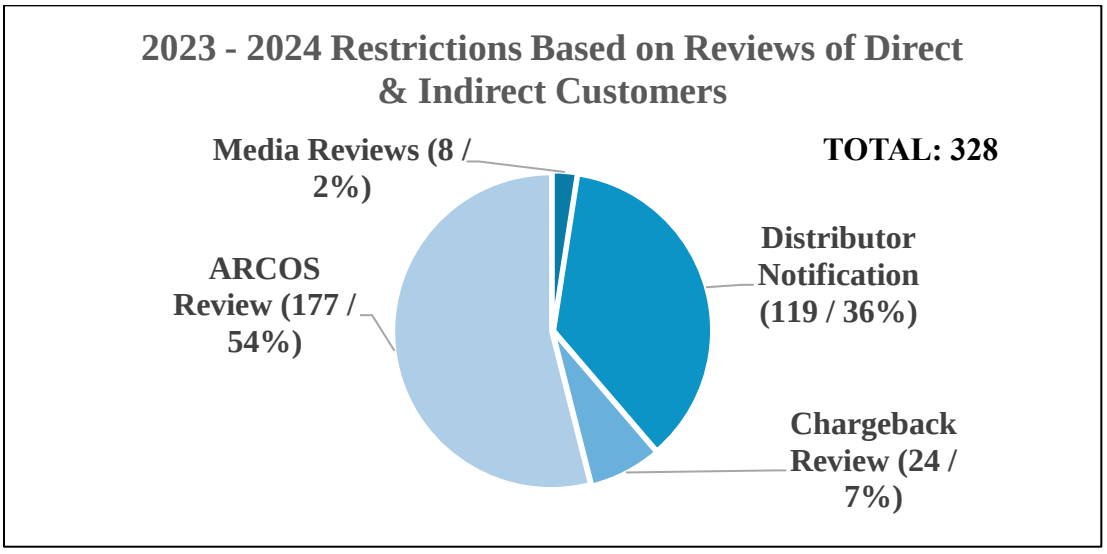

Figure 5.

[37] The tables in Figures 1-3 and the pie charts in Figures 4-5 use data from different time periods, which explains why the totals do not match. Specifically, the data in Figures 1-3 are from the relevant calendar year (January through December). The data in Figures 4-5 are from the period covered by the Annual Report drafted by the Director of CSC Analytics (*i.e.*, October 1, 2023 through September 30, 2024).

11.130 As previously noted, the Director of CSC Analytics informed the Monitor Team of his intention to focus more on distributors in his next Annual Report. *See* Eleventh Monitor Report at 59 ¶ 11.87. Review of the Annual Report confirms that distributors are a prominent part of the analysis.

a. Mallinckrodt should analyze, annually, whether the Annual Report reveals opportunities to update or refine other aspects of Mallinckrodt's SOM program

11.131 As has previously been the case with other Annual Reports the Director of CSC Analytics has prepared, the latest Annual Report produced a substantial number of restrictions (*e.g.*, 10 of the 25 restrictions in the February 2025 SOMT minutes), demonstrating the continued value of this exercise. While that is good news in one respect, it raised—once again—questions the Monitor has previously posed: why are these pharmacies not identified during the regular review of the indirect customer dashboard and ARCOS dashboard? Does this suggest a shortcoming of the dashboard system? And if so, how can the dashboard system be improved? *See* Tenth Monitor Report at 75 ¶ 12.131 ("[T]he Annual Review has once again served as a useful check on the accuracy of the SOMT's reviews, by confirming that some of the outliers identified in the Annual Review analysis were already reviewed by the SOMT in the normal course, while ***others had not been identified for review***.") (emphasis added); Eighth Monitor Report at 41 ¶ 11.38 ("[A] substantial number of chargeback restrictions resulted from the LCSCC's identification of suspicious downstream registrants through the analysis conducted to generate the Annual Report. ***The Monitor Team was curious why these suspicious pharmacies were not identified in the usual course through the LCSCC's routine review of flagged chargeback requests in the indirect customer dashboard***.") (emphasis added).

11.132 Mallinckrodt's outside counsel persuasively argues that the lack of perfect overlap between the dashboards and the Annual Report is not an indication of a shortcoming of either

exercise. Rather, the two approaches are different and complementary. Counsel analogizes to the difference between a blood test and a Magnetic Resonance Imaging ("MRI") test, which are designed to identify different issues. In this sense, the Annual Report is not a "test" of the adequacy of the dashboards; it serves a different purpose. Specifically, the Annual Report performs a function the dashboards do not: (1) it uses human analytics, based upon the Report author's judgment and experience (including not only DEA experience but extensive use of, and familiarity with the dashboards), and (2) it engages in a longer-term and higher level market analysis rather than the more focused analysis of the dashboards at a particular point in time. Thus, the Annual Report does not render the dashboards redundant, or vice versa. These complementary processes have distinct purposes and value.

11.133 Nonetheless, the Monitor Team discussed with Mallinckrodt whether the way in which the dashboards are being used to rank and prioritize pharmacies for review may be too narrow. For example, previously, the Monitor Team learned that the indirect customer dashboard's ranking is based upon the triggering of multiple criteria for order volume, per capita volume distributed in a geographic region, and order growth. If, as has previously been the case, a pharmacy only ranks high enough for restriction consideration because it satisfies ***multiple*** criteria, then this perhaps could explain why the SOMT was not identifying pharmacies that might still have warranted restriction but were only outliers on ***one*** metric. If that was the case, then a pharmacy ordering an unreasonably high volume, for example, may evade restriction merely because the other two criteria are missing.[38] However, as currently framed, a single

[38] The Monitor Team raised this issue in prior reports, while noting that "the SOMT may want to revisit the issue of statistically valid thresholds in time, as the SOMT program continues to evolve and mature." Tenth Monitor Report at 57 ¶ 12.84. *See also id.* at 56 ¶ 12.80 – 58 ¶ 12.84; Eighth Monitor Report at 40 ¶ 11.38 – 43 ¶ 11.43; *id.* at 57 ¶ 11.81.

metric on the dashboard is enough to trigger a "flag," provided a certain baseline or threshold level is reached on other metrics. (The baseline is necessary to triage the pharmacies for review, given the enormous volume of pharmacies.)

11.134 Relatedly, as discussed at an earlier stage in the monitorship, *see* Eighth Monitor Report at 42 ¶ 11.42 – 44 ¶ 11.44, members of the SOMT were previously not completing a review of all "flagged" pharmacies, which led the Monitor to make Recommendation 8(b), listed in Exhibit 1.[39] However, Mallinckrodt's counsel advised the Monitor Team in the Twelfth Reporting Period that the members of the SOMT, as of April 2025, have been able to review 100 percent of all flagged pharmacies as a result of additional hires, and the Company is adding additional resources in 2025 in order to maintain that progress. Consequently, Mallinckrodt feels there is no need for further enhancement of the ranking and prioritization at this time.

Recommendation 12(c). Ensure the Director of CSC Analytics (with assistance if needed) undertakes an annual analysis to determine what findings from the Annual Report may be applied to enhance Mallinckrodt's SOM program.

11.135 **The fact that the Annual Report apparently continues to identify pharmacies for restriction not identified through the usual dashboard review suggests there may be value in examining the Report to learn and apply new lessons to Mallinckrodt's SOM program more generally. That analysis may prove valuable in identifying potential limitations of the dashboards, among other areas, and help Mallinckrodt to enhance its SOM program.** ***Mallinckrodt agreed to implement this recommendation.***

[39] Recommendation 8(b) states: "Determine an appropriate statistically defensible marker for the ranking and prioritization of chargeback reviews, so as to determine which, if any, flagged pharmacies present the lowest risk of diversion and therefore may not warrant review."

7. Mallinckrodt's Working Group to Consider SOM-related Topics

11.136 As reported in the Eleventh Monitor Report, Mallinckrodt's outside counsel shared with the Monitor that a number of areas of interest to the Monitor are under review by an informal Working Group comprised of various in-house and outside counsel and subject matter experts. *See* Eleventh Monitor Report at 61 ¶ 11.92 – 66 ¶ 11.104. Given the involvement of legal counsel in the Working Group, Mallinckrodt (through its counsel) is asserting legal privilege as to the precise deliberations of the group. But Mallinckrodt has nonetheless agreed to share with the Monitor the outcomes of those deliberations, and the steps Mallinckrodt ultimately takes to implement its decisions.

11.137 During the Twelfth Reporting Period, Mallinckrodt's outside counsel updated the Monitor Team regarding the Working Group's observations as to certain SOM-related topics, including: (1) the creation of a comprehensive CSC handbook containing new and updated policies; (2) sales for which Mallinckrodt does not receive chargeback data; (3) the utility of incorporating the "867 Data" (defined below) Mallinckrodt receives into its SOM program; and (4) extending to other direct customers the contractual agreement Mallinckrodt has reached with certain distributors regarding reciprocal sharing of SOM-related intelligence and preventing supply of Mallinckrodt's products to restricted indirect customers. Updates on these topics are discussed below.

a. Mallinckrodt's planned creation of a comprehensive CSC handbook containing new and updated policies

11.138 As a result of the Working Group's discussions, Mallinckrodt plans to create a comprehensive CSC handbook containing all SOM policies and related Work Instructions. Mallinckrodt anticipates such a handbook will, among other things, help to onboard new

employees more efficiently. Mallinckrodt is in the process of creating the handbook, including by updating its existing SOM policies.

11.139 Specifically, the handbook will include updated policies concerning, among other things, the CSC Team's: (1) review of direct customer questionnaires; (2) due diligence visits to existing customers; (3) new customer site visits; (4) 90-day "rule of thumb" for completing reviews of indirect customers; and (5) 8-month chargeback restriction period before reinstatement of restricted pharmacies (while allowing for certain exceptions).

11.140 Towards the end of the Twelfth Reporting Period, Mallinckrodt provided the Monitor Team with revised policies that will be included in the handbook, as discussed below.

i. Policy regarding the CSC Team's review of direct customer questionnaires

11.141 As the Monitor previously reported, and as noted *supra* at 47 ¶ 11.38, Mallinckrodt requires customers to complete various questionnaires, which include questions about the customers' SOM programs, and the CSC Team is responsible for determining whether the customers' responses are satisfactory. In the Eleventh Reporting Period, Mallinckrodt informed the Monitor Team of two changes to the CSC Team's questionnaire review process: (1) distributor and manufacturer questionnaires were being reviewed by the CSC Team members at Mallinckrodt's facility in Webster Groves, Missouri, where the CSC Director and Director of CSC Analytics are based, rather than by the CSC Team members at Mallinckrodt's manufacturing plant in Hobart, New York; and (2) questionnaires for analytical lab / research customers were being reviewed by CSC Team members at either Mallinckrodt's Webster Groves facility or its Hobart, New York plant on an ad hoc basis.[40] *See* Eleventh Monitor Report at 48-

[40] The CSC Team members in Hobart continued to review the questionnaires for addiction treatment clinics.

49 ¶ 11.63. As of the Eleventh Monitor Report, Mallinckrodt had not yet finalized these changes to the CSC Team's process in an SOP.

11.142 In the Twelfth Reporting Period, the Monitor Team reviewed Mallinckrodt's revised *SOM Review of Direct Customer Orders* SOP. The SOP changes how customer questionnaires are reviewed, but that change does not incorporate the processes described above. Instead, the SOP provides that ***the CSC Director*** or his designee, rather than "CS Compliance," will review all customer questionnaires. § 6.4. That revision is satisfactory to the Monitor.

ii. Policy on due diligence visits to existing customers

11.143 Mallinckrodt updated the existing *SOM Review of Direct Customer Orders* SOP to incorporate the Working Group's discussions regarding direct customer due diligence visits. Previously, that SOP required the CSC Team to conduct annual due diligence visits, either in-person or virtually, with one of the "Big Three" distributors and six other distributors. The Working Group discussed instead requiring the CSC Team or a qualified contractor to conduct 10 direct customer due diligence visits each year, either in-person or virtually, depending on the reason(s) for the visit. The Working Group also discussed updating that policy to require the CSC Team to prepare a written, risk-based plan for due diligence visits for the upcoming year.[41]

11.144 The revised *SOM Review of Direct Customer Orders* SOP incorporates these changes. The SOP now requires the CSC Team to "adopt and execute a risk-based plan to conduct diligence meetings with Direct Customers ('Annual Diligence Meeting Plan')" and specifies that that the Annual Diligence Meeting Plan must include, at a minimum, due diligence

[41] Additionally, Mallinckrodt's outside counsel informed the Monitor Team that the final handbook will incorporate an updated template for the CSC Team's reports from such visits to further standardize the review process. The Monitor Team will discuss the status of that updated template with the CSC Team in the next reporting period.

visits for no fewer than ten direct customers per year, including one "Big Three" distributor. § 6.5.1. Under the SOP, the direct customer visits are to be conducted by the CSC Team or a qualified third-party selected by the CSC Team. *Id.* § 6.5.2.

iii. Policy on new customer site visits

11.145 In the Eleventh Reporting Period, the Monitor Team requested that the Working Group assess how many new customers Mallinckrodt typically onboards annually, in order to assess the feasibility and potential value of the SOMT conducting in-person due diligence visits before new customers' orders can be fulfilled. *See* Eleventh Monitor Report at 65-66 ¶ 11.03. Mallinckrodt's outside counsel informed the Monitor Team that the Working Group discussed the CSC Team conducting in-person site visits for any new customers that order controlled substances and for any reinstated customers.

11.146 Thus, under the revised *SOM Review of Direct Customer Orders* SOP, the Annual Diligence Meeting Plan must include visits for all direct customers that "have started purchasing controlled substances" or "have been reinstated" "within the past calendar year." § 6.5.3.

iv. Policy formalizing 90-day "rule of thumb" for conducting reviews of indirect customers

11.147 As discussed in the Tenth and Eleventh Monitor Reports, Mallinckrodt accepted the Monitor's recommendation to adopt a 90-day "rule of thumb"—*i.e.*, a presumption that the SOMT would make a decision whether to restrict a downstream customer within 90 days of beginning a chargeback review, while allowing for appropriate exceptions in the judgment of the SOMT. *See* Prior Recommendation 10(c). This rule was adopted in light of the persistent problem of distributor delay in providing responses to Mallinckrodt's requests for due diligence.

While Mallinckrodt implemented the 90-day rule in the Tenth Reporting Period, it deferred until a later date a formal update to the relevant SOP (relating to chargeback reviews).

11.148 During the Twelfth Reporting Period, Mallinckrodt shared with the Monitor Team the revised *SOM Program Media Searches & Chargeback Reviews of Direct Customers and Downstream Registrants* SOP, which now codifies the 90-day "rule of thumb." That policy will, in turn, be included in the CSC handbook. The revised SOP provides: "Within 90 days of initiating Downstream Registrant Review, the SOMT will review the Downstream Registrant Observations and issue a determination of whether the Downstream Registrant poses a risk of Diversion." *SOM Program Media Searches & Chargeback Reviews of Direct Customers and Downstream Registrants* SOP § 6.4.6. The SOP further provides:

> In situations where CSC is unable to prepare Downstream Registrant Observations within 75 days of initiating the Downstream Registrant Review, or where the SOMT is unable to issue a determination related to the Downstream Registrant within 90 days, the SOMT, in consultation with the CSC Director, may elect to extend the Downstream Registrant Review period or issue a Chargeback Restriction before the delivery of Downstream Registrant Observations.

Id. § 6.4.7.

11.149 The Monitor is satisfied that the revised SOP appropriately incorporates the 90-day "rule of thumb" while allowing for appropriate flexibility, in the SOMT's discretion, when necessary.

v. Policy establishing 8-month presumptive chargeback restriction period

11.150 In the Twelfth Reporting Period, Mallinckrodt undertook an extensive revision of its *SOM Program Review of Reinstatement Requests from Downstream Registrants* SOP. Among other changes, Mallinckrodt adopted what the policy calls a "Chargeback Restriction

Period." *See* § 6.2. The restriction period presumptively puts a restricted pharmacy in "timeout" for at least eight months before Mallinckrodt will consider reinstatement.[42] That provision does, however, permit exceptions. It states that "[t]he SOMT may grant an exception to the default timeframes above if the SOMT determines that the original decision to restrict the Downstream Registrant was based on inaccurate or incomplete information through no fault of the restricted party." *Id.* § 6.2.1.1.

11.151 Mallinckrodt's restriction is not intended to serve a punitive function. Rather, it ensures that Mallinckrodt has 6 months of ARCOS data to evaluate the pharmacy, with an additional 60 days for consideration. The restriction undoubtedly has additional benefits: it ensures that restricted pharmacies are not reinstated too quickly before demonstrating a longer period of compliance; and it reduces the administrative burden of a high volume of reinstatement requests Mallinckrodt must address.

11.152 One notable issue is that Mallinckrodt's "timeout" period may be substantially shorter than the equivalent rule of some of Mallinckrodt's direct customers. Thus, some distributors may have default policies that require an extended period of restriction before the distributor will even consider a request for reinstatement—in some cases even exceeding one year. In those instances, it will generally be unproductive for Mallinckrodt to return to a distributor who restricted a downstream registrant in order to clarify whether the distributor has itself reinstated the customer. If the distributor's default restriction period is lengthy, the distributor will invariably respond "yes," to the question "does Distributor X still restrict Pharmacy Y?" Consequently, Mallinckrodt's approach has been to make its own independent

[42] Specifically, the policy states that "Downstream Registrants are not eligible to seek or be reviewed for Chargeback Reinstatement for at least eight (8) months following the date of initial Chargeback Restriction." *Id.* § 6.2.1.

assessment regarding reinstatement, including with the benefit of a third-party compliance report.

11.153 Mallinckrodt's approach is reasonable. After all, every restriction—and every additional period of restriction—carries some legal risk for Mallinckrodt. Additionally, the impact of Mallinckrodt's restrictions, due to its more substantial market share, is likely to create correspondingly larger supply disruptions. Consequently, the Monitor understands the difficult position in which Mallinckrodt must make restriction and reinstatement decisions. The Monitor also appreciates that the distributors' policies should not control Mallinckrodt's own reinstatement decisions. That said, the idea of creating a restriction period, and ensuring that it is sufficiently lengthy for Mallinckrodt to conduct a fulsome analysis before reinstating a pharmacy, is worthwhile.

* * *

11.154 The Monitor Team will review the aforementioned policies in greater detail, as well as any other new or updated policies Mallinckrodt provides for the Monitor's review, in the Thirteenth Reporting Period. The Monitor will also provide an update on the completion of the CSC handbook.

b. Sales for which Mallinckrodt does not receive chargeback data

11.155 During the Twelfth Reporting Period, the Monitor, Mallinckrodt, and Mallinckrodt's outside counsel continued to discuss the "blind spot" in Mallinckrodt's chargeback data—*i.e.*, those sales for which Mallinckrodt does not receive chargeback requests, and therefore does not have a source of chargeback data for SOM analysis.

i. Mallinckrodt receives chargeback data from direct customers, which contains information about its indirect customers' purchases

11.156 As the Monitor has reported on several occasions throughout the monitorship, the CSC Team monitors Mallinckrodt's ***indirect*** customers using chargeback data submitted by ***direct*** customers (in addition to data from other sources such as ARCOS). Specifically, the SOMT uses chargeback data to populate the indirect customer dashboard, which uses an algorithm to "flag" and rank indirect customers for review. Mallinckrodt's use of chargeback data for SOM purposes dates back to at least Mallinckrodt's 2017 Memorandum of Agreement ("MOA") with the DEA, in which DEA explicitly required Mallinckrodt's use of available chargeback data for SOM analysis, along with other available data sources.[43]

11.157 A chargeback request is effectively a reimbursement claim submitted to Mallinckrodt by a ***direct*** customer, typically a distributor, for a particular purchase. When a direct customer submits a chargeback request, it must identify, among other things, the downstream registrant to which the distributor sold Mallinckrodt's product and the product and quantity sold. This information is referred to as "chargeback data." Thus, the chargeback data Mallinckrodt receives from its ***direct*** customers allows the CSC Team to identify which downstream registrants are its ***indirect*** customers (*i.e.*, the customers that purchase

[43] Specifically, the MOA criticized Mallinckrodt for failing to "use 'chargeback' information from its distributors to evaluate suspicious orders," and explained that "[c]hargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products." Administrative Memorandum of Agreement Between Mallinckrodt plc and U.S. Drug Enforcement Admin. (July 2017) at 2-3 § I.3.a.iv, *available at* https://www.justice.gov/d9/press-releases/attachments/2017/08/01/mallinckrodt_moa_executed_0.pdf (last visited May 1, 2025). The MOA required Mallinckrodt to "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion." *Id.* at 5 § II.1.b.

Mallinckrodt's products from its ***direct*** customers). Chargeback data also allows the CSC Team to track indirect customers' purchases of Mallinckrodt's products.

11.158 While Mallinckrodt receives chargeback data for the vast majority of its sales, including sales of Opioid Products, it does not receive chargeback data for every sale, for two reasons. First, not all direct customers submit chargeback requests to Mallinckrodt, and it is not mandatory that they do so. Second, some direct customers, including the "Big Three" distributors, submit chargeback requests for certain products but not others. [44]

11.159 Thus, regarding the sales for which Mallinckrodt does not receive chargeback data, the CSC Team cannot identify its indirect customers, or identify the relationships between its direct and indirect customers. Additionally, for direct customers that do not submit chargebacks at all, the CSC Team has no visibility into its indirect customers' purchases from those particular distributors, and, for direct customers that submit chargeback requests for some, but not all, purchases, the CSC Team cannot see the "full picture" of indirect customers' purchases of those Mallinckrodt products.

11.160 Additional data now available through ARCOS provides the CSC Team with full visibility into all downstream registrants' purchases, *i.e.*, the quantity of each ARCOS-reportable molecule and product each downstream registrant purchases from any source, filling in any data "gap" Mallinckrodt has ***for its known indirect customers' purchases***. However, ARCOS data, unlike chargeback data, does not reveal (1) which downstream registrants are Mallinckrodt's indirect customers, (2) the identity of each downstream registrant's distributor(s); or (3) the

[44] By way of example, Mallinckrodt conducted due diligence visits for "Big Three" Distributor D and non-"Big Three" Distributor Q. Both Distributors informed the CSC Team that they "participate in chargeback contracts" but also "sell controlled substances at full price (non chargeback)."

quantity of ***Mallinckrodt's*** products the downstream registrant purchased. As a result, when the CSC Team reviews the ARCOS dashboard for downstream registrants with statistically anomalous purchasing practices to identify indirect customers for review, it does not know whether Mallinckrodt has an indirect customer relationship with that particular downstream registrant unless a direct customer has submitted a chargeback request for a sale to that registrant. In other words, without that chargeback data, Mallinckrodt cannot identify its indirect customers and "connect the dots" between distributors and indirect customers.

11.161 The value in Mallinckrodt's ability to connect those dots was demonstrated as recently as the last reporting period, when Mallinckrodt suspended sales to six distributors after the SOMT observed a high percentage of restrictions among those distributors' customers. *See* Eleventh Monitor Report 54 ¶ 11.73 – 59 ¶ 11.87. After the CSC Team reviewed the basis for its restriction of so many of those distributors' customers, it became clear to the CSC Team that none of those distributors were incorporating ARCOS data into their SOM programs to the extent Mallinckrodt expects. If the CSC Team did not have the chargeback data identifying the indirect customers and showing from which distributor each of the restricted indirect customers purchased Mallinckrodt's products, the CSC Team would not have been able to conduct that analysis, and those distributors may have continued to purchase Mallinckrodt's products and sell them to pharmacies that might otherwise raise suspicions of potential diversion.

11.162 Because chargeback data is not universally available to Mallinckrodt, the Monitor Team wanted to better understand this "blind spot," given the historical importance of chargeback data to Mallinckrodt's SOM efforts. Accordingly, in the Eleventh Reporting Period the Monitor Team asked Mallinckrodt to compile data regarding the sales for which it does ***not*** receive chargeback data, which the Monitor Team analyzed and discussed with Mallinckrodt and

its outside counsel in the Twelfth Reporting Period. The Monitor Team's observations from its review of that data and those discussions follow below.

ii. Sales of products to distributors for which Mallinckrodt did not receive chargeback data between June 2017 and June 2024, by all products and by Opioid Products

11.163 From July 2017 to June 2024, Mallinckrodt received chargeback data for approximately 93% of its sales of all products to distributor customers. Of the 7% of those total sales for which Mallinckrodt did not receive chargeback data, (1) 6.4% of sales were to distributors that provide chargeback data but did not submit chargeback requests for some products and (2) 0.6% of sales were to distributors that never submitted chargebacks requests at all. When considering ***just Opioid Product*** sales in that timeframe, the percentages were the same.

11.164 In compiling that data, Mallinckrodt did not identify any distributors that selectively submitted chargebacks for non-Opioid products ***but not Opioid Products***, a practice that a distributor could potentially employ strategically to avoid SOM detection. In other words, all of the distributors that purchased non-Opioid Products ***and*** Opioid Products submitted chargebacks ***for at least some portion of their purchases of Opioid Products.***

iii. Distributors that purchased Opioid Products but did not submit chargebacks

11.165 Mallinckrodt provided additional data regarding the above-referenced 0.6% of Opioid Product sales to distributors that did not submit chargebacks, breaking down the number of distributors that purchased Mallinckrodt's Opioid Products between June 2017 and June 2024. Specifically, Mallinckrodt informed the Monitor Team that it made direct sales of Opioid Products to a total of 165 unique distributor entities (identified by "ship to number" and excluding pharmacy chain central fill locations), and 154 of those distributors (*i.e.*, 93.3%)

submitted chargebacks during the same time period. In other words, 11 out of 165 distributors, or 6.7%, purchased Opioid Products but did not submit chargebacks. Mallinckrodt informed the Monitor Team that three of those 11 distributors only purchased Opioid Products, though only one of them is a current customer (the other two have not made any purchases since 2021).

11.166 Additionally, Mallinckrodt provided the Monitor Team with the list of those 11 distributors and the volume of their purchases of Opioid Products, by dosage units, over that seven-year time period. However, those 11 distributors were effectively only eight different distributors because Mallinckrodt's system reflected different "ship-to" locations for the same distributor.

11.167 The quantity of Mallinckrodt's sales of Opioid Products to each of those distributors revealed that the overwhelming majority of Mallinckrodt's sales of Opioid Products to distributors that never submitted chargeback requests were to one distributor—Distributor O. Distributor O purchased more than 152 million dosage units of Opioids, amounting to 97.3% of Mallinckrodt's sales to those eight distributors. The remaining seven of those distributors purchased relatively small quantities of Opioids, less than approximately 4.1 million dosage units of Opioids in total (with one distributor purchasing only 34 units). For context, in 2024, Mallinckrodt sold almost ***5 billion*** dosage units of Opioids. In other words, those seven distributors' purchases combined were less than 0.1% of Mallinckrodt's sales of Opioids.

11.168 Thus, not only were Mallinckrodt's sales of Opioids to this category of distributors a relatively small portion of its sales, (*i.e.*, 0.6%), almost all of those sales were to Distributor O, which was suspended in the Twelfth Reporting Period.

11.169 Nonetheless, Mallinckrodt does not receive chargeback data for any of those eight distributors' sales and, thus, has no visibility as to which downstream registrants purchase

Mallinckrodt's products from those distributors. As a result, Mallinckrodt has no way of monitoring those indirect customers. Moreover, those distributors may not have the same resources to monitor their own customers in the way the "Big Three" distributors do, making it all the more important that the CSC Team can independently monitor them.

11.170 For all of these reasons, even though Mallinckrodt receives chargeback data for 93% of its sales of Opioids, distributors that do not submit chargeback requests create some SOM risk for Mallinckrodt, and distributors that do not submit chargeback requests for all products compromise the CSC Team's ability to monitor indirect customers using chargeback data.

11.171 In the case of Distributor O, in the Twelfth Reporting Period Mallinckrodt suspended sales to Distributor O in January 2025 after conducting a due diligence visit in December 2024. During that visit, the CSC Team learned that Distributor O was not incorporating ARCOS data in its SOM program to the extent Mallinckrodt expects. Thus, Distributor O had been selling Mallinckrodt's Opioid Products to unknown indirect customers Mallinckrodt had no way of monitoring, and Distributor O was not monitoring its customers' purchases with the same level of scrutiny Mallinckrodt applies.

11.172 Likewise, during the Twelfth Reporting Period, Mallinckrodt learned that one of the "Big Three" distributors sold its products to another distributor, Distributor R. Mallinckrodt had no visibility into Distributor R's sales to other distributors, or to downstream registrants, absent chargeback data.

iv. The Working Group is considering how to solve the "blind spot" in chargeback data

11.173 Mallinckrodt's Working Group has been considering how to address the "blind spot" in chargeback data, including by utilizing other data sources, like 867 Data discussed *infra*

at 103 ¶ 11.180 – 105 ¶ 11.184, or by ***requiring*** every distributor to provide data that reflects its downstream sales and would therefore be substantially equivalent to the transactional information contained in chargeback data.

11.174 To be sure, there may be legitimate business reasons why distributors do not submit chargeback requests, or submit chargeback requests for some but not all products. However, given the significance of chargeback data, it seems that Mallinckrodt should at least attempt to reach contractual agreements with distributors that require them to provide the same data identifying the downstream registrant that purchased Mallinckrodt's product (and the quantities), even if they do not submit chargeback requests. Mallinckrodt's distributor customers already provide that information to Mallinckrodt for the vast majority of their purchases, and there is no apparent legal barrier or confidentiality concern preventing them from doing so. Indeed, distributors that submit chargeback requests for some, but not all products, should have no objection to providing such information. However, the Monitor recognizes that distributors' willingness to provide chargeback data is fundamentally financially motivated—*i.e.*, distributors only provide chargeback data to Mallinckrodt to obtain chargeback payments from Mallinckrodt. Thus, without the incentive of receiving money back from Mallinckrodt, distributors may be reluctant to voluntarily disclose sales information.

11.175 Nonetheless, based on at least two examples, distributors may be willing to agree to provide that information. Indeed, Mallinckrodt broached the issue of providing chargeback data to large Grocery Chain A that does not submit chargeback requests. After discussion, Grocery Chain A expressed an openness to providing transactional data substantially equivalent to chargeback data (assuming it is technically feasible), so Mallinckrodt could have visibility into its downstream sales. Mallinckrodt also broached the issue with Distributor O before its

suspension. Distributor O had been amenable to providing such information. Accordingly, the Monitor makes the recommendation below.

> ***New Recommendation 12(d). Use best efforts to negotiate with direct customers that do not submit chargeback requests for all of their controlled substances orders, in order to obtain chargeback data for every such purchase (or substantially equivalent transactional data to the data accompanying chargeback requests for those purchases).***

11.176 **The Monitor has observed that Mallinckrodt does not have the same visibility into a limited amount of its sales because of distributors that either (1) do not submit chargeback requests for all products, or (2) do not submit chargeback requests at all. To date, Mallinckrodt has not been able to identify another source of data to substitute for chargeback data. Given the importance of chargeback data to Mallinckrodt's SOM program, the Monitor recommends that Mallinckrodt use best efforts to negotiate with direct customers that do not submit chargeback requests for all of their controlled substances orders, in order to obtain such chargeback data (or its equivalent) for every purchase.** ***Mallinckrodt has agreed to implement this recommendation.***

11.177 Moreover, in the event Mallinckrodt is unable to obtain an agreement to provide such data from distributors that do not submit chargeback requests at all, the Monitor does not anticipate it would be particularly onerous for Mallinckrodt to conduct an initial due diligence visit of those distributors, with periodic follow-up visits, given the small number of them. Accordingly, the Monitor makes the recommendation below.

> ***New Recommendation 12(e). Conduct a due diligence visit for every direct customer that does not submit chargeback requests for controlled substances (or that does not provide substantially equivalent transactional data to the data accompanying chargeback requests for such substances), if the customer has not had a due diligence visit in the past three years, with periodic follow-up visits as appropriate.***

11.178 **Chargeback data is an integral part of Mallinckrodt's ability to monitor direct and indirect customers. Without that data, the CSC Team cannot identify the**

relationships between direct and indirect customers (among other things). The value of the CSC Team's ability to identify those downstream customer relationships has been demonstrated by its recent restriction of numerous distributors, including Distributor O, based on the CSC Team's restrictions of *those distributors' customers*. Given (1) that Mallinckrodt has not yet been able to identify an appropriate substitute for chargeback data, and (2) the small number of direct customers that purchase Opioid Products but do not submit chargeback data, the Monitor recommends Mallinckrodt conduct due diligence visits for customers that purchase controlled substances but not submit chargeback requests for those purchases to ensure each of those distributors' SOM program is sufficiently robust. Specifically, the Monitor recommends the CSC Team conduct a due diligence visit for every direct customer that does not submit chargeback requests for controlled substances (or provide substantially equivalent data), if the customer has not had a due diligence visit in the past three years, with periodic follow-up visits as appropriate. ***Mallinckrodt has agreed to implement this recommendation.***

11.179 The Monitor will continue to discuss these recommendations with Mallinckrodt in the next reporting period.

c. The Working Group believes that incorporating 867 Data into Mallinckrodt's SOM program would have limited utility

11.180 At the Monitor's request, the Working Group considered whether there is any additional marginal utility to incorporating the 867 Data Mallinckrodt receives into its SOM program in addition to chargeback data or, in the case of customers that do not submit chargeback requests, in lieu of chargeback data. The Monitor's request is part of the ongoing discussions between the Monitor Team and Mallinckrodt concerning whether there are other sources of data, like 867 Data, that could afford the CSC Team greater visibility into purchases

by indirect customers that buy Mallinckrodt's products through direct customers (*i.e.*, distributors) that either (1) do not submit chargeback requests, or (2) only sometimes submit chargeback requests for certain purchases.

11.181 867 Data refers to an "EDI 867 Product Transfer and Resale Report." The report is used to share detailed information about product inventory movements between manufacturers, distributors, and retailers, and tracks sales, returns, and other product transfers to help manage inventory and sales data.

11.182 Early in the monitorship, the Monitor Team raised with Mallinckrodt's CSC Team whether there was value in utilizing 867 Data, particularly because the Operating Injunction requires Mallinckrodt to make effective use of ***all*** reasonably available data sources.[45] In consultation with Analysis Group, Inc. ("AGI"), Mallinckrodt concluded that chargeback data remained the most useful source of information for SOM surveillance. *See* Fifth Monitor Report at 30 ¶ 11.22.

11.183 After revisiting the issue with AGI in the Twelfth Reporting Period, the Working Group's impression is that the 867 Data Mallinckrodt receives would not materially enhance Mallinckrodt's SOM program, and Mallinckrodt's outside counsel shared the basis for this view with the Monitor Team. The Working Group believes the 867 Data would not materially ameliorate Mallinckrodt's "blind spot" (for indirect customers whose distributors either do not submit chargeback requests at all or do not submit chargeback requests for particular products) because Mallinckrodt's lack of chargeback data often overlaps with its lack of 867 Data. For

[45] *See* Operating Injunction § G.1.a (requiring Mallinckrodt to "[u]tilize all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer"); *id.* § G.1.b (requiring Mallinckrodt to "[u]tilize all reasonably available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product").

example, the CSC Team identified seven distributor customers that did not submit chargeback data, each of whom also did not submit 867 Data. Thus, for those distributors, 867 Data could not fill the chargeback data "gap." The Monitor is satisfied with the Working Group's explanation as to the limited utility of the 867 Data Mallinckrodt receives.

11.184 Notwithstanding the Working Group's observations regarding the potential utility of incorporating the 867 Data Mallinckrodt receives into its SOM program, the Company is committed to exploring the incorporation of additional data to gain greater visibility into both direct and indirect customers' purchases, where feasible. To that end, the Working Group is currently considering ways to incorporate both additional data sources, and additional data from existing sources, into the indirect customer dashboard. The Monitor will provide an update on any of the Working Group's discussions about further enhancements to its SOM program in the next reporting period.

d. Extending to other distributors the contractual agreement Mallinckrodt has reached with certain distributors regarding reciprocal sharing of SOM-related intelligence and preventing supply of Mallinckrodt's products to restricted indirect customers

11.185 As the Monitor's prior reports reflect, the Monitor has long advocated Mallinckrodt's entry into contractual agreements with distributors to achieve improved compliance and reciprocal assistance on four issues—*i.e.*, obtaining distributors' agreement to: (1) respond timely to Mallinckrodt's due diligence requests; (2) submit timely chargeback requests; (3) terminate supply of Mallinckrodt's products to customers Mallinckrodt identifies as posing a diversion risk; and (4) inform Mallinckrodt of the distributors' restriction of downstream registrants.

11.186 Of course, this all requires the consent of parties over which neither Mallinckrodt, nor the Monitor, have control (but which, in some instances, are now under monitorships of their

own). Nonetheless, the Monitor recommended Mallinckrodt use best efforts to reach agreements with direct customers on various anti-diversion efforts, as reflected in Prior Recommendation 2(d). *See* Second Monitor Report at 28-29; 32-33.

11.187 As previously reported, Mallinckrodt has reached agreements on these or similar terms with certain parties. One of the "Big Three" distributors, Distributor E, signed a letter agreement with Mallinckrodt committing Distributor E to the four tasks addressed above. *See* Seventh Monitor Report at 23 ¶ 11.19. Mallinckrodt also entered into an agreement with Distributor C for certain branded products that Distributor C purchased. In practice, Distributor C applied the provisions contained in the contract for certain branded products to all of Distributor C's purchases, including purchases of generic Opioid Products. *See* Eleventh Monitor Report at 64 ¶¶ 11.99-100. Additionally, by oral agreement, Mallinckrodt obtained a list of customers from another distributor, Distributor A, that Distributor A had decided to restrict, following a due diligence visit with Distributor A in April 2023. *See* Eleventh Monitor Report at 65 ¶ 11.101. The Monitor remarked that, while laudable, it was not an ideal substitute for a long-term agreement, which has now been achieved. Distributor A has since entered into a contractual agreement with Mallinckrodt.[46]

11.188 During the Twelfth Reporting Period, Mallinckrodt advised the Monitor Team that it was able to secure agreements with additional distributors and two buying groups, Buying Group A and Buying Group B, each containing substantially similar provisions (with minor variations) to the agreements discussed above. *See supra* at 105 ¶ 11.185 – 106 ¶ 11.187.

[46] In the Twelfth Reporting Period, Mallinckrodt provided the Monitor Team with the contracts for Distributor A and Distributor D.

11.189 Regarding the agreements with Buying Group A and Buying Group B, because a buying group requires all of its members to abide by its contractual agreement with Mallinckrodt, Mallinckrodt is able to apply those provisions more broadly, *i.e.*, to multiple distributors, through one agreement. In the case of Buying Group B, Mallinckrodt's agreement applies to between 6 and 10 distributors. Although Mallinckrodt does not expect to receive additional contracts from Buying Group B, the Company plans to use reasonable efforts to get member agreements in place with the distributor customers that are members of that buying group. The Monitor will provide a further update on these additional contracts in the next reporting period, as appropriate.

11.190 The Monitor is satisfied with Mallinckrodt's progress in implementing Prior Recommendation 2(d) and obtaining the aforementioned agreements with various direct customers, and he will continue to monitor Mallinckrodt's efforts to reach such agreements with additional customers.

8. Other SOM-related Issues

a. Government communications log

11.191 The Operating Injunction requires Mallinckrodt to "provide full cooperation and assistance to any federal, state or local law enforcement investigations of potential diversion or suspicious circumstances involving Opioid Products." Operating Injunction § G ¶ 3. In assessing Mallinckrodt's compliance with the Operating Injunction's requirement to provide law enforcement assistance, the Monitor Team reviewed the entries in Mallinckrodt's government communications log ("Communications Log")[47] for the fourth quarter of 2024 and the first

[47] As previously reported, *see* Fifth Monitor Report at 34 ¶ 11.30 – 36 ¶ 11.33, the Audit Plan requires Mallinckrodt to produce the Communications Log the SOMT maintains under the

quarter of 2025, as well as related correspondence concerning inquiries that appear related to Opioid Products, excluding medications typically prescribed for addiction treatment.

11.192 Of the 52 government inquiries Mallinckrodt received in the fourth quarter of 2024, two related to Opioid Products and were from the DEA and the FDA. In each instance, Mallinckrodt provided a timely and appropriate response.

11.193 Of the 70 government inquiries Mallinckrodt received in the first quarter of 2025, eight related to Opioid Products and were from the DEA, the FDA, the U.S. Department of Justice, and a local police department. Mallinckrodt also received two inquiries related to restrictions of indirect customers from the DEA, which were responded to by phone. In each instance, Mallinckrodt provided a timely and appropriate response.

b. SOM-related TrackWise entries

11.194 Under the relevant SOP, certain categories of TrackWise inquiry and complaint logs (discussed *supra* at 10 ¶ 6.10 – 6.12) are escalated to the CSC and / or Security Departments, among others, as a matter of course. However, in the Sixth Monitor Report, the Monitor recommended that any evidence of diversion risks appearing in the TrackWise entries be escalated by the Associate General Counsel (or her designee) to the CSC Director for his review and included in SOMT pharmacy reviews, as appropriate (*see* Prior Recommendation 6(f)). Since Mallinckrodt implemented Prior Recommendation 6(f), the Associate General

SOM Program Review of Direct Customer Orders SOP, so the Monitor Team can review the government inquiries Mallinckrodt receives and its responses.

Counsel has not identified any TrackWise entries evidencing the potential risk for diversion that would necessitate the CSC Director's review outside of the ordinary escalation process.

11.195 In the Twelfth Reporting Period, the Monitor Team reviewed the TrackWise entries related to Opioid Products for the third and fourth quarters of 2024, including the complaints escalated to the CSC and / or Security Departments. As in prior reporting periods, the narratives suggest that any issues of diversion, such as retail pharmacy robbery, and of potential diversion, such as shipments temporarily lost in transit, were outside Mallinckrodt's control.[48] Nonetheless, those inquiries and complaints were documented in TrackWise and, when appropriate, investigated.

11.196 For example, TrackWise contained inquiries in the fourth quarter of 2024 from distributors and pharmacies reporting theft (*i.e.*, robberies of delivery drivers or pharmacies). The TrackWise entries indicated the reported theft was, or would be, documented internally, and in some instances, reported to the FDA. For complaints related to purported bottle shortages of more than ten tablets, suspect product tampering, or potential counterfeits, the TrackWise entries reflected that, even where limited information was provided, the complaints were escalated to management, including to the Security and CSC Departments, and the investigation of each complaint was completed. The Associate General Counsel confirmed those investigations did not indicate possible diversion by Mallinckrodt employees.

[48] One example, as noted elsewhere in this Report, *see infra* at 110 ¶ 11.197 – 112 ¶ 11.204, is the several FedEx shipments that were diverted from delivery after leaving Mallinckrodt's Hobart plant in the third quarter of 2024.

c. Diversion of Product Shipped from Hobart, New York Manufacturing Plant

11.197 During the Eleventh Reporting Period, Mallinckrodt's outside counsel shared with the Monitor Team that a substantial volume of product was shipped from Mallinckrodt's Hobart, New York manufacturing plant in multiple shipments that did not reach the ordering distributor, Distributor K. The ten shipments took place from on or about July 8, 2024 through on or about July 16, 2024. Mallinckrodt learned of the issue on or about July 22, 2024, after receiving communication from Distributor K that the shipments had not arrived, and reported the theft to the DEA the following morning.

11.198 According to the affidavit in support of a criminal complaint filed on October 18, 2024, the undelivered shipments included the following substances and quantities:

DRUG	DOSAGE UNITS
FENTANYL TTS 12MCG/HR	120
OXYCODONE HCL 30MG	28,800
OXYCODONE/APAP 10/325MG	7,200
OXYCODONE TABS 20MG	9,600
HYDROCODONE APAP 10/325MG	672,000
HYDROCODONE APAP 5/325MG	36,000
HYDROCODONE APAP 7.5/325MG	48,000
HYDROMORPHONE HCL 8MG	43,200
LISDEXAMFETAMINE l0MG CAPS	1,200
Total dosage units	**846,120**

11.199 The affidavit states that the purchase price of those shipments to Distributor K was approximately $100,000.

11.200 Mallinckrodt's outside counsel reported to the Monitor Team that Mallinckrodt cooperated with investigators from the DEA, in addition to conducting an internal investigation. Specifically, as part of its internal investigation, Mallinckrodt reviewed electronic records and

video recordings to confirm no Mallinckrodt employee had copied a shipment's tracking number in order to have the order diverted.

11.201 From its internal investigation and discussions with law enforcement, Mallinckrodt concluded that the source of the diversion was external to Mallinckrodt and Mallinckrodt's Hobart, New York facility. Communication with the shipping company revealed that no restriction on a change in shipment had previously been implemented, which permitted unauthorized individuals with the tracking number of the deliveries to simply call the commercial carrier and redirect the delivery of the shipments. Accordingly, Mallinckrodt requested that the carrier implement a change. The carrier agreed that, in the future, any change in shipment would need to be authorized by a limited number of Mallinckrodt employees, including either the CSC Director or the CSC Senior Manager.

11.202 Supporting Mallinckrodt's conclusion that the source of diversion was external to Mallinckrodt was the fact that the affidavit referenced above identifies another company that distributed controlled substances to Distributor K, and whose product was also intercepted and redirected.

11.203 At Mallinckrodt's suggestion, and in light of the ongoing investigation, the Monitor Team refrained from publicly reporting on this matter in the Eleventh Monitor Report. However, the Monitor Team apprised representatives of the State Attorneys General of the matter following submission of the Eleventh Monitor Report, as discussed below. *See infra* at 114 ¶ 11.210 – 115 ¶ 11.214.

11.204 Subsequent to the filing of the Eleventh Monitor Report, and the initial criminal complaint referenced above, Mallinckrodt learned of the federal indictment of a number of

individuals filed in the U.S. District Court for the Western District of Kentucky in connection with the diverted shipments.[49]

d. Update on grand jury subpoenas from the U.S. Attorney's Office for the Western District of Virginia

11.205 As reported since the Ninth Monitor Report, and as Mallinckrodt disclosed in prior SEC filings, Mallinckrodt received grand jury subpoenas in 2023—and has continued to receive additional subpoenas since—in connection with a federal criminal investigation by the U.S. Attorney's Office for the Western District of Virginia. *See, e.g.*, Eleventh Monitor Report at 76 ¶ 11.135 – 78 ¶ 11.139; Tenth Monitor Report at 92 ¶ 12.179 – 93 ¶ 12.182; Ninth Monitor Report at 49 ¶ 14.1 – 52 ¶ 14.8. As also noted in those Monitor Reports, Mallinckrodt and its outside counsel have kept the Monitor Team informed regarding Mallinckrodt's productions in response to the subpoenas, and have shared with the Monitor Team the cover letters related to those productions. *See* Eleventh Monitor Report at 76-77 ¶ 11.135; Tenth Monitor Report at 92 ¶ 12.179 – 93 ¶ 12.182; Ninth Monitor Report at 50 ¶ 14.3 – 52 ¶ 14.8.

11.206 In the Twelfth Reporting Period, the U.S. Attorney's Office for the Western District of Virginia issued additional subpoenas to Mallinckrodt LLC and SpecGx LLC. Certain of the subpoenas are similar to those on which the Monitor previously reported, in that they generally relate to purchases of products and transaction data related to those purchases by Mallinckrodt's direct customers from July 17, 2017 to the date of production. Other subpoenas

[49] *See United States v. Newman, et al*, Case No. 24-cr-00044-GNS, Dkt. No. 6 (W.D. Ky. Nov. 13, 2024) (indictment charging defendants with conspiracy to engage in theft of medical products, and two counts of conspiracy to distribute controlled substances). As of the writing of this Report, one of the defendants, Sarah Dauria, entered a guilty plea (on March 13, 2025) to one count of conspiracy to commit theft of medical products, in violation of 18 U.S.C. § 670(a)(6), and one count of conspiracy to distribute controlled substances, in violation of 21 U.S.C. § 846.

concern records of Mallinckrodt's internal SOM efforts and investigations, policies and procedures, and due diligence, some of which were requested from as early as 2012 to present. And, more recently, as disclosed in Mallinckrodt's recent 10-K filing with the SEC, Mallinckrodt received a subpoena relating to Pharmacy Benefit Managers ("PBMs"), which seeks, for the period of 1996 to the present, production of: (1) data and information relating to the remuneration provided to or rebates negotiated with PBMs; and (2) communications with PBMs regarding the prescription, administration, or safety or efficacy of Opioids.

11.207 As the Monitor previously reported, the U.S. Attorney's Office's issuance of additional grand jury subpoenas has introduced additional counsel to Mallinckrodt's conversations with the Monitor Team. *See* Eleventh Monitor Report at 77-78 ¶ 11.138. As of this Report, the presence of additional counsel has not interfered with the Monitor's work.

e. Update on grand jury subpoenas from the U.S. Attorney's Office for the Eastern District of Pennsylvania

11.208 As reported in the Eleventh Monitor Report, and as Mallinckrodt disclosed in prior SEC filings, on May 29, 2024, the U.S. Attorney's Office for the Eastern District of Pennsylvania issued a federal grand jury subpoena to SpecGX LLC relating to its controlled substances business. Mallinckrodt advised the Monitor Team of the receipt of this subpoena. Mallinckrodt also publicly disclosed the receipt of this subpoena in its filings with the SEC.[50] Eleventh Monitor Report at 78 ¶ 11.140 – 79 ¶ 11.142.

[50] The Monitor reports here on only grand jury subpoenas that Mallinckrodt has itself deemed to be material to its investors by virtue of Mallinckrodt's disclosure of the subpoenas in SEC filings. Among the reasons Mallinckrodt might not publicly disclose a subpoena is, for example, when it is clear to Mallinckrodt that it is receiving the subpoena in the capacity of a mere witness in the government's investigation of an unrelated party.

11.209 Mallinckrodt continues to report on this subpoena publicly in its SEC filings.[51] The Monitor Team will continue to review Mallinckrodt's cover letters associated with the productions to determine what aspects, if any, may be relevant to the focus of this monitorship.

f. Meetings with representatives of the State Attorneys General

11.210 During the Twelfth Reporting Period, the Monitor Team met twice, via Zoom, with representatives of the State Attorneys General, on December 4, 2024 and on April 17, 2025. Those meetings included combinations of representatives from the States of New York, North Carolina, Tennessee, Texas, and Wisconsin, and the Commonwealths of Kentucky and Pennsylvania.

11.211 At the December 4 meeting, the Monitor Team provided the representatives of the State Attorneys General additional context to the Monitor's statement in the Eleventh Monitor Report that the issuance of additional subpoenas from the U.S. Attorney's Office for the Western District of Virginia "introduced additional counsel to the conversations the Monitor Team has had with Mallinckrodt." *See* Eleventh Monitor Report at 77-78 ¶ 11.138.

11.212 The Monitor Team also advised the representatives of the State Attorneys General about the Hobart diversion, discussed elsewhere in this Report. *See supra* at 110 ¶ 11.197 – 112 ¶ 11.204. One representative inquired whether Mallinckrodt proactively implemented safeguards to ensure that diversion via carrier could not occur through other shipping services. The Monitor Team confirmed that FedEx is the only carrier Mallinckrodt uses to ship smaller quantities of controlled substances and such safeguards are in place. However, Mallinckrodt advised of one additional carrier that the Company uses to ship larger quantities of controlled substances, and

[51] Mallinckrodt's SEC filing are available on its website: https://mallinckrodt.com/investors/sec-filings/.

Mallinckrodt confirmed the ability to re-route shipments through that carrier is similarly restricted.

11.213 At the April 17 meeting, the Monitor Team provided the representatives of the State Attorneys General with an update on the recently-announced merger between Mallinckrodt and Endo, discussed elsewhere in this Report. *See infra* at 124 ¶ 15.1 – 127 ¶ 15.7.

11.214 In addition to discussing the merger, the Monitor Team provided the representatives of the State Attorneys General with a general overview of the various topics discussed in greater detail in this Report, including: (1) discussions with the new chair of the SGGSAC (*supra* at 14 ¶ 8.2 – 15 ¶ 8.7), the Senior Director of Regulatory Affairs (*supra* at 19 ¶ 8.16 – 22 ¶ 8.21), and Senior Vice President of Commercial & Strategy; (2) the exit interview of Mallinckrodt's former Vice President of Communications (*supra* at 11-12 ¶ 6.17); (3) ongoing interviews with the SOMT to discuss monthly meeting minutes and the Director of CSC Analytics' Annual Report (*supra* at 61 ¶ 11.78 – 87 ¶ 11.135); (4) discussions with other monitors (*infra* at 116 ¶ 11.218 – 117 ¶ 11.219); (5) Mallinckrodt's Working Group (*supra* at 88 ¶ 11.136 – 107 ¶ 11.190); and (6) grand jury subpoenas from the Western District of Virginia (*supra* at 112 ¶ 11.205 – 114 ¶ 11.209).

g. Internal audit reports related to DEA requirements for controlled substances

11.215 As previously reported, the CSC Specialist's job responsibilities include: (1) conducting various internal process reviews and audits at Mallinckrodt's Hobart plant to assess Mallinckrodt's compliance with DEA requirements;[52] and (2) preparing reports detailing her

[52] The DEA's requirements are often also incorporated into Mallinckrodt's internal policies.

findings. *See* Tenth Monitor Report at 91 ¶ 12.175; Seventh Monitor Report at 37 ¶ 11.63 – 39 ¶ 11.67. Under the Audit Plan, Mallinckrodt agreed to produce those reports.

11.216 In the Twelfth Reporting Period, the Monitor Team reviewed six reports the CSC Specialist prepared in 2024. As in prior reporting periods, those reports related to Mallinckrodt's recordkeeping obligations and its practices related to access to, and storage of, controlled substances. The reports generally detailed the purpose of the process review or audit and the CSC Specialist's observations.

11.217 Five of the six reports did not identify any necessary corrective actions. However, in the sixth report, the CSC Specialist indicated that corrective action was necessary to rectify two recordkeeping issues she observed in the Quality Control Lab. Specifically, the CSC Specialist found that certain pooled sample log books either: (1) did not indicate the unit of measure in kilogram or gram; or (2) a correction was made in the log book, but was unaccompanied by either a signature or date. The Monitor is satisfied that the necessary corrective action was taken promptly.

h. Discussions with Monitors of other Opioid manufacturers

11.218 The Monitor Team has continued to review reports published by, and to meet with, the Purdue Monitor. The Purdue Monitor's observations regarding Purdue and the industry more generally have been of interest, and help, to the Monitor in this monitorship. During the Twelfth Reporting Period, the Monitor Team reviewed the Purdue Monitor's findings in his Twentieth[53] and Twenty-First[54] Monitor Reports, and met with the Purdue Monitor. The Purdue

[53] *In re: Purdue Pharma L.P., et al.*, No. 19-23649, Dkt. 6922 (S. D. N.Y. Bankr., Nov. 15, 2024).

[54] *In re: Purdue Pharma L.P., et al.*, No. 19-23649, Dkt. 7202 (S. D. N.Y. Bankr., Feb. 13, 2025).

Monitor's observation in his Twenty-First Monitor Report regarding Purdue's exit interviews for departing employees is discussed in greater detail *infra* at 117 ¶ 11.220 – 118 ¶ 11.222. The Monitor Team intends to continue to meet with the Purdue Monitor and to review the Purdue Monitor Reports in the next reporting period, as appropriate.

11.219 Additionally, the Monitor Team met again with the monitor of Teva Pharmaceuticals, Ltd. ("Teva"), Gil Soffer (the "Teva Monitor"). However, the Monitor Team is not able to review the Teva Monitor's reports since they are not published publicly, and the Teva monitorship was at a relatively early stage at the time of the discussion.

i. Exit interviews of departing Mallinckrodt employees

11.220 During the Twelfth Reporting Period, the Monitor Team learned that Purdue not only provides the Purdue Monitor with information regarding employee departures (as Mallinckrodt does for the Monitor Team), but that Purdue also provides the Purdue Monitor with summaries of the exit interview surveys voluntarily completed by departing employees. Twenty-First Purdue Report at 23 ¶¶ 77-78.

11.221 Notably, the Purdue exit interview survey includes the following compliance-related questions:

(1) "Are you aware of any violations of Purdue policies or procedures by any employees or others affiliated with Purdue that have not been reported or addressed?"

(2) "Are you aware of any violations of law, or regulations, or any illegal or unethical activity by any employees or others affiliated with Purdue that have not been reported or addressed?"

(3) "Are you aware of any violations of the Voluntary Injunction, entered by the bankruptcy court in In re Purdue Pharma, by any employees or others affiliated with Purdue other than matters you know have been reported or addressed?"

(4) "Are you aware of any potential conflicts of interest involving any employees or others affiliated with Purdue other than matters you know have been reported or addressed?"

(5) "Do you have any suggestions or anything else to share regarding ethics and compliance?"

Id. at 23 ¶ 78.

11.222 The Monitor Team requested similar information from Mallinckrodt. The Monitor will provide an update on this issue in the Thirteenth Monitor Report.

j. Potential for establishing a "Clearinghouse" with other industry participants in the Opioid supply chain

11.223 The Monitor, since early in the monitorship, has expressed interest in the promise of a potential industry-wide data clearinghouse that would be accessible to all industry participants, and make SOM much more effective—and interest Mallinckrodt has shared. *See* Second Monitor Report at 35-37. With this in mind, the Monitor previously discussed a data analytics project using ARCOS data conducted at the John M. Olin School of Business at Washington University in St. Louis, Missouri. *See* Fourth Monitor Report at 34 ¶ 11.36 – 36 ¶ 11.39. As noted in the Fourth Monitor Report, Mallinckrodt was "following with interest academic research developments into the use of 'big data' analytics to enhance anti-diversion efforts." *See* Fourth Monitor Report at 35-36 ¶ 11.39.

11.224 In the Twelfth Reporting Period, the Monitor Team brought to the attention of Mallinckrodt and its outside counsel a report publishing the results of the Olin School's analysis.[55] The abstract from the Report states:

[55] *See* Seethu Seetharaman *et al*., *Tackling the US Opioid Crisis: Data-Driven Detection of Suspicious Retail Buyers* (Feb. 8, 2024) *available at* https://assets-eu.researchsquare.com/files/rs-3645248/v1_covered_c7ee8c08-ba9e-4003-90e6-b7f082a13e3e.pdf?c=1722608711 (last visited May 1, 2025).

> Our objective in this research is to assist the DEA's effort to stop opioid shipments from reaching those at risk. We propose an anomaly detection algorithm to identify suspicious retail buyers of opioids. We implement our algorithm on the ARCOS database—which tracks all opioid drug shipments across the US from 2006 to 2012. Our algorithm effectively identifies suspicious retail pharmacies and practitioners involved in drug diversion. It achieves 100% precision and 100% sensitivity, resulting in 100% F-1 score for retail pharmacies. For practitioners, while precision remains at 100%, sensitivity is 30%, leading to 46% F-1 score. By applying our algorithm, the DEA gains a powerful tool for promptly detecting suspicious retail buyers. This enables prevention of large opioid shipments by identifying potentially negligent or criminal drug retailers early. By doing so, we can safeguard vulnerable communities and save lives by ensuring that dangerous drugs do not easily reach them.

11.225 As the paper explains, regarding the method of research and analysis:

> In order to tackle the pernicious issue of illegal drug diversion by retailers, we propose a novel anomaly detection algorithm—Density-based Disjunctive Gamma / Beta (DDGB)—to detect suspicious retail buyer activity. What sets our DDGB algorithm apart from existing methods is its commitment to safeguarding patient privacy. DDGB operates without the need for prescription-level data from drug retailers or physicians. We analyze longitudinal buying patterns of retail buyers, in terms of how much of a given opioid drug each retail buyer orders from a given drug wholesaler at any given point in time.[56]

11.226 The Monitor Team requested that Mallinckrodt share the research with AGI, in light of AGI's involvement in the deliberations of Mallinckrodt's informal Working Group, discussed elsewhere in this Report. *See supra* at 88 ¶ 11.136 – 107 ¶ 11.190. The Monitor Team was interested to learn AGI's perspective on the Olin School research and methodology.

11.227 The Monitor Team learned that AGI had a number of criticisms of the paper. Among them, AGI noted that: (1) the research is not yet peer reviewed; (2) the data set researchers used to train the model was available in that degree of detail through 2019, but the

[56] *Id*. at 2.

level of detail available to registrants like Mallinckrodt is different today, making it difficult for Mallinckrodt to extrapolate from the study's findings; (3) the study gives weight to just approximately 42 pharmacies and 141 practitioners, when the relevant universe involves many tens of thousands of pharmacies, which could lead to improper weighting of the characteristics of that small set of pharmacies and practitioners; (4) the data set is old (covering the timeframe of 2006 through 2012), and therefore does not reflect current market realities, again making it difficult for Mallinckrodt to extrapolate from the study; and (5) the data set is limited to the 99th percentile rather than incorporating outliers, whereas Mallinckrodt's efforts are greatly focused upon outliers.

11.228 In sum, it seems that AGI attributes little value to the Olin study for Mallinckrodt's purposes. Of course, AGI's skilled experts are in the best position to evaluate the statistical methods the Olin study deploys. Therefore, the Monitor defers to Mallinckrodt, its counsel, and AGI, in determining whatever value the Olin study may have for Mallinckrodt. At the same time, the Monitor continues to encourage any and all efforts aimed at establishing an industry-wide data clearinghouse, and the use of big data analytics and machine learning to improve both Mallinckrodt's and industry-wide SOM efforts.

k. DOJ Complaints against CVS and Walgreens

11.229 As noted in the Eighth Monitor Report, the Monitor has previously discussed with Mallinckrodt various complaints filed against distributors or retail pharmacy chains, including Amerisource Bergen (now known as Cencora) and Rite Aid. *See* Eighth Monitor Report at 54 ¶ 11.77 – 61 ¶ 11.91 (discussing U.S. Department of Justice complaints against Amerisource Bergen and Rite Aid).

11.230 In December 2024, the U.S. Department of Justice filed a nationwide lawsuit against CVS Pharmacy, Inc. and its subsidiaries ("CVS") in the U.S. District Court for the

District of Rhode Island. *See United States v. CVS Pharmacy, Inc.*, No. 22-cv-222-WES-PAS (D. R. I.) ("CVS Litigation").

11.231 The Monitor Team provided the complaint in the CVS Litigation to Mallinckrodt and its counsel to determine which, if any, of the CVS pharmacies referenced in the CVS Litigation were supplied (and subsequently restricted) by Mallinckrodt. The CSC Team was able to identify 43 CVS pharmacies that purchased Mallinckrodt product. The Monitor Team also interviewed the CSC Director about the CVS Litigation. In response, Mallinckrodt's counsel informed the Monitor that the CSC Team reviewed the complaint with a focus on prescriber trends. The CSC Director reported that the complaint's allegations described information about pharmacy-specific dispensing from certain prescribers—information that is not available to Mallinckrodt. In addition, because the events occurred before 2017, they are no longer actionable even if Mallinckrodt had the data to analyze them. The Monitor is satisfied with Mallinckrodt's review of the CVS Litigation.

XII. TRAINING (OI § III.K)

12.1 Mallinckrodt's training obligations under the Operating Injunction and the components of its new employee training program are generally described in the Monitor's prior reports. *See, e.g.*, Eleventh Monitor Report at 80 ¶ 12.4 – 83 ¶ 12.14; Fifth Monitor Report at 42 ¶ 12.1 and 43-44 ¶ 12.6; Fourth Monitor Report at 49 ¶ 13.1.

12.2 During the Twelfth Reporting Period, the Monitor audited Mallinckrodt's compliance with the Operating Injunction's training requirements by: (1) confirming whether all new employees[57] identified in the prior reporting period completed all required training

[57] New employees include both external and internal hires who are required to complete the Operating Injunction training.

components; (2) reviewing whether all relevant employees hired during the fourth quarter of 2024 and first quarter of 2025 completed the interactive Operating Injunction online training module and board service survey; and (3) discussing the initial feedback to the new interactive training module with relevant employees.

1. Completion of Training by Employees Hired in the Third Quarter of 2024

12.3 Mallinckrodt confirmed that the five employees hired in the third quarter of 2024 who had not yet completed all training requirements at the time of the Eleventh Monitor Report, *see* Eleventh Monitor Report at 81 ¶ 12.6, subsequently completed their Operating Injunction training requirements during the fourth quarter of 2024.

2. New Employee Trainings in the Fourth Quarter of 2024 and the First Quarter of 2025

12.4 In the Twelfth Reporting Period, Mallinckrodt identified 13 new employees hired in the fourth quarter of 2024 who were required to receive Operating Injunction training. All 13 of the new employees completed the online Operating Injunction training module during the fourth quarter of 2024, and all but two of the new employees completed the board service survey. The remaining two employees completed their board service surveys in the first quarter of 2025.

12.5 As for the first quarter of 2025, Mallinckrodt identified eight new employees who were required to receive Operating Injunction training. All eight of the new employees completed the online training module and board service survey.

3. New Interactive Online Operating Injunction Training Module

12.6 In the Tenth Reporting Period, Mallinckrodt launched the new interactive Operating Injunction online training module created by its third-party vendor. The Monitor

discussed the components of the new training module in the Eleventh Monitor Report. *See* Eleventh Monitor Report at 80 ¶ 12.4 – 83 ¶ 12.14.

12.7 During the Twelfth Reporting Period, the Monitor Team asked several employees for their impressions of the new interactive training module while conducting interviews related to other topics. By way of example, the Senior Director, Integrity & Compliance explained that she had a "heavy hand" in creating the training module, and thought it had been very well received by Company employees because it was "clear cut" and "easy to digest." The Senior Director of Regulatory Affairs initially could not recall partaking in the interactive training because she is frequently involved in trainings, but after prompting by the Monitor Team, she recalled completing it and expressed that she felt Mallinckrodt "does a really good job with training" by providing examples and walking through the rationale for certain provisions and restrictions.

12.8 The Monitor Team also noted that all employees hired during the fourth quarter of 2024 and the first quarter of 2025 had completed the online training module prior to Mallinckrodt's quarterly disclosure to the Monitor Team, which may indicate that the new training is more efficient, given that it does not depend on scheduling live training sessions.

XIII. 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 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 of the Operating Injunction is available through that

platform.[58] *See* First Monitor Report at 17 ¶ 64. 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, Mallinckrodt confirmed there were no requests for access to this clinical data during the fourth quarter of 2024 or the first quarter of 2025.

13.4 Likewise, there were no new Mallinckrodt Opioid Products, or indications for existing products, in the fourth quarter of 2024 or the first quarter of 2025.

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

XIV. 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). Mallinckrodt complied with this requirement as described in prior Monitor Reports. *See, e.g.*, Sixth Monitor Report at 69 ¶ 14.1 – 70 ¶ 14.5. There are no further updates at this time.

XV. THE PLANNED MERGER OF MALLINCKRODT PLC AND ENDO

15.1 As noted above, on March 13, 2025, the President and Chief Executive Officer of Mallinckrodt plc (Sigurdur "Siggi" Olafsson), and the Interim Chief Executive Officer of Endo (Scott Hirsch) held a joint call with investors to announce the planned merger of Mallinckrodt and Endo.[59] As stated in that call, the companies envision that "Mallinckrodt will be the holding

[58] Additional information regarding Mallinckrodt's clinical data archive is available at https://vivli.org/ourmember/specgx-llc-a-subsidiary-of-mallinckrodt-plc/ (last visited May 1, 2025).

[59] *See* Mallinckrodt and Endo Q4 2024 Earnings and Joint Transaction Call Transcript (Mar. 13, 2025) (hereafter "Earnings Transcript"), *available at* https://mallinckrodt.gcs-

company for the combined business, and Endo will become a wholly owned subsidiary of Mallinckrodt."[60] Mr. Olafsson will serve as the President and CEO of the combined entity. According to the announcement, "[t]he transaction has been approved by the Boards of both companies and is expected to close in the second half of 2025, subject to approval by shareholders of both companies, regulatory approvals and customary closing conditions."[61] The announcement further noted that Dublin, Ireland, would be the headquarters of the new combined company, with the U.S. headquarters to be announced at a later date.

15.2 As described, the transaction is intended to proceed in two stages: (1) in the first stage, Mallinckrodt and Endo will combine, and the combined company will develop a branded business and a separate sterile injectables and generics business; and (2) in the second stage, the combined company will separate the sterile injectables and generics business from the combined company.[62] Precisely what this separation means for the SpecGx business that has been the focus of this monitorship remains to be seen. As of the date of this Report, no additional information regarding the post-closing treatment of the generics business has been made available to the public.

15.3 Both CEOs also referenced compliance, but without explicitly referring to the monitorships under which both Endo and Mallinckrodt have been subject. Specifically, Mr.

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web.com/static-files/027a0b69-8517-492c-926d-137fb17edfe6 (last visited May 1, 2025). The slide presentation accompanying the conference call is available at the Investor Relations section of Mallinckrodt's website. *See* Creating a Global, Scaled, Diversified Pharmaceuticals Leader (Mar. 13, 2025) (hereafter, "Combination Presentation"), *available at* https://mallinckrodt.gcs-web.com/static-files/01d8a5d6-2c13-41b3-8e97-0d822dda3acb (last visited May 1, 2025).

[60] *See* Earnings Transcript at 3.

[61] *Id*.

[62] *Id*. *See also* Combination Presentation at Slide 6.

Olafsson stated "[t]he combined sterile injectables and generics business will also be poised for success, with a complementary product portfolio, leading controlled substances franchise, robust commercial and manufacturing infrastructure, extensive supply chain capabilities and strong compliance culture."[63] Similarly, Mr. Hirsch stated the respective Mallinckrodt and Endo teams have "deep expertise in complex, highly regulated products, and share a strong commitment to quality and compliance that will underpin all operations."[64]

15.4 As relevant to the topic of post-monitorship planning discussed below, *see infra* 128 ¶ 16.1 – 130 ¶ 16.8, the Monitor notes that the timing of the proposed merger is likely to overlap with the anticipated completion of the monitorship in October 2025.[65] The Monitor's view is that the Operating Injunction's post-monitorship provisions will remain in force, given the Operating Injunction's attention to the "successor liability" of any corporate "descendant" of Mallinckrodt. Specifically, the Operating Injunction defines "Mallinckrodt," in relevant part, as "Mallinckrodt Enterprises LLC, Mallinckrodt LLC, and SpecGX LLC, and each of their ***current and former subsidiaries, predecessors, successors, joint ventures, divisions and assigns.***" Operating Injunction § I.M (emphasis added).

[63] Earnings Transcript at 3.

[64] *Id*.

[65] The Operating Injunction contemplates a five-year monitorship term, beginning with the Petition Date, which was on October 12, 2020. *See* OI II.E.3 (noting that, barring "justifiable cause" for continuing the monitorship, "[t]he provisions of Section VI ("Independent Monitor") shall apply for five years from the Petition Date"). However, other provisions of the Operating Injunction continue after the monitorship concludes—some indefinitely, and some for 8 years after the Petition Date. *See id.* § II.E.2 (identifying OI provision that "shall not be subject to any term."); *id.* § II.E.1 ("Unless addressed in Section II.E.2–3, each provision of this Agreement shall apply for 8 years from the Petition Date.").

15.5 A representative of the State Attorneys General inquired of the Monitor Team how Mallinckrodt views its obligations under the Operating Injunction post-merger, and requested that Mallinckrodt memorialize its position. The Monitor Team referred the representative to the following statement in Mallinckrodt's March 2025 10-K, where the Company represented: "The obligations imposed by the Operating Injunction would apply to the operation of Mallinckrodt's opioid business by any subsequent purchaser."[66] Although the combination may not be a "purchase," the sentiment is the same and Mallinckrodt's post-monitorship commitment has been made clear by Mallinckrodt, as noted below.

15.6 More broadly, the representative queried, at a high level, how the terms of the Operating Injunction would apply to the successor entity, and if the stricter terms of the Operating Injunction would prevail over the comparably less strict terms of Endo's operating injunction. Mallinckrodt's outside counsel confirmed that if Endo's products are absorbed by Mallinckrodt's successor entity, then the stricter terms of the Mallinckrodt Operating Injunction would apply. On the other hand, given the stated intention to "spin off" the generics Opioid business, it is conceivable that some of Endo's products would not be subject to the Mallinckrodt Operating Injunction, and any Mallinckrodt entity that has no Opioid products post-merger would similarly not be subject to the Operating Injunction's terms.

15.7 In sum, there appears to be agreement between counsel for Mallinckrodt and representatives of the State Attorneys General, who each similarly interpret the Operating Injunction as having continuing obligations for any successor entity resulting from the Mallinckrodt-Endo merger that represents a continuation of the MNK Opioid business.

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[66] *See* Mallinckrodt plc Form 10-K for Year Ended December 27, 2024, filed with the SEC (Mar. 2025) (hereafter, "March 2025 10-K") at 37, *available at* https://mallinckrodt.gcs-web.com/static-files/f90bf943-4912-4de1-bb73-d3c2a434da3b (last visited May 3, 2025).

XVI. PLANNING FOR THE CONCLUSION OF THE MONITORSHIP

16.1 In the Twelfth Reporting Period, the Monitor Team continued to discuss with Mallinckrodt and its outside counsel preparations for the "day after" the conclusion of the monitorship, which is scheduled to conclude five years from the Petition Date in Mallinckrodt's bankruptcy—*i.e.*, on or about October 12, 2025 (assuming no extension of the monitorship).[67] Among the suggestions the Monitor Team has offered are: (1) convening an inter-company SOM working group with other industry participants to meet on a regular basis to exchange best practices; (2) creating an internal audit function to act as an in-house "monitor" capable of continuing the pressure-testing and verification the Monitor has undertaken in the course of this monitorship; and (3) continuing to review relevant policies, Work Instructions, and trainings across all relevant departments for compliance with those provisions of the Operating Injunction that will remain in effect after the monitorship concludes. These ideas are discussed below.

a. Convening an industry SOM working group

16.2 As noted elsewhere in this Report, *see supra* at 116-17 ¶ 11.218, and as previously reported, *see* Tenth Monitor Report at 84 ¶ 12.154 – 87 ¶ 12.158, the Monitor Team has benefitted from exchanges with the Purdue Monitor and believes this has been mutually beneficial to the Purdue Monitor as well. Accordingly, the Monitor Team suggested to Mallinckrodt and its outside counsel that convening an inter-company SOM working group, to include Mallinckrodt's SOMT and its counterparts at other manufacturers and distributors, would be a helpful way to ensure continued learning on a regular (*e.g.*, quarterly) basis to exchange best practices and SOM intelligence.

[67] Since the monitorship is scheduled to conclude on October 12, 2025, before the Monitor's next report is due on November 15, 2025 (*i.e.*, 180 days from May 19, 2025), the Monitor anticipates publishing his final report on October 12, 2025.

16.3 Mallinckrodt has expressed some reservations regarding this suggestion, without ruling out entirely the possibility of such an exchange. Mallinckrodt and its counsel have noted certain legal risks from such cooperation. For example, they recalled criticism of a similar working group that was alleged to have engaged in collusion among opioid companies as a contributing cause to the opioid crisis. Although the Monitor could imagine ways to mitigate these risks—such as by including legal counsel from the various companies in such meetings to reduce, for example, potential antitrust concerns—the Monitor recognizes the complexity and sensitivity, and defers to Mallinckrodt as to how it may wish to proceed in this regard, if at all.

b. Creating an internal audit function

16.4 In the absence of the Monitor Team, Mallinckrodt would continue to benefit from independent review and oversight of the subject areas the Operating Injunction addresses. For example, the Monitor Team suggested to Mallinckrodt and its outside counsel that Mallinckrodt create an independent audit function that could continue to probe, analyze, and verify the SOMT's continued adherence to strict compliance requirements, building upon the work of the Monitor Team, and monitoring the continued implementation of the Monitor's recommendations. For example, some representative members of the informal Working Group Mallinckrodt has convened would be sufficiently knowledgeable and experienced to form an internal SOM audit group.

16.5 The Monitor Team will continue to explore this possibility with Mallinckrodt in the next reporting period.

c. Continuing the review of policies, Work Instructions, and trainings for compliance with those provisions of the Operating Injunction that will remain in effect post-monitorship

16.6 Many of the Operating Injunction's provisions, such as the "Ban on Promotion" and "Monitoring and Reporting of Direct and Downstream Customers," are not subject to any

term, while others apply for eight years after the Petition Date. Operating Injunction § II.1-2. Thus, even after the monitorship ends, Mallinckrodt must still operate its Opioid Business in compliance with these aspects of the Operating Injunction. While Mallinckrodt conducted a review of at least some of its policies once the Operating Injunction became effective in order to identify polices that may have been impacted by the Operating Injunction, including policies related to SOM, and Mallinckrodt has continued to review and revise policies throughout the monitorship, including at the Monitor's request, the Monitor is not satisfied that Mallinckrodt had undertaken a comprehensive audit of its policies, Work Instructions, and trainings for all relevant departments to ensure they are in compliance with the Operating Injunction and include appropriate references to the Operating Injunction, based on the information received from Mallinckrodt to date.

16.7 Moreover, there will be a continued need for such review. For example, the polices that were revised to include references to the "Monitor" will need to be updated once the monitorship ends.

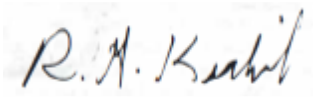
16.8 Accordingly, in the next reporting period, the Monitor will discuss with Mallinckrodt what, if any, work must be undertaken to ensure the Operating Injunction's provisions are appropriately incorporated into those materials and references to the Monitor are updated once the monitorship ends.

XVII. CONCLUSION

17.1 Based upon the Monitor's work to date, Mallinckrodt continues to provide helpful assistance to the Monitor in the exercise of his duties and, in the Monitor's view, is in compliance with the Operating Injunction.

* * *

17.2 Wherefore, the undersigned Monitor respectfully submits this Twelfth Monitor Report.



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

EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE TWELFTH MONITOR REPORT DATED MAY 19, 2024[1])

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)			Implementation Status
1.	**2(a)**	Modernize and enhance the SOM function using big data analytics, artificial intelligence, and automated processes and algorithms.	Implemented
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.	Implemented
3.	**2(c)**	Consider the sufficiency of both short-term and long-term human resource allocation in the SOM function.	Implemented and Ongoing
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.	Implemented and Ongoing
5.	**2(e)**	Use best efforts to obtain timely provision of chargeback data from direct customers.	Implemented and Ongoing

[1] This summary of the status of Mallinckrodt's implementation of the Monitor's recommendations is attached for convenient reference, and should be read in the context of the more fulsome discussion provided in the Reports that have addressed these recommendations to date.

6.	**2(f)**	Evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data.	Implemented
7.	**2(g)**	After analyzing turnaround times for chargeback reviews and restrictions, amend relevant SOPs to memorialize firm timelines.	Implemented
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.	Implemented and Ongoing
9.	**2(i)**	Assess the potential value of additional factors to consider in conducting chargeback reviews.	Implemented
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.	In Progress
11.	**2(k)**	Amend relevant SOPs to create a chargeback review task checklist, provide an audit trial, and ensure second-level review and approval.	Implemented
12.	**2(l)**	Memorialize and routinize the periodic review of (1) pharmacies reviewed but not restricted, and (2) pharmacies that are reinstated.	Implemented
13.	**2(m)**	Re-evaluate direct customer order thresholds with the assistance of Analysis Group, Inc. (AGI).	Implemented
14.	**2(n)**	Re-evaluate chargeback thresholds with the assistance of AGI.	Implemented
15.	**2(o)**	Determine whether flagging and releasing direct customer orders can be refined to better identify potentially suspicious orders, in collaboration with AGI.	Implemented
16.	**2(p)**	Implement two-level review and approval for release of flagged orders.	Implemented
17.	**2(q)**	Memorialize the confidentiality of thresholds, consistent with current practice.	Implemented
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.	Implemented (As Later Modified)

19.	**2(s)**	Revise direct customer questionnaires to yield helpful, actionable, and verifiable information and determine a method for sampling or randomly auditing questionnaires.	Implemented
20.	**2(t)**	Establish regularly scheduled interactions with direct customers.	Implemented
21.	**2(u)**	Explore options for making media review more effective.	Implemented

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

Section 6 – Ban on Promotion (OI § III.A)			**Implementation Status**
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.	Implemented
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.	Implemented
24.	**3(c)**	Implement a process by which Mallinckrodt reviews and audits its external lobbyists' public disclosures to ensure these reports accurately reflect the lobbyists' communications with Mallinckrodt and the company's stated priorities.	Implemented

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

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
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.	Implemented
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.	Implemented

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

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

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

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
29.	**6(a)**	Include explicit references to the Operating Injunction in Sales Compensation Plans for future years.	Implemented

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.	Implemented
31.	**6(c)**	Ensure greater consistency among direct customer audit reports, and more fulsome follow-up where necessary to obtain compliance assurances.	Implemented
32.	**6(d)**	Share with the SOMT, before each monthly meeting, CSC Director's separate tracking list of pharmacies pending due diligence review to ensure tabled pharmacies do not evade future review.	Implemented
33.	**6(e)**	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.	Implemented and Ongoing
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.	Implemented

VII. EIGHTH MONITOR REPORT (5/30/2023)

Section 9 – Lobbying Restrictions (OI § III.D)			**Implementation Status**
35.	**8(a)**	Provide annual training to Mallinckrodt's external lobbyists, focusing on the Operating Injunction's lobbying-related provisions.	Implemented

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			
36.	**8(b)**	Determine an appropriate statistically defensible marker for the ranking and prioritization of chargeback reviews, so as to determine which, if any, flagged pharmacies present the lowest risk of diversion and therefore may not warrant review.	Mooted by Present Practice[2]

VIII. TENTH MONITOR REPORT (5/24/2024)

Section 9 – Ban on Funding / Grants to Third Parties (OI § III.C)			**Implementation Status**
37.	**10(a)**	Revise the Specialty Generics Grant and Sponsorship Approval Committee standard operating procedure and related documents to formalize its requirements around the timeliness of funding requests and the payment of deposits.	Implemented
Section 12 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			
38.	**10(b)**	Require every distributor customer to provide a brief written description of its SOM program with its completed questionnaire, consistent with the questionnaire's request.	Implemented
39.	**10(c)**	Establish a defined endpoint (allowing for appropriate exceptions) by which Mallinckrodt will generally resolve open-ended due diligence requests to direct customers if Mallinckrodt does not receive timely responses to such due diligence requests, and memorialize this change in an applicable SOP.	Implemented

[2] As discussed at an earlier stage in the monitorship, *see* Eighth Monitor Report at 42 ¶ 11.42 – 44 ¶ 11.44, members of the SOMT were not completing a review of all "flagged" pharmacies, which led to this recommendation. Mallinckrodt's counsel advised the Monitor Team in the Twelfth Reporting Period that members of the SOMT, as of April 2025, had been able to review 100 percent of all flagged pharmacies as a result of additional hires. Consequently, Mallinckrodt feels there is no need for further enhancement.

IX. ELEVENTH MONITOR REPORT (11/20/2024)

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
40.	**11(a)**	Revise every customer questionnaire to ask whether any supplier has previously (1) requested the customer undertake SOM-compliance reforms or (2) suspended sales to the customer, and request further information from the customer as appropriate.	Implemented

X. TWELFTH MONITOR REPORT (5/19/2025)

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
41.	**12(a)**	Ensure the SOMT minutes (a) better reflect the SOMT's analysis by providing greater support and context for the decisions of the CSC Director and SOMT, and (b) are reviewed carefully to ensure the minutes reflect an accurate historical record of the SOMT's decisions and reasoning for future reference.	In Progress
42.	**12(b)**	Adopt a defined time for reporting suspended direct customers and restricted indirect customers to the DEA.	In Progress
43.	**12(c)**	Ensure the Director of CSC Analytics (with assistance if needed) undertakes an annual analysis to determine what findings from the Annual Report may be applied to enhance Mallinckrodt's SOM program.	In Progress
44.	**12(d)**	Use best efforts to negotiate with direct customers that do not submit chargeback requests for all of their controlled substances orders, in order to obtain chargeback data for every such purchase (or substantially equivalent transactional data to the data accompanying chargeback requests for those purchases).	In Progress
45.	**12(e)**	Conduct a due diligence visit for every direct customer that does not submit chargeback requests for controlled substances (or that does not provide substantially equivalent transactional data to	In Progress

		the data accompanying chargeback requests for such substances), if the customer has not had a due diligence visit in the past three years, with periodic follow-up visits as appropriate.	