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

November 20, 2024

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ELEVENTH 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 Eleventh Monitor Report covers the period from the filing of the Tenth Monitor Report on May 24, 2024, to the present (the "Eleventh Reporting Period").[1] The Eleventh 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 Eleventh 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 one new recommendation; and (5) describes anticipated next steps in future reporting periods.

1.2 During the Eleventh 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, and by conducting interviews. In response to the Audit Plan and the Monitor's ad hoc requests, during

[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 needed"). *See* Fourth Monitor Report at 2 ¶ 1.3.

the Eleventh Reporting Period Mallinckrodt provided approximately 920 files (consisting of approximately 1.29 GB of documents and data).

1.3 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**.

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

* * *

1.5 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.

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.

[3] *See* Mallinckrodt's "Corporate Compliance" webpage, *available at* https://www.mallinckrodt.com/corporate-sustainability/corporate-compliance/ (last visited October 31, 2024) (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 are in agreement that the Bankruptcy Court retains jurisdiction to adjudicate disputes the Settling States may bring related to enforcement of, or disputes concerning, the Operating Injunction if the states have not obtained a state court order enforcing the injunctive terms.

[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.

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 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]

[5] As noted above, *supra* at 2 ¶ 1.4 n.3, the Sixth Monitor Report and subsequent reports were not filed with the Bankruptcy Court, but are available on the Mallinckrodt website.

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.

IV. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Section 11, the Monitor has made one new recommendation related to the Operating Injunction's requirement to monitor and report direct and downstream customers. Mallinckrodt has agreed to implement this recommendation,[6] which is that Mallinckrodt should:

> 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.

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.

[6] This recommendation is prefaced by the number "11" to indicate it was made in the Eleventh Monitor Report.

5.2 Mallinckrodt performs quarterly tests of the Integrity Hotline to ensure any reports with the issue type "Operating Injunction" are received by the Monitor Team. *See* Tenth Monitor Report at 6 ¶ 5.2. During the Eleventh Reporting Period, Mallinckrodt conducted Integrity Hotline tests in the second and third quarters of 2024. 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.

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. As it has done in prior Reporting Periods, in order to ensure that Mallinckrodt is complying with these prohibitions, the Monitor Team reviewed materials that Mallinckrodt intended to use for presentations and new product launches, as well as materials that Mallinckrodt intended to use at conferences. In addition, the Monitor Team reviewed information pertaining to certain Mallinckrodt employees' attendance at conferences, customer inquiries and complaints, and Mallinckrodt's website and social media accounts.

1. The Monitor Team's Review of Materials and Information Provided by Mallinckrodt's Promotional Review Committee

6.2 Mallinckrodt's Promotional Review Committee ("PRC") reviews and approves new and existing promotional materials for, among other things, compliance with the Operating

Injunction. *See* Mallinckrodt Compliance Report, Adv. Pro. No. 20-50850, Dkt. No. 174-1 (Bankr. D. Del.) (hereafter, "Mallinckrodt Compliance Report") § 4.6.

6.3 Beginning in the Fourth Reporting Period, and on an ongoing quarterly basis as part of the Audit Plan, the Monitor has received PRC meeting minutes and promotional materials submitted to and approved by the PRC.

6.4 During the second quarter of 2024, the PRC met three times. On April 19, 2024, an ad hoc committee of the PRC met by email to review two launch announcements—the first was a template for announcements of different products, and the second was a customer notification for the launch of Lubiprostone, a generic version of the Amitiza® product. The PRC discussed the uses of the announcements and the need for additional review of the template by the relevant subject matter experts before it is used. Mallinckrodt provided copies of the announcements for the Monitor Team's review. The Monitor Team had no concerns regarding these materials.

6.5 On May 9, 2024, the PRC met for the second time by videoconference to review an addiction-treatment slide deck template to be used at the American Association for the Treatment of Opioid Dependence, Inc. conference, at which members of the Company's addiction-treatment team would be meeting with customers, and thereafter for other purposes. The slide deck contains information pertaining to the Company's products for medication-assisted treatment of opioid use disorder. The PRC members present at the meeting discussed the intended uses of the slide deck, updating the content for specific customers, revising or removing language appearing on one of the slides, and scheduling a review of the template every six months. Mallinckrodt provided the template to the Monitor Team for its review. The Monitor Team had no concerns regarding the template.

6.6 The PRC met by videoconference again on May 29, 2024, and submitted emails regarding their discussion over the following two business days. The purpose of the meeting was to review a presentation regarding anticipated shortages of controlled substances due to (1) the Drug Enforcement Administration's ("DEA") new quota policy, discussed *infra* at 73-74 ¶ 11.128, and (2) market consolidation resulting from manufacturers exiting the market during the period of July 2022 to April 2024. Mallinckrodt intends to use the presentation as a template for meetings with customers to provide detail regarding the Company's market share for particular controlled substances as opposed to that of other manufacturers. Mallinckrodt provided a copy of the presentation to the Monitor Team for its review. The Monitor Team had no concerns regarding the presentation.

6.7 During the third quarter of 2024, the PRC met once, on August 29, 2024, and had further discussions by email on September 5 and September 6, 2024. During the August 29 meeting, the PRC reviewed the artwork and related materials for the CPhI Worldwide Conference, which was held on October 8-10, 2024 in Milan, Italy. As has been previously noted, *see* Fifth Monitor Report at 14 ¶ 8.5, the CPhI Worldwide Conference is a large global pharmaceutical trade show held annually in Europe, which attracts companies from across the industry. Mallinckrodt provided samples of the artwork and related materials, along with the meeting minutes reflecting the PRC's discussion of those materials, to the Monitor Team for its review. The Monitor Team had no concerns regarding the artwork or the related materials.

6.8 At that meeting, the PRC also discussed a retractable banner intended to be used at events such as the CPhI Worldwide Conference as well as at Mallinckrodt's different locations. The banner highlights each of those locations with photographs and brief descriptions,

and includes a QR code that, when scanned, leads to the SpecGx page on Mallinckrodt's website. The Monitor Team reviewed the banner and had no concerns.

2. The Monitor Team's Review of Information Pertaining to Conference Attendance by Mallinckrodt's Employees

6.9 As in prior reporting periods, *see, e.g.*, Tenth Monitor Report at 10-11 ¶ 7.10; 28 ¶ 10.12, the Monitor Team inquired of Mallinckrodt whether any members of its Government Affairs Team had attended any conferences, meetings, or gatherings of state or federal legislators or officials during the Eleventh Reporting Period, and, if so, whether any of those Mallinckrodt employees received any inquiries from, or had any interactions with, other attendees relating to Opioid Products. In response, Mallinckrodt informed the Monitor Team that members of the Government Affairs Team had attended such conferences and meetings but did not have any discussions about the Operating Injunction or any topic prohibited by its restrictions; the discussions concerned, amongst other things, addiction treatment, onshoring of manufacturing, and economic development projects.

6.10 Mallinckrodt's Specialty Generics Grant and Sponsorship Approval Committee ("SGGSAC" or the "Committee") is the committee tasked with reviewing and approving funding for conference sponsorships and employee attendance at these sponsored conferences, *see infra* at 13-14 ¶ 8.2. In reviewing the SGGSAC's meeting minutes and materials for the second quarter of 2024, the Monitor Team learned that Mallinckrodt's employees occasionally take notes while attending these events, which are then occasionally circulated internally to the appropriate team or department. The Monitor Team requested production of any of these conference notes that may pertain to Opioids. Mallinckrodt agreed to determine whether any of these conference notes have been maintained, and if so, whether they relate to Opioids or other topics covered by the Operating Injunction, and to produce those notes as appropriate. Near the

end of this reporting period, Mallinckrodt produced the requested notes, which the Monitor Team will review during the next reporting period.

3. The Monitor Team's Review of Mallinckrodt's TrackWise Information

6.11 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."

6.12 Beginning in the Fourth Reporting Period, and on an ongoing basis as part of the Audit Plan, the Monitor has received and reviewed quarterly TrackWise inquiry and complaint entries pertaining to Opioids, as well as the results of the Company's auditing process. During the Eleventh Reporting Period, the Monitor Team reviewed TrackWise Opioid-related data for the second quarter[7] of 2024, as well as the corresponding audit reports.

6.13 Consistent with prior reviews, many TrackWise inquiries pertained to the composition of Mallinckrodt's Opioid products, such as whether the products contain allergens (*e.g.*, gluten), while TrackWise complaints generally encompassed areas such as defects in patch adhesives, broken or missing tablets, or other product quality issues. Further, the audits did not identify any instances of improper conduct by the PMT. The Monitor Team spot-checked the audit process by confirming that the number of entries audited matches the number of logged entries for each review period, and filtering the TrackWise entries using specific event codes to ensure that information was escalated appropriately, and did not find any errors or cause for concern.

[7] The Monitor Team received the TrackWise data for the third quarter of 2024 at the end of the Eleventh Reporting Period. The Monitor Team will include any findings from its review of that data in the Twelfth Monitor Report.

6.14 At the end of this reporting period, Mallinckrodt produced updated versions of several policies concerning the handling and escalation of TrackWise inquiries and complaints. The Monitor Team will review these polices and discuss any significant changes in the next reporting period.

6.15 As noted elsewhere in this Report, *see infra* at 71-72 ¶¶ 11.119-22, the Monitor Team also reviewed the TrackWise data more specifically for any issues that might implicate Mallinckrodt's Suspicious Order Monitoring ("SOM") obligations under the Operating Injunction. Findings from that review are separately discussed in Section XI, *infra*.

6.16 Based on the Monitor Team's review of the underlying TrackWise data and the audit reports for the second quarter of 2024, it appears the TrackWise intake, documentation, and audits are being conducted in a manner consistent with the applicable Work Instructions and the Operating Injunction.

4. Mallinckrodt's Website and Social Media Pages

6.17 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 made to Mallinckrodt's website and public social media pages that concern or relate to topics addressed by the Operating Injunction. During the second and third quarters of 2024, Mallinckrodt confirmed that no such changes had been made.

6.18 During Eleventh Reporting Period, Mallinckrodt informed the Monitor Team that it had located a fraudulent Mallinckrodt website, which was utilizing Mallinckrodt's name in its URL, as well as the address of Mallinckrodt's Webster Groves facility, without authorization. Mallinckrodt discovered this through a third-party internet monitoring service. As Mallinckrodt's counsel shared with the Monitor Team, Mallinckrodt's third-party service regularly searches the internet for references to the Company's primary domains, brands, and

executive committee members. This service provides an alert to Mallinckrodt for domain registrations, websites, social media, drug sales, account compromises, and any mention on dark web sites where bad actors share and sell illicit information.

6.19 Mallinckrodt's counsel shared with the Monitor Team screenshots of the webpage, which appeared to be advertising a hospice company, using the real name of a genuine hospice company, but also misusing Mallinckrodt's name and address. Based upon the Monitor Team's review of the screenshots, the Monitor Team could not conclude that this fraudulent website implicated any areas of the Operating Injunction at this time. Nonetheless, because the website may be part of a scheme to divert product, the Monitor Team recommended to Mallinckrodt reporting the discovery to law enforcement. Mallinckrodt complied with this request and reported the website to law enforcement through the Internet Crime Complaint Center, which is managed by the Federal Bureau of Investigation.

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 Audit Plan requires Mallinckrodt to produce to the Monitor on an annual basis updates to Mallinckrodt's sales compensation plans ("SCPs"). As was noted in the Tenth Monitor Report, *see* Tenth Monitor Report at 17 ¶ 8.2, the Monitor Team received the updated SCPs for 2024 at the end of the Tenth Reporting Period. During the Eleventh Reporting Period, the Monitor Team reviewed those materials, which included the 2024 Sales Compensation Plan Management by Objectives, which set forth a number of objectives to be achieved by specified individuals, as well as the SCP for the Addiction Treatment National Account Managers and the

SCP for Generics National Accounts, and generally applicable Terms and Conditions. The Monitor notes that the Monitor Team reviewed the SCP for the Addiction Treatment National Account Managers even though it is not within the scope of the Operating Injunction, which excludes addiction-treatment products from the definition of "Opioid Products," and had no concerns regarding that SCP. *See* Operating Injunction § I.Q; Section XI.4.b, *supra*.

7.3 Mallinckrodt continues to include explicit references to the Operating Injunction in the SCPs, as recommended by the Monitor in his *Recommendation 6(a).* *See* Eighth Monitor Report at 13-14 ¶¶ 7.3-5. As was also the case previously, the SCP for the Generics National Accounts Team, which awards bonuses based upon a weighted calculation of (1) SpecGx achieving Targeted Net Sales and Financial Net Contribution Margin (which accounts for 80% of the weighting), and (2) Individual Management by Objectives Achievements (which accounts for 20% of the weighting), continues to comply with the Operating Injunction. *See id*. at 14-15 ¶ 7.7.

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 Review of SGGSAC Meeting Minutes and Materials

8.2 As detailed in Mallinckrodt's Compliance Report, the SGGSAC reviews and approves third-party requests for grants and sponsorships to ensure, among other things, compliance with the Operating Injunction. *See* Mallinckrodt Compliance Report § 5.4. During the Eleventh Reporting Period, the Monitor reviewed the SGGSAC meeting minutes for the

second and third quarters of 2024. Additionally, the Monitor reviewed the accompanying third-party funding Request Forms, and any related materials the Committee considered in determining whether to approve or deny a request.

8.3 Given the volume of SGGSAC meeting minutes and accompanying request materials, below is a limited summary of the Monitor Team's significant observations and findings from its review of these materials during the Eleventh Reporting Period:

(1) On April 14, 2024, the Committee reviewed and approved a significant sponsorship for an exhibit booth and attendance at the 2025 CPhI Worldwide event, set to take place in October 2025 in Germany. The Monitor Team previously flagged this event when the Company paid a deposit to sponsor and attend the 2023 event without prior approval of the Committee, which ultimately voted to deny the funding request and forfeit the deposit. *See* Tenth Monitor Report at 20 ¶ 9.5(3). Requestors now appear to be submitting requests for this event with sufficient time for the Committee to review and approve the funding.

(2) During a meeting on April 24, 2024, the Committee met to discuss the final agenda for the Asembia AXS24 conference, scheduled for April 29-May 1, 2024, which had been conditionally approved for a sponsorship during the January 18, 2024 meeting. The Committee specifically analyzed three agenda topics: (1) "The Patient's Voice: How to Optimize the Oncology Patient Journey," (2) "CE: Innovations in Prostate Cancer: Unveiling Novel Therapies & the Role of the Specialty Pharmacist," and (3) "2024 Election Policy Issues and the Patient Journey Ripple Effect: IRA, The War on Cancer, and More." The Committee noted that none of these topic descriptions indicated that the Treatment of Pain would be discussed. Further, the Senior Director of Government Affairs & Patient Advocacy explained that the policy topic was expected to be a review of the federal government's Inflation Reduction Act and its effects on the pricing landscape. As such, the Committee gave its final approval of this funding request. The Monitor Team agrees with this assessment.

(3) During a meeting on June 28, 2024, while discussing a sponsorship of the National Commission on Correctional Healthcare's National Conference in October 2024, the Chair inquired as to whether attendees take notes at these events, and whether those notes are shared. The requestor, the National Accounts Manager for Addiction Treatment, responded that Company attendees do take notes, which are then reviewed and made available internally. As noted above, the Monitor Team has requested an opportunity to review any notes pertaining to Opioids in the next reporting period.

(4) Additionally, during the same June 28, 2024 meeting, the Committee reviewed and approved increased grant funding to the Legal Action Center, an advocacy organization that works with individuals who have arrest and conviction records, for its project entitled "Improving Substance Use Disorder Treatment Access." The Committee had previously awarded a grant to this organization, but increased the grant funding by $15,000 this year. The Mallinckrodt employee making the request noted that this increase in funding would support continuity of care by allowing inmates to continue their treatment after leaving a correctional facility upon release to a community-based program. The Committee approved the grant and the Company issued a Letter of Agreement to the Legal Action Center. The Monitor Team reviewed the Letter of Agreement and did not have any concerns.

(5) During a meeting on July 17, 2024, the Committee reviewed and conditionally approved a sponsorship for the National Association of Chain Drug Stores ("NACDS") Annual Meeting being held on April 26-29, 2025. During this discussion, the Compliance Manager inquired about older press releases on the NACDS website referring to Opioids and the Treatment of Pain. The Vice President, Sales and Commercial Operations explained that the Company previously discussed this issue with a representative of NACDS, who stated that these press releases would be removed from their website. In an addendum to the meeting minutes, dated July 23, 2024, the Senior Vice President of Commercial and Strategy confirmed that NACDS removed press releases dated prior to 2019 from their website. The Committee's review of additional materials beyond the required agendas and request forms, such as the organization's website, assisted in this determination.

(6) During a meeting on August 28, 2024, the Committee reviewed and approved a sponsorship of the American College of Correctional Physicians 2024 Fall Educational Conference, titled "Clinical Advances and Legal Knowledge for the Correctional Professional." This conference was scheduled to take place on September 7-8, 2024. Therefore, it appears the request was approved approximately one and a half weeks before the conference start date. Further, the meeting minutes did not reflect any discussion of the conference agenda topics. However, the Monitor Team's review of the agenda for the 2024 Fall Educational Conference revealed two session topics concerning the Treatment of Pain: (1) "Montana Update on Non-Pharmacologic treatments for Chronic Pain, Part 1: Mattress Initiative" and (2) "Montana Update on Non-Pharmacologic treatments for Chronic Pain, Part 2: TENS Unit Distribution." While the Monitor Team acknowledges that these sessions likely do not violate the spirit of the Operating Injunction, given that they appeared to be centered on ***alternatives*** to pain medication, the Monitor Team would have preferred to see the Committee discuss these topics prior to approval, given that they directly implicate the Treatment of Pain,

> which is defined in the Operating Injunction as the "provision of therapeutic modalities to alleviate or reduce pain." The Monitor Team encourages the Committee to closely review all conference agendas and discuss relevant session topics prior to funding approval.

8.4 In the Tenth Monitor Report, the Monitor Team offered *Prior Recommendation 10(a)*, which recommended the Company formalize the SGGSAC's requirements around the timeliness of funding requests and the payment of deposits. *See* Tenth Monitor Report at 22 ¶ 9.7. During the Eleventh Reporting Period, the Company provided the Monitor Team with a copy of the revised standard operating procedure ("SOP") effective August 12, 2024, which now provides that grant and sponsorship requests must be submitted at least 60 days in advance of the activity or opportunity, and also expressly prohibits advanced or conditional funding without final Committee approval. These changes addressed the two primary concerns the Monitor Team raised in prior Reports—the timeliness of funding requests and the distribution of conditional funding without final approval.

8.5 With regard to grant and sponsorship requests generally, as required under the prior version of the SOP, the revised SGGSAC SOP still provides that requests must include the amount of funds requested, the purpose of the grant or sponsorship, an overview of the third-party organization's mission, and any supporting materials or documentation. In addition, the revised SOP now requires the person responsible for making the request to certify in writing, in good faith and to the best of the requestor's knowledge, that the grant or sponsorship request is consistent with: the Operating Injunction; as well as any applicable federal, state, and local laws, regulations and guidance; and any Company policies, procedures, and standards, including the SOP.

8.6 The revised SOP also makes clear that, if a sponsorship includes participation at a trade show, conference, or other event, the person responsible for making the request must

include supporting materials and other relevant information, as the prior version of the SOP required, but also that this requirement must be satisfied even if no one from the Company plans to attend the respective meeting, presentation, course, session, or activity. Additionally, the SOP contains a new section entitled "Non-Compliance/Disciplinary Action" which outlines consequences that Company employees may face if they fail to comply with its requirements. These consequences range in severity from a ban on submitting requests for funding for a certain number of days, up to potential termination of employment. The SOP also requires that the Committee meet on a quarterly basis to evaluate the review and approval process for requests, including assessing compliance with the SOP and implementing any process improvements, as appropriate. The Monitor Team will review any Committee meeting minutes generated from these quarterly check-ins.

8.7 Lastly, under the revised SOP, the Company implemented the use of a new Request Form, which it provided to the Monitor Team for review. In the new Request Form, the timing requirements are expressly outlined in the Instructions section on the first page, which states: "Submission should be at least sixty (60) days in advance of the activity or opportunity." Further, as outlined in the revised SOP, funding requestors are now required to sign a certification at the bottom of the Request Form, which attests in good faith and to the best of the requestor's knowledge that "this Grant or Sponsorship request is consistent with the Operating Injunction, any applicable federal, state, and local laws and regulations and guidance, as well as Company policies, procedures, and standards including the SGGSAC SOP."

8.8 During the next reporting period, the Monitor will continue to review any grants or sponsorships the SGGSAC awards or rejects, along with any accompanying Request Forms and underlying materials, and the minutes and addenda of any SGGSAC meetings. The Monitor

will also continue to work with Mallinckrodt to ensure that the SGGSAC is operating in a manner consistent with Section III.C of the Operating Injunction as it relates to awarding grants and sponsorships to third parties.

8.9 Mallinckrodt informed the Monitor during the Eleventh Reporting Period that the then-SGGSAC Chair, the Senior Director, Clinical Affairs, would be leaving the Company on a date near the end of the third quarter of 2024. The Monitor Team interviewed the Senior Director shortly before his departure. He advised the Monitor Team that he believed the revisions to the SOP were satisfactory and that the SGGSAC is doing its best to ensure Mallinckrodt complies with the Operating Injunction.

8.10 Mallinckrodt informed the Monitor Team that the Senior Director, Integrity & Compliance would be taking over as Chair of the SGGSAC beginning November 1, 2024. The Monitor Team intends to interview the new Chair during the next reporting period.

2. <u>Mallinckrodt's Community Charitable Giving Program</u>

8.11 As the Monitor has previously reported, the Monitor Team reviewed Mallinckrodt's Community Charitable Giving Program ("CCGP"), which is managed by Mallinckrodt's Vice President, Government Affairs & Patient Advocacy. *See* Ninth Monitor Report at 16-18 ¶¶ 7.9-12. Individuals or entities seeking donations from Mallinckrodt may submit requests for funding from the CCGP through Mallinckrodt's website. Although the Vice President previously explained that the CCGP is focused on two specific funding priorities—namely, STEM education and health and wellness—and that everyone involved in the process of reviewing and approving donation requests has been trained on the Operating Injunction and its funding restrictions, the Monitor Team raised with Mallinckrodt the fact that the CCGP is apparently a separate and parallel funding mechanism independent of the SGGSAC and not subject to SGGSAC review and supervision.

8.12 As a result of those discussions, the webpage for the CCGP, as well as the application portal page, now reference, and provide a link to, the Operating Injunction. *See* Tenth Monitor Report at 22-24 ¶¶ 9.9-10. Additionally, under the revised Audit Plan, any funding requests and accompanying materials received through the portal concerning or relating to topics in the Operating Injunction are provided to the Monitor Team on a quarterly basis. Mallinckrodt informed the Monitor Team that no such requests were submitted during the second and third quarters of 2024.

3. The Monitor Team's Review of CMS Open Payments Data

8.13 During the Eleventh Reporting Period, the Monitor Team reviewed "Open Payments" data aggregated by the Centers for Medicare & Medicaid Services ("CMS"). CMS's mission is to provide the public with a more transparent health care system. Accordingly, CMS collects and publishes information about financial relationships between pharmaceutical and medical device companies and certain health care providers on its website, including but not limited to, payments to providers for, among other things, research, meals, travel, gifts, consulting fees, or speaking fees. 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.[8]

8.14 The Monitor Team was not previously aware of these payments, and did further independent research to determine whether there was any connection between Opioids, Medical Center A, and Dr. A. Additionally, the Monitor Team sought information from Mallinckrodt

[8] *See "*OpenPaymentsData.CMS.gov – Mallinckrodt LLC" webpage *available at* https://openpaymentsdata.cms.gov/company/100000005429 (last visited Nov. 4, 2024).

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 payments. They informed the Monitor Team that these payments were made in connection with Mallinckrodt's Risk Evaluation and Mitigation Strategies ("REMS") program, which the U.S. Food & Drug Administration (the "FDA") requires for its Opioid Products. They explained that, in order to comply with REMS requirements, the Company 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.

8.15 Following this discussion, Mallinckrodt produced, for the Monitor Team's review, the Consulting Agreement between the Company and Reporting Vendor A and Dr. A, as well as a spreadsheet showing its required payments into the REMS consortium. The Monitor Team reviewed these documents, and intends to further discuss Dr. A's consulting role with Mallinckrodt during the next reporting period.

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); Third Monitor Report at 18-19 ¶¶ 9.5-6. 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 Eleventh Reporting Period, under the Audit Plan, the Monitor received and reviewed the results of the Government Affairs Team's audits of Mallinckrodt's external state and federal lobbyists' public disclosure reports under the *Lobbying Certification and Activity Review* SOP for the second and third quarters of 2024. These reports, completed by the Director, Government Affairs & Advocacy, detail the corresponding states of each external lobbying firms, the applicable state or federal disclosure report filing schedule, and an assessment of whether the activities reported comply with the Operating Injunction. They also provide hyperlinks to the webpage where the disclosure reports are on file. Like the last several audit reports, this audit report did not identify any concerns or potentially violative activity.

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 second quarter of 2024 revealed: (1) no lobbying activity at the federal level; (2) lobbying on Mallinckrodt's behalf in support of one bill in Maine, entitled "An Act to Amend the Laws Relating to the Prevention of Perfluoroalkyl and Polyfluoroalkyl Substances Pollution," which was enacted during the second quarter of 2024; and (3) lobbying on Mallinckrodt's behalf in support of one bill in North Carolina, entitled "An Act to Provide Additional Regulatory Relief to the Citizens of North Carolina," which was enacted during the third quarter of 2024. The Monitor Team reviewed all of these bills and had no concerns that any of them implicated the Operating Injunction.

9.5 The disclosure for the second quarter of 2024 also revealed lobbying on Mallinckrodt's behalf in opposition to two bills in Massachusetts, which were identical and

which were introduced in the Massachusetts Senate and the Massachusetts House of Representatives. The bills seek to impose an annual requirement on opioid manufacturers and distributors to pay into a fund to be used to reduce the costs of naloxone based on their proportionate shares of revenues generated in Massachusetts. The Monitor notes that although lobbying against third-party reimbursement or payment for naloxone is not permitted under Section III.D.2.e of the Operating Injunction, lobbying against the enactment of state taxes, fees, assessments, or other payments ***is*** permitted under Section III.D.4.a of the Operating Injunction.[9]

9.6 The Monitor Team reviewed the bills, which seek to establish an Opioid Stewardship Fund and a Naloxone Co-Pay Assistance Program, to "improve access to those who seek to obtain naloxone and other medications approved by the U.S. Food and Drug Administration that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body." To fund the Opioid Stewardship Fund and support the Naloxone Co-Pay Assistance Program, the bills seek to impose an assessment, called an "opioid stewardship payment," against each manufacturer and distributor of opioids registered with the Massachusetts Commissioner of Public Health or the Board of Registration in Pharmacy that sells or distributes opioids in Massachusetts. The assessment is to be calculated by reference to each registrant's annual reporting of morphine milligram equivalents ("MME") sold or distributed in Massachusetts, with certain exceptions, as divided by the total MME sold or

[9] Section III.D.2. provides that "Mallinckrodt shall not Lobby against the enactment of any provision of any federal, state or local legislation or promulgation of any provision of any rule or regulation that supports … e. The prescribing and other means of distribution of naloxone to minimize the risk of overdose, including but not limited to third party reimbursement or payment for naloxone[.]" Section III.D.4. provides, however, that "[n]otwithstanding the foregoing restrictions in Sections III.D.1-3, III.A, and III.C, the following conduct is not restricted: a. Lobbying against the enactment of any provision of any state, federal, municipal, or county taxes, fees, assessments, or other payments[.]"

distributed in Massachusetts by all registrants. Based upon the Monitor Team's review of the bills and of the pertinent language of the Operating Injunction, the Monitor is satisfied that the lobbying efforts undertaken on Mallinckrodt's behalf in Massachusetts were consistent with the terms of the Operating Injunction.

9.7 The disclosure for the third quarter of 2024 showed that no lobbying activity was undertaken on the Company's behalf.

2. Implementation of *Prior Recommendation 8(a)*

9.8 In the Eighth Monitor Report, the Monitor recommended that Mallinckrodt provide annual training to Mallinckrodt's external lobbyists, focusing on the Operating Injunction's lobbying-related provisions. Prior Recommendation 8(a); Eighth Monitor Report at 24 ¶¶ 9.13. As noted in the Ninth Monitor Report, Mallinckrodt adopted the recommendation and implemented the training. *See* Ninth Monitor Report at 22 ¶ 8.11.

9.9 During the Eleventh Reporting Period, Mallinckrodt shared with the Monitor Team information regarding the annual lobbyist training it conducted on August 16 and August 23, 2024, including which individuals who are registered lobbyists for Mallinckrodt participated in each of the training sessions. Mallinckrodt also shared with the Monitor Team a slide deck used for the lobbyist training. The Monitor Team reviewed the slide deck and found it to be thorough and informative as to what the Operating Injunction prohibits and permits regarding lobbying activities on the Company's behalf.

3. Mallinckrodt's Political Contributions

9.10 The Mallinckrodt LLC Political Action Committee ("MNKPAC"), which is a federally registered political action committee, periodically contributes to political candidates and other political groups. The Company's Vice President, Government Affairs & Patient Advocacy decides which candidates or groups receive the contributions, which the Monitor

understands are funded by employees of the Company and not by the Company itself. Although the Company believes that these contributions do not touch or concern the Operating Injunction given the source of the funds contributed, the Monitor Team reviewed MNKPAC's federal lobbying expenditures during the second and third quarters of 2024. During the second quarter of 2024, MNKPAC donated $2,500 to one group and $2,500 to one candidate seeking re-election to Congress, and during the third quarter of 2024, MNKPAC donated $2,500 to one candidate seeking re-election to Congress. From the Monitor Team's review of the websites of those groups and individuals, none appeared to advocate for positions implicating the Operating Injunction's lobbying-related prohibitions.

4. Stateside Associates, Inc. Reports

9.11 As part of the latest updates 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. Stateside is a government relations firm that provides various services to its clients, including legislative tracking and regulatory intelligence. Mallinckrodt provided the Monitor Team with the reports Stateside prepared for the second and third quarters of 2024, which included an overview of pending federal and state legislation concerning regulating price gouging, reporting requirements for prescription drug manufacturers, sales marketing licensing of or disclosures by pharmaceutical sales representatives, and the creation of prescription drug affordability boards. Those reports further included a detailed summary of state legislative efforts pertaining to the regulation of one or more aspects of the pharmaceutical industry, a summary of a final rule adopted by CMS to establish new requirements for misreporting or misclassifying drugs under the Medicaid Drug Rebate Program effective as of November 19, 2024, and an overview of the elective offices in certain states for which elections are scheduled for November 5, 2024. The Monitor Team

reviewed those reports, which were informational in nature and not reflective of any actual or intended action on the part of Mallinckrodt or anyone acting on its behalf, and had no concerns regarding their 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 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 February 2024, the Associate General Counsel re-certified Mallinckrodt's compliance with these provisions of the Operating Injunction. The Monitor Team will request that the Associate General Counsel re-certify

Mallinckrodt's compliance with these provisions of the Operating Injunctions during the next reporting period.

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 Eleventh Reporting Period.

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

11.1 In the Eleventh 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,[10] both CSC Managers ("CSC Manager B" and "CSC Manager C"), the CSC Specialist, and the CSC Senior Manager; and (3) obtained updates from Mallinckrodt and its outside counsel regarding the grand jury subpoenas discussed below, *see infra* at 76-79 ¶¶ 11.135-42, the status of Mallinckrodt's implementation of the Monitor's recommendations related to SOM in prior reports, and other SOM-related matters.

[10] During the Eleventh Reporting Period, CSC Manager A, the former Lead CSC Consultant, was promoted to Director of CSC Analytics. With the addition of CSC Manager C, discussed *infra* at 72-73 ¶¶ 11.123-27, Mallinckrodt now has two CSC Managers, referred to here as CSC Manager B and C.

11.2 The Monitor's findings are described in the following sections: (1) documents the Monitor reviewed during the Eleventh Reporting Period; (2) direct customer due diligence; (3) SOM Team ("SOMT) meeting minutes and materials; and (4) other SOM-related issues.

1. Documents Reviewed During the Eleventh Reporting Period

11.3 Mallinckrodt timely produced all SOM-related documents requested under the Audit Plan for the second and third quarters of 2024 and on a monthly basis. Mallinckrodt also produced all documents and information in response to the Monitor's ad hoc requests.

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

(1) SOMT meeting materials and minutes for April, May, June, July, August, and September 2024;

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

(3) correspondence with the DEA regarding restriction and reinstatement of downstream registrants;

(4) the Opioid Product-related inquiries in the Government Communications log for the second and third quarters of 2024, as well as related correspondence;

(5) sales data for 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 April, May, June, July, August, and September 2024;

(8) TrackWise data for inquiries and complaints raising potential diversion concerns for the second quarter of 2024;

(9) The SOMT's list of suspended distributors;

(10) the CSC Team's[11] reports from due diligence visits to distributor customers and other documents obtained by the SOMT related to those due diligence visits;

(11) 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

(12) 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, Steven C. Bullock (the "Purdue Monitor"); a U.S. Department of Justice press release and related indictments; and relevant news articles.

2. <u>Direct Customer Due Diligence</u>

11.6 Mallinckrodt's two systems for monitoring potentially suspicious direct customer orders are (1) the direct customer dashboard monitoring orders for unusual quantity, pattern, or frequency, and (2) the "OI Hold system," which monitors direct customer orders for potential violations of the Operation Injunction's provisions. If an order flags on either the direct customer dashboard or the OI Hold system, Mallinckrodt will not ship the order until the CSC Team releases the hold—*i.e.*, by addressing or ruling out the suspicion.

[11] The CSC Team is comprised of employees in the Legal Department, including the CSC Specialist, the CSC Managers, the CSC Senior Manager, Director of CSC Analytics, and the CSC Director, whereas the SOMT is comprised of employees in both the Legal and Security Departments. All members of the CSC Team are also members of the SOMT.

11.7 Mallinckrodt's OI Hold system places an automatic hold on an order if the customer placing the controlled substance 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.

11.8 Each quarter, the Monitor Team reviews: (1) a report of all flagged orders for Opioid Products during that period, by product; and (2) a report of any orders flagged due to an OI Hold.

11.9 Additionally, the Monitor Team reviews a SOR for a randomly chosen week each month to confirm the CSC Specialist and a CSC Manager[12] 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 Eleventh Reporting Period, the Monitor Team reviewed SORs for April, May, June, July, August, and September 2024.

a. The flagged direct customer order reports for the second and third quarters of 2024

11.10 As the Monitor has previously reported, the CSC Specialist reviews all direct customer orders the dashboard flags. She determines whether to release each order after reviewing the customer's order history and other relevant documentation. *See infra* at 31-32 ¶¶ 11.16-18. If necessary, the CSC Specialist will confer with the Customer Service Department regarding any changes in the customer's contracts or product needs and contact the customer for

[12] The CSC Specialist and a CSC Manager typically perform 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.

additional information. A flagged order is only released after approval by both the CSC Specialist and a CSC Manager.

11.11 While almost all of the flagged direct customer orders are released after the CSC Specialist's and a CSC Manager's review, their review is still a necessary part of Mallinckrodt's efforts to prevent diversion. *See* Ninth Monitor Report at 29 ¶ 10.13.

11.12 In the second and third quarters of 2024, the CSC Specialist and a CSC Manager released all but two of the orders the direct customer dashboard flagged. In both cases, the customers mistakenly placed duplicate orders for addiction-treatment products that were cancelled.

11.13 In the second quarter, the direct customer dashboard flagged a customer's order for three addiction-treatment products because the customer had placed the exact same order two days before. The CSC Specialist contacted the Customer Service Department to learn why the customer had increased its ordering pattern. Before she received a response, the Customer Service Department cancelled the order at the customer's request. The customer, apparently realizing its mistake, informed the Customer Service Department that it had recently placed an order and the additional quantity was not needed.

11.14 Also in the second quarter, a customer mistakenly believed its order for methadose products was voided and placed a duplicate order. The duplicate order was flagged by both the CSC Specialist and the Customer Service Department, which cancelled one of the two identical orders.

11.15 In sum, the Monitor Team's review of the flagged order reports for the second and third quarters of 2024 did not present diversion concerns.

b. The SORs for select weeks in April, May, June, July, August, and September 2024

11.16 As noted above, the Monitor Team also reviews a random selection of SORs for one week each month to confirm all flagged orders for Opioid Products are only released after two members of the CSC Team 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 CSC Specialist and / or a CSC Manager indicates in the SOR such documentation exists.[13]

11.17 The SORs for selected weeks in the Eleventh Reporting Period show the CSC Specialist and either a CSC Manager or the CSC Senior Manager released each order after determining the customer's: (1) aggregate monthly orders did not represent an unusual quantity compared to orders by similar customers within the same industry segment; (2) aggregate monthly orders did not represent an unusual share compared to orders by similar customers within the same industry segment; (3) aggregate monthly orders did not represent an unusual volume compared to orders by similar customers within the same industry segment; (4) number / frequency of the customer's orders was not unusual compared to those placed by similar customers within the same industry segment, and the customer's aggregate monthly orders did

[13] In order to determine whether an order is not potentially suspicious, the CSC Specialist may review documents related to the customer's ordering history and practices and relevant market dynamics. Indeed, as a matter of course, the CSC Specialist 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 CSC Team will require additional information from the Commercial Department or the direct customer to release an order. When the CSC Specialist already possesses, or compiles as part of her review, supporting documentation that is specific to the released flagged order, she indicates so in the SOR by marking "Yes" in the "Supporting Documentation" column.

not represent an unusual quantity for the customer; or (5) order was for a new product that had to be manually entered into an item group.

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

c. The Monitor's interview with the CSC Specialist and CSC Senior Manager concerning reviews of flagged direct customer orders

11.19 During the Eleventh Reporting Period, the Monitor Team interviewed the CSC Specialist and the CSC Senior Manager concerning, among other things, review of flagged direct customer orders and the SORs and related documentation Mallinckrodt produced under the Audit Plan.

i. Distributor G's flagged July 2024 order and subsequent suspension

11.20 In July 2024, the direct customer dashboard flagged an order by Distributor G based on item share. In reviewing the order, the CSC Specialist referenced two emails Distributor G sent Mallinckrodt in May 2024 in response to the CSC Specialist's questions about Distributor G's increased orders. Distributor G explained it was ordering greater quantities because its customers were switching to Mallinckrodt from other manufacturers because Mallinckrodt's products were less expensive. Although the CSC Senior Manager supported releasing Distributor G's order based on this explanation, she noted that, to her knowledge, Mallinckrodt is not typically the least expensive supplier, unless other suppliers increased costs due to supply constraints. As a result, the CSC Senior Manager recommended close monitoring of Distributor G. The CSC Senior Manager did not identify any specific actions taken to monitor Distributor G but indicated she, the CSC Specialist, and the CSC Managers would typically

continue to discuss the customer and the customer's response would be in the "back of their minds" as they reviewed future orders.

11.21 The CSC Senior Manager and CSC Manager B released Distributor G's July order after concluding that Distributor G's aggregate monthly orders did not represent an unusual share when compared to orders placed by similar customers within this industry segment.

11.22 However, in late August, Mallinckrodt suspended sales to Distributor G after conducting a due diligence visit based on concerns about the adequacy of Distributor G's SOM program. The SOMT's suspension of Distributor G is discussed further below, *see infra* at 37-41 ¶¶ 11.33-43.

ii. The DEA's change to the quota application process continues to impact supply for certain products

11.23 The CSC Specialist and the CSC Senior Manager informed the Monitor Team they continue to observe direct customer orders flagging due to changing market dynamics—namely, an increase in quota-related supply constraints for certain controlled substances. When customers' primary suppliers are unable to meet their demand, they order greater quantities from Mallinckrodt. As discussed elsewhere in this Report, the DEA's changes to the quota application process have caused challenges for manufacturers, including Mallinckrodt. *See infra* at 73-75 ¶¶ 11.128-31. As a result, the CSC Specialist continues to frequently confer with the Commercial Department before releasing flagged orders.

iii. The Monitor Team and Mallinckrodt continue to discuss how the SOMT can provide documentation better reflecting the information it reviews and relies on to release flagged orders

11.24 As noted in the Tenth Monitor Report, the Monitor Team's interviews with the CSC Specialist are informative because the format of the SORs only provides the Monitor with limited insight into the information available to, and relied upon by, the CSC Specialist when she

releases the flagged orders. For example, the SORs do not contain the data available to the CSC Team on the direct customer dashboard, including the values of certain metrics the CSC Specialist analyzes 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* Tenth Monitor Report at 46-47 ¶ 12.49-53. During the Tenth Reporting Period, the Monitor Team and the members of the CSC Team discussed what other data or documentation could be provided to the Monitor for purposes of evaluating the CSC Team's review and release of flagged orders. The CSC Director agreed to consider whether additional documentation could be provided to the Monitor Team to better reflect the information the CSC Specialist reviews, and relies on, when deciding to release a particular order. As discussed *infra* at 61-66 ¶¶ 11.92-104, the Monitor's request is a subject of Mallinckrodt's ongoing "working group." The Monitor will continue to discuss this request with the SOMT and provide an update in a future report.

iv. Recently-hired CSC Manager C's role performing the second-level review of flagged direct customer orders

11.25 The Monitor Team, the CSC Specialist, and the CSC Senior Manager discussed CSC Manager C's training on the flagged order review process and his second-level review of those orders.

d. OI-Hold Reports for the second and third quarters of 2024

11.26 In the second quarter of 2024, none of Mallinckrodt's direct customer orders were flagged for potential violations of the Operating Injunction.

11.27 However, in the third quarter of 2024, two addiction-treatment clinics' orders for methadose and methadone products were flagged. The SOMT confirmed the customers could purchase such products, but their accounts were not set up correctly in Mallinckrodt's system,

resulting in the orders being flagged. After Mallinckrodt's Data Integrity Department corrected the customers' account information, the orders were appropriately released.

e. Mallinckrodt's direct customer due diligence visits

11.28 As the Monitor previously reported, Mallinckrodt's *SOM Review of Direct Customer Orders* SOP requires 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. *See* Sixth Monitor Report at 38 ¶ 11.23. During the Eleventh Reporting Period, the CSC Team provided an updated list of the six distributors it has already visited and the one distributor it intends to visit before the end of 2024, as well as the CSC Team's due diligence reports for three of those visits.[14]

i. The CSC Team's 2024 due diligence visits

11.29 In the Eleventh Reporting Period, the Monitor Team reviewed the reports the SOMT prepared for three direct customer due diligence visits conducted in 2024: Distributor C, Distributor G, and Distributor H.

11.30 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 in place (*i.e.*, 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" (*i.e.*, ordering excessive quantities of a limited variety of controlled substances while ordering few, if any, other

[14] The Monitor reported on one of the CSC Team's 2024 due diligence visits in the Tenth Monitor Report. *See* Tenth Monitor Report at 51 ¶ 12.66.

controlled or non-controlled substances). The CSC Team's findings, which may be discussed at SOMT meetings, are discussed further below.

ii. The CSC Team's due diligence visit to "Big Three" Distributor C

11.31 The CSC Team's report summarizing its due diligence visit to "Big Three" Distributor C described Distributor C's fulsome SOM-program and did not identify any concerns regarding its sufficiency. In discussing Distributor C's SOM program, Mallinckrodt's CSC Team members and Distributor C's regulatory employees discussed the high volume of oxycodone sales in Florida. Distributor C indicated it had more closely reviewed oxycodone sales this year and terminated 50 pharmacies in Florida as a result. The CSC Team members asked if Distributor C would share the names of those pharmacies and of any pharmacy that it terminates for SOM reasons—a request that Distributor C has not yet agreed to incorporate in its contracts with Mallinckrodt, as discussed *infra* at 64 ¶ 11.100. As the Monitor has previously reported, to date only "Big Three" Distributor E has agreed to such a contractual provision. *See* Tenth Monitor Report at 82 ¶ 12.149. Distributor C took the SOMT's request under consideration.

iii. The CSC Team's due diligence visit to Distributor H

11.32 In May, 2024, Mallinckrodt conducted a due diligence visit to Distributor H, which purchases controlled substances from Mallinckrodt to supply its own chain of pharmacies. In connection with that due diligence visit, the CSC Team reviewed the DEA's Automated Reports and Consolidated Ordering System ("ARCOS") data for Distributor H's pharmacies.[15]

[15] ARCOS is a data collection system to which manufacturers and distributors report their 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-

Members of the CSC Team had a subsequent meeting with Distributor H to discuss the high volume of hydrocodone Distributor's H pharmacies dispensed in Indiana. Thereafter, the CSC Team members had another meeting with Distributor H to discuss the volume of amphetamines dispensed at certain stores, including in Indiana. After each of these discussions, Distributor H provided responses to the CSC Team's questions in writing. After reviewing Distributor H's responses, the CSC Team was satisfied with Distributor H's explanations for the volumes of both drug families and how Distributor H monitors its pharmacies using IQVIA data,[16] and determined the due diligence review was complete.

iv. The CSC Team's due diligence visit and resulting suspension of Distributor G

11.33 As noted above, during the Eleventh Reporting Period, Mallinckrodt suspended sales to Distributor G, following a due diligence visit due to the CSC Team's concerns about the adequacy of Distributor G's SOM program. The CSC Team scheduled that due diligence visit with Distributor G following a telephone call between the Director of CSC Analytics and Distributor G, during which the Director of CSC Analytics became concerned that Distributor G was only monitoring customers' purchases based on Distributor G's own sales data, and without reference to other available data sources, such as ARCOS. The CSC Team developed additional

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reports.html (hereafter, "ARCOS Retail Drug Summary Reports") (last visited on Nov. 5, 2024); *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."

[16] 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 Nov. 5, 2024).

concerns concerning the sufficiency of Distributor G's SOM-program in the two-part due diligence visit that followed.

11.34 By way of background, on July 8, 2024, the direct customer dashboard flagged an order from Distributor G for mixed amphetamine salts. As noted above, *see supra*, Section XI.2.c.i at 32-33 ¶¶ 11.20-22, the CSC Specialist and the CSC Manager B released that order based on information Distributor G provided in May 2024, which explained that its orders had increased because Mallinckrodt's products were less expensive. Although the CSC Senior Manager supported releasing Distributor G's order based on this explanation, she noted that, to her knowledge, Mallinckrodt is not typically the least expensive supplier, unless other suppliers increased costs due to supply constraints. Accordingly, the CSC Senior Manager recommended close monitoring of Distributor G.

11.35 Separately, in July, the SOMT initiated reviews for two of Distributor G's customers that had been flagged by the indirect customer dashboard for purchases of mixed amphetamine salts.

11.36 Subsequently, in early August 2024, the SOMT contacted Distributor G in connection with the SOMT's review of another of Distributor G's pharmacy customers. The SOMT sought information regarding the ratio of the pharmacy's hydrocodone 10 mg orders to its orders of other hydrocodone products. But because Distributor G's response to the SOMT's inquiry did not address the SOMT's specific concern regarding the pharmacy's purchases, the CSC Director informed Distributor G that it had restricted the pharmacy.

11.37 Thereafter, Distributor G's general counsel called the Director of CSC Analytics to further discuss the SOMT's restriction of that pharmacy. During that conversation, the Director of CSC Analytics became concerned that the only data Distributor G was using to

monitor customers' purchases was its own sales data, rather than incorporating other data sources such as ARCOS. ARCOS data would have provided Distributor G with a more complete picture of its customers' total purchases, including, potentially, purchases from other distributors—*i.e.*, information necessary for distributors to properly evaluate whether customer orders are potentially suspicious in the fuller context.

11.38 In parallel with the above series of events, in late July 2024, Distributor G had provided Mallinckrodt an updated questionnaire. In that questionnaire, Distributor G answered "no" in response to several questions regarding its SOM program, such as whether Distributor G analyzes customers' dispensing data to evaluate ratios for cash purchases (*e.g.*, controlled substances versus non-controlled substances) or whether Distributor G compares customers' dispensing data to national, regional, or state averages.

11.39 Three members of the CSC Team, including the CSC Director, met with Distributor G's general counsel again in late August by video call and raised questions regarding Distributor G's responses to the questionnaire. The general counsel could not satisfactorily answer questions about Distributor G's SOM program, stating he was relatively new to the company and other employees would need to be on a call to answer the SOMT's questions. The CSC Director informed Distributor G's general counsel that the SOMT was uncomfortable with Distributor G's answers and was going to suspend sales to the Distributor until the SOMT's questions could be answered. The general counsel indicated he would arrange a subsequent call with key employees, which took place the following week.

11.40 During the second video call, Distributor G's employees confirmed the only data the Distributor uses to determine if an order is potentially suspicious is its own sales data. Furthermore, based on employees' responses to other SOM-related questions, the SOMT

concluded those employees were uninformed about Distributor G's processes. As a result, the SOMT suspended sales to Distributor G indefinitely.

11.41 What emerges from the experience with Distributor G is that the CSC Team obtained information from several disparate sources that raised potential concerns about Distributor G's SOM program. What is unclear to the Monitor Team is whether that combination of information was merely fortuitous, or whether it was the result of appropriate planning and coordination. This is not merely of academic interest. As discussed elsewhere in this Report, the SOMT has made important strides towards more holistically analyzing distributors for potential restriction. In bolstering this aspect of the SOM program, it is important that various pieces of intelligence are not just collected, but synthesized for analysis. This is particularly important for direct customer surveillance given the unavailability of data akin to chargeback data for direct customers, as well as Mallinckrodt's inability to access distributor-level ARCOS data, in contrast to the availability of such data to analyze pharmacy orders.

11.42 The sources of intelligence obtained in the case of Distributor G included direct and indirect customer dashboards flags, and Distributor G's questionnaires. Although the SOMT did ultimately suspend Distributor G, it is not yet 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 indirect customers. Although the CSC Specialist, CSC Manager B, and CSC Senior Manager 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 the Director of CSC Analytics' due diligence request in August 2024 prompted a visit with Distributor G.

11.43 As discussed below, there are certain challenges inherent in monitoring direct customers like distributors, given all of these different sources of disparate but nonetheless potentially relevant data regarding the distributors' and their customers' orders and SOM programs. A positive and helpful development is that the SOMT is now conducting a new analysis to better detect diversion risk through the analysis of indirect customer restrictions, which offers the SOMT a "bigger picture" perspective, allowing the SOMT to better observe relevant trends and detect potential diversion risk, at both the distributor and pharmacy levels. In the next reporting period, the Monitor Team will discuss with Mallinckrodt whether the CSC Team can track distributors that the CSC Team believes warrant further monitoring in a way that is evident to all members of the team. Likewise, the Monitor Team will discuss with Mallinckrodt 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 its downstream pharmacy customer restrictions. This exercise—or something similar—may help to achieve the goals of ensuring that disparate sources of intelligence are "fused," and that direct customer restriction decisions are made as promptly as reasonably possible.

v. The CSC Team's remaining due diligence visits for 2024

11.44 The CSC Team's reports from the two additional due diligence visits conducted to date are not yet finalized, and Mallinckrodt has informed the Monitor that the CSC Team's

remaining due diligence visits will be completed before the end of the year. The Monitor will review the reports for those visits in the next reporting period.

f. Second and third quarter 2024 sales data

11.45 In June 2024, Mallinckrodt's sales of hydrocodone / APAP 10/325 mg decreased significantly compared to sales in the prior five months. The Commercial Department explained that the decrease was due to two manufacturers returning to the hydrocodone market. As those manufacturers were the primary suppliers of hydrocodone products for many of Mallinckrodt's direct customers, Mallinckrodt's sales of such products increased during the period in which the other manufacturers were unable to supply them. Since those manufacturers returned to the market, Mallinckrodt has reverted to being a secondary supplier for certain customers, explaining the corresponding decline in its sales.

11.46 The Commercial Department's explanation is consistent with the factors both Mallinckrodt and its Vice President of Commercial and Strategy attributed to the company's increase in Opioid net sales in 2023. As the Vice President informed the Monitor, the increased sales in 2023 resulted, in part, from Mallinckrodt picking up market share due to the exit of some competitors, and from supply constraints on other remaining manufacturers in the market. *See* Tenth Monitor Report at 33-38 ¶ 12.6-23. Indeed, as the Monitor previously reported, Mallinckrodt served as the "backup supplier" to certain distributors, and when those distributors were unable to obtain products from their primary suppliers, they purchased from Mallinckrodt instead. *Id*. at 39 ¶ 12.19.

11.47 The Monitor observed a further decline in sales during the third quarter of 2024. Although the data provided to the Monitor Team showed Mallinckrodt's sales of hydrocodone / APAP 10/325 mg increased between July and August, sales again decreased in September to a quantity slightly lower than sales of that same product in June. The Commercial Department

informed the Monitor Team that the appearance of a rise in sales in August was due to the fact that Mallinckrodt closes its books and records on the last Friday of the month based on a "52-53"-week year ending on the last Friday of December 2024. Mallinckrodt's fiscal month of August represents a five-week reporting period, whereas June and July represent four-week periods. The Commercial Department informed the Monitor Team that Mallinckrodt's share of the market for hydrocodone / APAP 10/325 mg has declined at a relatively steady rate between October 2023 and September 2024, as other manufacturers, including one that re-entered the market in July, have gained market share.

g. The Monitor's continued review of Mallinckrodt's SEC filings for reporting on net Opioid Sales

11.48 During the Eleventh Reporting Period, the Monitor Team continued to analyze Mallinckrodt's filings with the SEC, with particular interest in reported net Opioid sales, based upon the Monitor Team's prior reporting in the Tenth Reporting Period. *See, e.g.*, Tenth Monitor Report at 33-35 ¶¶ 12.6-11; *id.* at 35-37 ¶¶ 12.12-20.

11.49 Specifically, the Monitor reviewed Mallinckrodt's SEC 10-Q filings for the quarterly periods ending March 29, 2024 (first quarter 2024) and June 28, 2024 (second quarter 2024). The reported net sales reflect continued increases in net Opioid sales when compared year-over-year. Specifically, the first quarter 2024 filing reported $81.9 million in net sales as compared to $62.2 million in the same quarter of 2023—*i.e.*, an increase of 31.7%. The second quarter 2024 filing reported $95.2 million in net sales as compared to $72.1 million in the same quarter of 2023—*i.e.*, an increase of 32%. This year-over-year increase is, nonetheless, relatively smaller than the increase of 41.7% that occurred in the third quarter of 2023. The Monitor Team will continue to analyze Mallinckrodt's quarterly SEC filings for any notable developments.

h. The indictment of distributor executives and sales representatives, along with pharmacy operators

11.50 On October 3, 2024, the U.S. Department of Justice announced the filing of federal criminal charges against five pharmaceutical distributor executives, five pharmaceutical sales representatives, and three Houston-area pharmacy operators.[17] As noted below, one of the charged distributor executives was the owner of a distributor Mallinckrodt suspended in early 2022. These and other charging documents can be a useful source of intelligence for Mallinckrodt to conduct retrospective reviews to determine whether Mallinckrodt was able to identify bad conduct as promptly as possible and what, if anything, the SOMT may seek to do differently in the future.

11.51 The conduct alleged in the charging documents seems to relate largely to the period prior to the onset of the monitorship, with some overlap with the first year of the monitorship in some instances. For instance, the individuals identified in the charging documents were alleged to have engaged in the conduct in the following periods:

Defendant	Charging Period
DCA	"Beginning in or around 2018, and continuing ***through February 2022***" (emphasis added)
JWS	"From in or around April 2015, and continuing ***through in or around February 2022***" (emphasis added)
JW	"From in or around mid-2017, and continuing ***through in or around October 2019***" (emphasis added)

[17] Press Release, U.S. Dep't of Justice, "Ten Pharmaceutical Distributor Executives, Sales Representatives, and Brokers Charged in Connection with Unlawful Sales of Nearly 70M Opioid Pills" (Oct. 3, 2024), *available at* https://www.justice.gov/opa/pr/ten-pharmaceutical-distributor-executives-sales-representatives-and-brokers-charged (last visited Oct. 21, 2024).

EB	"***August 12, 2022***" (emphasis added)

11.52 The Monitor Team naturally was interested in whether Mallinckrodt's SOMT had previously reviewed or restricted any of the relevant individuals or companies. The Monitor Team therefore inquired with Mallinckrodt and its counsel, and also conducted its own independent review of publicly available information and SOMT meeting minutes and related materials, to identify any possible overlap.

11.53 As discussed with the CSC Director, Director of CSC Analytics, CSC Manager B, and CSC Manager C, to the extent any of the involved entities were Mallinckrodt customers, Mallinckrodt had previously suspended them. Only one instance involved a customer with a similar name to an entity in an indictment, but Mallinckrodt's supply of oxycodone to that customer was low, therefore posing less risk of diversion. Additionally, the SOMT took the precaution of creating a customer profile for one of the entities identified from the indictment, solely for purposes of being able to preemptively restrict that entity from any future supply.

11.54 The Monitor Team was able to identify some overlap as well. For example, according to the allegations in an indictment of JWS and two sales representatives of his company, JWS was the owner and operator of a pharmaceutical consulting firm. The two sales representatives allegedly helped to facilitate sales to Houston-area pharmacies. Mallinckrodt restricted these pharmacies on January 4, 2022, following media coverage identifying them as part of a "pill mill," and detailing law enforcement's arrests of some of the pharmacists. *See* Fifth Monitor Report at 38 ¶ 11.41.

11.55 These restrictions enabled Mallinckrodt's SOMT to identify EB's distribution company as the common point of origin for the distribution of the product.

11.56 Indeed, as alleged in the indictment of EB, EB was notified by an unidentified drug manufacturer in December 2021 that unless EB's distributor company implemented improvements to its due diligence program, the manufacturer would no longer sell the company controlled substances. EB allegedly received compliance recommendations but did not implement them.

11.57 For its part, Mallinckrodt's SOMT contacted EB's distribution company, seeking due diligence, on December 30, 2021. After the SOMT failed to gain assurance that EB's company had appropriate controls in place, the SOMT suspended EB's company on or about January 10, 2022, as previously described in the Fifth Monitor Report. *See* Fifth Monitor Report at 38 ¶ 11.41. And upon further review, Mallinckrodt identified "at least ten other pharmacies . . . purchasing from [EB's company] and only buying one, two, or three controlled substances." *See* Fifth Monitor Report at 38 ¶ 11.41.

11.58 Notwithstanding Mallinckrodt's suspension of EB's company, according to the Indictment, in August 2022, EB allegedly purchased thousands of oxycodone and hydrocodone pills from a new drug manufacturer with the intent to distribute them to Houston-area pharmacy customers he knew would unlawfully distribute them.

11.59 The purchase by EB's company of thousands of highly diverted opioid products from ***another*** manufacturer that would not necessarily have known about Mallinckrodt's restriction of EB's company, is a reminder of the importance of communication among supply chain participants, and the need for shared data regarding compliance-driven supply restrictions. Otherwise, bad actors may seek to exploit the limitations on information sharing between distributors, and obtain controlled substances from another manufacturer. For that reason, the Monitor Team reviewed Mallinckrodt's SOM Questionnaire for Distributor Customers for

questions related to compliance recommendations and prior suspensions by other manufacturers. Though the Questionnaire contains numerous questions about criminal and disciplinary actions by government bodies, the Questionnaire does not presently contain any questions concerning recommendations and suspensions by other manufacturers. Accordingly, the Monitor makes the recommendation below.

> ***New Recommendation 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.***

11.60 **The Monitor has observed that Mallinckrodt's Questionnaire for distributor customers does not ask customers whether other suppliers have made SOM-related compliance recommendations to the customer, requested the customer undertake compliance reforms, or required the customer to implement changes to its SOM program in order to continue purchasing controlled substances. Likewise, the Questionnaire does not ask customers whether any manufacturer has restricted, suspended, or terminated sales to the customer. As answers to these questions may influence Mallinckrodt's decision to onboard new customers, or to continue sales to existing customers, the Monitor recommends Mallinckrodt revise its customer questionnaires to include questions seeking this information. Mallinckrodt has agreed to accept this recommendation. The Monitor will review the revised questionnaires in the next reporting period.**

i. Updated process regarding review of direct customer questionnaires

11.61 Unrelated to the substantive change to the questionnaires discussed in the immediately prior section accompanying *New Recommendation 11(a)*, Mallinckrodt has shared with the Monitor Team a change to Mallinckrodt's ***process*** for review of questionnaires.

11.62 Specifically, as the Monitor has previously reported, Mallinckrodt requires customers to complete various questionnaires and certain customers, such as distributors, must provide, among other things, information about the customers' SOM programs before Mallinckrodt ships products to them. *See, e.g.*, Seventh Monitor Report at 22-23 ¶ 11.15. Mallinckrodt also requires existing customers to submit updated questionnaires periodically, where applicable. For example, distributors must provide updated questionnaires annually. *Id.* at n.21. While the Customer Service Department receives the completed questionnaires, the CSC Team is responsible for determining whether the customers' responses are satisfactory. In the Tenth Monitor Report, the Monitor recommended Mallinckrodt require every distributor to provide a brief written description of its SOM program with its completed questionnaire, consistent with the questionnaire's request, after the Monitor Team observed that certain direct customers had failed to provide that information. *See* Tenth Monitor Report at 51-53 ¶¶ 12.70-73. Mallinckrodt agreed to implement that recommendation and informed the Monitor Team it would be making a change to how the questionnaires were reviewed. The only questionnaire the Monitor Team reviewed in the Eleventh Reporting Period contained this supplemental information in an attachment.

11.63 During the Eleventh Reporting Period, the CSC Director updated the Monitor Team regarding Mallinckrodt's change to the questionnaire review process. While all of the different types of customer questionnaires had been reviewed by the CSC Team members at Mallinckrodt's manufacturer plant in Hobart, New York, the distributor and manufacturer questionnaires are now being reviewed by the CSC Team members at Mallinckrodt's facility in Webster Groves, Missouri, including by the CSC Director and CSC Managers B and C. The Webster Groves CSC Team members will follow up with the distributors and manufacturers,

when necessary. The CSC Team members in Hobart will continue to review the questionnaires for addiction-treatment clinics. The questionnaires for analytical lab / research customers are reviewed by CSC Team members at either location on an ad hoc basis. Though Mallinckrodt has not yet finalized this change to the process in an SOP, the CSC Director informed the Monitor Mallinckrodt intends to do so in the future.

3. SOMT Meeting Minutes and Materials[18]

11.64 In the Eleventh Reporting Period, the Monitor Team reviewed SOMT meeting minutes and materials for April, May, June, July, August, and September 2024. The results of that review, and the Monitor's related findings from interviews with the SOMT's members, including the CSC Director, the Director of CSC Analytics, and CSC Managers B and C, are summarized below.

11.65 Several themes reported in the Tenth Monitor Report (and in prior reports) were also evident in the SOMT's second and third quarter meeting materials. Two warrant further discussion here: (1) as a result of what the Monitor Team and Mallinckrodt agreed were excessive delays by Mallinckrodt's direct customers in responding to the SOMT's requests for due diligence in connection with reviews of indirect customers, Mallinckrodt agreed to complete such reviews, presumptively, within 90 days, although there has been variability in this practice; and (2) the SOMT continues to review a large number of indirect customers, and impose restrictions on them, based upon analysis of ARCOS data.

[18] In past reports, the Monitor's discussion of SOMT meeting minutes and related materials was included in discussions of downstream registrant due diligence. Given the SOMT's recent increase in the number of distributors (*i.e.*, direct customers) reviewed and suspended, relative to downstream registrants (*i.e.*, indirect customers), the Monitor has included observations and findings related to both types of customers in this separate section of the Report. No other topics covered in this Report exclusively relate to downstream registrant due diligence; therefore, the Monitor has not included a separate section on that topic.

11.66 The Monitor Team also observed an additional two themes in the meeting minutes: (3) in June and July, the SOMT conducted reviews of ***distributors*** based upon analysis of the restrictions the SOMT imposed on the distributors' customers, leading Mallinckrodt to suspend sales to six distributors; and (4) the SOMT has received a larger number of chargeback reinstatement requests this year, likely as a result of increased reviews and restrictions of indirect customers in 2022, 2023, and 2024.

a. The SOMT's adoption of a 90-day "rule of thumb" for deciding whether to restrict a downstream customer

11.67 As discussed in the Tenth Monitor Report, 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. Mallinckrodt has deferred, for now, the update to its SOP relating to chargeback reviews to address the 90-day rule. The Monitor Team understands that this will be addressed by the "working group" that has formed to conduct a holistic overview of Mallinckrodt's SOM program, as discussed elsewhere in this Report. *See infra* at 61-66 ¶¶ 11.92-104.

11.68 In the Eleventh Reporting Period, the Monitor Team observed variability in the SOMT's approach to applying the 90-day presumption. For instance, in the July 2024 SOMT minutes, the SOMT occasionally restricted pharmacies by around the 60-day point, and sometimes even while a due diligence request remained pending with Distributor C or Distributor D. In other instances, the SOMT restricted pharmacies only at approximately the 90-day point, or even beyond.

11.69 In the September 2024 SOMT meeting minutes, there were multiple instances of pharmacies under review for 60 days and one instance of a pharmacy under review for approximately 90 days where the SOMT decided to take no further action pending a response to a due diligence request to Distributor C.

11.70 It is difficult for the Monitor to determine at this stage whether this variability is a result of the SOMT's appropriate application of the 90-day rule, while allowing for exceptions, or whether the SOMT has not yet begun to apply the rule in a manner consistent with the accepted Prior Recommendation 10(c). Accordingly, in the next reporting period the Monitor will endeavor to learn more from the SOMT about its approach and adoption of the 90-day rule.

b. The SOMT continues to review—and restrict—a large number of indirect customers based on ARCOS data

11.71 A key component of Mallinckrodt's SOM program is the SOMT's utilization of ARCOS data. As the Monitor previously reported, in addition to the direct and indirect customer dashboards, in 2022 Mallinckrodt further enhanced its SOM program by developing a third "dashboard" for ARCOS data (the "ARCOS Dashboard"). *See* Ninth Monitor Report at 35-37 ¶ 10.33-36 (discussing the SOMT's use of ARCOS data). Using the ARCOS Dashboard, the SOMT can quickly locate, and then review, downstream registrants with statistically anomalous ordering patterns based on all reportable ARCOS purchases. *See*, *e.g.*, Tenth Monitor Report at 61-62 ¶¶ 12.93-96. Indeed, the SOMT has been able to use ARCOS data to establish certain informative benchmarks regarding downstream registrants' purchases of certain controlled substances, including Opioid Products, to detect potential diversion.

11.72 Since developing the ARCOS Dashboard, the SOMT has continued to enhance it. Most recently, the SOMT analyzed what a "normal" or typical ratio of orders of certain drug

families (*e.g.*, oxycodone) is for all of a downstream registrant's ARCOS-reportable purchases.[19] Likewise, the SOMT analyzed what would be a statistically normal percentage of orders for high risk formulations of a drug family (*e.g.*, hydrocodone 10 mg) as compared to a downstream registrant's total orders of that same family. The SOMT incorporated an ARCOS ratio tool into the current iteration of the ARCOS Dashboard in January 2024.

11.73 In the first three quarters of 2024, the downstream registrant reviews the SOMT initiated based on ARCOS data constituted a significant percentage of the total reviews it conducted each quarter. As summarized in the chart below, data that Mallinckrodt provided the Monitor Team shows the SOMT conducted more reviews based on ARCOS data in each quarter of 2024 compared to the fourth quarter of 2023:

Chart 1: Reviews Initiated Based on ARCOS Data				
	Q4 2023	***Q1 2024***	***Q2 2024***	***Q3 2024***
Total Number of Reviews	103	205	184	224
Number of Reviews Initiated Based on ARCOS Data	30	96	69	45
Percentage of Reviews Initiated Based on ARCOS Data	29%	47%	38%	20%

The increase in the number of reviews initiated based on ARCOS data was the greatest in the first quarter of 2024 when the SOMT first incorporated the ARCOS ratios tool. In the first

[19] ARCOS stores order data for the distribution of controlled substances only, and only for substance in Schedules I-IV. *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 Nov. 5, 2024).

quarter of 2024, the SOMT initiated 99% more reviews based on ARCOS Data than it did in the prior quarter, the fourth quarter of 2023.

11.74 The reviews the SOMT initiated based on ARCOS data also constituted a significant portion of the total restrictions in the first three quarters of 2024. Mallinckrodt provided the Monitor Team with the following data regarding the total restrictions and the number of downstream registrants restricted based on ARCOS data in each quarter for the past year:

Chart 2: Restrictions Based on ARCOS Data				
	Q4 2023	***Q1 2024***	***Q2 2024***	***Q3 2024***
Total Number of Restrictions	57	87	94	104
Number of Restrictions Based on ARCOS Data	21	56	57	52
Percentage of Restrictions Based on ARCOS Data	37%	64%	61%	50%

As evident from this data, although the ***reviews*** the SOMT initiated based on ARCOS data constituted less than half of the total reviews initiated in each quarter of 2024 (Chart 1), the ***restrictions*** of downstream registrants based on ARCOS data accounted for ***50% or more*** of the total restrictions in each of those quarters (Chart 2). Notably, many of those restrictions were made by the SOMT on an ad hoc basis because the ARCOS data was sufficiently anomalous to warrant a restriction without seeking due diligence from the customers' distributor.

11.75 In sum, as the data Mallinckrodt provided reflects, the SOMT's enhancement to the ARCOS Dashboard has added powerful tools to the SOM program. Indeed, as summarized in the next section immediately below, the SOMT's reviews and restrictions of ***indirect***

customers based on ARCOS data led the SOMT to review and suspend as many as six ***direct*** customers supplying those indirect customers.

c. The SOMT's suspension of distributors based on its analysis of restrictions of the distributors' customers

11.76 Although the SOMT has previously suspended sales to distributors on occasion, those suspensions have occurred infrequently during the monitorship, and certainly far less frequently than the restrictions of downstream registrants that are routine. However, distributor suspensions may no longer be as rare, given a new approach the SOMT deployed in the Eleventh Reporting Period.

11.77 During this reporting period, the SOMT suspended sales to eight distributors. Six of those distributors—Distributor I, Distributor J, Distributor K, Distributor L, Distributor M, and Distributor N—were suspended after the SOMT observed a high percentage of restrictions among their customers.[20] Specifically, the SOMT's analysis revealed it had restricted 60% or more of each of those distributors' customers reviewed during the relevant period. For two of those Distributors (Distributors J and L), the SOMT restricted 100% of the distributors' customers reviewed during the relevant period. After reviewing the basis for the SOMT's reviews and restrictions of those customers, the SOMT concluded all six distributors failed to

[20] The SOMT suspended the seventh distributor, Distributor G, after determining that Distributor G's due diligence response was unsatisfactory, prompting the CSC Team to conduct a due diligence visit that raised additional concerns. *See supra* at 37-41 ¶¶ 11.33-43. The CSC Team's analysis and findings in connection with that visit are described more fully above. The SOMT suspended the eighth distributor based on the U.S. Department of Justice press release announcing the filing of federal criminal charges against certain pharmaceutical distributor executives and sales representatives and pharmacy operators. *See supra* at 44-47 ¶¶ 11.50-60. While this eighth distributor was not a direct customer of Mallinckrodt, Mallinckrodt created and suspended a "placeholder" account with this distributor's information in the event the distributor ever seeks to onboard at Mallinckrodt in the future.

appropriately incorporate ARCOS data into their SOM programs, and therefore voted to suspend sales to those distributors.

i. The SOMT's analysis of indirect customer restrictions, using the modified Tracking Spreadsheet, to determine distributor risk

11.78 As the Monitor previously reported, the SOMT maintains a spreadsheet to track reviews and restrictions of indirect customers, which has been referred to in prior reports as the "Tracking Spreadsheet." *See* Fourth Monitor Report at 31 ¶ 11.27. In 2024, the SOMT began identifying each indirect customer's distributor(s) in the Tracking Spreadsheet, and the SOMT also added the indirect customers' distributors for the reviews conducted over the past year to create an approximately 18-month data set. In order to analyze the SOMT's reviews of a given distributor's customers, the SOMT used the Tracking Spreadsheet to determine: (1) the total reviews the SOMT conducted of each distributor's customers over a period of time; and (2) the percentage of those reviews resulting in restrictions. The SOMT then looked more closely at the distributors for whom a high percentage of customers were restricted.[21] Specifically, the SOMT reviewed the basis for those reviews to discern any concerning patterns, and concluded they were all initiated based on anomalous ARCOS data. The SOMT then reviewed its findings in connection with those reviews, as documented in the chargeback restriction review sheets the SOMT prepares in connection with each review, and considered other relevant materials, including at least one report from a prior due diligence visit.

11.79 Based on this analysis, it became clear to the SOMT that none of the six distributors the SOMT reviewed were appropriately analyzing the ratios of their pharmacy

[21] For purposes of the SOMT's analysis, the SOMT did not consider reviews it initiated, or the resulting restrictions it issued, based on the notifications of restrictions Mallinckrodt received from the distributors.

customers' ARCOS reportable purchases, including: (1) the ratio of their customers' purchases of oxycodone or hydrocodone to all ARCOS reportable purchases; and/or (2) the ratio of their customers' purchases of highly diverted formulations of certain opioid products to total purchases within that drug family. Accordingly, the SOMT concluded Distributor I, Distributor J, Distributor K, Distributor L, Distributor M, and Distributor N "did not review or utilize ARCOS data regularly in an effort to find pharmacies with unusual purchasing patterns," and the SOMT voted to suspend sales to all six distributors.

ii. Examples of the SOMT's findings in connection with the new distributor analysis

11.80 The SOMT made similar findings and reached the same conclusion as to each of the six distributors it suspended based on the aforementioned analysis. The Monitor has summarized the SOMT's reviews for three of its distributor reviews to illustrate the SOMT's findings.

11.81 By way of example, Distributor J is a distributor Mallinckrodt had previously restricted but reinstated after it agreed to make certain changes to its SOM program to better detect potential diversion of controlled substances. After Mallinckrodt resumed sales to Distributor J, Distributor J proactively informed Mallinckrodt of over a dozen pharmacies it restricted, and it appeared to the SOMT that Distributor J had implemented the agreed-upon changes. However, after October 2023, Distributor J stopped informing Mallinckrodt of those restrictions. In June 2024, the SOMT analyzed the ratio of its reviews of Distributor J's customers to restrictions during an approximately 9-month period, which revealed that the SOMT had restricted 100% of Distributor J's customers reviewed. And the SOMT's reviews of Distributor J's customers revealed a troubling pattern: the SOMT would conduct a review of Distributor J's customer based on, among other things, abnormal ARCOS data; the SOMT would

request due diligence from Distributor J; and only then would Distributor J inform the SOMT that it had previously restricted the customer. As the SOMT's reviews demonstrated a pattern indicating that Distributor J did not sufficiently utilize ARCOS data as part of its SOM program, the SOMT suspended sales to Distributor J.

11.82 Regarding Distributor I, the SOMT conducted five reviews of Distributor I's customers between September 2023 and June 2024, and three of those reviews (60%) resulted in a chargeback restriction. Of the reviews of Distributor I's customers resulting in restrictions, the SOMT initiated those reviews based on ARCOS data reflecting that the ratio of the customers' purchases of highly diverted formulations of certain opioid products to total purchases within that drug family were abnormal. In each of these cases, Distributor I's responses to the SOMT's due diligence requests raised concerns because, among other responses, Distributor I's responses contradicted its prior representations regarding certain components of its SOM program.

11.83 Lastly, regarding Distributor K, the SOMT conducted five reviews of Distributor K's customers between July 2023 and June 2024, and four of those reviews (80%) resulted in a chargeback restriction. For three of the four reviews that resulted in restrictions, the SOMT performed the reviews on an ad hoc basis because the customers' ARCOS data was clearly abnormal.

iii. The Monitor Team's interview with the SOMT about its distributor reviews and the Monitor's observations regarding the SOMT's new analysis

11.84 During the Monitor Team's interview with the members of the SOMT, the CSC Director indicated that the SOMT intends to repeat its analysis of distributors' restricted pharmacies, potentially on a quarterly basis, so the SOMT has enough new data to conduct a meaningful analysis. The CSC Director also indicated the SOMT would explore whether it could use the indirect customer dashboard to automate aspects of this analysis. For example, the

Monitor Team and the SOMT discussed potentially adding a "toggle" that would allow the SOMT to see each indirect customer's distributor, without having to manually search for that information.

11.85 The Monitor agrees that it would be beneficial for Mallinckrodt to periodically conduct this analysis in the future. This would help to compensate for some of the limitations in Mallinckrodt's present ability to assess the adequacy of distributors' SOM programs, and to detect bad actors among distributors. In addition to the limitations discussed above, although Mallinckrodt gains some insight into the distributors' practices based on its customer questionnaires, the CSC Team's site visits to distributors, and the due diligence responses distributors provide, the value of that information depends, to some extent, on the truthfulness and accuracy of the distributors' representations. For example, of Distributor I, Distributor J, Distributor K, Distributor L, Distributor M, and Distributor N, many if not all of them responded 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?" However, in many cases, the CSC Team's discussions with the distributors revealed they were only using ARCOS data to verify customers' DEA registrations, rather than meaningfully analyzing the data to detect potential diversion. For this reason, the CSC Director relayed that Mallinckrodt is considering revising the distributor customer questionnaire to seek additional information on distributors' utilization of ARCOS data. The Monitor Team will provide an update on any revisions to the questionnaire in the next reporting period.

11.86 In sum, it would be difficult to extrapolate the important pattern revealed by the SOMT's new analysis from the distributor's flagged orders (if any) and the information the distributor provides, without more. The SOMT's analysis of its reviews and restrictions of a

distributor's customers organizes additional, highly relevant data points from different sources of information over time in one place, better allowing the SOMT to identify deficiencies in the distributor's SOM program.

11.87 To that end, the Director of CSC Analytics informed the Monitor Team that his next comprehensive annual review of highly diverted substances will feature a greater focus on distributors. As described in the most recent annual review, the purpose of the Director of CSC Analytics' analysis is to identify "trends, anomalies, and unusual patterns which may not be captured on the Downstream Customer Suspicious Order Monitoring Dashboard and could be indicative of red flags and possible downstream diversion." In the past, the Director of CSC Analytics has used the annual review to perform a high-level, big-picture analysis of an entire year of chargeback data. The Monitor Team expects such a holistic review of distributors, like the new analysis, will likely reveal other patterns potentially leading to additional suspensions. The Monitor Team will review the Director of CSC Analytics' report in the next reporting period.

d. In 2024, the SOMT has received a greater number of reinstatement requests

11.88 In 2022 and 2023, the Monitor Team observed a significant increase in the number of downstream registrants the SOMT reviews annually, and the number of such registrants restricted. *See* Tenth Monitor Report at 53 ¶ 12.74. Indeed, the SOMT completed more reviews and restricted more downstream registrants in 2023 than it had in any of the prior four years (2019 through 2022), and, as of the third quarter of 2024 Mallinckrodt has already reviewed and restricted more downstream registrants than it did in 2023. *Id.*

11.89 It is not surprising, then, that Mallinckrodt has received a greater number of reinstatement requests each year since 2021. The CSC Director informed the Monitor Team he

attributes the rising number of reinstatement requests in large part to the SOMT's increased number of downstream registrants restricted in recent years.

11.90 The increase in reinstatement requests has been substantial. Based on the data Mallinckrodt provided to the Monitor Team, in 2023 the SOMT received 220% more reinstatement requests than it did in 2022. And in just the first three quarters of 2024, the SOMT has already received 169% more reinstatement requests than it did in 2023. The number of reinstatement requests made and granted, by year, are summarized in the chart below:

Chart 3: Reinstatement Requests, By Year, from 2021 to Present[22]				
	2021	***2022***	***2023***	***Q1-Q3 2024***
Number of Reinstatement Requests Received	13	15	48	129
Number of the Above Reinstatement Requests Granted[23]	7	11	32	77
Percentage of Reinstatement Requests Granted	54%	73%	67%	57%

11.91 While the number of reinstatement requests granted has also risen each year since 2021, the percentage of reinstatement requests granted decreased slightly in 2023 as compared to the prior year. Partial year data reflects a similar percentage decrease for the first three quarters of 2024. Indeed, for the first three quarters of 2024, the percentage of reinstatement requests granted was only slightly higher than in 2021 (57% versus 54%), when Mallinckrodt received

[22] Reinstatement does not necessarily occur in the same year as when the reinstatement request is made.

[23] The granted reinstatements include reinstatements of both direct and indirect customers. However, indirect customer requests and reinstatements occur far more frequently than direct customer requests and reinstatements.

only 10% of the number of reinstatement requests it has to date in 2024 (13 versus 129). As the CSC Team's review of reinstatement requests can be time consuming, particularly when the restricted indirect customer provides a detailed third-party compliance report, the Monitor raised whether the increased reinstatement requests have imposed a burden on the CSC Team. Mallinckrodt's outside counsel relayed to the Monitor Team that the CSC Team intends to continue to thoroughly review any reinstatement requests and a reinstatement request will not be placed on the agenda for the SOMT's consideration until that request has been appropriately investigated.

4. Other SOM-related Issues

a. *Mallinckrodt convenes a "working group" to consider SOM-related topics*

11.92 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" in the Company comprised of various in-house and outside counsel and subject matter experts. 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 is committed to sharing with the Monitor the outcomes of those deliberations, and the steps Mallinckrodt ultimately takes to implement its decisions.

11.93 Among the topics the working group is considering are the following: (1) whether there is any additional marginal utility to the SOMT's use of "867 Data" (defined below) in addition to the SOMT's heavy reliance upon chargeback data (perhaps especially in the case of downstream registrants not enrolled in the chargeback program); and (2) extending to other distributors the contractual agreement Mallinckrodt has reached with certain distributors regarding reciprocal sharing of intelligence about suspicious customer orders. Both of these

topics, along with other topics under the working group's purview, are addressed in more detail below.

11.94 ***Use of 867 Data.*** The Monitor Team has discussed with the Purdue Monitor Purdue's use of detailed sales reporting data ("867 Data") to assist in Purdue's SOM efforts. The Monitor Team had previously raised with Mallinckrodt's SOMT whether there was value in utilizing this data source, particularly because the Operating Injunction requires Mallinckrodt to make effective use of ***all*** reasonably available data sources. *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"). Around the time of the Monitor's meeting with Analysis Group, Inc. ("AGI") in the Fifth Reporting Period, the Monitor Team asked Mallinckrodt to consider the potential value of 867 Data to its SOM efforts. *See* Fifth Monitor Report at 30 ¶ 11.22. In consultation with AGI, Mallinckrodt took the position that chargeback data remained the most useful source of information for SOM surveillance.

11.95 The Monitor Team and the Purdue Monitor discussed what, if anything, 867 Data might provide that chargeback data does not. The Purdue Monitor noted that 867 Data is generated contemporaneously and is available without delay each time a product moves from one location to another. Chargeback data, on the other hand, is frequently available only after a period of time, due to delay in the settlement of chargebacks (although the "Big Three" distributors may provide chargeback data quicker than smaller distributors). The Purdue Monitor also explained that 867 Data is helpful in the branded market since chargeback data is

generally unavailable in that market due to pricing contracts. Thus, 867 Data might have less utility to Mallinckrodt's Opioid business, given that it is almost exclusively a generics business.

11.96 At the same time, 867 Data may be useful in the instances where Mallinckrodt has no chargeback data—*i.e.*, where downstream registrants are not enrolled in Mallinckrodt's chargeback program. Additionally, the Monitor notes that in recent national settlements, certain large retail pharmacy chains (*e.g.*, Walgreens, CVS, and Walmart) have agreed to permit their distributors to share "unblinded" 867 Data with manufacturers.[24] Thus, Mallinckrodt's working group may wish to re-evaluate the potential usefulness of 867 Data, especially for downstream registrants not already part of Mallinckrodt's chargeback program.

11.97 ***Extending contractual agreements to other distributors.*** 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 primarily focused on four issues—*i.e.*, obtaining the distributors' agreement to: (1) respond timely to Mallinckrodt's due diligence requests; (2) submit timely chargeback requests; (3) terminate supply to customers Mallinckrodt identifies as posing a diversion risk; and (4) inform Mallinckrodt of the distributors' restriction of downstream registrants.

11.98 Of course, this all requires the consent of parties over which neither Mallinckrodt and still less 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

[24] *See, e.g.*, CVS Settlement Agreement at P-20 (Section XVI.1) (Feb. 3, 2023), *available at* https://nationalopioidsettlement.com/wp-content/uploads/2024/03/2022-12-09-CVS-Global-Opioid-Settlement-Agreement-with-2023-02-03-Technical-Correctios-and-2023-09-29-and-2023-12-15-Updates.pdf (last visited Nov. 5, 2024).

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.

11.99 As noted in prior Monitor Reports, one of the "Big Three" distributors, Distributor E, signed a letter agreement Mallinckrodt proposed containing the commitments on the four areas addressed above. *See* Seventh Monitor Report at 23 ¶ 11.19. Mallinckrodt's outside counsel has represented to the Monitor Team that other parties have agreed to the same kinds of terms as Distributor E, but that Mallinckrodt remains engaged in negotiations on the terms of confidentiality that would permit the Monitor Team to review such contracts. The Monitor looks forward to the opportunity for such review.

11.100 More recently, Mallinckrodt entered into a contract with one of the remaining two "Big Three" distributors, Distributor C, for certain branded products. As previously noted, that agreement took effect on January 1, 2024, and specifies how Mallinckrodt and Distributor C will resolve the SOMT's requests for due diligence regarding Distributor C's direct customers (*i.e.*, Mallinckrodt's indirect customers). *See* Ninth Monitor Report at 39-40 ¶ 10.44; *see also* Tenth Monitor Report at 80-82 ¶¶ 12.146-48. Although that particular contract related to branded products (including one branded but not promoted Opioid Product), rather than generic products, the Monitor observed the contract may provide the basis for applying the SOM notice and resolution provisions to additional contracts between Mallinckrodt and Distributor C for generic Opioid Products. In the Eleventh Reporting Period, Mallinckrodt informed the Monitor that Distributor C is, in practice, applying the provisions contained in the contract for certain branded products to all of Distributor C's purchases, including purchases of generic Opioid Products, but that these commitments are not yet formalized in writing.

11.101 Additionally, apparently through oral agreement, Mallinckrodt was able to obtain a list of customers from another distributor, Distributor A that the distributor had decided to restrict, following a due diligence visit with Distributor A in April 2023. During the Tenth Reporting Period, the CSC Director and CSC Manager informed the Monitor that Distributor A had provided Mallinckrodt with lists of customers Distributor A refused to onboard or had terminated in May and November 2023, though Distributor A has not provided Mallinckrodt with those lists since. *See* Tenth Monitor Report at 51 ¶¶ 12.68-69. Of course, that ad hoc solution is not an ideal substitute for a long-term arrangement. Accordingly, the Monitor looks forward to learning more about Mallinckrodt's efforts to roll out an agreement with distributors more broadly.

11.102 ***The return of Analysis Group, Inc. ("AGI").*** More generally, Mallinckrodt's counsel has informed the Monitor Team that Mallinckrodt has re-engaged the services of AGI to conduct a further review of Mallinckrodt's CSC compliance infrastructure. The Monitor Team previously reported on the role of AGI in designing the direct and indirect customer dashboards that have become a central feature of Mallinckrodt's SOM program. *See* Fifth Monitor Report at 37 ¶¶ 11.37-38; *see also* Prior Recommendations 2(m), 2(n), and 2(o). The Monitor Team looks forward to the opportunity to learn from AGI what compliance improvements it recommends for Mallinckrodt.

11.103 ***Other working group topics.*** Additionally, the Monitor Team raised a number of other topics it understands the working group is reviewing, including:

(1) what number and percentage of Mallinckrodt's direct customers are not part of the chargeback program, and for which Mallinckrodt therefore lacks chargeback data, and how Mallinckrodt might compensate for this potential "blind spot;"

(2) whether implementation of the Drug Supply Chain Security Act could reveal an additional source of data from the serialization of drug bottles, and what is the nature and expected timing of the availability of this data;

(3) 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; and

(4) whether there is a way to provide documentation to the Monitor Team that would better reflect the information available to, and considered by, the SOMT when it reviews flagged direct customer orders and the reasons for the SOMT's release of any flagged orders.

11.104 As of the publication of this Eleventh Monitor Report, the working group has not yet shared its conclusions with the Monitor Team. The Monitor Team has requested, and Mallinckrodt's counsel has agreed, to share the working group's actions in the next reporting period.

b. Government Communications Log

11.105 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. As previously reported, *see* Fifth Monitor Report at 34-36 ¶¶ 11.30-33, the Audit Plan requires Mallinckrodt to produce the government communications log ("Communications Log") the SOMT maintains under the *SOM Program Review of Direct Customer Orders* SOP.

11.106 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 Communication Log for the second and third quarters of 2024 and related correspondence concerning inquiries that appear related to Opioid Products, excluding medications typically prescribed for addiction treatment.

11.107 Of the 69 government inquiries Mallinckrodt received in the second quarter of 2024, seven related to Opioid Products or requested information regarding purchases including Opioid Products. Of those seven inquiries, six were from the DEA and one was from a state bureau of narcotics. In each instance, Mallinckrodt provided a timely and appropriate response.

11.108 The Monitor also reviewed correspondence for three government inquiries related to addiction-treatment products in the second quarter of 2024. As set forth above, the Monitor does not typically review the correspondence for inquiries related to addiction-treatment products for several reasons. ***First***, the Operating Injunction's definition of Opioid Products excludes two categories of products from the definition of Opioid Products: (1) "medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as 'their indications and usage,'" and (2) methadone 5 and 10 mg tablets, to the extent they are sold to addiction-treatment facilities. *See* Operating Injunction § I.Q.

11.109 ***Second***, a routine part of the DEA's inspection of addiction-treatment facilities includes contacting the facilities' distributors and verifying shipments of addiction-treatment products. As a result, a very high proportion of all inquiries related to addiction-treatment products documented in the Communication Log each quarter are the DEA's shipping verification requests. For example, in the second quarter of 2024, 55 of the 60 inquiries related to addiction-treatment products were shipping verifications.

11.110 However, three of the inquiries related to orders of addiction-treatment products that appeared on Mallinckrodt's SORs filed with the DEA, and the Monitor Team reviewed the correspondence related to those three inquiries.

11.111 Regarding the first of these three orders, Mallinckrodt initiated the inquiry by contacting the DEA about a customer's registration status. The CSC Senior Manager initiated

the inquiry after the customer, an addiction-treatment facility, contacted Mallinckrodt to report it had not received the entire quantity of a methadone product it ordered. The customer attached a copy of a DEA Form 222 reflecting the customer had ordered a larger quantity of product than it received. The larger quantity reflected on the customer's copy of the Form 222 was the amount the customer typically ordered. However, after investigating, the Customer Service Department confirmed the customer was shipped a smaller quantity of the methadone product based on the version of the customer's Form 222 submitted to Mallinckrodt. Upon reviewing the Form 222, Mallinckrodt concluded the customer's copy of the Form showed indications of being traced over or written in at a different time than the original form to reflect an order for a greater quantity. (In the past, customers filled out Form 222 using triplicate carbon forms that produced two identical copies of the Form 222, but now customers make their own copies of the original Form 222 submitted to the manufacturer).

11.112 The CSC Senior Manager informed the customer of the discrepancy between the two versions of the Form 222 and escalated the issue to management. The SOMT also filed a SOR report for the customer's order with the DEA, and the CSC Senior Manager contacted DEA to explain the situation and confirm the customer was in good standing to order and receive controlled substances. Mallinckrodt's outside counsel advised the Monitor Team that the DEA asked the CSC Senior Manager in a telephone call not to stop shipments to the customer. The DEA subsequently confirmed in writing that it acknowledged the details of the customer's order relayed by the CSC Senior Manager and confirmed the DEA had no opposition to Mallinckrodt continuing to fill legitimate orders from this registrant.

11.113 Although the CSC Senior Manager did not ship additional quantities of the methadone product as part of the order at issue, Mallinckrodt has continued to sell methadone

products to the customer, which are the only products it purchases. The CSC Senior Manager explained the customer's order was not flagged by the direct customer dashboard as potentially suspicious, likely because it was for a smaller quantity than the customer's prior purchases. Additionally, the CSC Senior Manager informed the Monitor Team she had not encountered any issue with the customer before, although the CSC Senior Manager could not recall whether she reviewed the customer's questionnaire before Mallinckrodt processed additional orders. The CSC Senior Manager further explained that, in her experience, there is a lot of employee turnover at addiction-treatment facilities (and, such facilities often change locations) and it is not uncommon for such customers to need education about filling out DEA Form 222. In the past, Mallinckrodt has provided customers with general guidelines about the forms, but typically directs any specific questions to a customer's local DEA field office.

11.114 Notwithstanding the customer's apparent modification of its DEA form, it continued to receive shipments of addiction-treatment products. This is evidently because the DEA had no opposition to Mallinckrodt continuing to fill legitimate orders for the customer, the customer's orders were not otherwise suspicious, and the CSC Senior Manager reported no prior issues with the customer. However, this incident suggests that Mallinckrodt should ensure any manual changes to electronic orders of controlled substances are updated in the ordering system and reviewed by the direct customer dashboard, to ensure a low electronic order (that would not trigger a flag) is not masking a subsequent higher manual order (that would trigger a flag).

11.115 Regarding the second of the three inquiries, the CSC Senior Manager appropriately responded to DEA's request for additional information regarding an order for addiction-treatment products Mallinckrodt reported on a SOR filed with DEA.

11.116 Finally, as for the third of the three inquiries, the Communications Log and related documentation reflected that a DEA investigator requested a telephone call with the CSC Specialist to discuss the explanations provided in Mallinckrodt's SORs. The CSC Specialist and the CSC Senior Manager explained to the Monitor Team that it is not uncommon for DEA field offices to request further information regarding SORs and Mallinckrodt's responses to specific SOR inquiries, but those requests typically seek to clarify the meaning of the terminology and descriptive phrases Mallinckrodt uses, rather than requesting substantive information such as the reason regarding Mallinckrodt's release of the flagged order(s). The CSC Senior Manager further explained that any substantive conversation with DEA in connection with a SORs inquiry would be documented by the SOMT member handling the inquiry in a memorandum.

11.117 In sum, for each of these three inquiries related to addiction-treatment products, it appears Mallinckrodt appropriately communicated with DEA and provided timely responses to its inquiries.

11.118 Of the 67 government inquiries Mallinckrodt received in the third quarter of 2024, ten related to specific Opioid Products or requested information regarding purchases that included Opioid Products. Of those ten inquiries, eight were from the DEA and two were from municipal law enforcement agencies in different states. In each instance, Mallinckrodt provided a timely and appropriate response.[25]

[25] The Communications Log also indicated the DEA performed an inspection of Mallinckrodt's facility in Hobart, New York in the third quarter of 2024, in connection with Mallinckrodt's importer license application. Mallinckrodt applied for an importer license so the Hobart facility could obtain a Schedule IV controlled substance from outside the United States, without using a broker. Before DEA issued Mallinckrodt's importer license, the DEA requested certain policies related to, among other things, storage of, and access to, controlled substances, which the CSC Specialist provided.

c. SOM-related TrackWise entries

11.119 In the Sixth Monitor Report, the Monitor recommended that any evidence of diversion risks appearing in the TrackWise inquiry and complaint logs (discussed *supra* at 10-11 ¶¶ 6.11-16) 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)). Thereafter, the Monitor amended the Audit Plan to require Mallinckrodt to provide, on a quarterly basis, copies of any inquiries elevated to the CSC Director and documents reflecting the outcome of any related investigation.

11.120 Since Mallinckrodt implemented Prior Recommendation 6(f), the Associate General Counsel has not identified any TrackWise entries evidencing the potential risk for diversion that would necessitate the CSC Director's review. However, she informed the Monitor that several TrackWise entries were escalated to the CSC Director, as well as to other members of management, in the second quarter of 2024 as a matter of course.

11.121 In the Eleventh Reporting Period, the Monitor Team reviewed the TrackWise entries for the second quarter of 2024 that were escalated to the Security and/or CSC Departments and again conducted a keyword search of the entries for indications of potential diversion. For the most part, the narratives suggest that any issues of diversion were outside Mallinckrodt's control, such as retail pharmacy theft and robbery. One issue identified, however, was a patient complaint that pills appeared to have been "scraped" or "incorrectly stamped." The pharmacist opened a new bottle and discovered the same issue, suggesting that this issue existed prior to arrival at the pharmacy. The CSC Director is looking into this matter in order to provide additional information to the Monitor Team.

11.122 Another incident involved a pharmacy report of a sealed 100-count pill bottle that, when opened, revealed just 75 tablets. Mallinckrodt's review of video surveillance footage

revealed that the likely cause of this was "a clogged filler chute coupled with an issue with the reject verification arm and operator error in clearing the line after the clog and when the line went into alarm." As a result, a number of bottles were not filled, resulting in variances in pill counts, but the possibility of diversion can be ruled out.

d. Mallinckrodt's hiring of an additional CSC Manager

11.123 As the Monitor previously reported, Mallinckrodt hired an additional CSC Manager, CSC Manager C, who started work at Mallinckrodt's Webster Groves facility in July. *See* Tenth Monitor Report at 82-83 ¶ 12.150. CSC Manager C has a law enforcement background and decades of experience as a criminal investigator with several federal government agencies. For the past ten years, CSC Manager C was a special agent with the FDA, where he conducted and oversaw criminal investigations, as well as engaged with regulatory and law enforcement officials in connection with inspections, criminal prosecutions, and other regulatory actions. When CSC Manager C left the FDA, he held the title of Senior Special Agent.

11.124 The Monitor Team interviewed CSC Manager C in October 2024 to discuss his background and training. CSC Manager C explained his interest in working on the SOMT at Mallinckrodt stemmed, in part, from his work at the FDA investigating counterfeit pharmaceuticals being smuggled into the United States. When CSC Manager C was asked about his prior experience with data analytics, which is a significant component of the SOMT's work, he informed the Monitor that he has experience interpreting large amounts of data and analyzing patterns and trends to detect potential criminal activity.

11.125 Over the past three months, CSC Manager C has received hands-on training on all aspects of the SOM program, including reviewing flagged orders and indirect customers. His training, which is ongoing, entails working side-by-side with more experienced members of the SOMT, including the Director of CSC Analytics and CSC Specialist. CSC Manager C praised

the quality of his training, and he did not inform the Monitor Team that there was any training he wanted or needed that he had not yet received.

11.126 The CSC Director and the CSC Senior Manager believe the new CSC Manager brings a valuable perspective to the SOMT, as none of the current members have FDA experience—most of them are former DEA agents. The Monitor agrees. He anticipates the addition of CSC Manager C will assist the SOMT's efforts in its core focus—preventing diversion—because of his experience and different perspective. Additionally, CSC Manager C will increase the SOMT's capacity for handling more work and conducting more analysis.

11.127 In the remaining reporting periods, the Monitor will continue to assess whether Mallinckrodt has adequate resources to effectively and efficiently perform the different components of its multi-faceted SOM program, including but not limited to reviewing flagged direct customer orders, conducting chargeback reviews, reviewing the ARCOS dashboard, and other data analysis. *See* Seventh Monitor Report at 28 ¶ 11.35.

e. Mallinckrodt's navigation of the DEA's semi-annual quota application process

11.128 As detailed in the Tenth Monitor Report, in 2023 the DEA announced it would require manufacturers to apply for procurement quota[26] allotments for commercial manufacturing of Schedule II controlled substances on a quarterly basis, instead of on an annual basis, starting in January 2024. *See* Tenth Monitor Report at 40 ¶ 12.30. However, the DEA's quarterly application process was short-lived. In April 2024, recognizing the practical challenges the quarterly requirement posed for manufacturers, given manufacturing lead times and the complexities of the drug supply chain, the DEA announced that it would instead require

[26] Procurement quota refers to the amount of API a manufacturer can acquire to manufacture finished dose products (*i.e.*, tablets, pills, and the like, in finished form).

manufacturers to apply for procurement quota allotments on a semi-annual basis. *Id.* at 41 ¶ 12.33.

11.129 During the Eleventh Reporting Period, the Monitor Team inquired with the CSC Director and the Director of CSC Analytics as to how Mallinckrodt is managing the DEA's change from annual to semi-annual procurement quota allotments and whether the Company has sufficient resources to navigate that change, given the already resource-intensive nature of the quota application process even prior to the semi-annual quota application change. They informed the Monitor Team that Mallinckrodt had hired two employees in St. Louis and Hobart to assist with both quota applications and managing the DEA's new quota monitoring requirements, which were announced in 2023 and took effect in 2024.

11.130 The CSC Director also informed the Monitor Team that the semi-annual application requirement, which took effect in July 2024, made the process for obtaining quota grants challenging, at least initially, because DEA was working through a backlog of quota requests, which delayed Mallinckrodt's receipt of its quota for certain molecules. As the change was only recently implemented, the CSC Director expects that 2025 will be a "truer test" of how the new application process works and whether Mallinckrodt has the resources it needs to comply with the DEA's allotment and monitoring requirements. The Monitor will provide an update regarding the sufficiency of Mallinckrodt's resources to manage these changes in the next reporting period.

11.131 The CSC Senior Manager and CSC Specialist echoed the CSC Director's thoughts, informing the Monitor Team that manufacturers, including Mallinckrodt, have faced challenges obtaining quota this year. Those challenges have led to shortages of certain products in the market. Indeed, the CSC Senior Manager explained that Mallinckrodt continues to see

distributors that use Mallinckrodt as a secondary supplier placing larger orders with Mallinckrodt because their primary suppliers cannot meet the demand for those products.

f. Mallinckrodt's response to a DEA administrative subpoena for records and correspondence related to a specific distributor's orders

11.132 In the first quarter of 2024, Mallinckrodt suspended Distributor B and notified the DEA of that suspension. Thereafter, Mallinckrodt responded to an administrative subpoena from the DEA seeking, among other things, all SORs for Distributor B and related communications with Distributor B during a multi-year time period. *See* Tenth Monitor Report at 77-78 ¶ 12.138. During the Eleventh Reporting Period, the Monitor Team inquired whether, after receiving that subpoena from the DEA, Mallinckrodt took any actions (other than responding to the subpoena) or made any changes to its practices or policies, including compliance or SOM-related changes, based on the documents it reviewed and compiled in response to the subpoena. Mallinckrodt's counsel informed the Monitor Team that Mallinckrodt had complied with the subpoena and did not believe any other actions or changes were necessary, since Distributor B had already been suspended. However, Mallinckrodt's counsel indicated the Company continues to review potential enhancements to its SOM program.

g. Monitors of other Opioid manufacturers

11.133 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 to the Monitor in this monitorship. During the Eleventh Reporting Period, the Monitor Team continued this practice, and reviewed the Purdue Monitor's

findings in his Eighteenth[27] and Nineteenth[28] Monitor Reports, including his observations regarding the utility of using 867 Data and PBM data[29] to monitor customers and detect potentially suspicious Opioid purchases.[30] The Monitor Team intends to continue to meet with the Purdue Monitor and to review the Purdue Monitor Reports in future reporting periods, as appropriate.

11.134 The Monitor Team's request—via the state Attorneys General—to review the reports of other monitors, even if in redacted form, was rejected by the "Big Three" distributors.

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

11.135 As reported in the Ninth and Tenth Monitor Reports, and as Mallinckrodt disclosed in prior SEC filings, Mallinckrodt received grand jury subpoenas in 2023, in connection with a federal criminal investigation by the U.S. Attorney's Office for the Western District of Virginia. *See* Ninth Monitor Report at 49-52 ¶¶ 14.1-8; Tenth Monitor Report at 92 ¶ 12.179. As also noted in those Monitor Reports, Mallinckrodt and its outside counsel have

[27] *In re: Purdue Pharma L.P., et al.*, No. 19-23649, Dkt. 6362 (S. D. N.Y. Bankr., May 17, 2024).

[28] *In re: Purdue Pharma L.P., et al.*, No. 19-23649, Dkt. 6621 (S. D. N.Y. Bankr., Aug. 16, 2024).

[29] PBM data refers to data derived from rebates a manufacturer pays to a Pharmacy Benefit Manager (or "PBM"). PBMs are third-party companies that function as intermediaries between insurance providers and pharmaceutical manufacturers.

[30] A representative of the Attorneys General asked the Monitor whether PBM data may have relevance to Mallinckrodt's SOM efforts. The Monitor Team, accordingly, raised this with Mallinckrodt's counsel, in addition to the issue of the potential usefulness of 867 Data. As noted above, *see supra* at 61-66 ¶ 11.92-104, the relevance of 867 Data is among the topics Mallinckrodt's "working group" is addressing. As to the PBM data, Mallinckrodt's counsel has advised that, unlike Purdue's branded products (such as OxyContin), Mallinckrodt does not have access to this data for the generic Opioid Products that SpecGx sells.

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* Ninth Monitor Report at 50-52 ¶¶ 14.3-8; Tenth Monitor Report at 92 ¶ 12.179. The Monitor Team will continue to review Mallinckrodt's responses to determine what aspects, if any, may be relevant to the focus of this monitorship.

11.136 As the Monitor previously reported, Mallinckrodt LLC, Mallinckrodt PLC, and SpecGx received three (largely identical) grand jury subpoenas on March 12, 2024 and informal requests for information from the U.S. Attorney's Office for the Western District of Virginia on April 18, 2024. The subpoenas generally related to purchases of products, and transaction data related to those purchases, by Mallinckrodt's direct customers—*i.e.*, distributors—from July 17, 2017 to the date of production. *See* Tenth Monitor Report at 92 ¶¶ 12.180-81.

11.137 On June 24, June 25, August 6, August 8, and October 4, 2024, 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 concerned contracts and records concerning reverse distributors and sought transaction data relating to chargebacks and other after-purchase payments relating to certain downstream registrants—*i.e.*, pharmacies—served by Mallinckrodt's customers.

11.138 The U.S. Attorney's Office's issuance of additional grand jury subpoenas has recently introduced additional counsel to the conversations the Monitor Team has had with Mallinckrodt. The Monitor is hopeful that open communication with this counsel will not

unduly interfere with the Monitor's role. That said, as a practical matter the involvement of additional counsel unquestionably adds a new layer of complexity to the monitorship.

11.139 As previously noted in the Ninth Monitor Report, *see* Ninth Monitor Report at 50-51 ¶ 14.3, the Monitor thought it important to advise the Attorneys General of the issuance of the Western District of Virginia subpoenas to Mallinckrodt, and to introduce himself to the U.S. Attorney's Office representatives running the investigation after the Monitor learned of the initial subpoenas issued to Mallinckrodt. Accordingly, the Monitor Team sought to advise the Attorneys General of the potential "chilling effect" a simultaneous federal investigation might create for Mallinckrodt employees, and hence the potential for conflict between the federal investigation and the monitorship, and therefore the need to "deconflict" with the federal investigation to the extent possible. The Monitor Team remains keenly aware of the unusual circumstance of a monitorship conducted while the subject of the monitorship remains under federal scrutiny, at some risk to the Company and the individual employees whose continued cooperation and assistance with the monitorship are essential to the Monitor's mission.

i. Grand jury subpoenas from the U.S. Attorney's Office for the Eastern District of Pennsylvania

11.140 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.[31]

[31] 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.

11.141 Mallinckrodt reported its receipt of the subpoena publicly in its Form 10-Q filing with the SEC on August 6, 2024.[32] The disclosure states, in relevant part:

> In May 2024, the Company received a grand jury subpoena from the U.S. Attorney's Office for the Eastern District of Pennsylvania seeking production of data and information with respect to a customer for the time period from January 1, 2020 to May 2024, including information and data relating to potentially suspicious orders for controlled substances. The Company suspended sales to this customer in October 2023 prior to receipt of the subpoena.

11.142 Mallinckrodt, through its outside counsel, has shared with the Monitor Team the cover letters accompanying materials produced in response to this grand jury subpoena. Such productions occurred on June 26, July 12, and July 26, 2024. 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.

XII. TRAINING (OI § III.K)

12.1 Mallinckrodt's training obligations under the Operating Injunction and the components of its employee trainings are generally described in the Monitor's prior reports. *See, e.g.*, Fourth Monitor Report at 49 ¶ 3.1; Fifth Monitor Report at 42 ¶ 12.1 and 43-44 ¶ 12.6.

12.2 During the Eleventh Reporting Period, the Monitor audited Mallinckrodt's compliance with the Operating Injunction's training requirements by: (1) reviewing whether all relevant employees hired during the second and third quarters of 2024 completed their Operating Injunction trainings; and (2) reviewing the new interactive Operating Injunction training module (the "Training Module") that replaced Mallinckrodt's live Operating Injunction training.

[32] The filing is available on Mallinckrodt's website here: https://mallinckrodt.com/investors/sec-filings/.

1. New Employee Trainings In the Second and Third Quarters of 2024

12.3 In the Eleventh Reporting Period, Mallinckrodt identified seven new employees hired in the second quarter of 2024 who were required to receive Operating Injunction training. Six of these new employees completed all of the training components in the second quarter of 2024; the remaining employee completed the board service survey and reviewed the Operating Injunction, but had not yet attended a live training or passed the Operating Injunction quiz because he joined Mallinckrodt near the end of the second quarter; he completed the training in the third quarter. Mallinckrodt also confirmed that the three employees hired in the first quarter of 2024 who had not yet completed all training requirements at the time of the Tenth Monitor Report (*see* Tenth Monitor Report at 94 ¶ 13.7) subsequently completed their Operating Injunction training.

12.4 During the third quarter of 2024 (as discussed *infra* at 81 ¶ 12.8) Mallinckrodt launched the new online Operating Injunction Training Module that combines three of the four components of the prior Operating Injunction training program—the live training, policy certification, and quiz. As a result, new employees who are required to receive Operating Injunction training must now complete (1) the Training Module and (2) the board service survey (the fourth element of the prior Operating Injunction training program).

12.5 For the third quarter of 2024, Mallinckrodt identified ten new employees who were required to receive Operating Injunction training. Mallinckrodt reported that, of those employees: (1) five completed the Training Module and the board service survey; (2) four completed the board service survey, only; and (3) one completed the Training Module only. One of the employees who completed the Training Module was the Customer Service Representative, who was the only employee with outstanding training requirements identified in the second quarter of 2024.

12.6 The Monitor will confirm that the four remaining employees have completed the Training Module, and the one remaining employee has completed the board service survey, during the next reporting period.

2. New Interactive Online Operating Injunction Training Module

12.7 During the monitorship, Mallinckrodt has required all relevant employees to attend an annual live Operating Injunction training that the Compliance Department develops and presents. However, as the Monitor previously reported, Mallinckrodt informed the Monitor Team that it intended to engage a third-party vendor to replace the live training and quiz components of its Operating Injunction training. Mallinckrodt anticipated that this new format would allow it to conduct a one-on-one computer-based training that is more interactive than the large group trainings it has conducted to date.

12.8 During the Eleventh Reporting Period, Mallinckrodt launched that new Training Module and provided a link to the Monitor Team for its review. A member of the Monitor Team was able to participate in the Training Module as if she was a Mallinckrodt employee.

12.9 The Training Module takes approximately one hour to complete. The training begins with a review of the events that led to the Operating Injunction and the Monitor's appointment, and provides a link to the Operating Injunction itself. The introduction also emphasizes the continuing nature of many of the Operating Injunction's provisions, stating: "Most of the terms of the Operating Injunction will be in effect indefinitely and is considered our new normal." This is important; although the Monitor's appointment may expire next year (assuming the monitorship is not extended), many of the Operating Injunction's substantive provisions will not.

12.10 The Training Module then reviews each section of the Operating Injunction and its corresponding requirements in detail, and includes informative summaries of recent revisions

to SOPs that touch on the Operating Injunction. For example, regarding the section on the Operating Injunction's Ban on Third-Party Funding, the Training Module informs participants: "Mallinckrodt has made significant revisions to this process for grants and sponsorships, including the documentation that needs to be provided to the SGGSAC before a requestor pays a deposit for an event or agrees to a sponsorship."

12.11 Participants must read through each page of the Training Module, listen to the relevant audio, and complete all of the activities on that page, before they are permitted to continue to the next page. Additionally, there are short mandatory quiz questions throughout the Training Module that participants must pass in order to proceed to the next section.

12.12 The Training Module also includes information about resources for reporting compliance concerns, and provides contact information for: employees in Mallinckrodt's Compliance Department; the Integrity Hotline; and a member of the Monitor Team.

12.13 Lastly, to complete the Training Module and move to the Certification page, participants must pass an 11-question quiz testing their knowledge of each section of the Operating Injunction. The quiz questions include true or false, single answer, and "select all that apply" questions. Participants must receive a grade of 80% or better to pass. Participants who do not pass are informed which questions they answered incorrectly, and they are required to retake the quiz, although the second quiz contains the same questions as the original quiz. Upon passing the quiz, participants are taken to a final page, where they are asked to certify that they reviewed the Operating Injunction and completed the Training Module. This page does not allow participants to complete the Certification unless they have opened the link to the Operating Injunction.

12.14 The Monitor Team concluded that the new Training Module is appropriate, comprehensive, and an improvement upon the prior live training, because the interactive format mandates participation from the participants throughout the module. Participants are not permitted to skip through sections without completing the activities and quizzes on each page, and must receive a passing score on the final quiz (and open the Operating Injunction itself), to certify completion. The Monitor Team's only suggestion for refinement is to pose a different set of final quiz questions if a participant does not pass on his or her first try, so that the participant is not able to see the answers before retaking the quiz.

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.[33] *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 second or third quarters of 2024.

13.4 Likewise, there were no new Mallinckrodt Opioid Products, or indications for existing products, in the second or third quarters of 2024.

[33] Additional information regarding Mallinckrodt's clinical data archive is available at https://vivli.org/ourmember/specgx-llc-a-subsidiary-of-mallinckrodt-plc/ (last visited Nov. 4, 2024).

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 69-70 ¶¶ 14.1-5. There are no further updates at this time.

XV. THE OPERATING INJUNCTION'S TERMS CONCERNING CONCLUSION OF THE MONITORSHIP

15.1 The Operating Injunction's provisions establishing and governing the monitorship apply for five years from the October 12, 2020 Petition Date—*i.e.*, until October 12, 2025 (unless the Settling States determine in good faith and in consultation with the Monitor that justifiable cause exists to extend the monitorship). OI § II.E.3. While the Monitor's appointment may expire next year, a number of the Operating Injunction's provisions will not. Specifically, the following provisions are not subject to any term and will remain in effect after the monitorship's conclusion: Section III.A ("Ban on Promotion"), Section III.B ("No Financial Reward or Discipline Based on Volume of Opioid Sales"), Section III.F ("Ban on Prescription Savings Program"), Section III.G ("Monitoring and Reporting of Direct and Downstream Customers"), Section III.H ("General Provisions"), Section III.I ("Compliance with All Laws and Regulations Relating to the Sale Promotion and Distribution of Any Opioid Product"), and Section V ("Public Access to Mallinckrodt Documents"). *Id.* § II.E.2. The Operating Injunction's remaining provisions apply for eight years from the Petition Date, including the following sections: Section III.C ("Ban on Funding/Grants to Third Parties"), Section III.D

("Lobbying Restrictions"), Section III.E ("Ban on Certain High Dose Opioids"), and Section III.K ("Training"). *Id.* § II.E.1.

15.2 Accordingly, in the only two remaining reporting periods (assuming no extension of the monitorship), the Monitor intends to raise with Mallinckrodt what steps, if any, Mallinckrodt will take to ensure its continued compliance with the Operating Injunction after the monitorship's conclusion. While Mallinckrodt has assured the Monitor that it intends to continue to comply with the Operating Injunction's provisions post-monitorship, and the Monitor does not doubt Mallinckrodt's intention, the Monitor intends to explore with Mallinckrodt how it intends to ensure such compliance in the absence of third-party oversight. For example, the Monitor intends to raise with Mallinckrodt whether it could position itself now to better ensure compliance in the future by, for example: making further changes to Mallinckrodt's existing policies and procedures, including changes to formally incorporate the Operating Injunction's provisions (to the extent they have not been incorporated already); establishing a mechanism for internal OI-compliance audits; and formalizing the CSC "working group" to continue to think strategically about continuous future improvement of CSC.

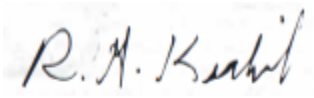
15.3 The Monitor will provide an update on these discussions with Mallinckrodt prior to the conclusion of the monitorship.

XVI. CONCLUSION

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

* * *

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



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

EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE ELEVENTH MONITOR REPORT DATED NOVEMBER 20, 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.	In Progress
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.	In Progress

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.	In Progress

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.	In Progress