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

October 10, 2025

TABLE OF CONTENTS

Page

THIRTEENTH 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 Thirteenth Monitor Report covers the period from the filing of the Twelfth Monitor Report on May 19, 2025, to the present (the "Thirteenth Reporting Period"), and is the final report of this monitorship.[1] The Thirteenth 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 Thirteenth 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) provides an update on the status of Mallinckrodt's merger with Endo, Inc. ("Endo"); (5) includes three new recommendations; and (6) shares the Monitor's latest understanding of what the "day after" the monitorship will entail.

1.2 During the Thirteenth Reporting Period, the Monitor once again assessed Mallinckrodt's compliance with the Operating Injunction by reviewing documents Mallinckrodt

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

produced in response to the Monitor's Audit Plan[2] requests and ad hoc requests, reviewing publicly available information pertaining to Mallinckrodt and the topics addressed in the Operating Injunction, and conducting interviews. In response to the Audit Plan and the Monitor's ad hoc requests, during the Thirteenth Reporting Period Mallinckrodt provided approximately 747 files (consisting of approximately 1 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 either Mallinckrodt's website,[3] or the website of its successor.

* * *

1.5 Mallinckrodt's employees and counsel have continued to be responsive, cooperative, and helpful to the Monitor. Based on the information reviewed to date, the Monitor believes that Mallinckrodt has made a good-faith effort to comply with the terms and conditions of the Operating Injunction, as discussed below.

[2] As described in the Fourth Monitor Report, the Audit Plan includes requests for documents and data related to each section of the Operating Injunction and requires Mallinckrodt to produce documents at different time intervals (*i.e.*, annually, quarterly, monthly, and "as soon as reasonably possible"). *See* Fourth Monitor Report at 2 ¶ 1.3.

[3] *See* Mallinckrodt's "Integrity and Compliance" webpage (formerly titled "Corporate Compliance"), *available at* https://www.mallinckrodt.com/corporate-sustainability/corporate-compliance/ (last visited Oct. 10, 2025) (listed under "Operating Injunction" drop-down). As previously discussed, the Monitor's reports are no longer filed with the Bankruptcy Court. Nonetheless, Mallinckrodt and the Ad Hoc Committee agree that the Bankruptcy Court retains jurisdiction to adjudicate disputes the Settling States may bring related to enforcement of, or disputes concerning, the Operating Injunction if the Settling States have not obtained a state court order enforcing the injunctive terms.

II. THE OPERATING INJUNCTION

2.1 On October 12, 2020, Mallinckrodt and the Settling States[4] agreed to the Mallinckrodt Injunctive Relief Draft Term Sheet. *See* Case No. 20-12522, Dkt. No. 128, Ex. 2 (Bankr. D. Del.). The Court adopted an amended and final Term Sheet on January 8, 2021 (referred to herein as the "Operating Injunction" or "OI"). *See* Adv. Pro. No. 20-50850, Dkt. No. 196-1 (Bankr. D. Del.). A copy of the Operating Injunction is attached as Exhibit 1 to the First, Second, and Third Monitor Reports.

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

2.3 The operative sections of the Operating Injunction, for purposes of the monitorship, are Sections III (Injunctive Relief), IV (Clinical Data Transparency), and V (Public Access To Mallinckrodt Documents).

2.4 Section III (Injunctive Relief) is comprised of the following subsections: (1) a ban on promotion (Operating Injunction § III.A); (2) a prohibition on financial reward or discipline based on volume of opioid sales (*id.* § III.B); (3) a ban on funding / grants to third parties (*id.* § III.C); (4) lobbying restrictions (*id.* § III.D); (5) a ban on certain high dose opioids (*id.* § III.E); (6) a ban on prescription savings programs (*id.* § III.F); (7) monitoring and reporting of direct and downstream customers (*id.* § III.G); (8) general terms (*id.* § III.H); (9) compliance

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

with all laws and regulations relating to the sale, promotion, and distribution of any opioid product (*id.* § III.I); (10) compliance deadlines (*id.* § III.J); and (11) training (*id.* § III.K).

2.5 Section IV (Clinical Data Transparency) is comprised of the following subsections: (1) data to be shared (*id.* § IV.A); (2) third-party data archive (*id.* § IV.B); (3) non-interference (*id.* § IV.C); (4) data use agreement (*id.* § IV.D); and (5) cost (*id.* § IV.E).

2.6 Section V (Public Access To Mallinckrodt Documents) is comprised of the following subsections: (1) documents subject to public disclosure (*id.* § V.A); (2) information that may be redacted (*id.* § V.B); (3) redaction of documents containing protected information (*id.* § V.C); (4) review of trade secret redactions (*id.* § V.D); (5) public disclosure through a document repository (*id.* § V.E); (6) timeline for production (*id.* § V.F); (7) costs (*id.* § V.G); and (8) suspension (*id.* § V.H).

III. PRIOR MONITOR REPORTS

3.1 ***The First Monitor Report.*** The Monitor submitted the First Monitor Report on April 26, 2021. *See* Case No. 20-12522, Dkt. No. 2117 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 212 (Bankr. D. Del.).

3.2 ***The Second Monitor Report.*** The Monitor submitted the Second Monitor Report on July 23, 2021. *See* Case No. 20-12522, Dkt. No. 3409 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 223 (Bankr. D. Del.).

3.3 ***The Third Monitor Report.*** The Monitor submitted the Third Monitor Report on October 21, 2021. *See* Case No. 20-12522, Dkt. No. 4863 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 277 (Bankr. D. Del.).

3.4 ***The Fourth Monitor Report.*** The Monitor submitted the Fourth Monitor Report on January 19, 2022. *See* Case No. 20-12522, Dkt. No. 6185 (Bankr. D. Del.); Adv. Pro. No. 20-50850, Dkt. No. 307 (Bankr. D. Del.).

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

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

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

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

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

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

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

3.12 ***The Twelfth Monitor Report***. The Monitor submitted the Twelfth Monitor Report on May 19, 2025.

IV. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Section XI, the Monitor has made three new recommendations related to the Operating Injunction's requirement to monitor and report direct and downstream customers, and related to its departing employee exit interview surveys.

[5] As noted above, *see 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.

Mallinckrodt has agreed to implement these recommendations,[6] which are that Mallinckrodt should:

13(a) Implement regular use of geographic concentration maps in connection with regularly scheduled due diligence visits with direct customers.

13(b) Implement a two-person review of Mallinckrodt's correspondence with DEA detailing restrictions and reinstatements to ensure such communications are complete and accurate.

13(c) Add compliance-related questions to exit interview surveys.

V. THE INTEGRITY HOTLINE

5.1 The Monitor and Mallinckrodt established a process by which compliance concerns related to the Operating Injunction could 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 agreed to share any such reports with the Monitor Team.

5.2 Mallinckrodt performed quarterly tests of the Integrity Hotline to ensure any report with the issue type "Operating Injunction" would be received by the Monitor Team. *See* Tenth Monitor Report at 6 ¶ 5.2. During the Thirteenth Reporting Period, Mallinckrodt conducted Integrity Hotline tests in the second and third quarters of 2025. The Monitor Team received proper notice of both tests when they were submitted to the Integrity Hotline, and Mallinckrodt promptly produced the underlying test reports at the Monitor Team's request.

5.3 As of the date of this Report, the Monitor has still not received any relevant substantive reports relating to the Operating Injunction through the Integrity Hotline.

[6] Each of these recommendations is prefaced by the number "13" to indicate they were made in the Thirteenth Monitor Report.

VI. BAN ON PROMOTION (OI § III.A)

6.1 Section III.A of the Operating Injunction prohibits Mallinckrodt from engaging in certain activities relating to the Promotion of Opioids, Opioid Products, products used for the treatment of Opioid-induced side effects, and the Treatment of Pain in a manner directly or indirectly encouraging the utilization of Opioids or Opioid Products.

1. The Promotional Review Committee

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

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

6.4 During the second quarter of 2025[7] the PRC did not meet. Accordingly, there were no meeting minutes or materials for the Monitor to review for that period.

2. Final Interview With the PRC Chair

6.5 In light of the monitorship's approaching end date, the Monitor Team conducted a final interview with the Product Analyst who serves as the PRC Chair. The Monitor Team had last met with the Product Analyst in January 2023, and thus inquired whether there had been any significant changes or updates to the PRC since her last interview. The Product Analyst

[7] Due to the cadence of the Audit Plan, which requires that these documents be produced within 10 days of the end of each quarter, the Monitor will not receive the materials for the third quarter of 2025 prior to the conclusion of the monitorship.

confirmed there had been no changes to the PRC's operation, including following the merger with Endo in August 2025.

6.6 The Product Analyst said she was aware that certain Operating Injunction provisions, including the Ban on Promotion, continue indefinitely following the conclusion of the monitorship. She also noted that, while she had not been informed of anything definitive from Mallinckrodt's leadership regarding the monitorship's conclusion, it was her understanding that no changes were contemplated regarding the PRC, and that the PRC would continue its regular review process. Given the continuing applicability of the Operating Injunction's Ban on Promotion, the Monitor Team agrees with this approach.

3. Conference Attendance

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

6.8 During the Thirteenth Reporting Period, the Company provided the Monitor Team with copies of notes taken by its attendees during four conferences held during the second and third quarters of 2025. The Monitor Team reviewed the notes, which were thorough and discussed a number of issues relevant to the Company's business and industry, and determined none of the notes appeared to reflect conversations that violated the Operating Injunction.

4. TrackWise Data Review

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

6.10 Beginning in the Fourth Reporting Period, and on an ongoing basis as part of the agreed-upon Audit Plan, the Monitor has received and reviewed quarterly TrackWise inquiry and complaint entries pertaining to Opioids, as well as the results of the Company's auditing process. During the Thirteenth Reporting Period, the Monitor Team reviewed TrackWise Opioid-related data for the second quarter of 2025,[8] as well as the corresponding audit reports.

6.11 Consistent with prior reviews, many TrackWise inquiries pertained to the availability of Mallinckrodt's products, as well as the content of Mallinckrodt's products (such as whether they contained gluten or animal byproducts). Like the TrackWise inquiries, the TrackWise complaints were also similar to those in prior reviews, and primarily concerned low quantities or missing tablets, broken tablets, and issues with adhesion of overlays for Mallinckrodt's fentanyl patches. Complaints raising other issues, such as suspected product tampering or diversion, were appropriately escalated.

6.12 One issue noted in the Eleventh Monitor Report related to a complaint regarding tablets that appeared to be "scraped" or "incorrectly stamped." *See* Eleventh Monitor Report at 71 ¶ 11.121. In the Thirteenth Reporting Period, Mallinckrodt provided an explanation for the appearance of these tablets, which is discussed in more detail below. *See infra* at 68 ¶ 11.121 – 69 ¶ 11.122.

[8] Due to the cadence of the Audit Plan, which requires that these documents be produced within 10 days of the end of each quarter, the Monitor will not receive the materials for the third quarter of 2025 prior to the conclusion of the monitorship.

6.13 Based on the Monitor Team's review of the underlying TrackWise data and the audit reports for the second quarter of 2025, as well as its interviews with members of the Product Monitoring Team, it appears the TrackWise entries and audits are being conducted in a manner consistent with the Work Instruction and the Operating Injunction.

5. Final Interviews With Members of the Product Monitoring Team

6.14 During the Thirteenth Reporting Period, the Monitor Team interviewed the Executive Director, Quality to learn about her plans for managing the Product Monitoring Team following the conclusion of the monitorship. The Executive Director, Quality informed the Monitor Team that she was aware that the Operating Injunction's Ban on Promotion provision continues indefinitely. Accordingly, she stated it would be "business as usual" following the end of the monitorship, because their "procedures and processes are here to stay" and had become "second nature" for the Product Monitoring Team. Specifically, she confirmed the TrackWise data process would remain the same, including the quarterly audits, which will continue to be handled by the same employee. She also said the Company will continue to utilize APCER for handling certain consumer calls, and ensure APCER remains trained on the Operating Injunction's promotional restrictions.

6.15 The Monitor Team also interviewed the Senior Manager, Pharmacovigilance, who reports to the Executive Director, Quality. The Senior Manager similarly confirmed her understanding that the Ban on Promotion will continue indefinitely, including beyond the termination of the monitorship, and so her work likewise would be "business as usual." She did not anticipate any changes to the TrackWise process.

6. Mallinckrodt's Website and Social Media Pages

6.16 As part of the latest update to the Audit Plan, Mallinckrodt agreed to provide the Monitor Team a quarterly summary of any substantive changes to Mallinckrodt's website and public social media pages relating to topics addressed by the Operating Injunction. During the second quarter of 2025, Mallinckrodt added a new paragraph in the opening section of the Integrity and Compliance page on its webpage. The new paragraph reads:

> Our commitment to compliance is unwavering and we will continue to operate in alignment with our shared values following the planned merger with Endo, Inc., because it is the right thing to do. Endo also maintains a robust compliance program, and the integration of both programs will prove to be extremely beneficial for the combined company. ***We also will continue to operate pursuant to our Corporate Integrity Agreement and Operating Injunction following the planned merger for the relevant parts of the business. In fact, we've concluded that the vast majority of the programs we have established in response to our obligations add value to the business and will become standard practice for the combined companies even after the obligations expire.*** We also believe that being transparent with the public about our compliance program helps to enhance our reputation and, ultimately, our business.[9]

The Monitor Team appreciates this clearly stated commitment by Mallinckrodt to continuing its existing compliance programs following the merger and beyond the termination of the monitorship.

6.17 As a result of Mallinckrodt's merger with Endo in August 2025, the new combined entity launched a website located at https://www.mnk-endo.com. The home page contains links to Mallinckrodt's and Endo's separate websites, as well as a consolidation of key information about the merger, including biographies of members of the new leadership team and

[9] *See* Mallinckrodt's "Integrity and Compliance" webpage (formerly titled "Corporate Compliance") *available at* https://www.mallinckrodt.com/corporate-sustainability/corporate-compliance/ (last visited Oct. 10, 2025) (emphasis added).

Board of Directors, a list of strengths of the combined entity, news updates, and a section for investors to access information about the merger, financial data, corporate governance, and their shares. The Monitor Team had no concerns about this new website's contents.

6.18 The Monitor Team also reviewed the latest posts on Mallinckrodt's social media pages, including LinkedIn and X (formerly known as Twitter). Mallinckrodt, through its outside counsel, informed the Monitor Team that it was planning to sunset the @MNK-Pharma X account due to low engagement.

6.19 Regarding LinkedIn, the Company's recent posts primarily concerned updates regarding the Endo merger, as well as posts about Mallinckrodt employees attending different conferences such as the World Transplant Congress, acknowledging different events such as Pride Month or World Multiple Sclerosis Day, and celebrating the end of the Company's summer internship program. Further, in line with Mallinckrodt's previously discussed policy, *see* Tenth Monitor Report at 13-14 ¶ 7.20, the Company did not appear to interact with or respond to commenters on its LinkedIn posts. The Monitor Team had no concerns about Mallinckrodt's LinkedIn social media presence.

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." Accordingly, the Monitor's Audit Plan requires Mallinckrodt, annually, to produce to the Monitor updates to Mallinckrodt's sales compensation plans.

7.2 The Monitor Team received the updated sales compensation plans for 2025 at the end of the Thirteenth Reporting Period. These materials included the 2025 versions of the

following: (1) API Sales Compensation Guidelines for independent contractors; (2) API Sales Compensation Plan ("SCP"); (3) SCP for Addiction Treatment National Account Managers; (4) SCP for Generics National Accounts; and (5) generally applicable Terms and Conditions for the various SCPs for business units of the Company.

7.3 The Monitor Team's review of the above materials confirms that Mallinckrodt has continued to implement *Prior Recommendation 6(a)*, which was that "Mallinckrodt should include explicit references to the Operating Injunction in Sales Compensation Plans for future years." Specifically, the generally applicable Terms and Conditions state:

> SCPs are intended to reward qualified, profitable, and ethical sales representatives who are employed in good standing by the Company, who comply with all requirements to be eligible for and to receive compensation, and ***who perform their work in a manner consistent with the Company's standards, requirements, and Operating Injunction*** (emphasis added).

7.4 Similarly, under a section titled "Employee Performance," the document makes clear that "[n]ot successfully meeting" certain "criteria . . . may impact [an employee's] plan and/or bonus compensation," including "adherence to and compliance with the requirements of the Operating Injunction."

7.5 Finally, as was the case in last year's iteration, the Terms and Conditions also mandate reporting of any information known to an employee regarding misconduct in connection with the sale of Opioids and provide for financial penalties for failure to properly report. Specifically, the document states:

> Through participation in the Plan, Participants agree that if a court of proper jurisdiction determines that Participant: (a) knowingly participated in any criminal misconduct in connection with their employment with Mallinckrodt or (b) were aware, other than from public information, of acts or omissions of another person in connection with Mallinckrodt's commercial practices in selling opioids that Participant knew at the time were fraudulent or

> criminal and that Participant failed to report to Mallinckrodt or to law enforcement, then Participant will forfeit any rights to payment under the Plan and, if requested by Mallinckrodt, Participant will repay all amounts paid to them under the Plan.

7.6 The clear statements in these 2025 SCP materials convey the appropriate message, in the Monitor Team's view, and correctly incentivize compliance with the Operating Injunction.

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 and Interview with the Committee Chair

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

8.3 During the Thirteenth Reporting Period, the Monitor Team reviewed the minutes of all SGGSAC meetings that took place in the second quarter of 2025.[10] Additionally, the Monitor Team reviewed the accompanying third-party funding Request Forms, and any related materials the Committee considered in determining whether to approve or deny a request. The

[10] Due to the cadence of the Audit Plan, which requires that these documents be produced within 10 days of the end of each quarter, the Monitor will not receive the materials for the third quarter of 2025 prior to the conclusion of the monitorship.

Monitor Team's observations from its review of those materials, and its subsequent interview with the SGGSAC Chair, are detailed below.

8.4 There were several changes to the Committee during the second quarter of 2025, as noted in the meeting minutes. ***First***, the composition of standing Committee members shifted to the following subset of the Specialty Generics Leadership Team: the Associate General Counsel and Senior Director, Integrity & Compliance (both of whom were already members of the Committee), as well as new additions, including the Vice President (Specialty Generics Finance), the Vice President (Research and Development), and the Senior Director (Strategic Planning). Further, the Director, Government Affairs, is no longer a standing member of the Committee. ***Second***, the Committee instituted a new voting process, whereby the Committee will review requests with Internal Requestors at the start of the meeting, and then the Internal Requestors will depart the meeting to allow the Committee to deliberate and vote on each request during a closed session.

8.5 The Monitor Team interviewed the SGGSAC Chair to discuss these recent changes. As to the change in composition to the Committee, the Chair explained this stemmed in part from a recently deadlocked 2-2 vote on a request, because the Director, Government Affairs, had made the funding request, and therefore was recused from voting on the SGGSAC's decision. As a result, the funding request was denied. Given that the Director, Government Affairs often submits requests for funding and has to recuse himself from voting as a result, which increases the likelihood of a tie vote, the Director, Government Affairs was removed as a Committee member.

8.6 As for the change requiring Internal Requestors to depart from a meeting at the time of voting, the Chair explained that she felt the Committee members would have more

independence if they were able to discuss the funding request without the requestor being present. She also felt the discussion would be more efficient if the Internal Requestor was not in the meeting to rebut every point raised by the Committee. The Monitor views these changes positively, and believes they will result in more forthright discussions about requests under review.

8.7 Given the volume of meeting minutes and accompanying request materials reviewed during the Thirteenth Reporting Period, below is a summary of some of the more noteworthy SGGSAC meetings and materials the Monitor Team reviewed:

(1) During the April 16, 2025 meeting, the Committee reviewed and approved two corporate memberships: one with the Carolina Industrial Group for Fair Utility Rates ("CIGFUR"), and one with the Consumer Healthcare Products Association ("CHPA"). The Director, Government Affairs, submitted both requests. Both organizations are involved in government advocacy in some capacity: CIGFUR lobbies the North Carolina Assembly on behalf its members regarding industrial utility rates, and CHPA monitors legislative developments concerning over-the-counter products and nutrition-based products. The Committee appeared to engage in fulsome discussion on both requests. The Monitor encourages the Committee to continue reviewing funding for corporate memberships in advocacy-related organizations with the Operating Injunction's lobbying restrictions in mind as well.

(2) During the April 30, 2025 meeting, the Committee reviewed and conditionally approved funding to attend the Informa PLC CPhI Worldwide conference in October 2026. According to the requestor, this event is the largest trade show in the pharmaceutical industry with upwards of 20,000 attendees from around the world. As discussed in the Tenth Monitor Report, funding for past attendance at this conference was previously provided without Committee approval. *See* Tenth Monitor Report at 20 ¶ 9.5(3). This may have occurred in part due to the need to secure a preferred exhibition space, which requires payment over a year prior to the event start date. The Monitor appreciates the way the Committee is now balancing this advanced timeline with its obligation to review funding requests prior to the disbursement of funds, by ensuring the request is submitted, reviewed, and approved well in advance of the conference date.

(3) Also during the April 30, 2025 meeting, the Committee reviewed and conditionally approved a sponsorship request for Cencora and Good

Neighbor Pharmacy's ThoughtSpot 2025 trade show. As discussed in the Twelfth Monitor Report, Mallinckrodt previously sought the Monitor Team's guidance regarding this funding request due to website links on the ThoughtSpot event website and a link called "Opioid Safety" that appeared on the Good Neighbor Pharmacy website. *See* Twelfth Monitor Report at 17 ¶ 8.10 – 19 ¶ 8.12. After careful review, the Monitor Team concluded this funding request did not violate the Operating Injunction. During this meeting, the Chair shared the Monitor Team's analysis with the Committee, resulting in questions by Committee members about the difference between this request and a previously denied request. The Committee members then engaged in additional discussion about what kinds of conversations and information the Company would share at this event. The Monitor Team is glad to see its analysis shared and thoroughly discussed by the Committee, and also commends the Committee for continuing to analyze this request from other angles, even in light of the Monitor Team's prior favorable analysis.

(4) During the May 28, 2025 meeting, the Committee reviewed and conditionally approved two grants and one sponsorship for the American Association for the Treatment of Opioid Dependence ("AATOD"). The sponsorship pertained to participation in the AATOD 2025 Conference. The requestor explained that the majority of Mallinckrodt's addiction treatment customers are AATOD members, and Company attendance at the conference provides an opportunity to speak to other potential customers. The Committee reviewed a historical agenda, and one member inquired about "the chronic pain and OUD in Methadone Treatment topic" in the prior agenda, to which the Chair responded that the topic is in the context of addiction treatment and does not promote Opioids. The Monitor Team agrees with this assessment. Regarding the grants under consideration, the Committee approved a grant for AATOD's Opioid Maintenance Pharmacotherapy educational course which was set to take place prior to the 2025 Conference. The goal of this course is for new clinicians to learn about medication assisted treatment ("MAT") and its implementation in their practices. The second grant to AATOD concerned AATOD's Criminal Justice Project 2025, which aims to expand access to MAT to correctional facilities through educational presentations at those facilities. Given the purpose of this organization and these educational opportunities—which is addiction treatment and expanding access and implementation of MAT—the Monitor Team agrees with the Committee's assessment and concludes these grants do not violate the Operating Injunction.

8.8 During the Thirteenth Reporting Period, Mallinckrodt sought the Monitor Team's guidance on whether a funding request from its Addiction Treatment team to sponsor and attend the 2025 National Conference of the National Commission on Correctional Healthcare complied

with the Operating Injunction. Mallinckrodt's outside counsel noted a topic in the conference agenda entitled "Managing Co-occurring Chronic Pain and Substance Use Disorder," and asked the Monitor Team for its thoughts. After reviewing the conference materials and request form, and taking into account Mallinckrodt's stated focus on increasing access to MAT in correctional facilities, the ongoing restrictions under the Operating Injunction, and the fact that Mallinckrodt's Addiction Treatment team members were the employees seeking to attend the conference, the Monitor Team determined that sponsorship would not violate the Operating Injunction.

2. Mallinckrodt's Community Charitable Giving Program

8.9 As previously noted, the Monitor reviewed Mallinckrodt's Community Charitable Giving Program ("CCGP"), through which individuals or entities seeking donations from Mallinckrodt may submit requests for funding through Mallinckrodt's website. *See* Ninth Monitor Report at 16 ¶ 7.9 – 18 ¶ 7.12.

8.10 However, during the Twelfth Reporting Period, Mallinckrodt informed the Monitor Team that the CCGP has been discontinued, because Mallinckrodt is no longer accepting unsolicited requests for charitable contributions.

8.11 During the Thirteenth Reporting Period, the Monitor Team reviewed the Community Giving webpage on Mallinckrodt's website, and confirmed that Mallinckrodt is no longer accepting unsolicited charitable requests. Instead, under the heading "Community Giving Program," the webpage now reads: "Mallinckrodt's Community Giving Program aims to make a positive impact within the communities we serve. Our grant program covers diverse focus areas, including but not limited to education, community health and wellness, and environmental sustainability. To stay aligned with our goals and priorities, the Community Giving Program

operates on an invitation-only basis. We extend invitations to organizations that share our commitment to the community and embody our core values. Unsolicited requests are not considered."[11]

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

8.12 As previously reported during the Eleventh Reporting Period, the Monitor Team reviewed publicly available data from the Centers for Medicare & Medicaid Services ("CMS") Open Payments website, which collects and publishes information about financial relationships between drug and medical device companies and certain health care providers.[12] *See* Eleventh Monitor Report at 19 ¶ 8.13 – 20 ¶ 8.15.

8.13 During the Thirteenth Reporting Period, the Monitor Team once again reviewed this data for 2024. For 2024, Mallinckrodt, LLC paid a total of $390,173.29 in consulting fees to Medical Center A. Mallinckrodt did not make any payments to individual physicians in 2024, according to the Open Payments website. These consulting fee payments are consistent with Mallinckrodt's Risk Evaluation and Mitigation Strategy ("REMS") requirements, which were discussed at length in the Twelfth Monitor Report. *See* Twelfth Monitor Report at 19 ¶ 8.16 – 21 ¶ 8.17. As previously discussed, to comply with its REMS obligations, the Company typically pays into a consortium that hires a third-party vendor to handle the mandatory monitoring and reporting. Here, that vendor is Reporting Vendor A, a department within Medical Center A. As

[11] *See* Mallinckrodt's "Community Outreach" webpage https://www.mallinckrodt.com/corporate-sustainability/community-outreach/ (last visited Oct. 10, 2025).

[12] *See* Mallinckrodt Llc – OpenPaymentsData.CMS.gov, *available at* https://openpaymentsdata.cms.gov/company/100000005429 (last visited Oct. 10, 2025).

such, the Monitor is not concerned by these consulting fee payments because they are related to Mallinckrodt's REMS program.

4. The Company's Post-Monitorship Plans for the Committee

8.14 As discussed above, during the Thirteenth Reporting Period the Monitor Team interviewed the Chair of the SGGSAC, who also currently serves as the Senior Director, Integrity and Compliance and will transition to lead compliance at the spin-off generics entity, Par Health, Inc. ("Par Health") resulting from the Mallinckrodt-Endo merger. In addition to discussing the SGGSAC's recent changes, the Monitor Team and the Chair discussed her plans for the Committee following the end of the Monitorship.

8.15 The Chair confirmed she was aware the Operating Injunction's funding restrictions continue for three years following the end of the Monitorship. *See* OI § II.E.1 ("Unless addressed in Section II.E.2–3, each provision of this Agreement shall apply for 8 years from the Petition Date."). Accordingly, she informed the Monitor Team that the Committee would continue to meet and review funding requests during that period, and did not anticipate any major changes to the Committee's review processes. She further stated that ensuring continued compliance with the Operating Injunction's provisions was at the forefront of her mind, and also high on the agenda of the proposed leadership team of Par Health.

IX. LOBBYING RESTRICTIONS (OI § III.D)

9.1 Section III.D of the Operating Injunction sets forth various restrictions on Mallinckrodt's lobbying activities, including lobbying activities related to legislation encouraging the prescribing of Opioid Products or limiting access to non-Opioid treatments.

9.2 In the Third Monitor Report, the Monitor recommended Mallinckrodt implement a process to ensure that its external lobbyists are accurately reporting their activities and that those activities comply with the Operating Injunction. *See Prior Recommendation 3(c)*. In the

Fifth Reporting Period, Mallinckrodt implemented the *Lobbying Certification and Activity Review* SOP, which formalizes the process by which the Government Affairs Team reviews, on a quarterly basis, external lobbyists' public disclosure reports and contemporaneously records the results of that review. Those reports, and the results of the Government Affairs Team's audit of them, are produced to the Monitor Team on a quarterly basis under the Audit Plan.

1. External Lobbyists' Efforts

9.3 During the Thirteenth Reporting Period, 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 for the second quarter of 2025. This audit, which the Director, Government Affairs & Advocacy prepared, details the states covered by the external lobbying firms encompassed in the review, the applicable state or federal disclosure report filing schedule, and an assessment of whether the activities reported comply with the Operating Injunction. It also provides links to the online filing locations of the disclosure reports.

9.4 During the Thirteenth Reporting Period, the Monitor Team also conducted a "spot check" of recent public lobbying disclosure reports filed by Mallinckrodt's external lobbyists during the second quarter of 2025 as referenced therein. The Monitor had no concerns regarding the external lobbyists' disclosures.

9.5 Under the Audit Plan, the Monitor Team 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 2025 showed that none of Mallinckrodt's external lobbyists lobbied for or against any federal or state bills.

9.6 During the Thirteenth Reporting Period, Mallinckrodt informed the Monitor Team that it had terminated its contract with its federal lobbying firm in June 2025. The decision to

terminate the contract was made as a result of the departure of the firm's principal with whom the Company had worked for a number of years, and as a result of the Company's evolving needs. The Company retained another federal lobbying firm, conducted the requisite training for its lobbyists, and provided the Monitor with the certifications referenced below.

2. Auditing Compliance With *Prior Recommendation 8(a)*

9.7 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. As noted in the Ninth Monitor Report, *see* Ninth Monitor Report at 22 ¶ 8.11, Mallinckrodt adopted the recommendation and implemented the training.

9.8 During the Thirteenth Reporting Period, Mallinckrodt provided the Monitor Team with a copy of the *Operating Injunction for Specialty Generics Opioid Business: Contract Lobbyist Awareness Training*, which had been updated during the third quarter of 2025. The Monitor reviewed the materials, which are interactive in nature and therefore require discussion of the issues pertaining to lobbying, and which address, amongst other things pertaining to the Operating Injunction, the background of the Operating Injunction and the various areas of Mallinckrodt's business on which it focuses, the restrictions on what Mallinckrodt may lobby for or against as well as what activities are permitted, the certifications to be completed by employees, agents, and lobbyists engaged in lobbying work, the Integrity Hotline, and the restrictions that will continue following the end of the monitorship. The Monitor found the training materials to be thorough and informative as to what the Operating Injunction prohibits and permits regarding lobbying activities on Mallinckrodt's behalf.

9.9 During the Thirteenth Reporting Period, Mallinckrodt also shared information with the Monitor Team regarding the annual lobbyist training that it conducted on August 21, 2025, August 25, 2025, and September 5, 2025, including which registered lobbyists for Mallinckrodt participated in each of the training sessions.

9.10 During the Thirteenth Reporting Period, Mallinckrodt also provided the Monitor Team with copies of the certifications executed by external lobbyists engaged during the second and third quarters of 2025. As was the case with prior certifications, these lobbyists: (1) acknowledged they received and reviewed the *Acknowledgement and Certification of Compliance with SpecGx Lobbying Restrictions*; (2) certified they were aware of the restrictions contained therein and agreed to be bound by those restrictions; and (3) further certified they were not engaged in any lobbying on behalf of Mallinckrodt that would violate those restrictions.

3. Mallinckrodt's Political Action Committee

9.11 Mallinckrodt contributes to political candidates and other political groups through the Mallinckrodt LLC Political Action Committee ("MNKPAC"), which is a federally registered political action committee. The Monitor Team reviewed MNKPAC's federal lobbying expenditures as reported to the U.S. Federal Election Commission ("FEC") during the second quarter of 2025 and the third quarter of 2025 through the date of this Thirteenth Monitor Report.

9.12 During the second quarter of 2025, MNKPAC made contributions totaling $12,500 to the campaigns of four members of the U.S. House of Representatives and one member of the U.S. Senate who are seeking reelection in 2026. The Monitor Team reviewed the official websites (and, where available, the campaign websites) of each of those members of Congress and determined that none of the websites contained any information that appeared to

refer to or advocate for positions implicating the Operating Injunction's lobbying-related prohibitions.[13]

9.13 During the portion of the third quarter of 2025 covered by this Thirteenth Monitor Report, MNKPAC made a contribution in the amount of $2,500 to the reelection campaign of a U.S. Representative. The Monitor Team reviewed the Representative's official and campaign websites and determined that neither contained any information that appeared to refer to or advocate for positions implicating the Operating Injunction's lobbying-related prohibitions. Also during that time, MNKPAC made a contribution in the amount of $2,500 to a trade organization for research-based biopharmaceutical and medical technology companies. The Monitor Team reviewed the trade organization's website's discussion of the federal and state policy topics with which it is engaged, and the discussion of its programs and initiatives, and was satisfied that nothing in those discussions contained any information that appeared to refer to or advocate for positions implicating the Operating Injunction's lobbying-related prohibitions.

9.14 On August 27, 2025, MNKPAC filed a Statement of Organization with the FEC, in which it identified Par Health, Inc. Political Action Committee ("Par Health PAC") as an affiliated organization and Ludlow Corporation ("Ludlow") as a connected organization. The Vice President, Government Affairs informed the Monitor Team that: (1) the reference to Par Health PAC was included as a result of the Company's merger with Endo and the intended

[13] The official website of the U.S. Senator includes a press release from February 2025 discussing the Senator's co-sponsorship of bipartisan legislation intended to provide greater access to non-Opioid treatments for pain management for senior citizens, which is represented as building upon legislation enacted in December 2022 that the Senator also supported, and a discussion of the Senator's past support for other legislation intended to address issues arising from Opioid use. The official website of one of the U.S. Representatives includes a press release from September 2020 discussing a federal agency's grant of funding to a non-profit organization to support a project focused on community engagement, treatment, and recovery assistance to help address Opioid issues in the Representative's district.

spinoff of the generics and sterile injectable business into Par Health; and (2) the reference to Ludlow was to an affiliated company that provides funds for the operation of MNKPAC. The Vice President, Government Affairs also informed the Monitor Team that due to the Company's merger with Endo, MNKPAC and Endo's political action committee have to be affiliated and as affiliates they are subject to, and must remain mindful of, the limits on a political action committee's contributions to any particular candidate.

4. Stateside Associates, Inc. Reports

9.15 As part of the Audit Plan, Mallinckrodt agreed to provide to the Monitor Team, on a quarterly basis, copies of any legislative reports or summaries that Stateside Associates, Inc. ("Stateside") produced for Mallinckrodt. In accordance with that agreement, Mallinckrodt provided the Monitor Team with reports that Stateside prepared during the second quarter of 2025. The Monitor Team reviewed those reports, which provided an overview of all 50 states' current governors, legislatures, and attorneys general, with information as to membership in one or the other of the two major political parties and seats for which elections will be held in 2025 and 2026. The reports also detailed growing efforts in a number of states to implement new, or revise existing, Prescription Drug Affordability Boards, and provided information as to ongoing efforts in each of those states. The reports also discussed other legislative issues relevant to the Company's business, such as the introduction of legislation in a handful of states aimed at addressing price gouging, imposing requirements for the reporting of, or advance notice of, price increases, and instituting requirements regarding prescription drug sales and marketing.

5. Final Interviews and Post-Monitorship Compliance

9.16 During the Thirteenth Reporting Period, the Monitor conducted final interviews of the Vice President, Government Affairs and the Director, Government Affairs & Advocacy.

Both confirmed to the Monitor their understanding that the Operating Injunction's lobbying restrictions continue for three years following the end of the monitorship. They similarly confirmed that Mallinckrodt's retained federal and state lobbyists are aware of the fact that those restrictions are continuing. Neither the Vice President, Government Affairs nor the Director, Government Affairs & Advocacy was aware of any planned changes to the audit process that is currently in place for Mallinckrodt.

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") (OI § 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, the Monitor requests an annual certification from a Mallinckrodt representative as to Mallinckrodt's compliance with these provisions of the Operating Injunction.

Consistent with the Audit Plan, in January 2025, the Associate General Counsel re-certified Mallinckrodt's compliance with these provisions of the Operating Injunction.

10.3 In the event Mallinckrodt becomes aware of any violations of the above-referenced provisions of the Operating Injunction or the Associate General Counsel is aware of a need to amend the representations in the most recent certification in the interim, Mallinckrodt agreed to promptly inform the Monitor. Mallinckrodt has provided no such notice of any needed amendment during the Thirteenth Reporting Period, and has confirmed that no update to the January 2025 certification is warranted.

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

11.1 In the Thirteenth 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, existing CSC Managers ("CSC Manager B" and "CSC Manager C"), new CSC Managers ("CSC Manager D" and "CSC Manager E"), the former CSC Senior Manager, and the Senior Vice President of Commercial & Strategy; and (3) obtained updates from Mallinckrodt and its outside counsel regarding the grand jury subpoenas discussed below, and the status of Mallinckrodt's implementation of the Monitor's recommendations related to suspicious order monitoring ("SOM") in prior reports and other SOM-related issues.

11.2 The Monitor's findings are described in the following sections: (1) documents the Monitor Team reviewed during the Thirteenth Reporting Period; (2) Opioid sales and market

dynamics; (3) direct customer due diligence; (4) SOM Team ("SOMT")[14] meeting minutes and materials; (5) other SOM-related issues; (6) Mallinckrodt's continued efforts to enhance its SOM program; and (7) reflections on Mallinckrodt's changes to its SOM program over the course of the Monitorship.

1. Documents Reviewed During the Thirteenth Reporting Period

11.3 Mallinckrodt produced SOM-related documents for the second quarter of 2025 and on a monthly basis.[15] The Monitor Team also made requests for documents and information on an ad hoc basis, and Mallinckrodt responded to those requests.

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

(1) SOMT meeting materials and minutes for March, April, May, June, and July 2025;

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

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

[15] The Monitor did not receive the CSC Handbook in time to review for inclusion in this Report.

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

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

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

(6) direct customer flagged order data;

(7) certain suspicious order reports ("SORs") and related correspondence for flagged direct customer orders in March, April, May, June, and July 2025;

(8) revised SOM questionnaires;

(9) various revised SOM policies;

(10) TrackWise data for inquiries and complaints raising potential diversion concerns for the first and second quarters of 2025;

(11) additional information related to the Director of CSC Analytics' 2024 Annual Controlled Substances Compliance Report, Analysis of Highly Diverted Controlled Substances Utilizing Chargeback & ARCOS[16] Data;

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

[16] "ARCOS," the acronym for DEA's "Automation of Reports and Consolidated Orders System," is a data collection system which manufacturers and distributors use to report controlled substances transactions to DEA, consistent with those registrants' regulatory reporting obligations. *See* U.S. Dep't of Justice, Drug Enforcement Admin., Diversion Control Division, "ARCOS Retail Drug Summary Reports," *available at* https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/arcos-drug-summary-reports.html (hereafter, "ARCOS Retail Drug Summary Reports") (last visited Oct. 10, 2025); *see also* 21 U.S.C. § 827(d)(1); 21 C.F.R. 1304.33. 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.

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

(14) a list of distributor customer suspensions;

(15) information related to Mallinckrodt's SOM algorithms;

(16) information regarding distributor customers that do not submit chargeback requests;

(17) Mallinckrodt's draft letter to direct customers concerning sharing SOM-related information;

(18) Mallinckrodt's 8-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

(19) Mallinckrodt's cover letters accompanying productions of documents to the U.S. Attorney's Office for the Western District of Virginia, in response to subpoenas.

11.5 The Monitor also reviewed other publicly available documents, as discussed below, including but not limited to reports published by the independent Monitor of Purdue Pharma, L.P., Steven C. Bullock (the "Purdue Monitor"), and relevant news articles.

2. <u>Opioid Sales and Market Dynamics</u>

11.6 Based on the Monitor Team's prior reporting (since the Tenth Monitor Report), the Monitor Team again reviewed information and data related to Mallinckrodt's sales of Opioid Products and the market for certain Opioid Products to ascertain whether Mallinckrodt's net sales continued to increase, and, if so, the reasons for this trend. Specifically, the Monitor Team reviewed: (1) Mallinckrodt's quarterly filings with the SEC, including Mallinckrodt's 10-Q filings for the periods ending March 28, 2025 (the "First Quarter 10-Q") and June 27, 2025 (the "Second Quarter 10-Q"), which each included reported net sales of Opioids during those time periods; (2) Mallinckrodt's first and second quarter 2025 sales data for the three most highly

diverted Opioid Products (*i.e.*, hydrocodone / APAP 10/325 mg, oxycodone 15 mg, and oxycodone 30 mg); and (3) certain IQVIA[17] market data. The Monitor Team also interviewed the Senior Vice President of Commercial & Strategy.

11.7 Based on this review, the Monitor Team concluded that: (1) Mallinckrodt's market share of the three most highly diverted Opioid Products continues to decline or remain relatively flat; and (2) an overall decrease in net Opioid sales through the second quarter of 2025 was driven by declines in volume and an erosion in revenue from Mallinckrodt's primary and secondary contracts. The Monitor's observations regarding Mallinckrodt's 2025 Opioid sales through the second quarter of 2025 are set forth in further detail below.

a. Mallinckrodt's SEC filings

11.8 The Monitor previously reported on Mallinckrodt's disclosure of a large increase in net sales of Opioids in 2023 and 2024.[18] *See* Twelfth Monitor Report at 35 ¶ 11.6 – 36 ¶ 11.7; Eleventh Monitor Report at 43 ¶ 11.49; Tenth Monitor Report at 33 ¶ 12.6 – 35 ¶ 12.11; *id.* at 35 ¶ 12.12 – 37 ¶ 12.20. Specifically, Mallinckrodt's total 2024 net sales of Opioids were $349.9 million, as compared to $262.3 million in 2023, and $206.7 million in 2022. *See* Twelfth Monitor Report at 35 ¶ 11.6. The Senior Vice President of Commercial & Strategy attributed that growth to market dynamics contributing to both higher sales volume and pricing, which together increased net sales. *See* Tenth Monitor Report at 34 ¶ 12.11 – 37 ¶ 12.20. However, unlike Mallinckrodt's filings in 2023 and 2024, which described increases in net sales,

[17] 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 Oct. 10, 2025).

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

Mallinckrodt's most recent SEC filings reflected a marginal increase, followed by a modest decrease, in net sales of Opioids over the first half of 2025.

11.9 In the First Quarter 10-Q, Mallinckrodt reported first quarter 2025 net sales of Opioids of $212.6 million, as compared to $210.5 million in the same quarter of 2024—*i.e.*, a slight increase of 2.2%. This reported year-over-year increase is significantly smaller than the 31.7% increase in the first quarter of 2024 as compared to the first quarter of 2023.

11.10 However, following this marginal increase in net Opioid Sales in the Second Quarter 10-Q, Mallinckrodt reported a modest ***decrease*** in net sales of Opioids. Specifically, Mallinckrodt reported second quarter 2025 net sales of Opioids of $485.1 million, as compared to $514.3 million in the same quarter of 2024—*i.e.*, a decrease of 5.7%. This reported year-over-year decrease contrasts with the 32% year-over-year increase in the second quarter of 2024 as compared to the second quarter of 2023. As in prior reporting periods, the Monitor Team found helpful the insights of Mallinckrodt's Senior Vice President of Commercial & Strategy (who is expected to take on the role of Chief Operations Officer of Par Health).

b. Mallinckrodt's Senior Vice President of Commercial & Strategy explains the reasons for Mallinckrodt's overall decrease in net Opioid sales through the second quarter of 2025

11.11 The Senior Vice President of Commercial & Strategy explained that Mallinckrodt's overall decline in net sales for Opioids through the second quarter of 2025 resulted from a confluence of two things: ***first***, a modest decline in sales volume (*i.e.*, dosage units); and ***second***, a significant erosion in revenue from primary and secondary contracts that originated in 2024.[19] In other words, volume and price both contributed to Mallinckrodt's recent decreased net sales of Opioids.

[19] As previously reported, when Mallinckrodt is not a "primary supplier," but rather is a "backup supplier" to distributors, its contracts are secondary and include premium pricing.

11.12 ***Decreasing sales volume attributable to declining opioid market.*** Mallinckrodt's declining Opioid sales by volume reflects the fact that the market (and Mallinckrodt's share of it) is in overall decline, an observation shared by both the Senior Vice President and Stephen Welch, the Executive Vice President & Head of Generics and Sterile Injectables, who is expected to become the CEO of Par Health.

11.13 As for specific product categories, the Monitor Team again discussed with the Senior Vice President Mallinckrodt's sales and market share for the most highly diverted products: hydrocodone / APAP 10/325 mg, oxycodone 30 mg, and oxycodone 15 mg.

11.14 The Senior Vice President informed the Monitor Team that Mallinckrodt's market share of hydrocodone / APAP 10/325 mg is modestly declining in an overall "flattening" of the market. Mallinckrodt's hydrocodone / APAP 10/325 mg volume rose sharply from January 2025 to February 2025, but declined from April 2025 through June 2025, leveling out to approximately the same volume as January 2025.

11.15 The Senior Vice President also informed the Monitor Team that Mallinckrodt's market share of oxycodone 30 mg declined, and its share of oxycodone 15 mg remained

---

Tenth Monitor Report at 37 ¶ 12.19. These contracts result from instances where a distributor is unable to obtain products from their primary suppliers and are therefore compelled to purchase from Mallinckrodt at higher prices instead, generating more revenue for Mallinckrodt as a result of the backup contract pricing. *See* Tenth Monitor Report at 37 ¶ 12.19-20. These arrangements can arise for a variety of reasons, including manufacturers' exits from those markets (sometimes arising from compliance-related issues and the challenges of government regulatory enforcement) and supply constraints on Mallinckrodt's remaining competitors. *See* Tenth Monitor Report at 36 ¶ 12.15.

As the Monitor previously reported, Mallinckrodt's Senior Vice President of Commercial & Strategy confirmed that the increase in net sales in 2024 was due primarily to Mallinckrodt's increase in price for both primary and secondary (*i.e.*, "backup" supply) contracts. *See* Twelfth Monitor Report at 37-38 ¶ 11.11. As explained in this section, that trend is now reversing and causing a decline. More competition (as competitors re-enter the market) is resulting in decreased revenue and more competitive pricing.

relatively flat. Oxycodone 30 mg volume remained relatively flat for the entirety of the first and second quarters of 2025. Oxycodone 15 mg volume significantly increased over the first quarter of 2025 and remained elevated into the second quarter of 2025. Despite spikes in the oxycodone 15 mg volume, the Senior Vice President confirmed an overall decline and flattening of volume in this period as a result of reduced quota allotments and an overall shrinking market.

11.16 ***Decreasing sales pricing attributable to increased competition.*** The Senior Vice President attributes the decrease in Opioid Product pricing to the fact that certain manufacturers who had previously exited the market (some due to compliance-related issues and the challenges of government regulatory enforcement) are beginning to re-enter the market. *See* Tenth Monitor Report at 36 ¶ 12.15. Naturally, more competitors in the market impacts both Mallinckrodt's primary and secondary contract revenue and drives more competitive pricing. *See supra* at 32 ¶ 11.11 n.19.

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

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

11.18 Additionally, the Monitor Team reviews randomly selected SORs for a chosen week each month to confirm that two appropriate CSC Team members[20] 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 Thirteenth Reporting Period, the Monitor Team reviewed SORs for March, April, May, June, and July 2025.

a. The flagged direct customer order report for the second quarter of 2025

11.19 As the Monitor has previously reported, the CSC Team conducts a two-level review of all direct customer orders the Algorithm flags. The first-level reviewer determines whether to release each order after consulting the direct customer dashboard and reviewing the customer's order history and other relevant documentation. *See infra* at 36 ¶ 11.24 – 37 ¶ 11.25. If necessary, the first-level reviewer will confer with the Customer Service Department regarding any changes in the customer's contracts or product needs and will contact the customer for additional information. A flagged order is only released after review and approval by two members of the CSC Team.[21]

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

[20] As discussed below, *see infra* at 35 ¶ 11.19, n.21, the *SOM Program Review of Direct Customers* SOP specifies which CSC Team members can complete each level of review.

[21] During the Twelfth Reporting Period, the *SOM Program Review of Direct Customers* SOP was revised to require: (1) the first-level review to be conducted by the CSC Specialist, a CSC Manager, the CSC Senior Manager, the Director of CSC Analytics, or the CSC Director; and (2) the second-level review to be conducted by the CSC Senior Manager, the Director of CSC Analytics, or the CSC Director. § 6.10.6. However, under the SOP, the first- and second-level reviews cannot be completed by the same person.

11.21 In the second quarter of 2025, two CSC Team members released all but three flagged direct customer orders. In two of these instances, the customers cancelled those orders because they had mistakenly ordered a higher quantity than intended. The CSC Team members released the third direct customer's order after the Customer Service Department appropriately corrected a "key punch" error—*i.e.*, the Customer Service Department itself had incorrectly entered the order—and reduced the quantity of the order prior to shipment. All three orders were for addiction treatment products.

b. No orders flagged by the OI Hold system during the second quarter of 2025

11.22 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 not authorized to purchase an Opioid Product under the Operating Injunction (*e.g.*, retail pharmacy), *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.

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

c. The Monitor's review of, and discussions related to, SORs

i. The SORs for select weeks in March, April, May, June, and July 2025

11.24 As noted above, the Monitor Team reviews the SOR for a randomly selected week each month to confirm all flagged orders for Opioid Products are only released after two CSC Team members review them and conclude the orders are not potentially suspicious per the

relevant SOP. The Monitor Team also reviews the supporting documentation for the flagged orders that are released where the reviewer indicates in the SOR such documentation exists.[22]

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

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

ii. The Monitor's discussions with Mallinckrodt concerning the method of auditing releases of flagged orders

11.27 As previously reported, the Monitor's ability to comprehensively audit the CSC Team's release of flagged direct customer orders is limited by the format of the SORs

[22] In order to determine whether an order is not suspicious, the first-level reviewer may review documents related to the customer's ordering history and practices and relevant market dynamics. The CSC Specialist (who has typically performed the first-level review for flagged orders) has informed the Monitor Team that, as a matter of course, she maintains documentation from the Commercial Department concerning customers' contract awards, issues with customers' primary suppliers, product shortages, and other information that may bear on whether an order the direct customer dashboard flags as potentially suspicious can be released. At times, the reviewer will require additional information from the Commercial Department or the direct customer to release an order.

Mallinckrodt is required to submit to DEA. While the SORs reflect some of the data available to the CSC Team on the direct customer dashboard and the CSC Team's reasons for releasing each flagged order, the SORs do not contain all of the data available to the CSC Team on the direct customer dashboard, including the values of certain metrics the reviewers analyze when determining if a flagged order should be released, because they largely contain only the information Mallinckrodt is required to provide to DEA for potentially suspicious orders, in the format DEA requires. *See* Twelfth Monitor Report at 46 ¶ 11.37; Eleventh Monitor Report at 33-34 ¶ 11.24; Tenth Monitor Report at 46 ¶ 12.49 – 47 ¶ 12.53. However, the Monitor Team's lack of access to that data is only one part of the issue. When members of the Monitor Team review the SORs each month, they do not have the benefit of the CSC Team's extensive knowledge of Mallinckrodt's direct customers' contracts and ordering practices, relevant market dynamics, and quota shortages—all information that, in addition to the data presented by the direct customer dashboard, may factor into the CSC Team's decision to release flagged orders.

11.28 As a result, the Monitor requested that Mallinckrodt consider whether additional documentation could be provided to the Monitor Team to better reflect the information the CSC Team reviews, and relies on, when deciding to release a particular order. *See* Twelfth Monitor Report at 46 ¶ 11.37; Eleventh Monitor Report at 61 ¶ 11.92 – 66 ¶ 11.104. The Monitor Team believes that information would also be helpful to whoever monitors Mallinckrodt's compliance with the Operating Injunction after the conclusion of the monitorship. In recent reporting periods, the Working Group[23] was considering the Monitor's request. *See* Twelfth Monitor Report at 46 ¶ 11.37.

[23] 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

11.29 In the Thirteenth Reporting Period, in response to the Monitor's request, Mallinckrodt provided additional information regarding: (1) the direct and indirect customer dashboards' algorithms and the data the dashboards analyze and display; and (2) the CSC Team's flagged order review process. Mallinckrodt's outside counsel also provided an update on the Working Group's consideration of the Monitor's request. The Monitor's observations based on that additional information and discussions with Mallinckrodt's outside counsel are summarized below.

11.30 Consistent with the Monitor Team's ongoing discussions with the CSC Team and Mallinckrodt's outside counsel, the additional information Mallinckrodt provided regarding the direct customer dashboard and flagged order review process reflects that members of the CSC Team consider a multitude of factors when reviewing flagged orders, including the data available in the direct customer dashboard, and that they confer with other departments, such as the Commercial Department, and the direct customers under review, when necessary. To the extent the CSC Team receives documentation supporting the release of the flagged order, those documents are saved for future reference. As a result, Mallinckrodt believes the flagged order review process satisfies DEA's relevant documentation and reporting requirements. Furthermore, Mallinckrodt believes the CSC Team's decisions to release flagged orders can be reviewed, if necessary, using: (1) the direct customer dashboard's audit capability, which can retrieve the data available on the dashboard at a specific point in time; and (2) by consulting any back-up documentation the CSC Team compiled in connection with the review. As a result, Mallinckrodt has not identified any additional information that could be made available to

(the "Working Group") in the Company comprised of in-house and outside counsel and subject matter experts. *See* Eleventh Monitor Report at 61 ¶ 11.92.

whoever audits its compliance with the Operating Injunction following the conclusion of the monitorship. However, Mallinckrodt is still considering whether the descriptions of the different bases for the CSC Team's release of flagged orders listed in the SORs can be revised to better reflect the information the CSC Team relied on to release each order.

11.31 The Monitor defers to Mallinckrodt regarding whether it can, or should, provide additional documentation reflecting the data and information the CSC Team considers to whoever audits Mallinckrodt's compliance with the Operating Injunction after the conclusion of the monitorship. However, the Monitor believes that any additional information reflecting the bases for the CSC Team's release of flagged orders would be helpful to that audit process, and therefore encourages Mallinckrodt to consider revising and / or enhancing the descriptions contained in the SORs, if they can be modified to better reflect the reason for the release.

d. Direct customer questionnaires

11.32 As the Monitor previously reported, and as discussed below, *see infra* at 41 ¶ 11.33 – 42 ¶ 11.37, Mallinckrodt requires direct customers to complete various questionnaires, which include questions about the customers' SOM programs. *See* Seventh Monitor Report at 22 ¶ 11.15. Towards the end of the Twelfth Reporting Period, Mallinckrodt provided the Monitor Team with revised questionnaires for each type of direct customer, *i.e.*, distributor, analytical lab / researcher, manufacturer, narcotic treatment program, and pharmacy.[24] *See* Twelfth Monitor

[24] While the Operating Injunction prohibits Mallinckrodt "from providing an Opioid Product directly to a ***retail*** pharmacy location or Health Care Provider," Mallinckrodt is permitted to sell Opioid Products to other types of pharmacies. OI § III.G.4 (emphasis added). The relevant provision of the Operating Injunction provides: "[n]othing in this provision, however, prevents Mallinckrodt from . . . providing an Opioid Product directly to a ***mail order pharmacy, distribution center serving a chain pharmacy, or pharmacy provider that exclusively serves long-term care or hospice providers and their patients***." OI § III.G.4 (emphasis added).

Report at 50 ¶ 11.46 – 52 ¶ 11.51. As previously reported, the questionnaires were updated to, among other things: (1) seek additional information regarding the specifics of the customer's SOM program; (2) incorporate the Monitor's recommendation that Mallinckrodt revise the questionnaires to ask each customer whether any supplier had "previously . . . requested the customer undertake SOM-compliance reforms or . . . suspended sales to the customer, and request further information from the customer as appropriate," *see Prior Recommendation 11(a)*; and (3) include additional questions regarding ARCOS data and the way in which the customer uses and evaluates that data. *See* Twelfth Monitor Report at 49 ¶ 11.44 – 52 ¶ 11.51.

11.33 During the Thirteenth Reporting Period, the Monitor Team analyzed additional updates to the customer questionnaires. For the non-pharmacy customer questionnaires, those updates included, among other things, questions concerning the customer's last FDA inspection and additional questions concerning the direct customer's customers (*i.e.*, Mallinckrodt's indirect customers). The questionnaires were also updated to inquire whether the customer: (1) conducts criminal background checks or random drug screenings of all prospective and current employees with potential access to controlled substances; (2) purchases controlled substances from other wholesalers or distributors; (3) distributes controlled substances purchased from a third-party to other wholesalers or distributors; and (4) submits EDI 844 data[25] to receive chargebacks.

11.34 For pharmacy customers, the questionnaire was updated to include questions concerning: (1) the percentage of total prescriptions paid for out of pocket as compared to the

[25] Direct customers, typically distributors, provide EDI 844 data to Mallinckrodt in connection with chargeback requests. A chargeback request is effectively a reimbursement claim submitted by a distributor to Mallinckrodt for a particular purchase. This data identifies, among other things, the downstream registrant to which the distributor sold Mallinckrodt's product and the product and quantity sold. This data is often referred to as "chargeback data."

percentage of controlled substances prescriptions paid for out of pocket; and (2) whether the customer verifies the DEA registration status of the prescriber for every prescription filled.[26]

11.35 The Monitor Team discussed these updates, and the updates reported in the Twelfth Monitor Report, with the CSC Team. The CSC Director conveyed that the updates were intended to obtain additional information regarding each customer's SOM program. Certain updates, like the additional questions regarding the customer's SOM program and use of ARCOS data, were included to give more direction to customers regarding the information the CSC Team needs to assess the adequacy of the customer's SOM program. Those updates were necessary because the CSC Team observed customers failing to provide a sufficient level of detail (as discussed in past Monitor Reports). *See, e.g.*, Twelfth Monitor Report at 47 ¶ 11.40 – 48 ¶ 11.43.

11.36 Other questions, like those related to sales to other wholesalers and distributors and submission of EDI 844 data to receive chargebacks, were included based on certain "blind spots" in the chargeback data Mallinckrodt receives (as also discussed in past Monitor Reports). *See, e.g.*, Twelfth Monitor Report at 94 ¶ 11.155 – 98 ¶ 11.162; *id.* at 100 ¶ 11.172.

11.37 The CSC Director shared that Mallinckrodt's use of updated questionnaires since April 2025 has been beneficial. These questionnaires result in more fulsome and detailed responses from customers, and enhance the SOMT's evaluation of direct customer responses.

[26] In the Twelfth Monitor Report, the Monitor inadvertently omitted that the Pharmacy SOM Questionnaire, like the other customer questionnaires, was updated to incorporate *Prior Recommendation 11(a)*, which recommended that Mallinckrodt "[r]evise 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." *Prior Recommendation 11(a)*; *see* Twelfth Monitor Report at 50 ¶ 11.47; Eleventh Monitor Report at 46 ¶ 11.59 – 47 ¶ 11.60.

e. Direct customer due diligence visits

11.38 As previously reported, Mallinckrodt's recently revised *SOM Review of Direct Customers* SOP[27] now requires the CSC Team to annually "execute a risk-based plan to conduct due diligence meetings" with direct customers (the "Annual Diligence Meeting Plan"). *See* Twelfth Report at 90-91 ¶ 11.144; *SOM Review of Direct Customers* SOP § 6.5.1. Under the SOP, the Annual Diligence Meeting Plan must include no fewer than 10 direct customer due diligence visits (either in-person or virtually), including a visit with one of the "Big Three" distributors. *SOM Review of Direct Customers* SOP § 6.5.2. The SOP also requires the Annual Diligence Meeting Plan to include due diligence visits for all direct customers that, within the past calendar year, have either (1) started purchasing controlled substances; or (2) been reinstated. *Id.* § 6.5.3.

11.39 During the Thirteenth Reporting Period, the Monitor Team reviewed: (1) supplemental information regarding the CSC Team's due diligence visit with Distributor P[28] in 2024; (2) materials related to the SOMT's reinstatement of Distributor O, which was suspended following a due diligence visit in 2024; (3) an updated list of 10 distributors the CSC Team visited in 2025; and (4) the CSC Team's reports for the due diligence visits with Distributor T, Distributor U, Distributor V, and Grocery Chain A in 2025.

[27] The revised version of this SOP, produced shortly before issuance of this Report, changed the name of the SOP from *Suspicious Order Monitoring Program Review of Direct Customer Orders* to a more encompassing title: *SOM Review of Direct Customers*.

[28] For Distributors A through N, the references in the Thirteenth Monitor Report correspond to the anonymized references in the Tenth and Eleventh Monitor Reports. For Distributors A through S, and Grocery Chain A, the references in the Thirteenth Monitor Report also correspond to the references in the Twelfth Monitor Report.

i. Follow-up from the CSC Team's 2024 Due Diligence Visit with Distributor P

11.40 In the Twelfth Reporting Period, the CSC Team conducted a due diligence visit with Distributor P, during which Distributor P informed the CSC Team that it would start incorporating the downloadable ARCOS data file into its SOM process. *See* Twelfth Monitor Report at 55 ¶ 11.61 – 56 ¶ 11.62. Accordingly, the Monitor Team requested that the CSC Team inquire about the status of Distributor P's incorporation of that data following the visit.

11.41 During the Thirteenth Reporting Period, the CSC Team provided the Monitor Team with an updated report for Distributor P reflecting subsequent communications between Distributor P and the CSC Team concerning the status of its incorporation of the ARCOS data in December 2024 and February 2025 (*i.e.*, prior to the Monitor's Twelfth Report). The CSC Team's updated report reflected that Distributor P had incorporated ARCOS data into its SOM program as of the Twelfth Monitor Report. The Monitor is satisfied that the CSC Team conducted prompt and appropriate follow-up with Distributor P regarding that issue.

ii. The CSC Team's conditional reinstatement of Distributor O

11.42 As the Monitor previously reported, the SOMT suspended Distributor O following the CSC Team's due diligence visit in December 2024. *See* Twelfth Monitor Report 53 ¶ 11.55 – 55 ¶ 11.60. During that due diligence visit, the CSC Team representatives learned Distributor O failed to incorporate ARCOS data into its SOM program to the extent Mallinckrodt believes is appropriate. Additionally, Distributor O was one of the distributors that purchased Opioid Products but did not submit chargebacks. As a result, Mallinckrodt had a "blind spot" for sales of its products to Distributor O's customers, *i.e.*, Mallinckrodt's indirect customers. Accordingly, the SOMT voted to suspend Distributor O in February 2025.

11.43 Shortly thereafter, the SOMT considered Distributor O's request for reinstatement. In connection with that reinstatement request, Distributor O: (1) agreed to provide chargeback data for all future purchases; (2) submitted an independent consultant's report detailing the components of its SOM program, including Distributor O's purchase of a third-party software product, ARCOS IQ, that analyzes ARCOS data; and (3) provided additional information regarding its training on, and use of, ARCOS IQ. In the Monitor's view these are notable reforms that Distributor O undertook very promptly. Indeed, based on that information, the SOMT voted to conditionally reinstate Distributor O in March 2025, subject to pending contractual negotiations between the parties. In light of the ongoing negotiations, the CSC Team informed the Monitor Team that Mallinckrodt had not yet resumed sales to Distributor O.

iii. The CSC Team's updated due diligence visit list

11.44 In the Thirteenth Reporting Period, the CSC Team provided an updated list of the 10 direct customers it visited in 2025. As the Monitor previously reported, the CSC Team informed the Monitor that one of those customers, Grocery Chain A,[29] was selected because Mallinckrodt does not receive chargeback data from that customer.[30] However, as discussed in the Twelfth Monitor Report, in connection with the CSC Team's due diligence visit, Grocery Chain A expressed openness to sharing downstream transaction data akin to chargeback data,

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

[30] The newly-revised *SOM Program Review of Direct Customers* SOP now provides: "Every Direct Customer that 1) distributes controlled substances to Downstream Registrants, and 2) does not submit Chargeback requests to the Company shall be scheduled for a diligence meeting under the Annual Diligence Meeting Plan every three years." *SOM Program Review of Direct Customers* § 6.5.4.

provided it is technologically feasible to do so. *See* Twelfth Monitor Report at 56 ¶ 11.63. Since the visit, Mallinckrodt and Grocery Chain A have engaged in continued discussions concerning how Grocery Chain A can provide that data.

11.45 In the Thirteenth Reporting Period, the CSC Team shared with the Monitor Team that the CSC Team had selected another distributor for a due diligence visit because it was a potential new customer, and three additional direct customers due to the passage of time since those customers' last due diligence visits.

iv. The CSC Team's 2025 due diligence visits

11.46 In the Twelfth Reporting Period, Mallinckrodt conducted two of the required 10 due diligence visits—one with Distributor D; and one with Distributor T. The Monitor previously reported on the CSC Team's visit with Distributor D. *See* Twelfth Monitor Report at 56 ¶ 11.63 – 57 ¶ 11.67. In the Thirteenth Reporting Period, the Monitor Team reviewed the CSC Team's report for the due diligence visit with Distributor T.

11.47 Mallinckrodt conducted eight additional due diligence visits during the Thirteenth Reporting Period, and the Monitor Team reviewed the reports for the visits with Distributor U, Distributor V, and Grocery Chain A. However, the Monitor Team did not receive reports from five of those visits prior to the filing of this Report.

11.48 The reports from the CSC Team's visits with Distributor T, Distributor U, and Distributor V reflect that, among other things, the CSC Team representatives attending each visit reviewed the Distributors' SOM procedures, including but not limited to whether those Distributors: (1) had various written policies regarding onsite due diligence visits to customers; (2) evaluated relevant metrics related to their customers (*e.g.*, the ratio of controlled substances to non-controlled substances dispensed by the customer); and (3) monitored customers'

purchases for common "red flags" (*e.g.*, ordering excessive quantities of a limited variety of controlled substances while ordering few, if any, other controlled or non-controlled substances).

11.49 The CSC Team's findings from the visits with Distributor T are discussed further below.

11.50 ***The CSC Team's due diligence visit with Distributor T and resulting suspension.*** Distributor T is a pharmacy chain warehouse that services its own retail stores as well as other pharmacies. Prior to Distributor T's suspension, it purchased Mallinckrodt's products directly, as well as through one of the "Big Three" distributors.

11.51 Although the CSC Team's report reflected that Distributor T's SOM program included many appropriate components, the CSC Team representatives attending the visit were concerned by Distributor T's response concerning its use of ARCOS data (or lack thereof), among other things. Specifically, Distributor T indicated it was using the ARCOS "lookup tool" but not downloading and analyzing ARCOS data. Furthermore, while Mallinckrodt received chargeback requests containing the data for Distributor T's purchases through one of the "Big Three" distributors, Distributor T did not submit that same data to Mallinckrodt for its purchases that are distributed to its own retail stores.

11.52 As a result, the CSC Team sought additional information from Distributor T regarding its SOM program, including incorporation of ARCOS data, and submission of chargeback data. After Distributor T's responses indicated Distributor T did not incorporate ARCOS data into its SOM program to the extent Mallinckrodt believes is appropriate, and based on Distributor T's failure to submit chargeback data, the SOMT voted to suspend sales to Distributor T on May 28, 2025.

11.53 The SOMT's suspension of Distributor T once again demonstrates the value of the CSC Team's direct customer due diligence visits. As the Monitor has previously reported, these visits give the CSC Team an opportunity to learn more about direct customers' SOM programs than can be gleaned from the direct customers' SOM questionnaires alone. Indeed, as detailed as those questionnaires are, the Monitor has previously reported on a number of due diligence visits in which the CSC Team learned information during a visit, including concerning the direct customer's failure to utilize available ARCOS data, leading the SOMT to suspend the direct customer. *See, e.g.*, Twelfth Monitor Report at 47 ¶ 11.38; *id.* at 49 ¶ 11.44; *id.* at 50 ¶ 11.46 – 51 ¶ 11.50; *id.* at 53 ¶ 11.55 – 55 ¶ 11.59 (discussing the expanded scope of Mallinckrodt's direct customer questionnaires and the SOMT's suspension of Distributor O following a due diligence visit). Thus, the Monitor continues to believe that due diligence visits are an essential component of Mallinckrodt's SOM program and believes Mallinckrodt's revised SOP requiring additional due diligence visits is bearing fruit. The Monitor understands that Mallinckrodt will continue to conduct such visits following the conclusion of the monitorship.

11.54 ***The CSC Team's due diligence visit with Distributor U and subsequent (but unrelated) suspension.*** In the Thirteenth Reporting Period, the Monitor Team reviewed the CSC Team's report from its June 26, 2025 due diligence visit with Distributor U. Approximately two months later, on August 27, 2025, as a result of unrelated analysis of the direct customer dashboard, the SOMT suspended sales to Distributor U.

11.55 Distributor U is a secondary market distributor that serves independent retail pharmacies. The CSC Team's report reflects that Distributor U's SOM program included many appropriate components. Aside from minor concerns that the CSC investigated and resolved

satisfactorily, the CSC Team was satisfied with Distributor U's review and took no action to suspend sales to Distributor U in June 2025.

11.56 However, following the June 2025 due diligence visit, in mid-August 2025, the CSC Team restricted an indirect customer for which Distributor U was either the sole or primary distributor of Mallinckrodt products.

11.57 This caused a member of the CSC Team to look more broadly at other indirect customers for which Distributor U was either the sole or primary distributor of Mallinckrodt products. At that point, the CSC Team discovered that prior to August 2025, the CSC Team reviewed four such indirect customers. These reviews occurred in September 2023, July 2024, May 2025, and August 2025. All four reviews resulted in restrictions based on the pharmacies' anomalous ARCOS data.

11.58 Utilizing a geographic chargeback analysis tool, referred to as a "heat map" or "concentration map," the CSC Team generated a visual depiction of where Distributor U's product shipments were concentrated.[31] This revealed an anomaly in Distributor U's distribution patterns. Specifically, its oxycodone 30 mg shipments were only appearing in discrete markets known for diversion—such as Houston, Texas, and parts of Florida and New Jersey. Yet, the geographic analysis showed that Distributor U distributed other Mallinckrodt products nationwide. Additionally, Distributor U distributed all other oxycodone formulations far more broadly (geographically) than the oxycodone 30 mg formulation alone.

[31] This map was not generated solely for purposes of the due diligence visit with Distributor U, although it is a relatively recently adopted tool (in use for a little over a year). In fact, the DCSCA utilizes the map on a roughly quarterly basis, separate and apart from the due diligence visits. But the tool is only effective for those direct customers with an existing order history (*i.e.*, not initial due diligence for new customers) because the map relies upon accumulated chargeback data, which of course new customers will not have without a prior order history.

11.59 This information caused the CSC Team concern regarding Distributor U's ability to adequately detect and deter diversion of controlled substances, and the SOMT voted to suspend Distributor U on August 27, 2025.

11.60 The Monitor notes that the suspension of Distributor U is a positive indicator of the value of Mallinckrodt's multi-level SOM program. Despite Distributor U's satisfactory due diligence visit just two months before, the CSC Team continued to scrutinize indirect customers that Distributor U served and, upon detecting irregularities, pursued further investigation resulting in a direct customer suspension. The Monitor understands Mallinckrodt will continue regularly using the geographic chargeback analysis tool following the conclusion of the monitorship.

New Recommendation 13(a). Implement regular use of geographic concentration maps in connection with regularly scheduled due diligence visits with direct customers.

11.61 **As the above discussion reflects, the SOMT's relatively recently adopted geographic concentration mapping tool is a valuable visual representation that may assist the SOMT in quickly determining where highly divertible products are shipped by Mallinckrodt's established direct customers to markets known for diversion.**

11.62 **The Monitor recommends Mallinckrodt incorporate concentration map review as a component of regularly scheduled due diligence visits.** ***Mallinckrodt has agreed to implement this recommendation.***

v. The CSC Team's efforts to enhance its due diligence for direct customers that do not submit chargeback data

11.63 During the Thirteenth Reporting Period, the Monitor, Mallinckrodt, and Mallinckrodt's outside counsel continued to discuss the "blind spot" in Mallinckrodt's

chargeback data—*i.e.*, those sales for which Mallinckrodt does not receive chargeback requests, and therefore does not have a source of chargeback data for SOM analysis.

11.64 As the Monitor previously reported, Mallinckrodt did not have the same degree of visibility into a limited number of its sales because certain of its distributor customers either: (1) do not submit chargeback requests for all products; or (2) do not submit chargeback requests at all. *See* Twelfth Monitor Report at 102 ¶ 11.176. This led to two recommendations in the Twelfth Monitor Report. *See Prior Recommendation 12(d)* ("Use best efforts to negotiate with direct customers that do not submit chargeback requests for all of their controlled substances orders, in order to obtain chargeback data for every such purchase (or substantially equivalent transactional data to the data accompanying chargeback requests for those purchases)."); *Prior Recommendation 12(e)* ("Conduct a due diligence visit for every direct customer that does not submit chargeback requests for controlled substances (or that does not provide substantially equivalent transactional data to the data accompanying chargeback requests for such substances), if the customer has not had a due diligence visit in the past three years, with periodic follow-up visits as appropriate.").

11.65 In this reporting period, Mallinckrodt took steps to implement *Prior Recommendation 12(d)* and *Prior Recommendation 12(e)*. Specifically, Mallinckrodt identified 13 of its direct customers that do not provide chargeback data: two traditional distributors, and 11 grocery or retail chains (two of which stopped purchasing Mallinckrodt products within the last year and for which Mallinckrodt is deactivating their accounts).

11.66 Mallinckrodt's outside counsel informed the Monitor Team that it continues to address this issue with the distributors, grocery chains, and retail chain stores it identified, as those parties' contracts become due for renewal or further negotiations. Mallinckrodt's outside

counsel expressed that this is a significant change for some direct customers, whose systems may not be set up in a way that readily allows the transfer of information comparable to chargeback data. However, this is a work in progress that Mallinckrodt will continue to explore with direct customers falling into the "blind spot."

11.67 Mallinckrodt conducted due diligence visits with the two traditional distributors. As described above, *see supra* at 46 ¶ 11.47, the CSC Team completed these due diligence visits. The Monitor Team did not receive reports of those visits before the filing of this Thirteenth Monitor Report.

11.68 The Monitor is satisfied with Mallinckrodt's progress in implementing *Prior Recommendation 12(d)* and *Prior Recommendation 12(e)*.

4. SOMT Meeting Minutes and Materials

11.69 In the Thirteenth Reporting Period, the Monitor Team reviewed SOMT meeting minutes and materials for March, April, May, June, and July 2025. The results of that review, 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), and any resulting recommendations, are discussed below.

a. The evolution of the SOMT meeting minutes over the course of the monitorship

11.70 As previously reported, the Monitor Team and Mallinckrodt's outside counsel engaged in extensive conversations about the SOMT's meeting minutes in the last reporting period. *See* Twelfth Monitor Report at 62-63 ¶ 11.79. These discussions ultimately resulted in *Prior Recommendation 12(a)*, which states minutes should "better reflect the SOMT's analysis by providing greater support and context for the decisions of both the CSC Director and the SOMT, and be reviewed to eliminate errors, in order to ensure the minutes create an accurate

record of the bases for those decisions for future reference." Twelfth Monitor Report at 63 ¶ 11.80.

11.71 During the Thirteenth Reporting Period, the Monitor Team reflected upon the evolution of the SOMT's meeting minutes, as described in greater detail below.

i. The beginning of the monitorship (2021 – 2022)

11.72 The Monitor Team began reviewing the SOMT's meeting materials and minutes in 2021. *See* Second Monitor Report at 21 ¶ 11.6. At that time, the SOMT's findings in connection with direct and indirect customers' reviews were detailed in the "review sheet"[32] summaries, but the meeting minutes were exceedingly brief. The meeting discussions were summarily reflected in bullet point entries without any analysis.

11.73 For example, the minutes for one of the SOMT's January 2021 meetings memorialized four restrictions in four lines of text. Each line included the indirect customer's name, location, DEA number (and whether the DEA number was active or inactive), the SOMT's decision (*e.g.*, "RESTRICTED"), and the date of the SOMT's decision.

11.74 Reinstatements were memorialized in similar fashion. In another January 2021 meeting, for example, the minutes reflect the reinstatement of an indirect customer in a single line of text including only the indirect customer's name, location, DEA number, and the SOMT's decision: "Reinstated 1/29/2021 continue to monitor."

[32] As discussed in prior reports, when a pharmacy is under review, the SOMT member conducting the review creates a "review sheet" documenting his or her findings, which is circulated (or otherwise made available) to the entire SOMT for its review before the meeting at which the pharmacy will be discussed. *See, e.g.*, Twelfth Monitor Report at 62 ¶ 11.79 n.27; Eleventh Monitor Report at 55 ¶ 11.78; Fifth Monitor Report at 30-31 ¶ 11.23.

11.75 With this approach, meeting minutes would regularly fit on a single page. And while the SOMT's detailed review was reflected in review sheet summaries, those review sheets have also evolved over time and are far more substantive today.

ii. The middle of the monitorship (2022 – first quarter 2025)

11.76 To assist in the Monitor's audit of Mallinckrodt's compliance with Section III.G of the Operating Injunction—monitoring and reporting of direct and downstream customers—the Monitor Team and Mallinckrodt engaged in discussions regarding the substance of the minutes. Further, to provide an objective basis for Mallinckrodt to analyze its turnaround time for chargeback reviews and to enhance the SOMT's excel tracking spreadsheet,[33] the Monitor issued *Prior Recommendation 4(a)* in January 2022. *See* Fourth Monitor Report at 31 ¶ 11.27. That recommendation—for Mallinckrodt to "[c]ollect[] data regarding time lags in the chargeback review process in a more detailed way"—coincided with a new era of more detailed meeting minutes. This followed the Monitor's observation of a SOMT meeting in July 2021, as reported in the Third Monitor Report. *See* Third Monitor Report at 21 ¶ 11.3 – 25 ¶ 11.13.

11.77 As a result, by the end of 2021 and starting in earnest in 2022, the SOMT began incorporating narrative sections in the meeting minutes with content derived from individual review sheets. Thus, the minutes became more detailed and provided, in one place, some of the

[33] Under *Prior Recommendation 4(a)*, the Monitor recommended tracking all steps in the chargeback review process, namely: "(1) the date the chargeback data was made accessible to the LCSCC for review; (2) the date the LCSCC began review; (3) the date of any due diligence request the LCSCC made to the distributor; (4) the date of the direct customer's response to the due diligence request; (5) the date of the SOMT's review of the LCSCC's analysis and / or recommendation; (6) the date of the SOMT's chargeback restriction decision; (7) the date the restriction decision is communicated and executed; and (8) the date of chargeback reinstatement (if applicable)." Fourth Monitor Report at 31 ¶ 11.27. During the Ninth Reporting Period, Mallinckrodt changed the title of the Lead CSC Consultant to CSC Manager.

most important information known to and considered by the SOMT in the meetings. The individual entries in the minutes usually ranged from 10 to 15 lines of text. In total, the SOMT's meeting minutes were approximately five to seven pages in length.

11.78 For example, the SOMT's January 2022 meeting minutes detailed the same identifying information described above, but also included relevant dates and actions taken in the SOMT's investigation, requests for due diligence from direct customers, a high level summary of the SOMT's discussion, and the SOMT's ultimate decision.

11.79 By the end of 2022, driven by an uptick in the number of reviews and more comprehensive summaries derived from review sheets, the meeting minutes became more comprehensive and lengthy. Meeting minutes more regularly were between 10 and 15 pages in length. This trend continued through the end of 2024, when meeting minutes grew to as many as 20 to 30 pages in length. In some months, for example April 2025, the SOMT's meeting minutes were as many as 45 pages in length.

11.80 In part, though, the minutes grew in length because they contained extraneous information sometimes erroneously copied and pasted from the review sheets. As a result, the minutes did not always concisely reflect the actual discussion that occurred in the SOMT's meetings and the basis for the SOMT's determination.

iii. The conclusion of the monitorship (second quarter 2025)

11.81 In light of what the meeting minutes had become over the course of the monitorship, in the Twelfth Monitor Report the Monitor encouraged the SOMT to produce minutes that more closely aligned with the meeting. *See Prior Recommendation 12(a)* ("Ensure the SOMT minutes (a) better reflect the SOMT's analysis by providing greater support and context for the decisions of the CSC Director and SOMT, and (b) are reviewed carefully to

ensure the minutes reflect an accurate historical record of the SOMT's decisions and reasoning for future reference.").

11.82 During the Thirteenth Reporting Period, the SOMT's meeting minutes have evolved once more, now reflecting an effort to implement *Prior Recommendation 12(a)* and, as a result, became more concise. While they are reminiscent of early meeting minutes, many of the meeting minutes reviewed in this Thirteenth Reporting Period more accurately reflected the topics of discussion at the SOMT's meeting instead of repeating information contained in individual pharmacy review sheets. The SOMT's ultimate decision and primary rationale are included, while leaving out the detailed historical path contained in review sheets (which remain available for reference, if needed). As a result, the minutes are more accessible and not nearly as voluminous.

b. The SOMT must strike the appropriate balance in developing meeting minutes that accurately reflect and record its discussions, but also that provide a comprehensive summary of information available to the SOMT at the time of its decision

11.83 As the SOMT continues to evaluate and ultimately determines what form its meeting minutes should take, a threshold question remains: what purpose do its minutes serve? That is, of course, for the SOMT to determine.

11.84 To that end, the Monitor Team discussed with the SOMT several "pros" and "cons" of the new minutes format. For example, on one hand, these minutes more accurately reflect the SOMT's actual discussion and, therefore, more closely resemble true "minutes." On the other hand, when information from the review sheets is not included in the minutes, the minutes no longer contain all relevant information in a single document. Put another way, subsequent review of the SOMT's decision-making process requires reference to the minutes, Excel tracking spreadsheet, and review sheets.

11.85 It also remains to be seen if this new format is more or less efficient. The CSC Director observed that the revised format did not necessarily result in a reduced investment of time on the SOMT's part. While the length of the minutes the Monitor Team reviewed during this Thirteenth Reporting Period are generally shorter than in other recent reporting periods, the Monitor noted an increase in the time to prepare and produce minutes for the Monitor Team's review.[34] For example, the SOMT met on June 26, 2025 for its monthly meeting. The Monitor Team did not receive the minutes of that meeting until September 10, 2025. And the Monitor Team received July 2025 meeting minutes on September 24, 2025, with limited time for review in finalizing this Thirteenth Monitor Report.

11.86 The Monitor Team learned that, in pivoting to the SOMT's new format, Mallinckrodt's Associate General Counsel volunteered to serve in a "recording secretary" function, taking on the role of recording the meeting minutes. However, given competing obligations and demands on the time of the Associate General Counsel, this may have had the unintended effect of extending the time to generate and finalize meeting minutes.

11.87 Mallinckrodt has not yet settled on what will be the "best practice" for documenting the decision making in its SOMT meetings. That, again, is Mallinckrodt's choice to make.

[34] The Monitor recognizes that the Endo merger, discussed elsewhere in this Thirteenth Monitor Report, placed significant resource constraints on Mallinckrodt during this Thirteenth Reporting Period. Furthermore, Mallinckrodt's outside counsel advised the Monitor Team that the change in formatting also resulted in additional review by internal counsel and outside counsel. This additional review is not intended to become a regular part of the SOMT's practice in generating meeting minutes, but also contributed to the delayed delivery of minutes to the Monitor Team in the Thirteenth Reporting Period.

c. The SOMT's codification of the 90-day "rule of thumb" has led to more prompt restrictions

11.88 As discussed in the Tenth and Eleventh Monitor Reports, *see* Eleventh Monitor Report at 50 ¶ 11.67; Tenth Monitor Report at 67 ¶ 12.111 – 68 ¶ 12.112, 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).*

11.89 During the Twelfth Reporting Period, Mallinckrodt codified the 90-day "rule of thumb" in its then-current *SOM Program Media Searches & Chargeback Reviews of Direct Customers and Downstream Registrants* SOP. *See* Twelfth Monitor Report at 92 ¶ 11.148.

11.90 Over the course of the Thirteenth Reporting Period, the Monitor observed a significant increase in new business restrictions due to implementing the 90-day "rule of thumb."

11.91 For example, the SOMT restricted 18 indirect customers at its April 2025 meeting. Of those 18 restrictions, 17 resulted from a distributor's failure to timely respond to the CSC Team's due diligence request and mitigate the reason for the flag within 90 days. Put another way, 94% of the restrictions in April 2025 resulted from the enforcement of Mallinckrodt's newly-codified rule of thumb. Similarly, in May 2025, 15 of 21 new business restrictions (76%) resulted from a distributor's failure to timely respond to the CSC Team's due diligence request and mitigate the reason for the flag.

11.92 The Monitor is satisfied that the SOMT is enforcing the 90-day "rule of thumb" in accordance with the above-referenced SOP.

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

11.93 As in prior reporting periods, the Monitor Team reviewed Mallinckrodt's correspondence with DEA regarding restriction and reinstatement of downstream registrants because Mallinckrodt's SOPs require the SOMT to notify DEA of such restrictions and reinstatements. *See Downstream Registrants Reviews* SOP § 6.4.5;[35] *SOM Program Review of Reinstatement Requests from Downstream Registrants* SOP § 6.3.5.2.

11.94 In the Twelfth Reporting Period, the Monitor found that in most instances the SOMT's communications completely and accurately conveyed the SOMT's restrictions and reinstatements of downstream registrants. *See* Twelfth Monitor Report at 74 ¶ 11.105. Yet, the Monitor Team observed limited instances where certain restrictions were not conveyed to DEA because the customers were reinstated shortly after restriction, or they were not conveyed until months after the restriction occurred—and only after the Monitor Team called this to the SOMT's attention. *See* Twelfth Monitor Report at 74 ¶ 11.106 – 78 ¶ 11.117. This led to the implementation of *Prior Recommendation 12(b)*, which urged Mallinckrodt to "adopt a defined time for reporting suspended direct customers and restricted indirect customers to the DEA." *See* Twelfth Monitor Report at 78 ¶ 11.118.

11.95 During the Thirteenth Reporting Period, Mallinckrodt's outside counsel informed the Monitor Team that Mallinckrodt revised the relevant SOPs to include a defined timeline for reporting suspensions and restrictions to DEA. Shortly before the submission of this Report, Mallinckrodt produced newly-revised SOPs establishing a defined time for reporting restrictions

[35] The revised version of this SOP, changed the name of the SOP from *SOM Program Media Searches & Chargeback Reviews of Direct Customers and Downstream Registrants* to *Downstream Registrants SOP*.

to DEA. *See Downstream Registrant Reviews* § 6.4.7 ("If the SOMT issues a Chargeback Restriction for a Downstream Registrant, the Director, CSC will report to DEA the following information no later than 10 business days following the relevant monthly SOMT meeting. . . ."; *SOM Program Review of Direct Customers* § 6.11.4 ("If the SOMT [r]estricts sales to a Direct Customer, the CSC Director or designee will report to DEA the following information within 10 business days of the Restriction: Direct Customer's name; DEA registration number; and a copy of the letter the Company sent to the Direct Customer notifying them of the Restriction.").

11.96 The Monitor is satisfied with Mallinckrodt's implementation of *Prior Recommendation 12(b)*.

11.97 During the Thirteenth Reporting Period, the Monitor Team reviewed the SOMT's correspondence with DEA from March 2025 to July 2025. In general, the Monitor Team found that the SOMT's communications completely and accurately conveyed the SOMT's restrictions and reinstatements of downstream registrants. However, the Monitor Team observed limited instances where certain SOMT decisions were not conveyed to DEA or inaccurately conveyed to DEA. These instances are described further below.

i. The SOMT did not report a reinstatement to DEA until the Monitor informed it that DEA had not yet been notified of the reinstatement

11.98 ***Reinstatement of Pharmacy I***. The SOMT restricted Pharmacy I in March 2025. Two days later, Pharmacy I's distributor, Distributor E, provided additional information about Pharmacy I, which Mallinckrodt credited as a thorough review. After consideration of Distributor E's supplemental response, among other things, Mallinckrodt voted to reinstate Pharmacy I.

11.99 Despite reinstating Pharmacy I, in its May 2025 correspondence with DEA Mallinckrodt omitted its reinstatement of Pharmacy I.

11.100 When the Monitor Team inquired about the reason Pharmacy I was not reported as reinstated, Mallinckrodt responded that it was erroneously omitted. Mallinckrodt corrected its omission in July 2025 correspondence with DEA.[36]

ii. The CSC Team incorrectly reported Pharmacy J as reinstated when it had actually voted to deny reinstatement

11.101 ***Denial of Pharmacy J's Reinstatement Request***. The SOMT restricted Pharmacy J in February 2025. Pharmacy J, through a third-party consultant, inquired about reinstatement days later. The SOMT considered the reinstatement request at its April 2025 SOMT meeting and voted to deny reinstatement. Yet, in its May 2025 correspondence with DEA, Mallinckrodt incorrectly reported Pharmacy J as reinstated.

11.102 When the Monitor Team inquired into the reason Pharmacy J was reported as reinstated, Mallinckrodt responded that it was erroneously included in the May 2025 correspondence. Mallinckrodt corrected its erroneous report in its July 2025 correspondence with DEA.

11.103 Mallinckrodt confirmed that, while it reported Pharmacy J as reinstated to DEA, the SOMT's decision to deny reinstatement was correctly implemented in the Company's systems. For that reason, Pharmacy J remained appropriately restricted at all relevant times despite its identification as reinstated in DEA correspondence. Nevertheless, additional care and attention to the accuracy of Mallinckrodt's correspondence with DEA is warranted.

[36] Following a June 2025 restriction, the SOMT similarly omitted a pharmacy from its notice to DEA. The SOMT detected its omission and sent follow-up correspondence to DEA five days after the original correspondence. Thus, in this instance, the SOMT self-detected and self-corrected its omission.

iii. Typographical errors in the May 2025 correspondence

11.104 In the May 2025 correspondence with DEA, the Monitor Team noted a series of typographical errors. For example, the correspondence at times excluded a restricted pharmacy's DEA number in full, omitted a single digit therein, or incorrectly included a value that did not belong in the actual DEA number.

11.105 The Monitor Team raised these typographical errors with Mallinckrodt after receiving Mallinckrodt's May 2025 correspondence with DEA. The Monitor Team learned that hours before the Monitor Team's inquiry the SOMT had sent clarifying correspondence fixing the various typographical errors.

11.106 The Monitor understands that typographical errors can occur for a number of reasons. However, this underscores the importance of an internal audit function, described elsewhere in this Thirteenth Monitor Report, *see infra* at 108 ¶ 15.7 – 110 ¶ 15.11, especially as it relates to informing DEA of Mallinckrodt's restriction and reinstatement decisions.

> ***New Recommendation 13(b). Implement a two-person review of Mallinckrodt's correspondence with DEA detailing restrictions and reinstatements to ensure such communications are complete and accurate.***

11.107 **As the above discussion reflects, Mallinckrodt is taking affirmative steps to review its correspondence with DEA to confirm restrictions and reinstatements are completely and accurately reported. However, it is clear that because the correspondence is manually generated, there exists a persistent chance for error—substantive or typographical.**

11.108 **The Monitor recommends Mallinckrodt implement a two-level review of correspondence with DEA to ensure restrictions and reinstatements are accurately reported.** ***Mallinckrodt has agreed to implement this recommendation.***

5. Other SOM-related Issues

a. Updated SOM-related policies

11.109 At the end of the Twelfth Reporting Period, Mallinckrodt provided the Monitor Team with revised copies of four SOM-related SOPs: (1) *Disclosure of Government Communications to the Monitor*; (2) *SOM Program Review of Direct Customer Orders*;[37] (3) *Downstream Registrants Reviews*; and (4) *SOM Program Review of Reinstatement Requests from Downstream Registrants*. The Monitor Team previously reviewed certain changes to these policies in connection with the Working Group's discussions, as discussed in the Twelfth Monitor Report. *See* Twelfth Monitor Report at 88 ¶ 11.138 – 94 ¶ 11.153.

11.110 During the Thirteenth Reporting Period, the Monitor Team reviewed the revised policies in their entity. Aside from the changes discussed in the Twelfth Monitor Report, the four policies were revised to incorporate updated definitions and employee titles, and to reflect current practices. For example, the *Disclosure of Government Communications to the Monitor* SOP ("Government Communications SOP") previously required Mallinckrodt to provide "subpoenas, civil investigative demands, or requests for information directed at Mallinckrodt and related to Opioid Products served by the federal or any state government" "to the Monitor or his representatives ***upon request.***" *Government Communications SOP* §§ 6.2.1-2 (emphasis added). In accordance with the Audit Plan and Mallinckrodt's and the Monitor's agreed-upon practice, the SOP was revised to require Mallinckrodt to provide such documents to the "Monitor or his representatives ***promptly after receipt***." *Id.* at §§ 6.2.1-2 (emphasis added).

[37] As described above, *see supra* at 43 ¶ 11.38 n.27, this SOP was again revised and produced in the Thirteenth Reporting Period.

b. Revision to the Downstream Registrants Reviews *SOP regarding review of reinstated pharmacies*

11.111 As for the *Downstream Registrants Reviews* SOP, the Monitor Team observed that the then-current policy required the Director of CSC Analytics to record a date for at least one future annual review of an indirect customer after the SOMT granted the indirect customer's chargeback reinstatement request. Specifically, the relevant provision of the SOP, entitled, "SOMT Continued Monitoring Following Chargeback Reinstatement or Other Circumstances," stated:

> The Analytics Director will record dates ***for at least one annual review of reinstated Downstream Customers by entering the date in the tracker***.[38] Other subsequent reviews of any Downstream Customer requested by the SOMT will also be noted in the tracker. The SOMT may determine the need for further reviews. Such decision must be documented in the meeting minutes and in the Review Form in the Downstream Customer file.

§ 6.5.1 (emphasis added). The Monitor Team was interested to know whether such reviews are now being conducted and recorded in accordance with the SOP, and put this question to the CSC Team.

11.112 The CSC Director and the Director of CSC Analytics confirmed the SOMT had not previously conducted an annual re-review of every reinstated indirect customer as a matter of course (as the SOP, as currently written, now requires). As Mallinckrodt's outside counsel explained, this provision of the SOP was incorporated in response to the Monitor's *Prior Recommendation 2(l)*, which was that Mallinckrodt should "[m]emorialize and routinize the

[38] 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* Eleventh Monitor Report at 55 ¶ 11.78. The policy defines that Tracking Spreadsheet as the "tracker."

periodic review of (1) pharmacies reviewed but not restricted, and (2) pharmacies that are reinstated." Second Monitor Report at 38. As detailed in the Second Monitor Report, the Monitor made that recommendation based upon an unwritten practice of the former CSC Auditor / Analyst to create "a 'tickler' reminder on her Outlook calendar to follow up on the chargeback data of reinstated pharmacies." *Id*.

11.113 But the regular review of all reinstated pharmacies makes less sense now, in an era of constantly updating dashboards that are reviewing downstream registrants, making the SOP's provision anachronistic. Indeed, Mallinckrodt's outside counsel noted that the recommendation was made and incorporated in the SOP ***before*** Mallinckrodt implemented the indirect customer dashboard in 2022. In the view of the CSC Director and the Director of CSC Analytics, after Mallinckrodt implemented the indirect customer dashboard (and more recently the ARCOS dashboard), there is less need for regular re-reviews of reinstated indirect customers as a matter of course, because the dashboards should flag the indirect customer for a chargeback review if it had sufficiently anomalous metrics at any future time. Additionally, conducting regular annual reviews of all such indirect customers would be much more burdensome now, given the increased volume of restricted and reinstated indirect customers (including 100 reinstatements last year alone). *See* Twelfth Monitor Report at 83 ¶ 11.128. And so, in the view of CSC Director and Director of CSC Analytics, performing such reviews, absent a specific reason to do so, is not a productive use of the CSC Team's time and resources.

11.114 As a result, Mallinckrodt revised the SOP to reflect the SOMT's current practice—*i.e.*, if the SOMT recommended a specific reinstated indirect customer be re-reviewed at a future date for a particular reason, that re-review would be conducted, and the date of the re-review reflected in the Tracking Spreadsheet, review sheet, and SOMT minutes.

c. Government communications log

11.115 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." OI § G ¶ 3. In assessing Mallinckrodt's compliance with the Operating Injunction's requirement to provide law enforcement assistance, the Monitor Team reviewed the entries in Mallinckrodt's government communications log ("Communications Log")[39] for the second quarter of 2025, as well as related correspondence concerning inquiries that appear related to Opioid Products, excluding medications typically prescribed for addiction treatment.

11.116 Of the 52 government inquiries Mallinckrodt received in the second quarter of 2025, Mallinckrodt's Communications Log reflected that 10 of those inquires related to Opioid Products and were from DEA, the FDA, or a municipal police department. Mallinckrodt also received an inquiry from DEA regarding a chargeback restriction. In each instance, Mallinckrodt provided a timely and appropriate response.

d. SOM-related TrackWise entries and investigation

i. SOM-related TrackWise entries

11.117 Under the relevant SOP, certain categories of TrackWise inquiries and complaints, *see supra* at 9 ¶¶ 6.9-11, are escalated to the CSC and / or Security Departments, among others, as a matter of course. However, in the Sixth Monitor Report, the Monitor recommended that any evidence of diversion risks appearing in the TrackWise entries be

[39] As previously reported, *see* Fifth Monitor Report at 34 ¶ 11.30 – 36 ¶ 11.33, the Audit Plan requires Mallinckrodt to produce the Communications Log the SOMT maintains under the *SOM Program Review of Direct Customers* SOP, so the Monitor Team can review the government inquiries Mallinckrodt receives, and its responses.

escalated by the Associate General Counsel (or her designee) to the CSC Director for his review and included in SOMT pharmacy reviews, as appropriate. *See Prior Recommendation 6(f)*. Since Mallinckrodt implemented *Prior Recommendation 6(f)*, the Associate General Counsel has not identified any TrackWise entries evidencing the potential risk for diversion that would necessitate the CSC Director's review outside the ordinary escalation process.

11.118 In the Thirteenth Reporting Period, the Monitor Team reviewed the TrackWise entries related to Opioid Products for the first and second quarters of 2025 including complaints escalated to the CSC and / or Security Departments. As in prior reporting periods, the narratives suggest that any issues of diversion, such as retail pharmacy robbery, were outside Mallinckrodt's control. Likewise, the narratives suggest that any issues of potential diversion, such as purported bottle shortages of more than 10 tablets, were escalated appropriately and investigated. The Associate General Counsel confirmed those investigations did not indicate possible diversion by Mallinckrodt employees.

11.119 For example, regarding the purported tablet shortages, TrackWise contained three inquiries in the first quarter of 2025 from different pharmacies reporting bottle shortages of more than 10 tablets: (1) a shortage of 37 tablets in a 100-count bottle of oxycodone / APAP 5/325 mg; (2) a shortage of 31 tablets in a 500-count bottle of oxycodone / APAP 5/325 mg; and (3) a shortage of 23 tablets in a 100-count bottle of hydromorphone HCl 2 mg. TrackWise also contained three inquiries in the second quarter of 2025 from different pharmacies reporting bottle shortages of more than 10 tablets: (1) a shortage of 22 tablets in a 100-count bottle of hydromorphone 2 mg; (2) a shortage of 13 tablets in a 100-count bottle of hydrocodone / APAP 10/300 mg; and (3) a shortage of 12 tablets in a 100-count bottle of oxycodone / APAP 10/325 mg. In each instance, the TrackWise entry indicated the inquiries were escalated to the CSC and

/ or Security Departments and investigated. However, given the amounts of the purported shortages, the Monitor Team requested additional information regarding the findings of those investigations.

11.120 Mallinckrodt informed the Monitor Team that all of the inquiries related to products manufactured at its Hobart, New York plant. The investigations consisted of, among other things, reviewing Mallinckrodt's: (1) processes, including analyzing whether Mallinckrodt's packaging system would permit the bottles to be packaged if they contained the purported shortages; (2) records related to the products' batches; and / or (3) video footage of the products' packaging, when available. Based on the information provided by the pharmacies and the investigations, in each instance Mallinckrodt concluded there was no indication of diversion within the Hobart facility. However, in two of the instances, Mallinckrodt concluded the purported shortage was likely a result of equipment malfunction and / or operator error and took corrective action by: (1) assessing and evaluating relevant aspects of the machinery's functionality; and (2) conducting a training with packaging personnel on appropriate responses to such situations. The Monitor is satisfied that Mallinckrodt appropriately investigated these purported shortages based on the available information and took corrective action when necessary.

ii. Resolution of scraped tablet issue in TrackWise patient complaint

11.121 In the Eleventh Monitor Report, the Monitor Team observed, in connection with a review of TrackWise, that a patient complained that pills appeared to have been "scraped" or "incorrectly stamped." *See* Eleventh Monitor Report at 71 ¶ 11.121. Upon opening a new bottle, the pharmacist was able to confirm the issue, indicating that problem existed prior to arrival at the pharmacy. *Id.* The Monitor Team sought to rule out the possibility of intentional

diversion—*i.e.*, deliberate scraping of the tablets—as an explanation for the tablets' appearance. In the Thirteenth Reporting Period, Mallinckrodt's outside counsel advised that the problem was due to a quality control issue arising from the use of a particular kind of oil in the tablet manufacturing process, rather than a diversion issue.

11.122 Specifically, Mallinckrodt's outside counsel explained that: (1) there were three separate complaints relating to tablet defects in this particular product lot; and (2) a quality investigation revealed that the wrong oil had been used in the tablet press during preventative maintenance. In fact, the oil typically used for an encapsulating machine, not a tableting machine, was inadvertently used on the tablet press. Mallinckrodt's outside counsel explained that while both oils are vegetable-based, the oil used on the encapsulator machine is less viscous. As a result, Mallinckrodt believes that the tablet punches and dyes got warmer than usual during the manufacturing process, causing the tablets to stick. Consequently, the tablets appear to have debossing defects—namely, the stamps imprinted on the tablets are not as clean. In sum, this is a plausible explanation for the "scraped" appearance.

e. Retirement of the CSC Senior Manager, and interview of her replacement

i. Retirement of CSC Senior Manager

11.123 In the Thirteenth Reporting Period, the Monitor Team learned of the planned retirement of Mallinckrodt's CSC Senior Manager, who was based out of its finished dose manufacturing facility in Hobart, New York. The CSC Senior Manager had worked for Mallinckrodt (or its predecessors) for over 25 years by the time of her retirement on July 3, 2025. Her experience, by then, covered most major areas of controlled substances compliance. This included her role as a member of the SOMT, her second-level review of suspicious direct orders,

her investigation of CSC-related TrackWise reports, and her involvement in physical inventory / biennial inventory and quota management, as well as in internal CSC-related auditing.

11.124 The Monitor Team interviewed the CSC Senior Manager on several prior occasions during the course of the monitorship, and in the Thirteenth Reporting Period conducted an exit interview with her. During that interview, the Monitor Team inquired about areas the CSC Senior Manager thinks the CSC Team has most improved upon over the last five to seven years, and what if anything she believes could or should be done differently or better.

11.125 As for improvement, the CSC Senior Manager believes suspicious order monitoring, and the SOMT itself, have improved. She attributed the improvement to additional resources, the contracted work of Analytics Group, Inc. ("AGI") to review SOM analytics and build an algorithm to identify bad actors, the adoption of multiple dashboards to support analytics, the hiring of the Director of CSC Analytics with his prior work with DEA and his background in analytics, and the addition of the CSC Specialist, with her statistical background.

11.126 The CSC Senior Manager did not note any areas for improvement by the SOMT. Indeed, she regards Mallinckrodt as the industry leader in SOM, and noted she is frequently asked at conferences and networking events how Mallinckrodt does direct order review. She believes Mallinckrodt is unique in having contracted with an analytics company like AGI, and in incorporating ARCOS data.

11.127 The CSC Senior Manager identified the CSC Team's biggest challenge as managing quota needs to ensure that legitimate patient need is met. She noted that DEA's move to a quarterly quota application submission system (which then changed last year to a semi-annual quota request system) created great difficulty for companies like Mallinckrodt, and for industry in general, resulting in product shortages.

ii. Interview of new CSC Manager overseeing compliance at Hobart, New York facility

11.128 The CSC Senior Manager shared that her retirement prompted the hiring of a new Manager of CSC ("CSC Manager D"). CSC Manager D has extensive prior experience in CSC compliance, including from his prior employment at three different pharmaceutical companies. At Company 1, between the years 2014 and 2025 (until his move to Hobart), he had the titles (in increasing order of seniority) of Diversion Operations Manager, Senior Manager DEA Compliance, and Director of DEA Compliance. At Company 2, between the years 2008 and 2014, he held the titles of Corporate Investigator and Diversion Control Program Manager. And at Company 3, between 2002 and 2008, he held the title Regulatory Affairs Specialist. In other words, CSC Manager D brings substantial relevant experience to his new role.

11.129 In an interview with CSC Manager D, the Monitor Team and CSC Manager D discussed, among other things, his employment background, onboarding at Mallinckrodt, job responsibilities, and early impressions of Mallinckrodt's SOM program.

11.130 As part of CSC Manager D's onboarding, he received training on, among other things, the Operating Injunction. He also relayed that he was able to work with the former Senior CSC Manager prior to her departure and continues to receive support from other employees at the Hobart, New York plant and members of the SOMT as he becomes familiar with Mallinckrodt's processes.

11.131 Regarding his current role, CSC Manager D informed the Monitor Team that his primary responsibility is ensuring the Hobart, New York plant operates in compliance with DEA's regulations. To that end, he oversees physical security of Mallinckrodt's products, record keeping, and quota management. Like other Mallinckrodt employees, CSC Manager D conveyed the ongoing challenges of obtaining adequate quota under the revised quota policy

DEA announced in April 2024, as discussed in prior reports. *See, e.g.*, Eleventh Monitor Report at 73 ¶ 11.128 – 75 ¶ 11.131. However, CSC Manager D did not indicate any concerns about the sufficiency of Mallinckrodt's current resources given the number of employees with CSC compliance responsibilities.

11.132 CSC Manager D and the Monitor Team also discussed his experience using artificial intelligence as a SOM tool and his observation that similar technology could supplement the algorithms underlying Mallinckrodt's existing SOM program to identify potentially suspicious direct and indirect customers for the SOMT's review. Specifically, CSC Manager D and the CSC Team had preliminary discussions concerning incorporating machine assisted learning, based on statistical analysis of ARCOS data, into the SOM dashboards.

11.133 CSC Manager D's suggestion is of particular interest to the Monitor, as the Monitor Team had previously inquired of Mallinckrodt whether AGI had considered the potential value of artificial intelligence in its SOM program. As discussed elsewhere in this Report, *see infra* at 101 ¶ 11.202 – 103 ¶ 11.204, Mallinckrodt informed the Monitor Team that it is actively exploring this issue with AGI.

f. Interview of new CSC Manager overseeing compliance at new Fenton, Missouri manufacturing facility

11.134 During the Thirteenth Reporting Period, the CSC Director informed the Monitor Team that Mallinckrodt had opened a new manufacturing facility in Fenton, Missouri[40] and hired an additional CSC Manager ("CSC Manager E") in April 2025 to oversee compliance at the facility. CSC Manager E joined Mallinckrodt with more than twenty years of management-level experience in CSC compliance at pharmaceutical companies. In her prior roles, CSC Manager E

[40] Mallinckrodt expects the new facility will manufacture finished dosage diphenoxylate / atropine products—a Schedule V controlled substance in this combined formulation.

also had security responsibilities, including monitoring and ensuring compliance with all state and federal CSC regulations and laws and performing security investigations. The CSC Director informed the Monitor Team that CSC Manager E's role at Mallinckrodt will similarly involve both compliance and security responsibilities, such as overseeing compliance with federal and state security regulations, maintaining records, and handling quota.

11.135 In an interview with CSC Manager E, the Monitor Team discussed, among other things, her employment background, onboarding at Mallinckrodt, job responsibilities, and impressions of Mallinckrodt's SOM program.

11.136 As part of CSC Manager E's onboarding, she received training on, among other things, the Operating Injunction. CSC Manager E advised that her training also consisted of in-person and online sessions on other topics, including regulatory training and Mallinckrodt's standard operating procedures.

11.137 Regarding her current role, CSC Manager E explained that because the Fenton facility is new, she is focusing on the security aspects of the Fenton facility in order to obtain DEA approval and ultimately a DEA number for the facility. CSC Manager E is also working to create written policies and procedures for the Fenton facility.

11.138 The Monitor Team inquired about CSC Manager E's initial impressions of Mallinckrodt's SOM program. CSC Manager E was involved in SOM processes with prior employers and reported that the Mallinckrodt process evaluates a large amount of meaningful data. CSC Manager E believed that Mallinckrodt had sufficient resources to adequately ensure controlled substances compliance at the Fenton site. At the time of CSC Manager E's interview, CSC Manager E did not have any recommendations that would enhance the SOMT's function,

but noted that any opportunity to involve automation and analysis of large amounts of data would assist the SOMT in performing its duties.

g. Update on grand jury subpoenas

i. U.S. Attorney's Office for the Western District of Virginia

11.139 As reported since the Ninth Monitor Report, and as Mallinckrodt disclosed in prior SEC filings, Mallinckrodt received grand jury subpoenas in 2023 (and has continued to receive additional subpoenas since) in connection with a federal criminal investigation by the U.S. Attorney's Office for the Western District of Virginia. *See*, *e.g.*, Twelfth Monitor Report at 112 ¶ 11.205 – 113 ¶ 11.207; Eleventh Monitor Report at 76 ¶ 11.135 – 78 ¶ 11.139; Tenth Monitor Report at 92 ¶ 12.179 – 93 ¶ 12.182; Ninth Monitor Report at 49 ¶ 14.1 – 52 ¶ 14.8. As also noted in prior Monitor Reports, Mallinckrodt and its outside counsel have kept the Monitor Team informed regarding Mallinckrodt's productions in response to the subpoenas, and have shared with the Monitor Team the cover letters related to those productions. There were no notable substantive developments of relevance to the monitorship in the Thirteenth Reporting Period. The Monitor is satisfied with Mallinckrodt's sharing of information with the Monitor in connection with these subpoena responses.

ii. U.S. Attorney's Office for the Eastern District of Pennsylvania

11.140 In addition to the grand jury subpoenas from the U.S. Attorney's Office for the Western District of Virginia, and as also previously reported in prior Monitor Reports and disclosed in Mallinckrodt's prior SEC filings, on May 29, 2024, the U.S. Attorney's Office for the Eastern District of Pennsylvania issued a federal grand jury subpoena to SpecGx LLC relating to its controlled substances business. *See* Twelfth Monitor Report at 113 ¶ 11.208 – 114 ¶ 11.209; Eleventh Monitor Report at 78 ¶ 11.140 – 79 ¶ 11.142. Mallinckrodt most recently

reported on this subpoena, without substantive change, in its August 2025 10-Q. Mallinckrodt's last production in response to the subpoena was in October 2024. There have been no subsequent developments.

h. Meeting with representatives of the State Attorneys General

11.141 During the Thirteenth Reporting Period, on July 14, 2025, the Monitor Team met via Zoom with representatives of the State Attorneys General. That meeting included representatives from the states of New York, North Carolina, and Texas, and the Commonwealth of Pennsylvania.

11.142 The Monitor Team provided updates regarding various topics discussed in greater detail in this Report, including: (1) the merger of Mallinckrodt and Endo, *see infra* at 75 ¶ 11.143 – 77 ¶ 11.145; (2) Mallinckrodt's and the Monitor Team's discussions regarding the anticipated conclusion of the monitorship and how Mallinckrodt intends to audit its compliance with those provisions of the Operating Injunction that survive the monitorship, *see infra* at 108 ¶ 15.7 – 110 ¶ 15.11; (3) the Monitor Team's work during the Thirteenth Reporting Period, including interviews with various employees, *see supra* at 69 ¶ 11.123 – 74 ¶ 11.138; and (4) Mallinckrodt's ongoing work with AGI to enhance the SOM dashboards, *see infra* at 101 ¶ 11.202 – 103 ¶ 11.204, and identify the universe of customers that do not submit chargeback data, *see supra* at 51 ¶ 11.65.

11.143 Mallinckrodt and Endo announced their merger on August 1, 2025.[41] In connection with the merger, they announced that Mallinckrodt's and Endo's respective generics businesses and Endo's sterile injectables business are to be combined under the name "Par

[41] *See* Mallinckrodt, Endo Complete Merger to Create Global, Scaled, Diversified Therapeutics Leader, available at https://mallinckrodt.com/about/news-and-media/news-detail/?id=32691 (last visited Oct. 10, 2025).

Health, Inc.," and they expect that entity to be spun off as an independent company in the fourth quarter of 2025. As Mallinckrodt's outside counsel informed the Monitor Team, the companies expect that Par Health will operate as a parent entity with various subsidiaries comprised of portions of Mallinckrodt's and Endo's legacy businesses. The Mallinckrodt entities will remain subject to the provisions contained in Mallinckrodt's Operating Injunction. Mallinckrodt's outside counsel also informed the Monitor Team that the companies expected that structure to remain in place even after the anticipated spinoff, although they expected the entities to become more integrated in the long term.

11.144 Regarding the merger, one of the representatives of the State Attorneys General inquired of the Monitor Team: (1) which Endo products would become part of Par Health; and (2) whether Par Health's sterile injectables business would derive solely from Endo's products. The Monitor Team discussed the representative's questions with Mallinckrodt and its outside counsel initially by email and subsequently, via Zoom, at a meeting on July 30, 2025. Mallinckrodt's outside counsel provided a copy of Endo's product portfolio and its expectation as to which legal entity would manufacture each product in future, although this remained somewhat in flux as of the date of the meeting. Mallinckrodt's outside counsel informed the Monitor Team that only one of Endo's Opioid products, a sterile injectable buprenorphine product, was expected to become part of Par Health. However, any buprenorphine products would be manufactured by one of the Par Health subsidiary entities subject to Endo's Opioid-related injunction, not Mallinckrodt's Operating Injunction. Additionally, Mallinckrodt's expectation is that Endo's other Opioid products, including Endocet (a product containing oxycodone and acetaminophen) would not continue to be part of the Par Health product portfolio. Mallinckrodt, in any event, manufactures a similar product.

11.145 Finally, Mallinckrodt confirmed that the sterile injectable portion of Par Health's product portfolio would consist solely of portions of Endo's legacy business.

i. Discussions with Purdue Monitor

11.146 The Monitor Team has continued to review reports published by, and to meet with, the Purdue Monitor, as the Purdue Monitor's observations regarding Purdue and the industry more generally have been of interest, and help, to the Monitor in this monitorship. Specifically, during the Thirteenth Reporting Period, the Monitor Team reviewed the Purdue Monitor's findings in his Twenty-Second[42] and Twenty-Third[43] Monitor Reports, and met with the Purdue Monitor. The Purdue Monitor's observations in these reports regarding Purdue's inadvertent supply of controlled substances without first clearing SOM review and its direct customer order algorithm are discussed in greater detail below.

i. The SOMT confirmed that Mallinckrodt's systems would not permit the supply of controlled substances to a new customer without first clearing SOM review

11.147 The Purdue Monitor's Twenty-Second Report previewed a new customer order anomaly: certain controlled substances orders were released without SOM review. *See* Twenty-Second Purdue Report at 27 ¶ 101 – 28 ¶ 105. As the Purdue Monitor reported, "a new direct customer was onboarded by [Purdue] and approved by the SOM Team to order controlled substances. Thereafter, a limited number of controlled substances orders were released for shipment to the new customer, despite the orders not having been routed to the SOM Team for review." Twenty-Second Purdue Report at 27 ¶ 101. The Purdue Monitor's Twenty-Third

[42] *In re: Purdue Pharma L.P., et al.*, No. 19-23649, Dkt. 7438 (S. D. N.Y. Bankr., May. 14, 2025).

[43] *In re: Purdue Pharma L.P., et al.*, No. 19-23649, Dkt. 7741 (S. D. N.Y. Bankr., Aug. 12, 2025).

Report explored this anomaly in greater detail, noting that an inquiry was completed and corrective actions taken. *See* Twenty-Third Purdue Report at 18 ¶ 64 – 25 ¶ 80.

11.148 The Monitor Team discussed this aspect of the Purdue Monitor's reports with the SOMT to ensure a similar anomaly had not occurred, and could not occur in the future, at Mallinckrodt.

11.149 The CSC Director advised that he raised the issue with Mallinckrodt's Customer Data Integrity Group and Customer Service Department. In those discussions, the CSC Director reviewed the entire order intake process, encompassing both electronic and paper orders, and confirmed Mallinckrodt's direct order process would not permit an order to circumvent SOM review prior to shipment because: (1) any electronic order for controlled substances requires a DEA number; and (2) all orders with a DEA number are automatically reviewed by the direct customer dashboard's algorithm that flags potentially suspicious orders for review. Similarly, paper orders (often from methadone clinics) must have a DEA number, which is ultimately entered into the electronic system during processing. Put differently, without a DEA number, it is not possible for Mallinckrodt to process an order and ship controlled substances. The CSC Director also noted that Mallinckrodt does not rely upon a third-party vendor for order processing, as Purdue apparently does to some extent, which removes a partial cause of the Purdue incident.

11.150 The Monitor Team accepts the CSC Director's review of Mallinckrodt's systems and does not believe further action to evaluate Mallinckrodt's processes is warranted.

ii. Purdue's changes to suspicious order monitoring of smaller distributor customers

11.151 The Purdue Monitor's Twenty-Second Report also noted contemplated changes to Purdue's suspicious order monitoring of smaller distributor customers. *See* Twenty-Second

Purdue Report at 22 ¶ 78 – 24 ¶ 89. These efforts were described as: (1) individually reviewing pharmacy customers of the smaller distributors for a two-month period; (2) reviewing and updating the thresholds of smaller distributors at least twice annually; (3) obtaining additional data from smaller distributors not providing 867 data to Purdue; (4) for smaller distributors not providing 867 data to Purdue, identifying the downstream customers of those distributors to identify ordering or geographic anomalies; and (5) for smaller distributors not providing 867 data to Purdue, obtaining data from the smaller distributors regarding their downstream customers under certain circumstances.

11.152 The above-described steps are analogous to some of the steps Mallinckrodt takes to identify potential diversion risks among its smaller distributors. For example, as discussed above, *see supra* at 45-46 ¶ 11.44, Mallinckrodt has sought to obtain substitute data for chargeback data in instances where a direct customer is not seeking chargeback payments from Mallinckrodt. *See also* Twelfth Monitor Report at 100 ¶ 11.173 – 102 ¶ 11.176. Additionally, Mallinckrodt is continuing its effort to identify common origins for the supply of its products to restricted downstream registrants. In this way, as described more fully elsewhere in this Report, Mallinckrodt was able to terminate Distributor U in August 2025. *See supra* at 48 ¶ 11.54 – 50 ¶ 11.60.

iii. Mallinckrodt's exit interviews with departing Mallinckrodt employees

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

11.154 During the Thirteenth Reporting Period, the Monitor Team requested and received a list of exit interview questions as well as summaries of the exit interview surveys voluntarily completed by departing Mallinckrodt employees for the year 2024 and the second quarter of 2025. The questions covered six topics: (1) Reason for Leaving; (2) Exit Treatment (which asked how happy the employee was with their treatment regarding their departure from the Company); (3) Rehire (which asked whether the employee would consider working at the Company again in the future); (4) Disengagement Duration (which asked how long the employee had been looking for a job elsewhere); (5) Disengagement Trigger (which asked what event or circumstance led the employee to consider leaving); and (6) Recommend (which asked whether the employee would recommend Mallinckrodt as a great place to work). Some questions asked the departing employee to rate their feelings about the Company on a scale of 1 to 5, while others listed options for the employee to select, such as reasons for leaving the Company. One question, the Disengagement Trigger, was open-ended and allowed the employee to write a narrative response.

11.155 The surveys had response rates of 50% to 67%, with approximately 5 to 7 departing employees completing the survey per quarter. The departing employees' reasons for leaving the Company varied greatly, and several indicated they were leaving for reasons outside the Company's control.

11.156 Notably, none of the exit interview questions touched upon compliance topics or potential compliance issues. Given that departing employees may feel more comfortable honestly expressing compliance concerns as they are leaving the Company, the Monitor suggests adding to the exit interviews questions that address the employees' feelings regarding

compliance-related issues, and solicit pertinent details the employee may be willing to share upon departing the Company.

New Recommendation 13(c). Add compliance-related questions to exit interview surveys.

11.157 **The inclusion of compliance-related questions in Mallinckrodt's exit interview process can be easily accomplished. This is worth including in order to elicit any additional helpful information that might improve Mallinckrodt's compliance program, or identify weaknesses an employee may be reluctant to share during the term of employment. Accordingly, the Monitor recommends Mallinckrodt include compliance-related questions in its exit interview surveys.** ***Mallinckrodt has agreed to implement this recommendation.***

j. Mallinckrodt's Letter to Direct Customers

11.158 As previously reported, Mallinckrodt has pursued contractual agreements with certain distributors and buying groups regarding reciprocal sharing of SOM-related intelligence and preventing supply of Mallinckrodt's products to restricted indirect customers. *See* Twelfth Monitor Report at 105 ¶ 11.185 – 107 ¶ 11.190. While Mallinckrodt has not secured any new contractual agreements during the Thirteenth Reporting Period, the Monitor Team inquired whether Mallinckrodt would informally request such information from its direct customers while negotiations are ongoing.

11.159 The Purdue Monitor's Twenty-Second Report reflected a similar effort by Purdue and described Purdue's efforts to require its direct customers to notify Purdue if the direct customer ceases to distribute Purdue products to downstream consumers. *See* Twenty-Second Purdue Report at 25 ¶ 94 – 27 ¶ 100. Several of Purdue's direct customers agreed to the request verbally.

11.160 During the Thirteenth Reporting Period, Mallinckrodt provided the Monitor a draft of a letter it intends to send to all direct customers that have not otherwise contractually agreed to engage in reciprocal information sharing of SOM-related intelligence. In pertinent part, the letter provides:

> [I]f [you, the direct customer, are] aware of—or maintain a list of—pharmacies or other downstream registrants that you believe have exhibited red flags of potential diversion or to which you have restricted sales of controlled substances due to compliance concerns, we ask that you provide their names, DEA numbers and any relevant date of restriction. Finally, going forward, we request that you notify us promptly in writing of any downstream registrants that you learn pose a risk of diversion or to which you have decided to restrict sales of controlled substances due to compliance concerns.

11.161 Mallinckrodt's outside counsel confirmed that Mallinckrodt intends to use best efforts to include provisions to this effect in its contracts with direct customers, and to continue to raise this issue in negotiations on such contracts. The Monitor is satisfied with Mallinckrodt's continuing efforts to maximize information sharing and to memorialize the same in contractual language with its direct customers. This is different than, but broadly consistent with, *Prior Recommendations 2(d)* (ensuring chargeback restrictions restrict not only chargeback payments, but also the supply of Opioid Products to a restricted pharmacy), *Prior Recommendation 2(e)* (timely provision of chargeback data), and *Prior Recommendation 2(h)* (obtaining more detailed retail data to conduct more effective chargeback reviews).

6. Reflecting on Mallinckrodt's Changes to Its SOM Program Over the Course of the Monitorship

11.162 With the conclusion of the monitorship, the Monitor Team has reflected upon the enhancements to Mallinckrodt's SOM program over the past five years, including through the implementation of the Monitor's over 40 SOM-related recommendations. This implementation

was, of course, supported by the daily work of the CSC Team itself, including through its hiring of additional skilled personnel with significant law enforcement backgrounds, and its partnership with AGI, which assisted Mallinckrodt in modernizing its SOM program and developing the foundational systems Mallinckrodt now relies heavily upon to monitor its direct and indirect customer ordering patterns.

11.163 At the outset of the monitorship, the Monitor reported on changes Mallinckrodt had already implemented to improve its SOM program, including those changes that Mallinckrodt's 2017 Memorandum of Agreement with DEA precipitated. At that time (July 23, 2021), the Monitor reported that he "found Mallinckrodt willing to further strengthen its SOM program—including through its work with its third-party consultant [AGI]—and receptive to the Monitor's recommendations." Second Monitor Report at 19-20 ¶ 11.2 (discussing changes to Mallinckrodt's SOM program from 2011 to 2021 and work with AGI). The Monitor's initial observation in the Second Monitor Report has held true. Since that time, from the Monitor's perspective, the Monitor Team and Mallinckrodt, with AGI's assistance, have engaged in a collaborative effort to identify potential ways to both enhance and refine Mallinckrodt's SOM program in order to improve its efficiency and efficacy, and to implement iterative changes to the program when appropriate.

11.164 Four themes are apparent from Mallinckrodt's improvements to its SOM program over the past five years:

(1) leveraging technology and available data to modernize and automate, leading to more efficient and effective review of an increasingly large number of targets;

(2) strategic hires in CSC compliance roles;

(3) formalization and standardization of SOM and compliance-related processes; and

(4) strengthening Mallinckrodt's knowledge of and relationships with direct customers.

The Monitor elaborates upon each of these themes below.

a. Leveraging technology and available data to modernize and automate, leading to more efficient and effective direct and indirect customer reviews

11.165 Since the Monitor's *Prior Recommendation 2(a)*—that Mallinckrodt "modernize and enhance the SOM function with the use of big data, artificial intelligence, and automated processes and algorithms"—Mallinckrodt has worked with AGI to do so. Second Monitor Report at 24. Indeed, at the start of the monitorship, many of Mallinckrodt's processes and procedures were manual and labor-intensive. The then-existing version of the SOM program required a significant amount of data collection, manipulation, and analysis by individual employees. The analysis of disparate sources of information with very limited searchability across records for comparison purposes made this a somewhat cumbersome and inefficient process. It necessarily meant the review of a far smaller number of targets. The relatively low volume of targets reviewed was compounded, of course, because much of that work fell on the CSC Auditor / Analyst—a single member of the SOMT. *Id*. at 25. Further, Mallinckrodt's systems were not built to incorporate, much less analyze in a meaningful way, voluminous data, including the greater ARCOS data that DEA made available to the industry during the course of the monitorship.[44]

11.166 By leveraging technology and incorporating additional data, Mallinckrodt, with the assistance of AGI, developed three separate dashboards—the direct, indirect, and ARCOS

[44] In 2018, before the monitorship began, Mallinckrodt could query data using an individual pharmacy's DEA number. In May 2021, DEA began providing bulk data downloads

dashboards—which automated important aspects of the CSC Team's monitoring efforts. *See, e.g.*, Third Monitor Report at 26 ¶ 11.16 – 28 ¶ 11.25 (discussing direct and indirect customer dashboards); Tenth Monitor Report at 58 ¶ 12.85 – 62 ¶ 12.96 (discussing ARCOS dashboard). Mallinckrodt's deployment of those dashboards, together with its increased investment in human capital discussed below, dramatically increased the SOMT's productivity. As a result, the SOMT is able to review (and, where appropriate, restrict) more pharmacies in less time, with restriction decisions now made more quickly than before.

11.167 By way of example, the SOMT's productivity, measured by numbers of pharmacies reviewed and pharmacies restricted, increased each year since the monitorship began in early 2021. Indeed, the SOMT has reviewed 510% more pharmacies through August 31, 2025, as compared to pharmacies reviewed in all of 2020. Likewise, the SOMT has restricted 420% more pharmacies through August 31, 2025 as compared to pharmacies restricted in all of 2020. This data is summarized below:

Annual Reviews and Restrictions (2020 to August 31, 2025)[45]						
	2020	***2021***	***2022***	***2023***	***2024***	***1/1/2025 to 8/31/2025***
Number of Pharmacies Reviewed for Restriction	98	76	231	403	742	598
Total Number of Restrictions	55	50	133	200	357	286

Figure 1.

that do not reveal the identity of distributors, but do reveal the identity of indirect customers, enabling much richer analysis.

[45] Mallinckrodt implemented its direct customer dashboard in 2021. The indirect dashboard became partly functional around March 10, 2022 and fully functional by June 1, 2022. Mallinckrodt incorporated ARCOS data into its indirect customer dashboard in 2023.

11.168 The graph below, provided by Mallinckrodt, reflects the significant increase in pharmacy reviews and due diligence requests the SOMT has made to direct customers over the past five years:

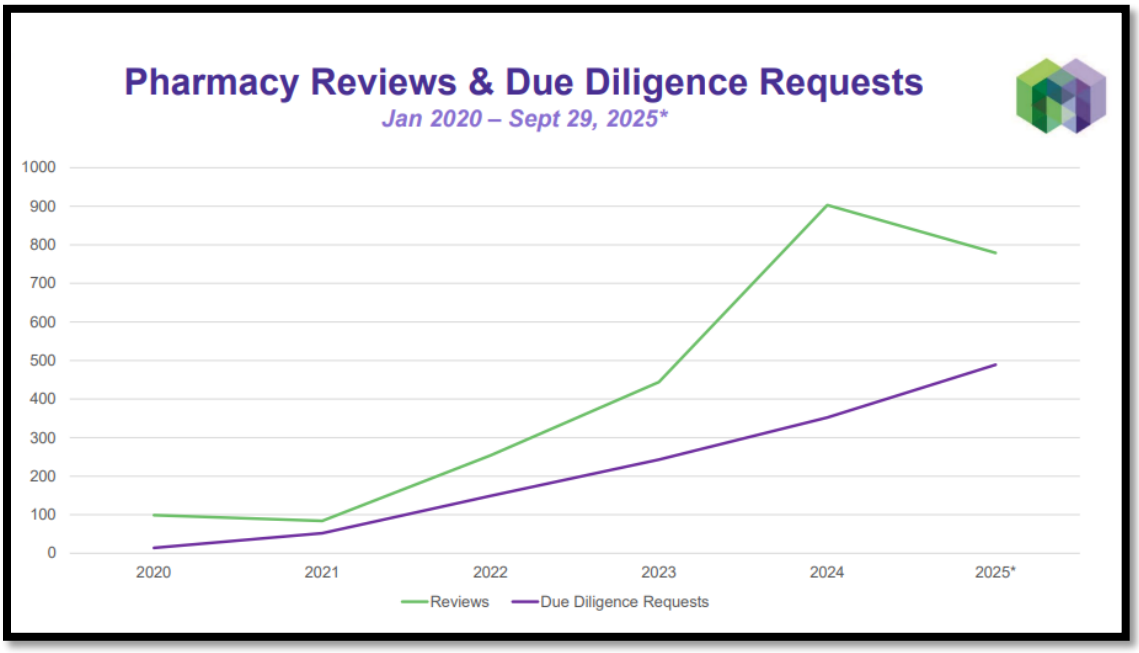


Figure 2.

Comparison of 2025 (through August 31) and 2020	
Percentage Increase in Reviews	510%
Percentage Increase in Restrictions	420%

Figure 3.

11.169 This increased productivity is evidenced in other ways as well. For example, the ARCOS dashboard enables the CSC Team to quickly conduct and resolve the indirect customer reviews triggered by chargeback growth "flags" when a customer's overall purchases of a product have not increased and the customer's ordering practices do not indicate any other "red flags." (Under those circumstances, a nefarious cause for the chargeback increases can be relatively quickly ruled out.) In other words, because each customer's ARCOS data is

incorporated in the ARCOS dashboard, the CSC Team can quickly discern whether the indirect customer's chargeback growth is due to its purchase of more Mallinckrodt products while maintaining a constant overall purchase volume (*i.e.*, not suspicious), or whether it is purchasing more of the product overall (*i.e.*, potentially suspicious), providing helpful context for the CSC Team to investigate potential diversion. Previously, conducting these reviews based upon chargeback flags in the absence of the broader context ARCOS data provides would have led the CSC Team to spend unnecessary time resolving "false positive" flags, diverting the CSC Team's valuable resources from higher risk chargeback reviews.

11.170 At the same time, the SOMT has reviewed, and granted, a greater number of reinstatement requests each year since the monitorship began. This data is summarized below:

Reinstatement Requests,[46] By Year, from 2020 to August 31, 2025						
	2020	***2021***	***2022***	***2023***	***2024***	***1/1/2025 to 8/31/2025***
Number of Pharmacies Reviewed for Reinstatement	1	8	18	45	157	135
Number of those Pharmacies Reinstated	0	5	11	30	100	76
Percent of reviews resulting in reinstatement	0%	63%	61%	67%	64%	56%

Figure 4.

[46] Although this chart reflects data for indirect customers only, "reinstatement" generally includes reinstatement of both direct and indirect customers. Indirect customer requests and reinstatements occur far more frequently than direct customer requests and reinstatements.

11.171 The graph below, provided by Mallinckrodt, reflects the number of indirect customer reviews, restrictions, and reinstatements over the last five years:

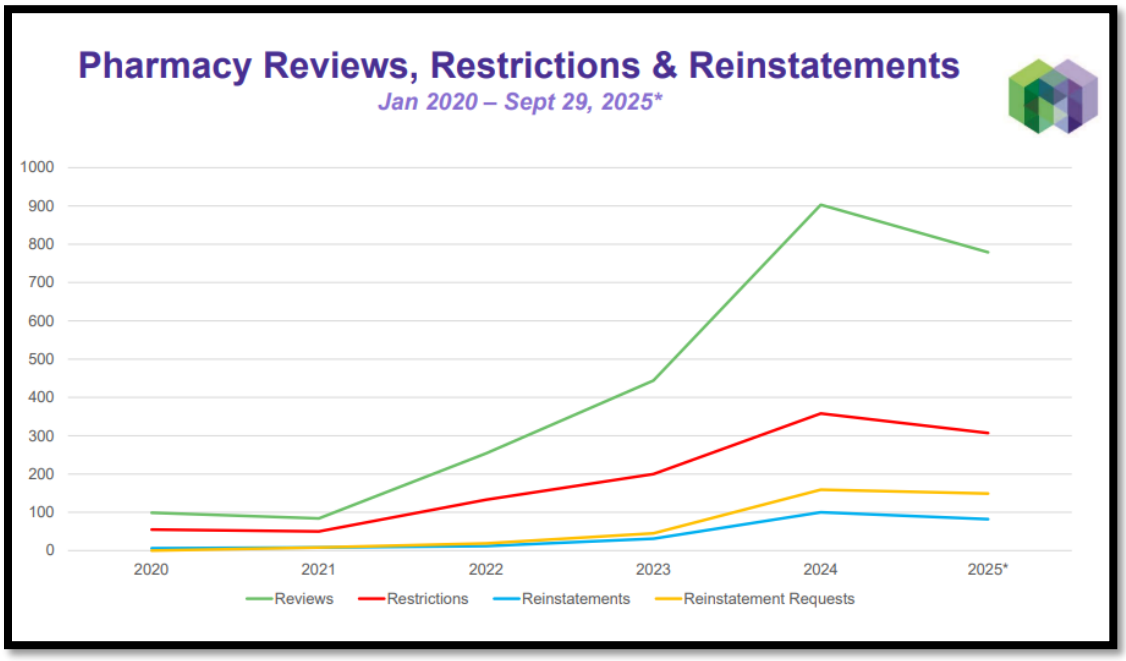


Figure 5.

11.172 Thus, the CSC Team is now able to conduct increased reviews of "true positives" and fewer reviews of "false positives," which is better for Mallinckrodt and of course for the market participants that comply with legal requirements.

11.173 As noted above, the percentage of reviews resulting in reinstatement has decreased over the past several years. And that reduction is likely to become even more pronounced, as a result of Mallinckrodt's decision to adopt a policy of delaying any future reinstatements for a period of approximately eight months (allowing for exceptions in appropriate cases). This length of time will give the SOMT an additional six months' worth of ARCOS data in order to evaluate the reinstatement candidate. While this delay may not lower the rate of reinstatements in absolute terms, it is likely to manifest as a decrease due to the time delay.

11.174 Furthermore, by incorporating both greater quantities of data and additional sources of information in Mallinckrodt's SOM program, the CSC Team is better able to detect potential diversion in a multitude of ways. Specifically, over the course of the monitorship, the CSC Team's indirect customer review process has evolved from a primarily chargeback- and media alert-based system to one based on numerous data sources, including not just chargeback flags and media alerts, but ARCOS data and distributor notifications to Mallinckrodt as well.

11.175 Each of the metrics the indirect customer and ARCOS dashboards analyze, and the other data sources it incorporates, provides important information in combating diversion. For example, while chargeback flags still comprised a significant portion of the triggers for direct and indirect customers reviewed in 2023-2024 and to-date in 2025, other "triggers" such as ARCOS data and distributor notifications made up a significant percentage of the reviews and restrictions in those periods as well.

11.176 Specifically, as summarized in the chart below, while chargeback flags were responsible for 46% of the indirect reviews initiated in 2023-2024, other "triggers" made up 54% of the SOMT's reviews in that same period:

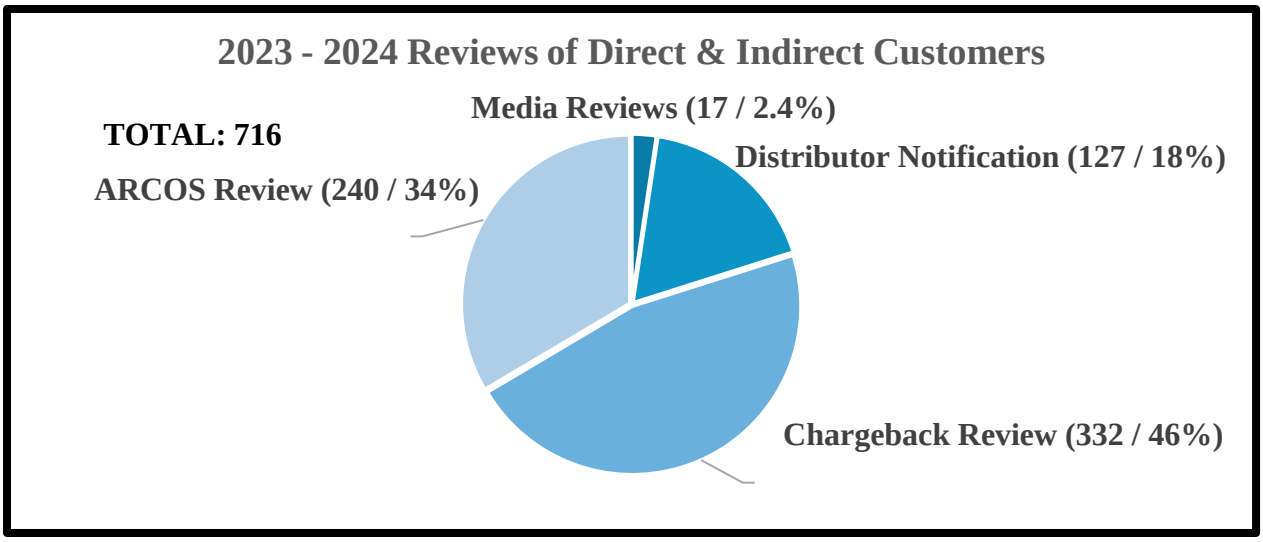


Figure 6.

11.177 Moreover, as reflected below, ARCOS flags and distributor notifications to Mallinckrodt made up 90% of the restrictions and suspensions:

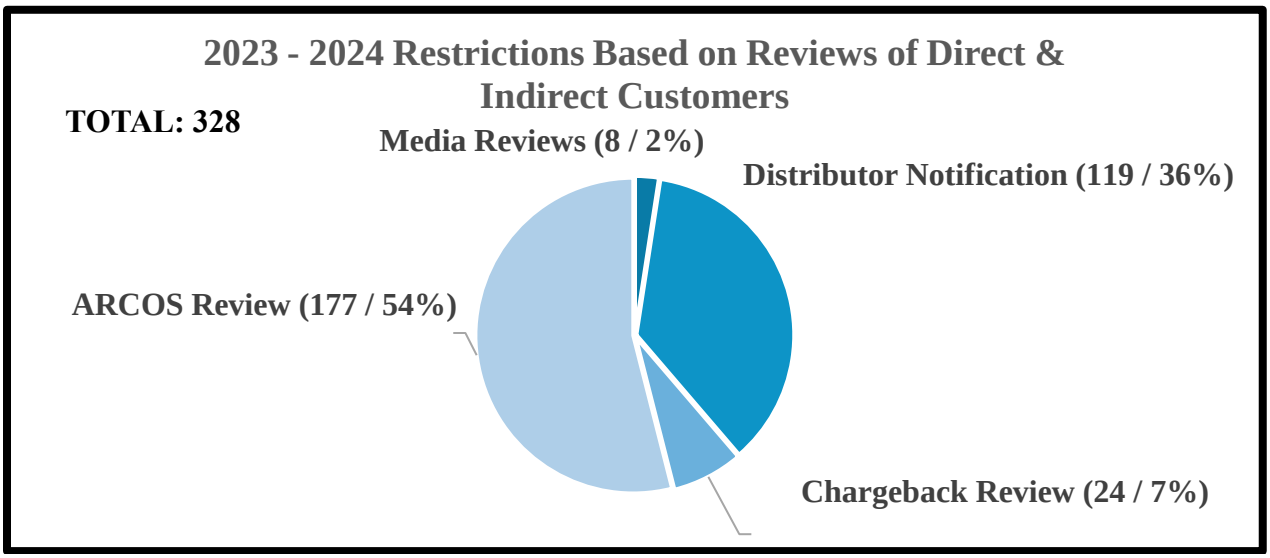


Figure 7.

11.178 In 2025 (through August 31), chargeback flags continue to account for a significant percentage of the indirect reviews (57%), with other "triggers" making up the remainder of the SOMT's reviews in that same period:

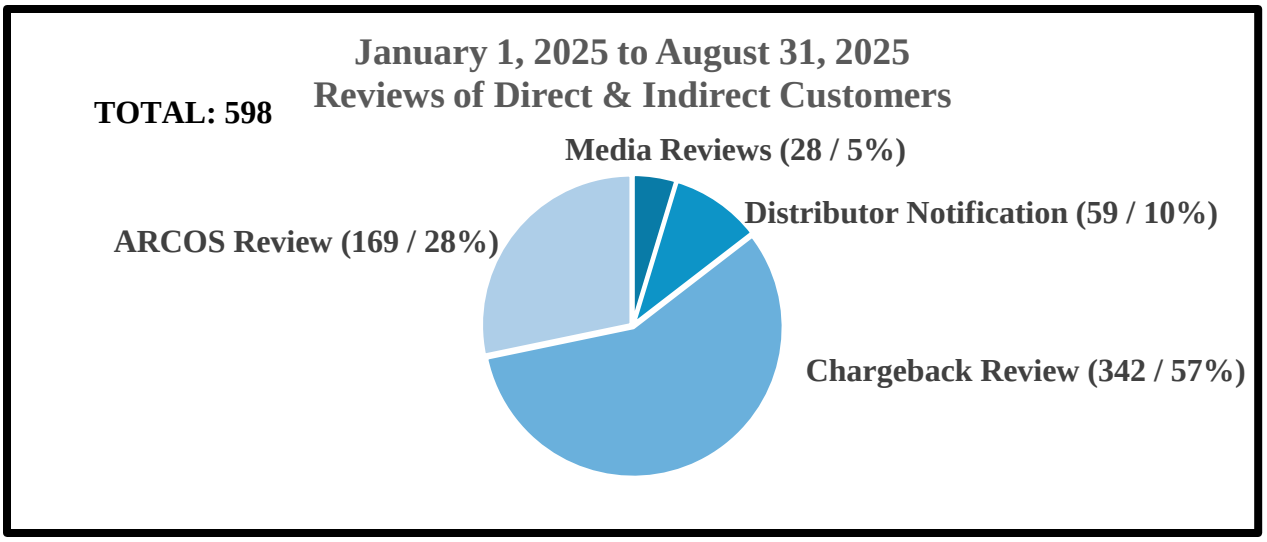


Figure 8.

11.179 In this same time period, ARCOS flags and distributor notifications to Mallinckrodt made up 70% of the restrictions and suspensions. Chargeback reviews accounted for 21% of restrictions:

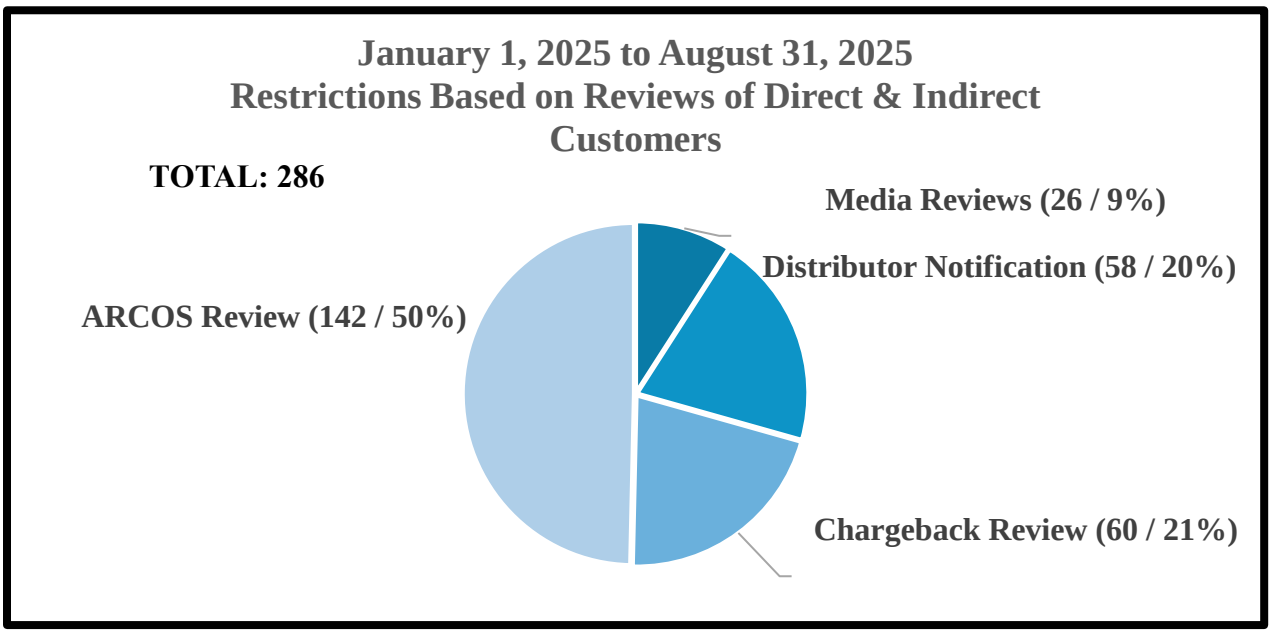


Figure 9.

11.180 Indeed, the following bar graph, provided by Mallinckrodt, represents the increased diversification in the sources for restrictions over the last five years:

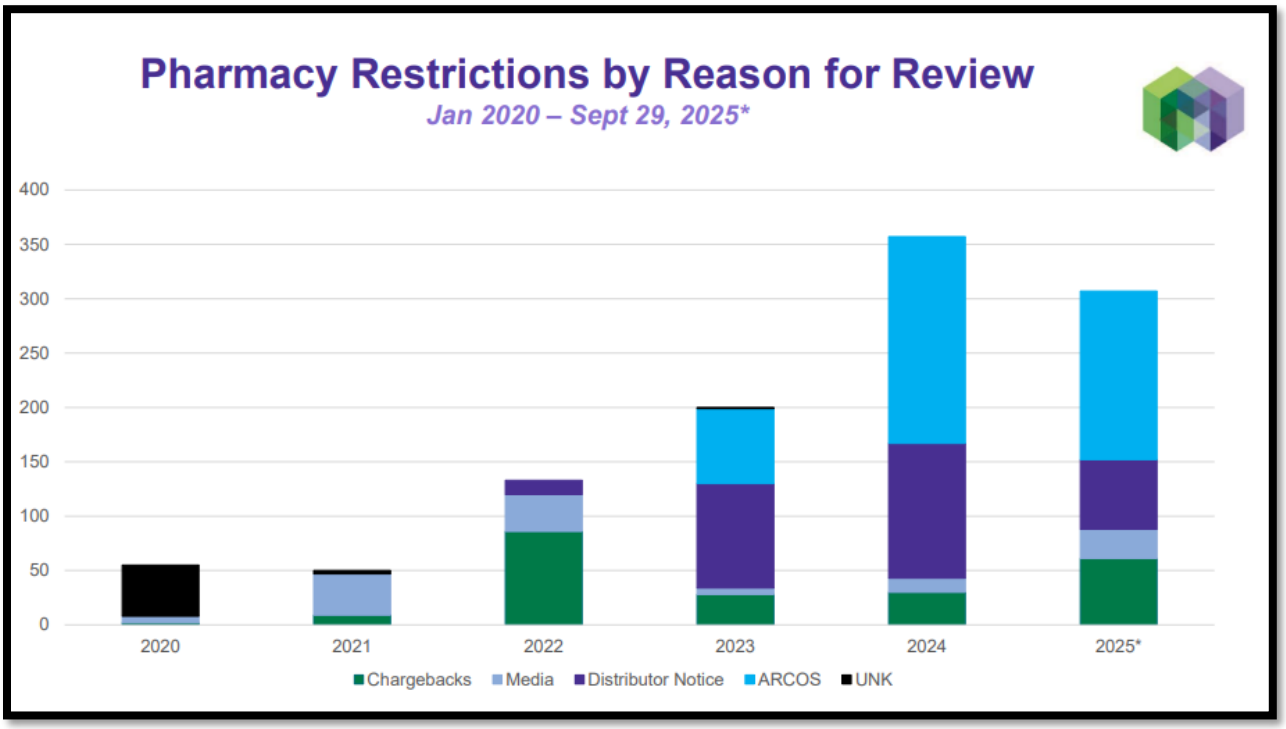


Figure 10.

11.181 Finally, the dashboards' compilation of more voluminous data over longer periods of time has enabled the CSC Team to make both micro ***and*** macro observations regarding direct and indirect customers, enhancing Mallinckrodt's surveillance capabilities. In addition to conducting reviews of individual indirect customers, the CSC Team can now more easily analyze data across the entire industry to identify potentially suspicious anomalies and unusual purchasing practices based on longer-term trends. That analysis, typically conducted by the Director of CSC Analytics as part of his annual review, has revealed repeatedly that certain pharmacies warrant restriction even if the dashboard does not prioritize them for review. *See, e.g.*, Twelfth Monitor Report at 85 ¶ 11.131 – 86 ¶ 11.132 (discussing the Director of CSC Analytics' 2024 report that produced a substantial number of pharmacies for restriction and the

potential reasons why those pharmacies were not flagged by the indirect customer dashboard, including that the Annual Report performs a function the dashboards do not by utilizing human analytics and expertise and engaging in a longer-term and higher-level market analysis).

11.182 Similarly, the accumulation of greater volumes of ARCOS data presents new possibilities for Mallinckrodt in an era of "big data" analytics, particularly with the advent of predictive analytics, machine learning, and artificial intelligence, as discussed elsewhere in this Report. *See supra* at 84 ¶ 11.165 – 85 ¶ 11.166. Moreover, as discussed above, *see infra* at 101 ¶ 11.202 – 103 ¶ 11.204, Mallinckrodt informed the Monitor team of numerous dashboard enhancements it is currently considering, or implementing, to further strengthen its ability to detect potential diversion.

11.183 In sum, Mallinckrodt's incorporation of "big data" and statistical analysis to perform automated analyses, as well as its investment in human talent capable of managing and analyzing that information, have made its SOM efforts more efficient and effective. The Monitor encourages Mallinckrodt to continue its commitment to enhancing the dashboards to streamline monitoring efforts further, to incorporate additional information as it becomes available, and to invest in additional technological improvements as necessary.

b. Strategic hires in CSC compliance roles

11.184 While Mallinckrodt's leveraging of technology and "big data" has been a key driver of enhancements to its SOM program, the data is of course only as helpful as are the humans analyzing it. Thus, Mallinckrodt's continued investment in human capital, including hires for important CSC compliance roles, has been critical to enhanced review process and the SOMT's productivity. These human resources improvements were consistent with the Monitor's recommendations related to resource sufficiency and allocation, which Mallinckrodt accepted. *See, e.g., Prior Recommendation 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."); *Prior Recommendation 2(c)* ("Consider the sufficiency of both short-term and long-term human resource allocation in the SOM function.").

11.185 Since January 2021, Mallinckrodt has hired seven employees with CSC responsibilities, including five members of the SOMT. These employees not only have significant industry experience, with many coming directly from DEA or FDA, but, equally importantly, several also have statistics and data analytics backgrounds and experience with artificial intelligence—skills necessary to work with, and further develop, Mallinckrodt's modernized SOM program. *See, e.g.*, Second Monitor Report at 26 (discussing the CSC Specialist's background, including Masters in Predictive Analytics and experience with coding, inputting, and interpreting data sets). That includes Mallinckrodt's recent hiring of CSC Manager D, discussed above, *see supra* at 71 ¶ 11.128 – 72 ¶ 11.133, who has significant prior experience working with artificial intelligence in pharmaceutical SOM programs.

11.186 The importance of these additional strategic hires is two-fold. The hires have increased productivity and increased innovation. ***First***, as a direct result of additional human resources, Mallinckrodt is able to perform a greater number of indirect customer reviews. Previously, the CSC Team was not able to complete a review of all "flagged" pharmacies each month, but, as of the Twelfth Monitor Report, Mallinckrodt's outside counsel advised the Monitor Team that the CSC Team has been able to review all flagged pharmacies as a result of Mallinckrodt's additional hires. *See* Twelfth Monitor Report at 87 ¶ 11.134. ***Second***, the Monitor has observed that these additional members of the CSC Team have directly contributed to the enhancements and refinements to Mallinckrodt's SOM program and development of new analyses to detect potential diversion, such as the "upward" reviews of distributors based on

Mallinckrodt's restrictions of those distributors' customers (*i.e.*, Mallinckrodt's indirect customers). *See* Tenth Monitor Report at 82-83 ¶ 12.150 (describing benefits of onboarding CSC Managers A, B, and C). From the Monitor's perspective, their contributions have unquestionably strengthened the CSC Team's ability to prevent diversion.

11.187 Given its successful integration of these new hires to date, the Monitor hopes Mallinckrodt will continue to make appropriate investments in human resources in the future.

c. Formalization and standardization of SOM and compliance-related processes

11.188 When the monitorship began, the CSC Team did not have formal guidance for many of its routine practices. *See supra* at 64-65 ¶ 11.112 (noting, in Second Monitor Report, the use of a Microsoft Outlook "tickler"). Accordingly, starting in the Second Monitor Report, and continuing in several subsequent reports, the Monitor made a series of recommendations intended to encourage formalizing and standardizing the CSC Team's processes and procedures. *See, e.g., Prior Recommendation 2(l)* ("Memorialize and routinize the periodic review of (1) pharmacies reviewed but not restricted, and (2) pharmacies that are reinstated."); *Prior Recommendation 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.").

11.189 Based on the Monitor's recommendations and Mallinckrodt's own efforts in this regard, the CSC Team developed checklists for: (1) the chargeback review process; (2) chargeback reinstatement for indirect customers; and (3) direct customer due diligence visits. *See, e.g.,* Fourth Monitor Report at 32 ¶¶ 11.30-32 (discussing the *Suspicious Order Monitoring Program Indirect Customer Pharmacy Review Cover Sheet Checklist*, which memorialized existing aspects of the SOMT's chargeback review process); Fourth Monitor Report at 36-37 ¶ 11.41; 38 ¶ 11.46 – 39 ¶ 11.48 (discussing *the Requirements for 3rd Party Assessment for*

Chargeback Reinstatement Requests, which standardized the information and practices Mallinckrodt evaluates when considering a chargeback reinstatement request); Sixth Monitor Report at 39 ¶ 11.26 – 40 ¶ 11.28 (discussing the template *CSC/Suspicious Order Monitoring Distributor Customer Audit Checklist* and the *SOM Distributor Review Security Questions* the CSC Team uses in connection with direct customer due diligence visits).

11.190 Furthermore, Mallinckrodt took those recommendations a step further by creating a comprehensive CSC Handbook, which the Monitor expects will be helpful for existing employees, in the event of vacations, leaves, personnel changes, and onboarding new employees. Mallinckrodt did not produce, and the Monitor therefore did not review, the CSC Handbook for inclusion in this Report.

d. Strengthening Mallinckrodt's knowledge of, and relationships with, direct customers

11.191 As detailed in prior reports, from the beginning of the monitorship the Monitor observed opportunities for Mallinckrodt to conduct enhanced due diligence concerning its direct customers, and for improved information sharing along the supply chain to detect and prevent diversion. By way of example, the Monitor observed that: (1) Mallinckrodt's two-page direct customer questionnaire sought limited information regarding the customers' business, SOM program, training, compliance with law, and onsite inspections—information that is relevant to the CSC Team's ability to assess the customer's diversion risk; (2) the CSC Team did not have a regular schedule for "check ins" with direct customers or for conducting onsite visits; (3) the SOMT's chargeback restriction of an indirect customer determined to be a diversion risk did not necessarily result in direct customers terminating supply of Mallinckrodt's Opioid Products to that indirect customer; and (4) there were lengthy delays in direct customers responding to the CSC Team's requests for due diligence, which negatively impacted Mallinckrodt's ability to

monitor downstream registrants, and risked continued supply of Mallinckrodt's Opioid Products to downstream registrants the SOMT may have been inclined to restrict. *See* Second Monitor Report at 23-24 ¶¶ 11.10-11; *id.* at 28; *id.* at 43-44; Fourth Monitor Report at 29 ¶ 11.23 – 30 ¶ 11.24.

11.192 Based on those and other observations, the Monitor considered the ways in which Mallinckrodt could strengthen its process for monitoring direct customers, and gain increased cooperation from them to help prevent diversion. As a result, the Monitor made a number of related recommendations. *See, e.g.*, *Prior Recommendation 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."); *Prior Recommendation 2(e)* ("Use best efforts to obtain timely provision of chargeback data from direct customers."); *Prior Recommendation 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."); *Prior Recommendation 2(s)* ("Revise direct customer questionnaires to yield helpful, actionable, and verifiable information and determine a method for sampling or randomly auditing questionnaires."); *Prior Recommendation 2(t)* ("Establish regularly scheduled interactions with direct customers.").

11.193 By implementing those recommendations, in conjunction with the CSC Team's independent efforts to increase its focus on monitoring direct customers, Mallinckrodt has advanced the objectives of the Monitor's recommendations. For example, Mallinckrodt significantly expanded its direct customer questionnaires to yield actionable information regarding its customers' SOM programs, and, in many instances, the CSC Team's reviews of unsatisfactory questionnaire responses have prompted discussions with customers, resulting in

suspensions. *See* Twelfth Monitor Report at 47 ¶ 11.38 – 48 ¶ 11.42 (discussing suspension of distributor after distributor's questionnaire raised concerns regarding adequacy of its SOM program and CSC Team's subsequent meetings with distributor did not alleviate those concerns); Fourth Monitor Report at 37 ¶ 11.42 – 38 ¶ 11.45 (discussing certain revisions to direct customer questionnaires).

11.194 Moreover, as a result of two separate updates to the *SOM Review of Direct Customers* SOP, Mallinckrodt began conducting regular due diligence visits with its direct customers, and now conducts no fewer than 10 such visits each year. Twelfth Monitor Report at 90 ¶ 11.143 – 91 ¶ 11.144; Third Monitor Report at 37 ¶ 11.51. The value of those visits has been two-fold: (1) the CSC Team is not only able to obtain more information regarding the direct customers' SOM programs, but (2) those visits also provide an opportunity for the CSC Team to have informal discussions with the direct customers regarding the benefit of sharing information, including promptly responding to due diligence requests and informing the CSC Team when the direct customers receive concerning information about, or restrict, Mallinckrodt's indirect customers.

11.195 Consequently, those visits have borne fruit. For example, a greater number of direct customers now notify Mallinckrodt when they restrict downstream registrants. Indeed, during the CSC Team's due diligence visit with Distributor U in the Thirteenth Reporting Period, the CSC Team and Distributor U discussed that very issue, and Distributor U indicated it was willing to notify Mallinckrodt of any customer restrictions. But for that due diligence visit, Mallinckrodt may not have gained Distributor U's valuable cooperation. Such distributor notifications are invaluable, and have led Mallinckrodt to restrict numerous indirect customers that it may not have restricted otherwise, because the CSC Team did not have access to the

information provided by the direct customers, which of course have greater visibility into the orders of ***their*** direct customers (*i.e.*, Mallinckrodt's indirect customers) than does Mallinckrodt.[47] *See, e.g.*, Eighth Monitor Report at 49 ¶ 11.59 (discussing the value of proactive intelligence received from a distributor regarding restriction of Mallinckrodt's indirect customer, which led Mallinckrodt to restrict the customer as well).

11.196 Likewise, the CSC Team now has monthly meetings with its SOM counterparts at Distributor C regarding, among other things, indirect customers under review. *See* Tenth Monitor Report at 65 ¶ 12.105. Further, Mallinckrodt reached an informal agreement with Distributor C concerning the time for the parties to exchange information enabling Mallinckrodt to complete a due diligence review (based on the terms of the parties' written agreement for branded products). *See* Eleventh Monitor Report at 64 ¶ 11.100. As a result of the CSC Team's increased communication with Distributor C, the CSC Team reports receiving faster due diligence responses. As discussed above, and as the Monitor observed in numerous reports, direct customers' failure to timely respond to the CSC Team's requests for due diligence regarding indirect customers flagged for review significantly delayed the CSC Team's ability to complete those reviews. *See, e.g.*, Fourth Monitor Report at 29 ¶ 11.23 – 30 ¶ 11.24.

11.197 Additionally, for direct customers that do not provide chargeback data, the CSC Team is able to use these visits as an opportunity to educate the customer regarding the importance of Mallinckrodt obtaining chargeback data (or the equivalent) to monitor its indirect customers. For example, as a result of one recent due diligence visit discussed above, Grocery

[47] For example, given Mallinckrodt's position in the supply chain, Mallinckrodt does not have the ability to obtain and analyze its ***indirect*** customers' dispensing data. Mallinckrodt's direct customers have access to such information. Eighth Montor Report at 49 ¶ 11.60.

Chain A agreed to provide the equivalent of chargeback data, and is currently working with Mallinckrodt to develop a way to do so. *See supra* at 45-46 ¶ 11.44.

11.198 Lastly, to improve reciprocal information sharing between Mallinckrodt and its direct customers, Mallinckrodt continues to make efforts to update its contractual agreements with direct customers to obtain their 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. 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 secured agreements with additional distributors and two buying groups, each containing substantially similar provisions. *See* Twelfth Monitor Report at 106 ¶ 11.188 – 107 ¶ 11.189. Mallinckrodt advises that it continues to seek additional contractual agreements as contracts expire and require renewal. *See supra* at 81 ¶ 11.158.

11.199 In sum, to put Mallinckrodt's efforts into perspective, since the monitorship began, Mallinckrodt has:

(1) obtained due diligence leading to the suspension of 37 direct customers;

(2) conducted 34 targeted direct customer due diligence visits, with 11 of those visits leading to suspensions;

(3) reached written or verbal agreements with 6 direct customers to restrict the supply of Mallinckrodt's opioid products to downstream registrants; and

(4) obtained information regarding indirect customer restrictions from 10 different direct customers, leading to over 222 restrictions.

11.200 In the Monitor's opinion, there is no question that Mallinckrodt's increased knowledge of, and stronger relationships with, its direct customers have enhanced its SOM

program, and the Monitor understands that Mallinckrodt will continue to pursue these efforts in the future.

* * *

11.201 As these data points confirm, Mallinckrodt's periodic enhancements to its SOM program over the course of the monitorship have driven its ability to more effectively and efficiently identify potential diversion. Mallinckrodt continues to review and implement additional enhancements as described in greater detail below.

e. Mallinckrodt's continued efforts to enhance its SOM program

11.202 As discussed above, *see supra* at 82 ¶ 11.162 – 84 ¶ 11.164, and in prior reports, Mallinckrodt's efforts to enhance its SOM program are ongoing. Some of those efforts have been under the purview of the Working Group, and are part of Mallinckrodt's continued work with AGI. That includes review of the automation of aspects of the CSC Team's review processes and changes to the direct and indirect customer dashboards. Regarding such potential updates, in the Twelfth Monitor Report the Monitor observed:

> (1) "[T]he Monitor Team asked the CSC Director whether he had determined how frequently [the CSC Team would conduct the "upward" review of distributors based on the CSC Team's restriction of distributors' indirect customers].[48] The CSC Director reiterated that he expects the CSC Team to conduct this analysis at regular intervals but has not yet determined how frequently. He also informed the Monitor Team that Mallinckrodt is currently determining whether aspects the analysis can be automated. In the next reporting period, the Monitor Team will provide an update on how frequently the CSC Team will conduct this analysis and whether the analysis can be conducted more efficiently using technology." Twelfth Monitor Report at 60 ¶ 11.73;

[48] As discussed in the Eleventh and Twelfth Monitor Reports, the SOMT suspended six distributors after identifying deficiencies in their SOM programs based on the SOMT's restriction of those distributors' customers. *See* Twelfth Monitor Report at 59 ¶ 11.71 – 60 ¶ 11.73; Eleventh Monitor Report at 54 ¶ 11.76 – 59 ¶ 11.87.

(2) "Mallinckrodt's outside counsel informed the Monitor Team that the Working Group . . . is exploring potential changes to the direct and indirect customer dashboards. The Working Group expects those changes to include indicators of some kind to track information like [the decision to continue to monitor a specific direct customer] that is not evident from the information currently contained in the dashboards. The Monitor will provide an update on any changes to the dashboards in the Thirteenth Monitor Report." *Id.* at 59 ¶ 11.70;

(3) "The fact that the [Director of CSC Analytics'] Annual Report apparently continues to identify pharmacies for restriction not identified through the usual dashboard review suggests there may be value in examining the Report to learn and apply new lessons to Mallinckrodt's SOM program more generally. That analysis may prove valuable in identifying potential limitations of the dashboards, among other areas, and help Mallinckrodt to enhance its SOM program." *Id.* at 87 ¶ 11.135; and

(4) "[T]he Working Group is currently considering ways to incorporate both additional data sources, and additional data from existing sources, into the indirect customer dashboard. The Monitor will provide an update on any of the Working Group's discussions about further enhancements to its SOM program in the next reporting period." *Id.* at 105 ¶ 11.184.

11.203 In the Thirteenth Reporting Period, the Monitor Team discussed these potential enhancements to the SOM program with Mallinckrodt, including members of the CSC Team, and its outside counsel. They relayed that Mallinckrodt, with the assistance of AGI and Mallinckrodt's Information Technology ("IT") Department, continues to assess the feasibility and utility of these and other potential enhancements. As of the date of this Thirteenth Monitor Report, Mallinckrodt's outside counsel confirmed that the SOMT's distributor scorecard feature is operational and in use, with more enhancements to follow over time.

11.204 Mallinckrodt's outside counsel also shared that the Company's work with AGI includes: (1) exploring the potential to incorporate ARCOS data into the indirect customer review process by using that data to prioritize indirect customers for review; (2) assessing ways in which the labor-intensive Annual Report produced by the Director of CSC Analytics can be automated; and (3) evaluating the universe of Mallinckrodt's direct customers that do not submit

chargeback requests and the valuable data otherwise accompanying such requests, discussed above, *see supra* at 51 ¶ 11.65. Additionally, the CSC Team and the IT Department added metrics for liquid products to the dashboards.

11.205 The Working Group also considered, as part of its ongoing discussions, "whether implementation of the Drug Supply Chain Security Act ("DSCSA") could reveal an additional source of data from the serialization of drug bottles." Eleventh Monitor Report at 65-66 ¶ 11.103(2). Specifically, the Working Group undertook to determine the nature and expected timing of the availability of this data. *See id.* In the Thirteenth Reporting Period, Mallinckrodt's outside counsel informed the Monitor Team that such data has little, if any, utility in Mallinckrodt's SOM program. Specifically, Mallinckrodt does not receive such data from downstream customers. Additionally, DSCSA data does not create a data set that is comparable to, or available to be utilized with, chargeback data. Instead, the DSCSA data allows for narrow inquiry into specific bottles in question. Thus, at this time, Mallinckrodt views DSCSA data as providing little added value to its SOM efforts.

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.,* Fifth Monitor Report at 42 ¶ 12.1; 43-44 ¶ 12.6; Fourth Monitor Report at 49 ¶ 13.1.

12.2 During the Thirteenth Reporting Period, the Monitor audited Mallinckrodt's compliance with the Operating Injunction's training requirements by: (1) confirming all relevant employees hired during the second quarter of 2025 completed training via the interactive Operating Injunction online training module and the board service survey; (2) speaking with Mallinckrodt employees and its outside counsel to determine whether the annual employee

training would continue following the conclusion of the monitorship; and (3) reviewing the 2025 interactive Operating Injunction online training module.

1. New Employee Trainings in the Second Quarter of 2025

12.3 In the Thirteenth Reporting Period, Mallinckrodt identified four new employees hired in the second quarter of 2025 who were required to receive Operating Injunction training. Mallinckrodt advised that all four of those employees completed the online Operating Injunction training module and the board service survey.

2. Status of Relevant Employee Training Post-Monitorship

12.4 During the Thirteenth Reporting Period, the Monitor Team met with Mallinckrodt's Associate General Counsel and outside counsel to discuss what aspects of the Company's compliance training program would continue after the conclusion of the monitorship. Mallinckrodt confirmed that it would continue to train employees using the online interactive training module that it debuted in September 2024. Mallinckrodt also noted that, while there would be some non-substantive updates and changes to the training module (such as removing the Monitor's contact information), the contents of the training module would remain largely the same.

3. The Monitor Team's Review of the 2025 Interactive Operating Injunction Employee Training Module

12.5 During the Thirteenth Reporting Period, Mallinckrodt provided the Monitor Team with a link to review the 2025 interactive Operating Injunction online training module. A member of the Monitor Team was able to participate in the training module as if she was a Mallinckrodt employee.

12.6 The training module takes approximately one hour to complete. Its introduction informs employees that "many of the terms of the Operating Injunction apply indefinitely, while others will be in effect for several years."

12.7 The substantive content of the 2025 training module was similar to the content of the 2024 training module the Monitor Team reviewed during the Eleventh Reporting Period. The 2025 training module reviews each section of the Operating Injunction and its corresponding requirements in detail. Participants must read each page, listen to the relevant audio, and complete all of the activities on the 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. The training module also includes information about resources for reporting compliance concerns, and provides contact information for Mallinckrodt's compliance team and its Integrity Hotline.

12.8 Like the 2024 training module, in order to complete the training and move to the Certification page, participants must pass a quiz testing their knowledge of all of the Operating Injunction's sections. The quiz questions take different forms, including true / false questions, single answer questions, and "select all that apply" questions. Participants must receive a grade of 80% or better to pass. If they do not pass, they are informed what questions they got wrong and 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 employees to complete the Certification unless they have opened the link to the Operating Injunction.

12.9 The Monitor Team concludes that the 2025 online Operating Injunction training module is appropriate and comprehensive, and encourages Mallinckrodt to continue to annually train its employees on those provisions of the Operating Injunction that continue to apply post-monitorship.

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.[49] *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 2025.

13.4 Likewise, there were no new Mallinckrodt Opioid Products, or indications for existing products, in the second or third quarters of 2025.

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.

[49] Additional information regarding Mallinckrodt's clinical data archive is available at https://vivli.org/ourmember/specgx-llc-a-subsidiary-of-mallinckrodt-plc/ (last visited Oct. 10, 2025).

See, e.g., Sixth Monitor Report at 69 ¶ 14.1 – 70 ¶ 14.5. There are no further updates at this time.

XV. THE DAY AFTER THE MALLINCKRODT MONITORSHIP

15.1 In the Thirteenth Reporting Period, the Monitor Team continued discussions regarding Mallinckrodt's preparations for the "day after" the conclusion of the monitorship on October 12, 2025. These discussions included interviews with various Mallinckrodt executives and employees, as well as with Mallinckrodt's outside counsel. Mallinckrodt executives interviewed included Stephen Welch, who is expected to be the Chief Executive Officer of the new Par Health entity, when spun off from the merged Mallinckrodt-Endo entity.

15.2 Among the topics discussed were the Monitor's suggestions in the Twelfth Monitor Report that Mallinckrodt: (1) convene an inter-company SOM working group with other industry participants to meet on a regular basis to exchange best practices; (2) create an internal audit function to act as an in-house "monitor" capable of continuing the pressure-testing and verification the Monitor has undertaken in the course of this monitorship; and (3) continue to review relevant policies, SOPs, Work Instructions, and trainings across all relevant departments for compliance with those provisions of the Operating Injunction that will remain in effect post-monitorship. *See* Twelfth Monitor Report at 128 ¶ 16.1. Conclusions from these discussion are detailed below.

a. Convening an industry SOM working group

15.3 As discussed elsewhere in this Thirteenth Monitor Report, *see supra* at 77 ¶ 11.146 – 81 ¶ 11.156, and as previously reported, *see, e.g.*, Twelfth Monitor Report at 116-17 ¶ 11.218, the Monitor Team has benefitted from exchanges with the Purdue Monitor and believes this has been mutually beneficial to the Purdue Monitor as well. Accordingly, the Monitor Team suggested to Mallinckrodt and its outside counsel that convening an inter-company SOM

working group, to include Mallinckrodt's SOMT and its counterparts at other manufacturers and distributors, would be a helpful way to ensure continued learning on a regular (*e.g.*, quarterly) basis to exchange best practices and SOM intelligence. *See* Twelfth Monitor Report at 128 ¶ 16.2.

15.4 In the Twelfth Reporting Period, Mallinckrodt initially expressed reservations regarding this suggestion based on the potential legal risks from such cooperation across the industry, including under antitrust law, without ruling out entirely the possibility of such a group. *See id.* 129 ¶ 16.3 (discussing Mallinckrodt's concern regarding potential legal risk and considering ways to mitigate that risk).

15.5 In the Thirteenth Reporting Period, the Monitor Team and Mallinckrodt discussed this suggestion again. Mallinckrodt's outside counsel reiterated the Company's concern regarding potential legal risk, but also shared the difficulties Mallinckrodt had encountered trying to bring other industry participants to the table voluntarily in the past, albeit in a different context. As a result, Mallinckrodt does not anticipate that pursuing an inter-company working group is a viable initiative at this time.

15.6 As the Monitor stated in the Twelfth Monitor Report, the Monitor recognizes the complexity and sensitivity of this suggestion, *see id.* 129 at ¶ 16.3, as well as the practical challenges of convening such a group. The Monitor defers to Mallinckrodt as to how it may wish to proceed in this regard in the future, if at all.

b. Creating an internal audit function

15.7 Although the "Independent Monitorship" provisions of the Operating Injunction will no longer apply after October 12, 2025, many of the Operating Injunction's provisions, such as the "Ban on Promotion" and "Monitoring and Reporting of Direct and Downstream Customers," are not subject to any term, and others apply for eight years after the Petition Date.

OI §§ II.1-2, VI. Thus, even after the monitorship ends, Mallinckrodt must still operate its Opioid Business in compliance with these aspects of the Operating Injunction. Indeed, as Mr. Welch relayed to the Monitor, notwithstanding the merger and anticipated spinoff, he expects Par Health to continue manufacturing and distributing generic Opioid Products through SpecGx LLC, an entity he acknowledges remains subject to the Operating Injunction's provisions. Mr. Welch made clear his continuing commitment to compliance with the Operating Injunction even through the absorption of SpecGx into Par Health.

15.8 In light of Mallinckrodt's ongoing compliance obligations following the conclusion of the monitorship, the Monitor observed that Mallinckrodt would continue to benefit from an independent review and audit of the subject areas the Operating Injunction addresses. Mallinckrodt agrees. *See* Twelfth Monitor Report at 129 ¶ 16.4.

15.9 As a result, during the Thirteenth Reporting Period, the Monitor Team and Mallinckrodt discussed the processes Mallinckrodt anticipates implementing to probe, analyze, and verify the Company's continued adherence to the Operating Injunction, building upon the work of the Monitor Team, and monitoring the continued implementation of the Monitor's recommendations.

15.10 As Mallinckrodt's outside counsel informed the Monitor Team, Mallinckrodt expects Par Health's Compliance Department and CSC Compliance Group to oversee compliance with the Operating Injunction. Given the recent merger, Mallinckrodt is still in the process of determining the specific audit processes the Company will implement. However, at present, Mallinckrodt expects to audit compliance by, among other things, replicating aspects of the Monitor's work, and Mallinckrodt is in the process of determining what aspects of that auditing process will be conducted internally versus externally. Mallinckrodt expects that the

SOM-related review will be performed by an external auditor and intends to solicit proposals for such work in the coming months.

15.11 Additionally, Mallinckrodt's outside counsel confirmed Mallinckrodt will maintain an integrity hotline and informed the Monitor Team that any complaints will be reviewed by the Compliance Department and other departments as appropriate. Mallinckrodt will also continue to require relevant employees to complete training on the Operating Injunction's requirements.

c. Inquiry of the representatives of the State Attorneys General regarding external visibility into post-monitorship compliance

15.12 After reviewing the Monitor's suggestion in the Twelfth Monitor Report concerning Mallinckrodt's creation of an internal audit function, one of the representatives of the State Attorneys General inquired whether Mallinckrodt is willing to consider publicly publishing any findings regarding its continuing compliance with the Operating Injunction after the monitorship concludes, to ensure external visibility into Mallinckrodt's ongoing adherence to its terms. The Monitor Team shared that inquiry with Mallinckrodt.

15.13 In response, Mallinckrodt's outside counsel observed that continued public reporting is not a requirement of the Operating Injunction, which was heavily negotiated. Additionally, while Mallinckrodt recognizes the benefits of public accountability and transparency, Mallinckrodt must take into account that by ***not*** making compliance-related findings public, the Company may encourage more candid internal reporting and auditing, making audits more effective. Nonetheless, Mallinckrodt's outside counsel advised that Mallinckrodt was considering the representative's inquiry, which is still the subject of internal

discussions, and will continue to consider the prudence of making public any future findings regarding compliance with the Operating Injunction.

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

15.14 Over the course of the monitorship, Mallinckrodt reviewed and revised its policies, SOPs, Work Instructions, and trainings to incorporate the Operating Injunction's relevant provisions in those materials. Since many of Mallinckrodt's obligations under the Operating Injunction continue post-monitorship, *see* OI §§ II.1-2, VI, in the Twelfth and Thirteenth Reporting Periods the Monitor Team discussed with Mallinckrodt what, if any, work must be undertaken to ensure the Operating Injunction's surviving provisions are appropriately incorporated into those materials and references to the Monitor are updated once the monitorship ends.

15.15 As Mallinckrodt's outside counsel informed the Monitor Team, Mallinckrodt has thousands of policies, SOPs, Work Instructions, and trainings, the vast majority of which do not implicate the Operating Injunction. When the Operating Injunction became effective, Mallinckrodt conducted an internal review to identify those materials that may have been impacted by the Operating Injunction. By way of example, in 2021, Mallinckrodt reviewed data from its learning management system, ComplianceWire, reflecting all formal education and training that Mallinckrodt employees had undergone in the past two years. Based on that review, and other related efforts, Mallinckrodt revised numerous such materials, including certain SOPs and Work Instructions referenced in prior Monitor Reports. Further, Mallinckrodt has continued to review and revise those materials throughout the monitorship, including at the Monitor's request and under Mallinckrodt's policy titled *Document Management - Quality*Stream DMS Module* discussed in the Twelfth Monitor Report. *See* Twelfth Monitor Report at 80 ¶ 11.123

(discussing policy, which was referred to as the "Management of Change" policy or "MOC"). As discussed in the Twelfth Monitor Report, the MOC provides that "[p]rocedural documents . . . will be reviewed at least once every two years from the effective date of the document." *Id.*; *Document Management - Quality*Stream DMS Module* § 6.12.1.

15.16 In the Thirteenth Reporting Period, Mallinckrodt provided the Monitor Team with additional data from ComplianceWire reflecting all trainings on policies, SOPs, and Work Instructions completed by employees in 2024. Unsurprisingly, that data reflects that a significant number of the trainings employees completed concerned policies that, based on the title, do not appear to implicate the Operating Injunction. For example, employees received training on the "St. Louis Plant Tobacco-Free Policy" and the "Information Technology Mobile Device Usage Policy." Mallinckrodt subsequently provided the Monitor Team with a list of its policies, SOPs, and Work Instructions, which confirmed the same.

15.17 Based on the Monitor's discussions with Mallinckrodt and its outside counsel concerning the Company's efforts to incorporate the Operating Injunction's provisions into relevant policies, SOPs, Work Instructions, and trainings to date, and given the volume of those materials, the Monitor is satisfied that Mallinckrodt has made a good-faith effort to identify relevant materials that may have been impacted by the Operating Injunction and updated them accordingly. Moreover, based on the MOC, the Monitor is reassured that there is a document review policy in place to regularly review Mallinckrodt's "Procedural Documents," including policies, SOPs, and Work Instructions, in the event relevant documents were not identified initially or will require further revisions in the future. Accordingly, at this time, the Monitor does not recommend that Mallinckrodt undertake a formal audit of all of its policies, SOPs,

Work Instructions, trainings, and other "Procedural Documents" for compliance with the Operating Injunction, but rather continue to update those materials in the usual course.

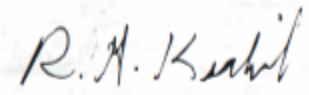
XVI. CONCLUSION

16.1 The Monitor is appreciative of Mallinckrodt's cooperation over the course of the monitorship. This has influenced several successful outcomes. Mallinckrodt's attention to Monitor requests and implementation of Monitor recommendations has assisted the Monitor in fulfilling the function for which he was appointed to serve. The Monitor is confident that, with the foundation Mallinckrodt has built over the last five years, and continued attention to the importance of compliance—which, in his experience, the Company has shown consistently throughout his tenure—the "day after" the conclusion of the monitorship will be promising.

16.2 In sum, based upon the Monitor's work to date, Mallinckrodt has consistently provided helpful assistance to the Monitor in the exercise of his duties and, in the Monitor's view, has complied with the Operating Injunction.

* * *

16.3 Wherefore, the undersigned Monitor respectfully submits this Thirteenth, and final, Monitor Report.



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

EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE THIRTEEN MONITOR REPORT DATED OCTOBER 10, 2025[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.

6.	**2(f)**	Evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data.	Implemented
7.	**2(g)**	After analyzing turnaround times for chargeback reviews and restrictions, amend relevant SOPs to memorialize firm timelines.	Implemented
8.	**2(h)**	Incorporate all existing data sources available to Mallinckrodt, and use best efforts to reach agreements with direct customers to provide more detailed retail data to conduct more effective chargeback reviews.	Implemented and Ongoing
9.	**2(i)**	Assess the potential value of additional factors to consider in conducting chargeback reviews.	Implemented
10.	**2(j)**	Continue actively pursuing opportunity for a public-private "clearinghouse" concept, in collaboration with the U.S. Drug Enforcement Administration and industry partners.	In Progress
11.	**2(k)**	Amend relevant SOPs to create a chargeback review task checklist, provide an audit trial, and ensure second-level review and approval.	Implemented
12.	**2(l)**	Memorialize and routinize the periodic review of (1) pharmacies reviewed but not restricted, and (2) pharmacies that are reinstated.	Mooted by Present Practice[2]
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

[2] As discussed in the Thirteenth Monitor Report, *see supra* at 64 ¶ 11.111 – 65 ¶ 11.114, improvements in the dashboards used to conduct SOM reviews, including constant updates to the data analyzed in the dashboards, have rendered this recommendation anachronistic.

17.	**2(q)**	Memorialize the confidentiality of thresholds, consistent with current practice.	Implemented
18.	**2(r)**	Establish minimum standards and criteria for conducting retail pharmacy due diligence, potentially with the advice and input of a third-party compliance consultant.	Implemented (As Later Modified)
19.	**2(s)**	Revise direct customer questionnaires to yield helpful, actionable, and verifiable information and determine a method for sampling or randomly auditing questionnaires.	Implemented
20.	**2(t)**	Establish regularly scheduled interactions with direct customers.	Implemented
21.	**2(u)**	Explore options for making media review more effective.	Implemented

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

Section 6 – Ban on Promotion (OI § III.A)			**Implementation Status**
22.	**3(a)**	Expand TrackWise, Mallinckrodt's internal system for logging unsolicited customer inquiries and complaints, to include results of the Product Monitoring Team's consultation with and referral of inquiries to other Mallinckrodt departments.	Implemented
Section 9 – Lobbying Restrictions (OI § III.D)			
23.	**3(b)**	Ensure all external lobbyists performing work on Mallinckrodt's behalf have executed an Acknowledgment and Certification of Compliance with SpecGx Lobbying Restrictions, certifying compliance with the Operating Injunction.	Implemented
24.	**3(c)**	Implement a process by which Mallinckrodt reviews and audits its external lobbyists' public disclosures to ensure these reports accurately reflect the lobbyists' communications with Mallinckrodt and the company's stated priorities.	Implemented

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

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

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

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

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

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

30.	**6(b)**	Provide additional training to the Human Resources Department (by Mallinckrodt's legal counsel) to prevent consideration of improper incentives in bonus recommendations.	Implemented
31.	**6(c)**	Ensure greater consistency among direct customer audit reports, and more fulsome follow-up where necessary to obtain compliance assurances.	Implemented
32.	**6(d)**	Share with the SOMT, before each monthly meeting, CSC Director's separate tracking list of pharmacies pending due diligence review to ensure tabled pharmacies do not evade future review.	Implemented
33.	**6(e)**	Raise with the "Big Three" distributors, the persistent issue of delayed provision of due diligence, which in turn delays Mallinckrodt's chargeback restrictions, potentially affecting the diversion of Opioid Products.	Implemented and Ongoing
34.	**6(f)**	Ensure evidence of diversion risks appearing in the TrackWise inquiry and complaint logs escalated by the Associate General Counsel (or designee) is reviewed and included in SOMT pharmacy reviews, as appropriate.	Implemented

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

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

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			
36.	**8(b)**	Determine an appropriate statistically defensible marker for the ranking and prioritization of chargeback reviews, so as to determine which, if any, flagged pharmacies present the lowest risk of diversion and therefore may not warrant review.	Mooted by Present Practice[3]

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

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

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

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

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

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

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

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

XI. THIRTEENTH MONITOR REPORT (10/10/2025)

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
46.	**13(a)**	Implement regular use of geographic concentration maps in connection with regularly scheduled due diligence visits with direct customers.	In Progress
47.	**13(b)**	Implement a two-person review of Mallinckrodt's correspondence with DEA detailing restrictions and reinstatements to ensure such communications are complete and accurate.	In Progress
48.	**13(c)**	Add compliance-related questions to exit interview surveys.	In Progress