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

May 24, 2024

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TENTH 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 Tenth Monitor Report covers the period from the filing of the Ninth Monitor Report on November 27, 2023, to the present (the "Tenth Reporting Period").[1] The Tenth 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 Tenth Reporting Period, including the Monitor Team's review of documents and data, and interviews and meetings with Mallinckrodt employees and contractors; (3) summarizes observations from the Monitor's fact-finding; (4) includes three new recommendations (New Recommendations 10(a)-(c)); and (5) describes anticipated next steps in future reporting periods.

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

[1] In the Seventh Reporting Period, the Monitor, Mallinckrodt, and the Ad Hoc Committee agreed that the Monitor would submit future reports, effective January 1, 2023, every 180 days. However, as the due date for the Tenth Monitor Report falls on Saturday, May 25, 2024, the Monitor has issued the Tenth Monitor Report a day early. *See* Operating Injunction § VI.B.2.b.

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

the Tenth Reporting Period Mallinckrodt provided over 680 files (consisting of more than one gigabyte of documents and data).

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

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

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

II. THE OPERATING INJUNCTION

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

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[3] *See* Mallinckrodt's "Corporate Compliance" webpage, *available at* http://www.mnk.com/corporate-responsibility/corporate-compliance/ (last visited May 8, 2024) (listed under "Operating Injunction" drop-down). As previously discussed, the Monitor's reports are no longer filed with the Bankruptcy Court. Nonetheless, Mallinckrodt and the Ad Hoc Committee are in agreement that the Bankruptcy Court retains jurisdiction to adjudicate disputes the Settling States may bring related to enforcement of, or disputes concerning, the Operating Injunction if the states have not obtained a state court order enforcing the injunctive terms.

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

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

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

2.4 Section III (Injunctive Relief) is comprised of the following subsections: (1) a ban on promotion (Operating Injunction § III.A); (2) a prohibition on financial reward or discipline based on volume of opioid sales (*id.* § III.B); (3) a ban on funding / grants to third parties (*id.* § III.C); (4) lobbying restrictions (*id.* § III.D); (5) a ban on certain high dose opioids (*id.* § III.E); (6) a ban on prescription savings programs (*id.* § III.F); (7) monitoring and reporting of direct and downstream customers (*id.* § III.G); (8) general terms (*id.* § III.H); (9) compliance with all laws and regulations relating to the sale, promotion, and distribution of any opioid product (*id.* § III.I); (10) compliance deadlines (*id.* § III.J); and (11) training (*id.* § III.K).

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

2.6 Section V (Public Access To Mallinckrodt Documents) is comprised of the following subsections: (1) documents subject to public disclosure (*id.* § V.A); (2) information that may be redacted (*id.* § V.B); (3) redaction of documents containing protected information (*id.* § V.C); (4) review of trade secret redactions (*id.* § V.D); (5) public disclosure through a

document repository (*id.* § V.E); (6) timeline for production (*id.* § V.F); (7) costs (*id.* § V.G); and (8) suspension (*id.* § V.H).

III. PRIOR MONITOR REPORTS

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

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

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

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

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

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.

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

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.

IV. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Sections IX and XII, *infra*, the Monitor has made three new recommendations related to the Operating Injunction's ban on funding provisions and its requirement to monitor and report direct and downstream customers. Mallinckrodt has agreed to implement these recommendations.[6] The recommendations are that Mallinckrodt should:

10(a) Revise the Specialty Generics Grant and Sponsorship Approval Committee ("SGGSAC" or the "Committee") standard operating procedure ("SOP") and related documents to formalize the SGGSAC's requirements around the timeliness of funding requests and the payment of deposits.

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.

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.

V. THE INTEGRITY HOTLINE

5.1 The Monitor and Mallinckrodt established a process by which compliance concerns related to the Operating Injunction can be reported to the Monitor, through his counsel, utilizing a system known as the Integrity Hotline. Specifically, Mallinckrodt modified this

[6] These recommendations are prefaced by the number "10" to indicate they were made in the Tenth Monitor Report.

reporting system to enable reporters to identify a reported issue type as "Operating Injunction" based upon a menu of categories. Mallinckrodt has agreed to share any such reports with the Monitor Team.

5.2 In the Ninth Reporting Period, the Monitor Team learned of an issue with the selection process for Integrity Hotline reports—*i.e.*, that a reporter was required to select both "Specialty Generics" and "Operating Injunction" for the Monitor to receive a notification that a report had been submitted. *See* Ninth Monitor Report at 6-7 ¶¶ 4.2-4.3. While the issue was corrected during the Ninth Reporting Period, it led the Monitor Team to inquire about the frequency of testing of the Integrity Hotline for reports related to the Operating Injunction. The Monitor Team sought to ensure similar issues are discovered in a timely manner, and that the Monitor Team receives notifications for reports categorized with the "Operating Injunction" issue type. As a result, during the Tenth Reporting Period, the Monitor Team proposed that the Integrity Hotline be tested on a quarterly basis by submitting test reports that select the "Operating Injunction" issue type, and asked Mallinckrodt to confirm such testing has occurred. Mallinckrodt agreed to conduct quarterly tests and to produce confirmation those tests had occurred under the Monitor's updated Audit Plan, discussed *infra* 7 ¶¶ 6.1-4.

5.3 At the end of the Tenth Reporting Period, Mallinckrodt conducted the first quarterly Integrity Hotline test under the updated Audit Plan. The Monitor Team received proper notice of the test report when it was submitted to the Integrity Hotline, and Mallinckrodt promptly produced the underlying test report at the Monitor Team's request.

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

VI. THE AUDIT PLAN

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

6.2 During the Tenth Reporting Period, the Monitor Team provided Mallinckrodt with an updated version of the Audit Plan. Specifically, the Monitor Team updated document requests in the sections of the Audit Plan related to the Operating Injunction's Ban on Promotion, Ban on Funding / Grants to Third Parties, Lobbying Restrictions, and requirements for Monitoring and Reporting of Direct and Downstream Customers.

6.3 The updated Audit Plan largely incorporated additional requests for documents based on the Monitor Team's review of documents and interviews of employees during the prior reporting periods and omitted requests that were no longer relevant because Mallinckrodt's practices had changed and the documents no longer exist. For example, Mallinckrodt had previously provided downstream registrants (or "indirect customers") seeking reinstatement with a list of independent consultants whom the indirect customer could contact to perform a reinstatement review, at the customer's expense. Mallinckrodt no longer provides such a list to indirect customers. The Monitor Team therefore struck that request from the Audit Plan.

6.4 Mallinckrodt reviewed the updated Audit Plan and agreed to its provisions. The updated Audit Plan went into effect on April 12, 2024.

VII. BAN ON PROMOTION (OI § III.A)

7.1 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. PRC Review of Promotional Materials

7.2 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 ("Mallinckrodt's Compliance Report") at 17-18 § 4.6.

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

7.4 The PRC met twice during the fourth quarter of 2023. At the first meeting on October 5, 2023, the PRC reviewed the artwork and related materials Mallinckrodt intended to use for the CPhI Worldwide Conference, which was held in Barcelona, Spain, on October 24-26, 2023. As the Monitor previously reported, the CPhI Worldwide Conference is a large global pharmaceutical trade show held annually in Europe, which attracts individuals and companies from across the industry. *See* Fifth Monitor Report at 14 ¶ 8.5. Mallinckrodt provided samples of the artwork and related materials to the Monitor Team for its review, and the Monitor had no concerns regarding these materials. However, as noted below, a decision was made that Mallinckrodt would not sponsor the CPhI Worldwide Conference, even though representatives of Mallinckrodt did attend. *See infra* 20 ¶ 9.5(3).

7.5 The PRC met again on December 14, 2023 to review updates to the PDF, Interactive Website, and Excel versions of the SpecGx Product Catalog. Members of the PRC commented that certain information in the Interactive Website version needed to be updated. In addition, four types of products (Generic Mydayis products, Generic Vyvanse products,

Morphine Sulfate Immediate Release Tablet products, and Generic Noxafil products) were added to the Interactive Website Catalog, and the Oral Transmucosal Fentanyl Citrate products that had been discontinued were removed. Mallinckrodt provided copies of the three versions of the Product Catalog to the Monitor Team for its review. The Monitor had no questions or concerns about the Product Catalog or the changes made.

7.6 On January 30, 2024, a subset of the PRC, comprised of the individuals whom Mallinckrodt designated as the "MetricStream approvers," conferred on an ad hoc basis by email to review changes to the Excel version of the HZQS Catalog. Specifically, the revised Excel version of that catalog increased the national drug code number from ten digits to eleven digits and omitted any spaces, hyphens, or other characters in the number. After an inquiry from one of the MetricStream approvers, the changes were approved. Mallinckrodt provided a copy of the Excel version of the product catalog to the Monitor Team for its review. Again, the Monitor had no questions or concerns about the changes made.

7.7 During the first quarter of 2024, the PRC met three additional times: on February 1, March 13, and March 29. The PRC met on February 1, 2024 to review changes to the Stearates Website that were intended to align: (1) product specifications with changes made over the past couple of years; (2) product names with the product catalog; and (3) certifications for Kosher for Passover and Halal with the product catalog. Mallinckrodt provided a copy of a printout of the website with the proposed changes to the Monitor Team for review. The Monitor again had no questions or concerns about Mallinckrodt's changes.

7.8 On March 13, 2024, the PRC met to discuss the new addiction treatment display banner to be used at events where the Addiction Treatment Team has a booth. After a discussion of the products the banner would cover and of the banner's QR code directing users to

Mallinckrodt's Addiction Treatment products webpage, and after confirming that prior banners would be retired, the PRC adjourned the meeting to allow the Addiction Treatment Team to make further edits to the proposed banner. The Addiction Treatment Team's edits were circulated to the PRC by email on March 21, 2024, and the next day the banner was routed to MetricStream for approval. Mallinckrodt provided a copy of the banner to the Monitor Team. The Monitor against had no questions or concerns about the banner's contents.

7.9 Lastly, the PRC conferred via email on March 29, 2024 to review an announcement pertaining to the launch of Amitiza® (Lubiprostone) capsules on April 1, 2024, pursuant to a license with Sucampo Pharma Americas LLC. After discussing the announcement's content and making necessary revisions thereto, the PRC concluded its review of the materials on April 1, 2024. Mallinckrodt provided a copy of the materials to the Monitor Team, and the Monitor had no questions or concerns about its contents. However, the Monitor Team notes that with the product launch planned for April 1, 2024, there did not appear to be much time provided to the PRC to review the announcement and to make any necessary changes.

2. <u>Conference Attendance</u>

7.10 The Monitor asked Mallinckrodt's Vice President of Commercial and Strategy, who attended the CPhI Worldwide Conference referred to above on Mallinckrodt's behalf, *supra* 8 ¶ 7.4, whether he or any other Mallinckrodt employees who also attended received any inquiries from, or had any interactions with, other attendees relating to Opioid Products. In response, the Vice President of Commercial and Strategy informed the Monitor that CPhI Worldwide is an industry conference where active pharmaceutical ingredient ("API") manufacturers and customers convene. As such, and in light of the significant training that the Vice President of Commercial and Strategy and members of his team have had regarding the

Operating Injunction's restrictions, the Monitor was assured there were no inquiries with other attendees relating to finished dosage Opioid Products.

3. TrackWise

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

7.12 Beginning in the Fourth Reporting Period, and on an ongoing basis as part of the Audit Plan, the Monitor has received and reviewed quarterly TrackWise inquiry and complaint entries pertaining to Opioids, as well as the results of Mallinckrodt's auditing process.

7.13 During the Tenth Reporting Period, the Monitor Team reviewed TrackWise Opioid-related data for the third and fourth quarters of 2023, and the first quarter of 2024. Consistent with the Monitor Team's prior reviews, many TrackWise inquiries pertained to the composition of Mallinckrodt's Opioid Products, such as whether the products contain allergens (*e.g.*, gluten), while TrackWise complaints generally encompassed areas such as defects in patch adhesives, broken or missing tablets, or other product quality issues. Further, as discussed in the Eighth and Ninth Monitor Reports, there continued to be an increase in TrackWise inquiries pertaining to the availability of Mallinckrodt's Opioid Products. *See* Eighth Monitor Report at 9 ¶ 6.16, Ninth Monitor Report at 9 ¶ 5.9.

7.14 Upon review of the TrackWise inquiry data for October 2023, the Monitor Team noticed a call-taker responded to a consumer inquiry about the availability of Mallinckrodt's hydrocodone / APAP 325 mg tablets. The consumer stated she could not find this product at her usual pharmacy. The call-taker explained that SpecGx sells products to wholesalers and distributors that in turn supply pharmacies, and does not actively track which pharmacies purchase Mallinckrodt's products. However, the call-taker also advised the caller to call the

pharmacies in her area to check the product's availability. The Monitor Team inquired with the Manager of Pharmacovigilance whether in her opinion this response, particularly the advice to call other pharmacies, was proper and permissible under the PMT policies and the Operating Injunction. The Manager responded by noting that the caller indicated she had a valid prescription and was having trouble locating the product, and was correctly informed by the call-taker that SpecGx does not have visibility into which pharmacies stock its products. The Manager further explained that "there was no promotion of the product. The call handler provided no encouragement to fill the prescription, nor did they make any statements on the effectiveness or use of opioids," and therefore, she believed the response complied with the relevant PMT policies and the Operating Injunction. The Monitor Team found this explanation satisfactory.

7.15 Based on the Monitor Team's review of the underlying TrackWise data and the audit reports for the third and fourth quarters of 2023, as well as the email discussion with the Manager of Pharmacovigilance, it appears the TrackWise entries and audits are being conducted in a manner consistent with the Work Instruction and the Operating Injunction.

4. Social Media

7.16 During the Tenth Reporting Period, the Monitor Team interviewed Mallinckrodt's Vice President of Communications, whose duties and responsibilities include overseeing internal and external communications for the Specialty Brands and for SpecGx, including Mallinckrodt's press releases, LinkedIn and X (formerly Twitter) accounts, and website.

7.17 Regarding the Operating Injunction generally, the Vice President of Communications stated she was a Mallinckrodt employee prior to the Operating Injunction taking effect, but that it has not affected her role because she and her team do not promote Opioids, or any SpecGx product. She confirmed she undergoes the annual Operating Injunction

training, which she described as very thorough, and that she is comfortable asking questions when clarification is necessary.

7.18 As for Mallinckrodt's social media accounts, the Vice President of Communications informed the Monitor that she and two of her team members responsible for enterprise communications (which includes both SpecGx and Specialty Brands) have access to the accounts. She explained the development and approval process for posts that pertain to matters such as corporate or cultural news, or diversity, equity, and inclusion efforts, which are developed and reviewed by Mallinckrodt's communications and internal legal departments. She also explained that posts pertaining to the Specialty Brand segment must be reviewed and approved by the Specialty Brands PRC. This review process includes not only communications team members, but also medical, regulatory, legal, and brand review and approval.

7.19 Both Mallinckrodt employees and a third-party vendor review the Company's social media channels for compliance with the Operating Injunction. (The third-party vendor also reviews them for other matters such as product quality complaints or adverse events). The Vice President of Communications confirmed the third-party vendor has been instructed on the Operating Injunction and is required by its scope of work to provide real-time alerts to Mallinckrodt, in addition to its periodic reports to Mallinckrodt. The Monitor Team reviewed the Terms and Conditions executed by Mallinckrodt and the third-party vendor that governed these services, as well as the two most recent social media reports provided by the vendor. This review did not raise any concerns.

7.20 Importantly, the Vice President of Communications also confirmed that no one interacts with or responds to users on either social media account, though the third-party vendor

does monitor comments. That said, she did not recall ever seeing a user post on either the LinkedIn account or the X account concerning Opioids.

7.21 The Monitor also discussed the Company's website with the Vice President of Communications. She works with the IT department when a new page or section needs to be built, and updates the content after following the processes described above regarding social media posts. When necessary, a subject matter expert or content owner will also review the update to ensure its accuracy. In addition, she confirmed the Monitor Reports are posted on the website.

7.22 The Vice President of Communications informed the Monitor that Mallinckrodt's social media policy had been updated in the third quarter of 2023. The Monitor last received a copy of that policy in 2021. The Monitor Team reviewed the updated policy, which contains guidelines regarding personal use of social media when referencing Mallinckrodt and its products, services, research, programs, and other activities, and regarding Company-authorized use of social media by approved representatives of the Company. The Monitor Team's review did not raise any concerns regarding the policy's content.

7.23 The Monitor Team also conducted a spot-check review of Mallinckrodt's social media pages. The Monitor Team reviewed all of Mallinckrodt's LinkedIn and X posts in 2024, as well as comments by and any potential interactions with commenters, for compliance with the Operating Injunction. The majority of the posts concerned days or months dedicated to certain groups or health topics (for example, National Minority Health Month or World Kidney Day), as well as publicizing Mallinckrodt's attendance at upcoming events. None of the posts touched upon areas covered by the Operating Injunction, and none of Mallinckrodt's official social media

accounts responded to commenters. This was consistent with the information provided by the Vice President of Communications.

5. Marketing Budget for Opioid Products

7.24 The Monitor receives Mallinckrodt's annual marketing budget for Opioid Products on an annual basis and may request that Mallinckrodt identify and explain significant changes from the budget for the prior year.

7.25 In reviewing the 2024 marketing budget, the Monitor noted increases, including some very meaningful increases, in the amounts budgeted for a number of categories compared to the budget for those same categories in 2023, as well as at least one new category that did not appear in any prior budgets. The Monitor Team interviewed Mallinckrodt's Vice President of Commercial and Strategy, and asked him to explain those increases and the new category. Below is a summary of the specific categories the Monitor identified as having significant increases in their budgeted amounts or as being newly added, and the Vice President of Commercial and Strategy's explanations for those budget items:

(1) The budgeted amounts for categories related to travel to and attendance at, or sponsorship of, meetings and other events increased significantly from 2023 to 2024. The Vice President of Commercial and Strategy explained that the amounts budgeted for 2024 are consistent with Mallinckrodt's spending during the pre-Covid period, and while it was operating in bankruptcy. Presently, members of Mallinckrodt's domestic and international sales teams are meeting in-person, and attending industry events, more than they did during the past few years;

(2) The Monitor noted a new budget category for outside or agency temporary employees. Mallinckrodt explained that a former Mallinckrodt employee has returned to work for the Company on a part-time basis under a consulting contract, but that her employment status will be changed from consultant to employee, such that the amount budgeted will be reallocated to salary; and

(3) The amount budgeted for subscriptions and corporate memberships increased from 2023 to 2024. The Vice President of Commercial

> and Strategy explained some of those costs fall within the Opioid Products marketing budget, while others fall within the API budget, and that some of the increases reflect increases in outside organizations' membership dues or fees. That said, the Vice President of Commercial and Strategy anticipates the actual amounts spent will be less than those budgeted depending on how the subscription costs are allocated between the two budgets, whether the Company actually joins or renews its membership in an organization for which an amount has been budgeted, and whether membership payments are remitted early in order to obtain a discounted rate.

7.26 Related to the corporate membership budget discussed above, the Monitor requested a list of outside organizations in which Mallinckrodt participates or to which it pays dues, in order to confirm that Mallinckrodt's participation in, or paying dues to, any of those organizations does not run counter to the Operating Injunction's restrictions. In addition, the Monitor asked whether any of Mallinckrodt's directors, officers, or management-level employees serve on the boards of any of those organizations. In response, Mallinckrodt provided the Monitor Team with a copy of Mallinckrodt's Board Service Survey and identified three outside organizations in which two high-level Mallinckrodt employees—the Vice President of Commercial and Strategy, and the Director of Government Affairs & Patient Advocacy—serve as board members. The Monitor Team reviewed the survey and found it to be satisfactory because those organizations do not appear to implicate the Operating Injunction.

7.27 The Monitor will continue to review the annual marketing budget for Opioid Products and raise any questions it presents.

6. <u>Marketing Budget for API Products</u>

7.28 The Monitor also noted significant increases in the amounts budgeted for outside consulting and subscriptions in Mallinckrodt's 2024 annual budget for API products. The Monitor asked for an explanation of those increases; in response, the Vice President of Commercial and Strategy informed the Monitor that Mallinckrodt utilizes a third-party service to

collect and analyze data pertaining to the import and export of products to and from different countries, in order to identify market trends.

7.29 The Monitor was satisfied with Mallinckrodt's explanations, and will continue to review the annual marketing budget for API products and to raise any questions it presents.

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

8.1 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."

8.2 The Monitor's Audit Plan requires Mallinckrodt, annually, to produce to the Monitor updates to Mallinckrodt's sales compensation plans. Mallinckrodt last produced to the Monitor (on or about April 6, 2023) updated sales compensation information for 2023. The Monitor Team received the updated sales compensation information for 2024 at the end of the Tenth Reporting Period, and will review those materials during the next reporting period.

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

9.1 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. SGGSAC

9.2 As detailed in Mallinckrodt's Compliance Report,[7] the SGGSAC reviews and approves third-party requests for grants and sponsorships to ensure compliance with the Operating Injunction. *See* Mallinckrodt Compliance Report at 24-25 § 5.4. During the Tenth Reporting Period, the Monitor reviewed the minutes of all SGGSAC meetings that took place in the third and fourth quarters of 2023 and the first quarter of 2024, as well as several addenda to prior meeting minutes. Additionally, the Monitor reviewed the accompanying third-party funding Request Forms, and any related materials the Committee considered in determining whether to approve or deny a request.

9.3 During the Ninth Reporting Period, the Monitor learned that one of the Committee members had left Mallinckrodt and would be replaced by a new hire. *See* Ninth Monitor Report at 13 ¶ 7.3. In reviewing the minutes during the Tenth Reporting Period, the Monitor Team observed that the aforementioned new hire, the Senior Director of Clinical Affairs, was now the Committee Chair and leading the discussion on various funding requests. He first appeared to be serving as Chair in the October 4, 2023 SGGSAC meeting. In several subsequent meetings, the Senior Director of Clinical Affairs seemed to ask probing questions of requestors who appeared before the Committee to speak about their funding. For example, during the October 12, 2023 SGGSAC meeting, the Senior Director of Clinical Affairs inquired about the number of attendees at a potential sponsored event, and further inquired about maintaining Operating Injunction compliance when Mallinckrodt employees responded to inquiries from other attendees at the event.

[7] This document was previously filed by Mallinckrodt in its first bankruptcy case. *See* Mallinckrodt Compliance Report, Adv. Pro. No. 20-50850, Dkt. No. 174-1.

9.4 The Monitor Team spoke with the Senior Director of Clinical Affairs to learn more about his goals as the new Committee Chair and his thought process when reviewing a funding request. The Senior Director of Clinical Affairs explained that he joined Mallinckrodt's Clinical Affairs Department in September 2023. His primary job responsibility is managing Mallinckrodt's clinical trials, though he is also responsible for working with the formulations group. In addition to his regular responsibilities, Mallinckrodt asked him to serve as Chair of the SGGSAC approximately three weeks after joining Mallinckrodt. Prior to joining the Committee, he received training on the Operating Injunction and reviewed the relevant SOPs. When asked for his understanding of the Committee's purpose, the Senior Director of Clinical Affairs responded that the goal is to make sure that employees who go to events and represent Mallinckrodt understand their role in light of the Operating Injunction, while also making sure the Company is not funding anything that promotes Opioids. He explained that his questions at Committee meetings are aimed at accomplishing these goals by learning who might be involved in each sponsored event and what kind of discussions will take place at the event, particularly because he is not as familiar with these events coming from a clinical background. The Monitor Team also reviewed several specific SGGSAC meetings with the Senior Director of Clinical Affairs, which are discussed further *infra* 19-21 ¶ 9.5. In sum, the Monitor Team welcomes the thorough analysis of funding requests led by the Senior Director of Clinical Affairs and the Committee during its open meetings, and encourages these discussions to continue.

9.5 Given the volume of meeting minutes and accompanying request materials reviewed during the Tenth Reporting Period, below is a summary of some of the more noteworthy SGGSAC meetings that prompted additional analysis by the Monitor Team:

(1) On July 25, 2023, the Committee reviewed and approved a request for an exhibitor booth at Mallinckrodt's customer

AmerisourceBergen's annual event, ThoughtSpot 2023, which was scheduled to take place on August 2-5, 2023 in Las Vegas, Nevada. The Monitor Team noted that the funding contract for this event was signed by Mallinckrodt on June 7, 2023, and the Request Form stated that payment was due July 2, 2023, but the request was not reviewed and approved by the Committee until approximately one week before the event, leading the Monitor Team to be concerned that funding was distributed to a direct Mallinckrodt customer prior to approval by the Committee.

(2) In an August 12, 2023 addendum to the May 30, 2023 meeting minutes, the Committee noted that "the final agenda for the American Correctional Association (ACA) event was reviewed by Integrity & Compliance due to timing considerations related to the receipt of the final agenda and the inability to obtain email votes from all Committee members prior to the start of the event. Integrity & Compliance and Legal made the determination that this request is still approved." However, the event was already taking place at that time because it was scheduled for August 10-13, 2023. While the Monitor Team is cognizant that conditional approvals pending the receipt of final agendas are often necessary due to difficulties with timely obtaining a final agenda, receiving and approving a final agenda while the event was already taking place and Mallinckrodt was already participating is not within the letter or the spirit of the conditional approval policy.

(3) On October 12, 2023, the Committee reviewed a request for a significant exhibitor fee for 2023 CPhI Worldwide, scheduled to take place in Barcelona, Spain on October 24-26, 2023. CPhI Worldwide is a pharmaceutical industry gathering that takes place annually in Europe. SpecGx typically uses the forum to have supplier, customer and partner meetings, and planned to send approximately 22 employees from various departments to the event. The Committee noted that a 50% deposit of the total funding requested was paid on November 9, 2022, and the remaining balance was pending payment. This deposit appeared to be a violation of the Committee's standard procedures, which was particularly concerning to the Monitor Team in light of the other event participants and the number of Mallinckrodt employees scheduled to attend. The Committee extensively discussed the request with the requestor, the Vice President of Commercial and Strategy, who noted that "the intent and expectation moving forward is to submit request forms and materials in advance of events and payments made to third parties." The new Chair also had thorough questions, discussed *supra* 19 ¶ 9.4. Ultimately, the Committee voted 3-2 to decline the request and forfeit the deposit.

(4) On November 16, 2023, the Committee reviewed and approved several requests, including a sponsorship of the American Correctional Association's Winter Conference, which sparked questions by the new Chair. The Chair inquired whether there would be any discussions "geared towards promotion" at this event. When the Monitor Team asked about this question, the Chair explained he was not familiar with the event and wanted to understand who was attending and what kind of discussions take place. During this meeting, the Associate General Counsel also noted that "enhancements" to the Committee's SOP that incorporated timing requirements for request submissions were in the process of being prepared. The Monitor looks forward to reviewing the revised SOP, particularly in light of the observations in this Tenth Monitor Report and his New Recommendation 10(a).

(5) On February 18, 2024, the Committee reviewed and approved a sponsorship of the North Carolina Life Sciences Organization's 2024 Legislative Reception. The Director of Government Affairs, who is also a member of the Committee, explained that Company participation at this event exposes the Company to legislatures and other pharmaceutical companies in attendance. Given the presence of legislators, the Committee also discussed whether the sponsorship of the event needed to be reported as a lobbying expense. The Director confirmed it would be reported even though "lobbying per se" would not be conducted. He also abstained from voting on his own request per the Monitor's prior suggestion. *See* Eighth Monitor Report at 17 ¶ 8.5. The Monitor Team was pleased to see the Committee analyzing a funding request regarding other areas covered by the Operating Injunction, such as the lobbying restrictions, and encourages this holistic approach in future.

9.6 The Monitor Team spoke with the Vice President of Commercial and Strategy to better understand the discussion that took place during the October 12, 2023 SGGSAC meeting, and how the CPhI deposit was paid prior to approval by the Committee. The Vice President of Commercial and Strategy admitted that he made a "mistake"; he explained that while attending the previous year's CPhI conference in Frankfurt, Germany, he was told that Mallinckrodt needed to sign up for the next year right away in order to secure a spot in the exhibit hall. He thought because CPhI was primarily an API-focused conference, it was outside the purview of the Operating Injunction. He later realized that the deposit had been paid without approval from

the SGGSAC, and determined that he made an incorrect decision based on his misunderstanding of the Operating Injunction. Once he realized there was an error, he submitted the paperwork to have the funding reviewed by the SGGSAC, which ultimately declined to sponsor the event and decided to forfeit the deposit. As a result of this experience, the Commercial Department made a number of changes to its process regarding conferences and events. It now maintains a tracker of all sponsorships and funding requests based upon the yearly budget for conference attendance to ensure requests are submitted on a timely basis.

New Recommendation 10(a). Formalize the SGGSAC's requirements around the timeliness of funding requests and the payment of deposits.

9.7 **In light of the circumstances surrounding the CPhI deposit, as well as other deposits and conditional approvals, the Monitor Team recommends that the Company revise the SGGSAC SOP and related documents to formalize the SGGSAC's requirements around the timeliness of funding requests and the payment of deposits, and make clear to requestors that deposits cannot be paid without review and approval by the Committee, to ensure this issue does not reoccur.**

9.8 During the next reporting period, as part of the Audit Plan, the Monitor will continue to review a list of any grants and sponsorships awarded or rejected by the SGGSAC, along with any accompanying Request Forms and underlying materials, and the minutes and addenda of any SGGSAC meetings on a quarterly basis. The Monitor will continue to work with Mallinckrodt to ensure that the SGGSAC is operating in a manner consistent with Section III.C of the Operating Injunction as it relates to awarding grants and sponsorships to third-parties.

2. <u>Community Charitable Giving Program</u>

9.9 As previously reported, the Monitor reviewed Mallinckrodt's Community Charitable Giving Program ("CCGP"), which was previously managed by the Director of

Sustainability & Social Impact and is now managed by the Vice President of Government Affairs & Patient Advocacy. Through the CCGP, individuals or entities seeking donations from Mallinckrodt may submit requests for funding through its website. *See* Ninth Monitor Report at 16-18 ¶¶ 7.9-7.12. The Director of Sustainability & Social Impact and Mallinckrodt's Vice President of Government Affairs & Patient Advocacy previously explained that the CCGP is focused on two specific funding priorities—namely, STEM education and health and wellness—and that everyone involved in the process of reviewing and approving donation requests has been trained on the Operating Injunction and its funding restrictions. However, the Monitor Team concluded that further discussion of the CCGP was necessary with Mallinckrodt, given the fact that there is apparently a separate and parallel funding mechanism independent of the SGGSAC that is not subject to its purview.

9.10 During the Tenth Reporting Period, the Monitor Team further discussed its CCGP-related concerns with Mallinckrodt's Associate General Counsel and outside counsel. As a result of these discussions, the CCGP webpage and the application portal page now reference and provide a link to the Operating Injunction. Specifically, the webpage now states that "the Company will not fund any grants or sponsorships (and the like), that the Company determines, in its discretion, are prohibited by the Operating Injunction (OI)." In light of this change, combined with Mallinckrodt's assurances that funding requests received through this portal are generally small dollar amounts focused on STEM education and health and wellness initiatives within the Company's footprint, the Monitor is satisfied that funding through the CCGP is being reviewed with the restrictions of the Operating Injunction in mind. However, in order to continue to monitor this funding mechanism, the Monitor Team has requested that any funding requests and accompanying materials received through the portal that concern or relate to topics

addressed by the Operating Injunction be provided to the Monitor Team on a quarterly basis. The Company has agreed to implement this request and to a conforming update to the Audit Plan.

X. LOBBYING RESTRICTIONS (OI § III.D)

10.1 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.

10.2 In the Third Monitor Report, the Monitor recommended Mallinckrodt implement a process to ensure 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.

10.3 Under the Audit Plan, each quarter, Mallinckrodt provides the Monitor with the results of the Government Affairs Team's audits of Mallinckrodt's external state and federal lobbyists' public disclosure reports required by the *Lobbying Certification and Activity Review* SOP. During the Tenth Reporting Period, the Monitor Team reviewed the report for the fourth quarter of 2023, which was completed by the Director of Government Affairs & Patient Advocacy. Like past reports, it listed 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 provided links to the online filing location of the disclosure reports. As was the case with the

last several audit reports, the fourth quarter 2023 audit report did not identify any concerns or potentially violative activity in Mallinckrodt's review of its lobbyists' disclosures.

10.4 Under the Audit Plan, the Monitor also receives a list of bills that Mallinckrodt's external lobbyists reported lobbying for or against on the Company's behalf during the reporting period. The disclosure for the fourth quarter of 2023 revealed lobbying activity concerning only one bill at the federal level, which was introduced in the U.S. Senate during the fourth quarter of 2023. The bill directed the Secretary of Health and Human Services to conduct a demonstration program to test providing preferential treatment under the Medicare, Medicaid, and CHIP programs for certain drugs and biologicals manufactured in the United States. Mallinckrodt's federal lobbying firm lobbied in support of the bill on Mallinckrodt's behalf. The disclosure revealed no lobbying activity on new bills at the state level. The Monitor Team reviewed the federal bill and had no concerns that it implicated the Operating Injunction.

10.5 The disclosure for the first quarter of 2024 revealed no new lobbying activity at the federal level but some lobbying activity at the state level—namely, lobbying on Mallinckrodt's behalf in support of three bills in Missouri, two bills in New York (which were identical and which were introduced in the New York Senate and the New York Assembly), and one bill in Illinois. The Monitor Team reviewed all of these bills and had no concerns that any of them implicated the Operating Injunction.

10.6 During the Tenth Reporting Period, the Monitor Team conducted its annual "spot check" of recent public lobbying disclosure reports by Mallinckrodt's external lobbyists. The Monitor Team reviewed this information to confirm that: (1) Mallinckrodt's external lobbyists were not lobbying on legislative topics concerning increased access to Opioids or the Treatment of Pain as prohibited by the Operating Injunction; (2) the work Mallinckrodt's external lobbyists

were reporting to their respective states aligned with the quarterly list of bills provided to the Monitor by Mallinckrodt; and (3) Mallinckrodt had obtained a Certification and Operating Injunction Acknowledgement from each lobbyist and lobbying firm publicly listed as performing advocacy work on the Company's behalf.

10.7 While performing this annual "spot check" of publicly available information, the Monitor Team identified a lobbying firm in California (the "CA Lobbying Firm") of which Mallinckrodt appeared to be a client, according to the CA Lobbying Firm's filed reports and its website. However, Mallinckrodt did not have a signed Acknowledgement and Certification of Compliance with SpecGx Lobbying Restrictions. When asked about the CA Lobbying Firm, Mallinckrodt explained that the CA Lobbying Firm does not lobby on Mallinckrodt's behalf relating to the SpecGX business or Opioid Products, and instead focuses on the Brands side of the business. Mallinckrodt agreed to ask the CA Lobbying Firm to update its materials accordingly. The Monitor Team was satisfied with the explanation and the resolution of the issue. Based on its review and this subsequent discussion, the Monitor Team has confirmed that Mallinckrodt has Certifications on file for all of its active lobbyists, and current Acknowledgments from its lobbying firms. The Monitor Team did not discover any additional concerns in its annual review of these public lobbying materials.

1. Interviews with External Lobbyists

10.8 During the Tenth Reporting Period, the Monitor Team spoke with a representative from Mallinckrodt's external lobbying firm that covers lobbying in the State of Washington (the "WA Lobbyist"). Mallinckrodt engaged the WA Lobbyist during the fourth quarter of 2023 for services which began in January 2024, after Mallinckrodt concluded its prior relationship with another lobbying firm in Washington.

10.9 The WA Lobbyist described his background and experience dating back to 2007, when he worked with a consulting firm attached to a state political group, followed by an eleven-year period running campaign operations and his subsequent formation of his lobbying firm. The WA Lobbyist explained the services he renders for his clients and the connections some of his other clients have to the pharmaceutical industry generally. None of the work the WA Lobbyist performs for any of those clients pertains to Opioid Products.

10.10 The WA Lobbyist demonstrated an understanding of the Operating Injunction's lobbying related-prohibitions. The WA Lobbyist informed the Monitor that, after being retained, he met with Mallinckrodt to discuss the Operating Injunction, which he referred to as a "major point of emphasis," and reviewed slide decks pertaining to the Operating Injunction, signed the Acknowledgement and Certification of Compliance with SpecGx Lobbying Restrictions (a copy of which Mallinckrodt provided to the Monitor), and had multiple calls with Mallinckrodt regarding what he can and cannot do. In addition, the WA Lobbyist indicated he is aware of the requirement that he participate in the annual training to be held later in 2024. When asked to describe his understanding of the Operating Injunction's lobbying restrictions, the WA Lobbyist stated he is prohibited from anything that is arguing or advocating regarding Opioid Products, treatment-related functions that would encourage Opioid use or restrict alternatives, and any changes in drug classifications.

10.11 With the WA Lobbyist's engagement having only recently begun, he has not yet worked on any specific legislation for Mallinckrodt, and instead has been monitoring activities before the state House and Senate Healthcare Committees, and understands Mallinckrodt is interested in issues unrelated to Opioid Products or the Treatment of Pain.

2. Conference Attendance

10.12 The Monitor inquired of Mallinckrodt whether any members of its Government Affairs Team had attended any conferences, meetings, or gatherings of state or federal legislators or officials during the Tenth Reporting Period, and whether any of those individuals received any inquiries from, or had any interactions with, other attendees relating to Opioid Products. In response, Mallinckrodt informed the Monitor that two members of the Government Affairs Team had attended conferences and meetings but did not recall any discussions about the Operating Injunction or a topic prohibited by its restrictions on lobbying, and recalled generally that the discussions concerned, amongst other things, addiction treatment, onshoring of manufacturing, and infrastructure and economic initiatives related to Mallinckrodt's business.

3. Mallinckrodt's Political Contributions

10.13 Mallinckrodt contributes to political candidates and other political groups through the Mallinckrodt LLC Political Action Committee ("MNKPAC"), which is a federally registered political action committee. The Monitor Team reviewed MNKPAC's federal lobbying expenditures during the fourth quarter of 2023 and the first quarter of 2024. During that period, MNKPAC donated $17,500 to various political groups and candidates from both major national parties (*i.e.* Republicans and Democrats). From the Monitor Team's review of the websites of those groups and individuals, none appeared to advocate for positions implicating the Operating Injunction's lobbying-related prohibitions.

4. Lobbying-Related Aspects of Mallinckrodt's 2022 Sustainability Report

10.14 In the Ninth Monitor Report, the Monitor noted that Mallinckrodt's *Policy on U.S. Political Contributions and Lobbying Activities* (the "Political Contributions Policy"), which is discussed in and linked to Mallinckrodt's 2022 Sustainability Report, does not expressly reference the Operating Injunction or its lobbying and funding restrictions, although the

Sustainability Report does indicate the Operating Injunction has been implemented since 2020 and does provide a link to Mallinckrodt's website where the Monitor Reports can be accessed. *See* Ninth Monitor Report at 23 ¶ 8.16.

10.15 Nevertheless, in the Ninth Monitor Report, the Monitor encouraged Mallinckrodt to review the Political Contributions Policy and consider whether revisions may be warranted to cross-reference Mallinckrodt's lobbying-related obligations under the Operating Injunction. *See* Ninth Monitor Report at 23 ¶ 8.16. After discussing the issue with Mallinckrodt during the Tenth Reporting Period, the Monitor received an updated version of the Political Contributions Policy. That version includes a summary of the Operating Injunction as well as a hyperlink to the Operating Injunction maintained on Mallinckrodt's website.

5. Membership and Participation in Outside Organizations

10.16 Mallinckrodt periodically asks its employees to state whether they serve as a director, board member, agent, or officer of any entity or organization other than Mallinckrodt, and if so, to identify: (1) the entity or organization; (2) whether it is a for-profit or a non-profit entity or organization; (3) the role in which the employee serves; (4) how long the employee has served in that role; and (5) the termination date for the position, if any. During the Tenth Reporting Period, one employee reported serving in such a capacity, provided the required information, and confirmed none of the entities or organizations identified relate in any way to Opioid Products or the Treatment of Pain.

XI. 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)

11.1 Some sections of the Operating Injunction establish outright bans on certain activity, or establish requirements that do not readily lend themselves to independent verification. These include the Operating Injunction's ban on the manufacture, promotion, or distribution of "high dose opioids" (*i.e.*, "any Opioid Product that exceeds 30 milligrams of oxycodone per pill") (Operating Injunction § III.E.1); its ban on prescription savings programs (*id.* § III.F); its requirement that Mallinckrodt not provide an Opioid Product directly to a pharmacy or Healthcare Provider (*id.* § III.G.4); its requirement that Mallinckrodt comply with a number of miscellaneous general provisions (*e.g.*, in the event of a conflict between the Operating Injunction and federal or state law; truthful statements about Opioids and Opioid Products; the sharing of any subpoenas, Civil Investigative Demands, or warning letters) (*id.* § III.H); and compliance with laws and regulations relating to the "sale, promotion, distribution, and disposal of any Opioid Product" (*id.* § III.I).

11.2 As noted in the Fourth and Eighth Monitor Reports, Mallinckrodt's Associate General Counsel and Vice President of Legal, General Counsel executed annual certifications under the Audit Plan in January 2022 and January 2023 respectively, certifying Mallinckrodt's compliance with these provisions.

11.3 Consistent with the Audit Plan, in February 2024, the Associate General Counsel re-certified Mallinckrodt's compliance with these provisions of the Operating Injunction.

11.4 In the event Mallinckrodt becomes aware of any violations of the above-referenced provisions of the Operating Injunction or the Associate General Counsel's

representations in the most recent certification in the interim, Mallinckrodt has agreed to promptly inform the Monitor.

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

12.1 In the Tenth Reporting Period, the Monitor continued his assessment of Mallinckrodt's compliance with Section III.G of the Operating Injunction. Specifically, the Monitor: (1) continued his review of data and documents Mallinckrodt provided in response to the Audit Plan, the Monitor's ad hoc requests, or publicly available materials; (2) conducted interviews with the Director of Controlled Substances Compliance ("CSC"), two CSC Managers ("CSC Manager A" and "CSC Manager B"), and the CSC Specialist; (3) conducted an interview with the Vice President of Commercial and Strategy; (4) obtained updates from Mallinckrodt and its outside counsel regarding the grand jury subpoenas discussed *infra* 92-93 ¶¶ 12.179-182, the status of Mallinckrodt's implementation of the Monitor's recommendations related to suspicious order monitoring ("SOM") in prior reports, and other SOM-related matters, including TrackWise reports; and (5) met with the monitors for two other companies also subject to injunctions regarding the manufacture and sale of opioid products.

12.2 The Monitor's findings from this activity are described in the following sections: (1) documents the Monitor reviewed during the Tenth Reporting Period; (2) Opioid market dynamics; (3) direct customer due diligence; (4) downstream registrant due diligence; and (5) other SOM-related issues.

1. Documents Reviewed During the Tenth Reporting Period

12.3 Mallinckrodt timely produced all SOM-related documents requested under the Audit Plan for the fourth quarter of 2023 and the first quarter of 2024. Mallinckrodt also timely

produced all documents requested under the Audit Plan on a monthly and annual basis, and in response to the Monitor's ad hoc requests.

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

(1) SOMT meeting materials and minutes for October, November, and December 2023, as well as January, February, and March 2024;

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

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

(4) the Opioid Product-related inquiries in the Government Communications log for the fourth quarter of 2023 and the first quarter of 2024, as well as related correspondence;

(5) sales data for highly diverted Opioid Products;

(6) annual sales data for all Opioid Products;

(7) direct customer flagged order data;

(8) certain suspicious order reports and related correspondence for flagged direct customer orders in October, November, and December 2023, as well as January, February, and March 2024;

(9) direct customer questionnaires;

(10) audit reports related to controlled substances compliance;

(11) TrackWise data for inquiries and complaints potentially raising potential diversion concerns;

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

(13) the annual review by CSC Managers A and B entitled "Analysis of Highly Diverted Controlled Substances Utilizing Chargeback Data";

(14) the aggregate production quota DEA issued for each opioid molecule from 1995 to 2024;

(15) Mallinckrodt's manufacturing and procurement quotas for oxycodone and hydrocodone;

(16) a relevant portion of Mallinckrodt's distribution agreement with Distributor C;[8]

(17) the SOMT's reports from due diligence visits to distributor customers and other documents obtained by the SOMT related to those due diligence visits;

(18) a list of the direct customers Mallinckrodt intends to visit, either virtually or in person, to conduct due diligence in 2024;

(19) a summary of data concerning Mallinckrodt's review and restriction of pharmacies since 2019; and

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

12.5 The Monitor also reviewed other publicly available documents referenced *infra* 84-5 ¶ 12.155, including the Purdue monitor's reports and relevant news articles.

2. Opioid Market Dynamics

a. *Mallinckrodt's increase in Opioid Product net sales*

12.6 During the Tenth Reporting Period, the Monitor Team sought to understand why Mallinckrodt's fall 2023 quarterly SEC report revealed significant increases in net Opioid sales.

12.7 By way of background, a representative of the State Attorneys General noted that Mallinckrodt reported a large increase in net sales of Opioids (by dollars) in the third quarter of 2023 as compared to the same period a year earlier. Specifically, the representative cited Mallinckrodt's 10-Q filing with the SEC for the third quarter of 2023, in which Mallinckrodt

[8] "Distributor C" refers to the same "Distributor C" identified in the Ninth Monitor Report. However, all other anonymized references to distributors and pharmacies do not necessarily correspond to references in prior reports.

reported net Opioid sales of $65.9 million as compared to $46.5 million in the third quarter of 2022—*i.e.*, an increase of 41.7%. The representative expressed concern that the magnitude of the increase could be inconsistent with the purpose of many of the Operating Injunction's provisions, and requested that the Monitor Team look into this further.

12.8 In response, the Monitor Team requested additional Opioid Products sales data from Mallinckrodt. The Monitor also interviewed the Vice President of Commercial and Strategy to fully understand what drove Mallinckrodt's increase in net Opioid sales, and to discuss changing market dynamics generally. As noted earlier in this Report, the Monitor also interviewed the Vice President of Commercial and Strategy to discuss promotion-related issues. *See supra* 15-16 ¶ 7.25.

i. Mallinckrodt's sales data for Opioid Products

12.9 The Monitor Team reviewed five years' worth of Mallinckrodt's Opioid Product sales data (from 2019 through 2023). For both hydrocodone and oxycodone, the two key drug "families" (*i.e.*, molecules of varying dosages) with products at most risk for abuse, the data reflects either a reversal of a previous downward trend in sales (both in terms of volume of doses sold, and also in terms of dollar value of sales) or a sharper increase in sales in 2023.

12.10 However, the increase in sales was not consistent across all Opioid Product categories. For instance, due to particular manufacturing issues related to a key component of Mallinckrodt's transdermal fentanyl patch, Mallinckrodt had to redesign the product with different material, requiring Mallinckrodt to temporarily take the product off the market. This resulted in a precipitous decline in sales of this product, although sales are expected to increase with the ability to sell the product with a new mechanism.

12.11 Nonetheless, as Mallinckrodt reported to the SEC, there was a large increase in its 2023 Opioid net sales overall. As discussed further below, the Vice President of Commercial

and Strategy attributes this growth to market dynamics resulting in both higher sales volume and pricing.

ii. Interview with the Vice President of Commercial and Strategy

12.12 The Monitor Team discussed with Mallinckrodt's Vice President of Commercial and Strategy the issue the State Attorneys General representative raised. In order to explain several factors the Vice President of Commercial and Strategy attributed to Mallinckrodt's growth in Opioid sales in 2023, he shared with the Monitor Team his analysis of the controlled substances competitive landscape from July 2022 through December 2023, focusing on six products: (1) hydrocodone / APAP; (2) oxycodone / APAP; (3) oxycodone IR; (4) codeine / APAP; (5) hydromorphone; and (6) morphine ER.

12.13 The Vice President of Commercial and Strategy shared slides with the Monitor Team showing the number of Mallinckrodt's competitors for the first four products listed above (namely, hydrocodone / APAP; oxycodone / APAP; oxycodone IR; and codeine / APAP) shrank drastically during the 18-month period, resulting in understandable increases in Mallinckrodt's market share over that time. But even in the case of the last two products listed above (namely, hydromorphone, and morphine ER), where the number of competitors in the market remained the same, Mallinckrodt's market share increased.

12.14 The Vice President of Commercial and Strategy provided helpful explanations for these dynamics. Notably, he stated the data reflects an overall decline in the markets for each of the above-referenced products since 2019. Why Mallinckrodt's sales have increased, particularly given the context of a shrinking market, relates to both Mallinckrodt's capture of greater market share and its higher prices.

12.15 ***First***, Mallinckrodt has picked up market share in the markets for the first four products due to the exit of some competitors (sometimes arising from compliance-related issues and the challenges of government regulatory enforcement), or supply constraints on those remaining in the market. As to those exiting the market, Mallinckrodt has been able to fill the gap in supply and satisfy the market demand. Why competitors are exiting the market is not entirely surprising. Threats of litigation, bankruptcy, DEA quota limits (discussed elsewhere in this Report, *infra* 39 ¶ 12.29), and compliance risk all make this a challenging market.

12.16 For example, in the market for hydrocodone / APAP, the Vice President of Commercial and Strategy reported four competitors have either: (1) already exited the market; (2) contemplated a market exit; (3) closed a site; or (4) experienced challenges obtaining quota from DEA.

12.17 In the oxycodone / APAP market, the Vice President of Commercial and Strategy reported two competitors have reported quota constraints. And in the oxycodone IR market, one competitor's declining market share coincides with its announcement of the diversion of thousands of oxycodone tablets from the company's site in late 2022. In the case of codeine / APAP, one competitor is the subject of a criminal inquiry, while another shut down a plant allegedly due to U.S. Food and Drug Administration ("FDA") violations.

12.18 Finally, in the markets for hydromorphone and morphine ER, where there are relatively few competitors to begin with (only two, in the case of hydromorphone; just three for morphine ER), the Vice President of Commercial and Strategy reported the story is again about challenges Mallinckrodt's competitors have experienced, which in turn has shifted demand to Mallinckrodt.

12.19 ***Second***, Mallinckrodt's sales revenue has increased due to contracted price increases. The Vice President of Commercial and Strategy shared that this is due to the fact that, in many instances, Mallinckrodt does not serve as a primary supplier of the products. For example, he explained that Mallinckrodt may serve as a "backup supplier" to distributors, and its contracts with those distributors include premium pricing. Thus, when those distributors were unable to obtain products from their primary suppliers and purchased from Mallinckrodt instead, those sales generated greater revenue for Mallinckrodt as a result of the backup contract pricing.

12.20 In sum, this all combined to produce a double effect: an increase not only in the ***volume*** of product Mallinckrodt supplied to market, but also at a higher ***price***. Together, these increases in both volume and price resulted in Mallinckrodt's substantial increase in net Opioid sales (*i.e.*, sales revenue) in 2023.

iii. Mallinckrodt's March 2024 8-K Report attributes the increase in net sale of Opioid Products in 2023 to changing market dynamics

12.21 Mallinckrodt announced total year-end financial metrics for 2023 in an 8-K Report filed with the SEC dated March 26, 2024. The total year-end numbers reflect similar dynamics to those the State Attorneys General noted regarding the 2023 third quarter financials. Consistent with the discussion above, the 8-K Report noted the increase in fourth quarter net sales for the SpecGx segment of the business "was primarily due to growth in finished-dosage products as ***the broader market experienced ongoing disruptions in product quality and supply.***" Mallinckrodt 8-K (Mar. 26, 2024) at 2 (emphasis added). The Company noted that "Mallinckrodt's Specialty Generics business will continue to be differentiated as a reliable, consistent supplier, creating stable pricing dynamics and a competitive advantage with customers amidst ongoing shortages and supply chain constraints." *Id.* at 3.

12.22 The report notes total fiscal year 2023 net sales growth for the SpecGx segment, as compared to total 2022 net sales, of 20.5%—*i.e.*, $776.9 million as compared to $664.8 million the prior year. *Id.* at 21. As for Opioids specifically, total 2023 net sales were $262.3 million, as compared to $206.7 million the prior year, reflecting a 26.9% increase. *Id.* at 22; *see also* Mallinckrodt 10-K (Mar. 26, 2024) at 73.

12.23 Given the explanation provided by the Vice President of Commercial and Strategy—some of which is apparently based upon market intelligence and some of which the Monitor Team corroborated through publicly available sources—it seems the reasons for the sales increase should not raise concerns regarding Mallinckrodt's compliance with the Operating Injunction.

b. *DEA quota for Opioids, including oxycodone and hydrocodone*

i. DEA aggregate Opioid quota, by molecule

12.24 Under the Audit Plan, Mallinckrodt provided the Monitor Team with the DEA's aggregate industry production quota, by molecule, for hydrocodone, oxycodone, and other opioids for 2019 to 2024.

12.25 From 2019 to 2023, the DEA decreased the aggregate production quota for oxycodone and hydrocodone each year. This downward trend continued in 2024. From 2023 to 2024, the DEA decreased the aggregate production quota for both hydrocodone and oxycodone slightly (by 0.4% and 0.3% respectively).

c. *Mallinckrodt's manufacturing and procurement quotas for 2023*

12.26 Under the Audit Plan, Mallinckrodt also provided the Monitor Team with Mallinckrodt's own manufacturing and procurement quotas from 2019 to 2023. Mallinckrodt's manufacturing quota refers to the amount the DEA allots to Mallinckrodt's St. Louis plant for the production of API. Mallinckrodt's procurement quota refers to the amount of API Mallinckrodt

can acquire to manufacture finished dose products (*i.e.*, tablets, pills, and the like, in finished form).

12.27 Despite the DEA's decrease in aggregate production quota for oxycodone and hydrocodone from 2019 to 2023, Mallinckrodt's manufacturing and procurement quotas for both hydrocodone and oxycodone increased from 2022 to 2023, as follows:

Mallinckrodt's DEA-Approved Manufacturing Quota Change 2022-2023	
Molecule	***% Increase***
Hydrocodone	23%
Oxycodone	27%
Mallinckrodt's DEA-Approved Procurement Quota Change 2022-2023	
Molecule	***% Increase***
Hydrocodone	46%
Oxycodone	11%

12.28 Mallinckrodt's quotas for hydrocodone and oxycodone fluctuated between 2019 and 2022. However, its manufacturing quotas for both hydrocodone and oxycodone, and its procurement quota for oxycodone in 2023, were higher than the comparable quotas DEA allotted Mallinckrodt in 2019. (The Monitor previously provided a summary of Mallinckrodt's changes in quota for hydrocodone and oxycodone between 2019 and 2022 in the Eighth Monitor Report. *See* Eighth Monitor Report at 35 ¶¶ 11.17-18.)

12.29 Mallinckrodt's recent increases in its quotas (against the backdrop of continued decreases in DEA aggregate quotas for both hydrocodone and oxycodone) is perhaps attributable to the market changes discussed above. *See supra* 33-38 ¶¶ 12.6-23.

d. *DEA announces a new quarterly quota application process for manufacturers, then moves to a semi-annual quota application process instead, in response to manufacturers' concerns*

12.30 In 2023, DEA announced it would require manufacturers to apply for procurement quota allotments on a quarterly basis, instead of annual basis, starting in January 2024. DEA Administrator Anne Milgram described that change in a letter, dated November 1, 2023, addressing the shortage in stimulants used to treat illnesses such as ADHD, binge eating disorder, and narcolepsy.[9] Among other things, Ms. Milgram noted DEA would now "[r]equir[e] drug manufacturers to apply for quota allotments on a quarterly (instead of yearly) basis, so that we are able to provide quota allotments to manufacturers that have demonstrated they are using them to actually make and sell medications for current use." She explained this and other changes were "designed to help us see shortages coming and adjust more quickly over the long run."

12.31 As discussed *infra* 88-90 ¶¶ 12.162-170, the Monitor Team interviewed a now-retired Mallinckrodt employee who was previously a Senior Compliance Consultant ("Employee A") at Mallinckrodt's Webster Groves Plant, and was involved in applying to DEA for drug quotas on behalf of Mallinckrodt. She expressed concerns about the DEA's new quarterly quota application process because the change further complicated the process for obtaining quota, which was already resource intensive. (Though, as discussed *infra* 89 ¶ 12.167, Employee A did

[9] *See* Dear Americans Letter of Anne Milgram, Administrator, U.S. Dep't of Justice, Drug Enforcement Admin. (Nov. 1, 2023), *available at* https://www.dea.gov/sites/default/files/2023-11/Quota-Shortages%20Letter.pdf (last visited Apr. 28, 2024). Shortages in the United States drug market are well known and have been widely reported upon. *See* Liz Essley Whyte & Peter Loftus, Drug Shortages in America Reach a Record High, Wall St. J. (Apr. 12, 2024), *available at* https://www.wsj.com/health/healthcare/drug-medication-shortages-us-olympic-amoxicillin-107fa9d8 (last visited May 9, 2024).

not have any concerns about Mallinckrodt's compliance with the Operating Injunction, or generally.)

12.32 Mallinckrodt is not alone in its concerns expressed by the manufacturing community. For example, Pfizer submitted a comment in response to the DEA's proposed quota rule changes, noting, among other concerns, that "DEA's proposal to allocate quota on a quarterly basis will make manufacturing lead times, planning schedules, and resource allocation extremely difficult if not untenable. As an example, from the time API is received at a manufacturing plant to the time finished product is ready for shipment, the lead time can be as long as six months, stretching over multiple quarters."[10]

12.33 DEA's quarterly quota application process was short-lived, and remained in place for less than five months before DEA repealed it. Recognizing the challenges the quarterly requirement posed for manufacturers, the DEA announced in late April 2024 that "applications for procurement quota for commercial manufacturing of schedule II controlled substance will be calculated on a ***semi-annual*** basis," instead.[11] In a letter from DEA Acting Deputy Assistant Administrator Marsha L. Ikner, dated April 25, 2024, Ms. Ikner stated:

> In December, DEA announced that drug manufacturers would be required to apply for quota allotments on a quarterly basis. In years past, DEA found that manufacturers have not used the full amount of yearly quota allocated, resulting in shortages of critical medications.

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[10] *See* Letter from Jennifer Walton, Senior Vice President, U.S. Policy & Government Relations, Pfizer (Nov. 28, 2023), *available at* https://static1.squarespace.com/static/54d50ceee4b05797b34869cf/t/658f4c094f9465338182ed88/1703889930197/Pfizer+comment+on+2024+quotas.pdf (last visited Apr. 28, 2024).

[11] *See* Letter from Marsha Ikner, Acting Deputy Assistant Administrator Diversion Control Divisions, U.S. Dep't of Justice, Drug Enforcement Admin. (Apr. 25, 2024), *available at* https://www.documentcloud.org/documents/24630258-dea-letter-to-manufacturers (last visited May 18, 2024) (emphasis added).

> Since then, DEA has met with several manufacturers to discuss the impact of these changes. Numerous drug manufacturers asked DEA to consider allocating quota semi-annually to assist with production planning and execution. DEA understands and appreciates the complexities of the drug supply chain. Effective immediately, applications for procurement quota for commercial manufacturing of a schedule II controlled substance will be calculated on a semi-annual basis, except for injectable drug products containing schedule II controlled substances, which will be calculated on an annual basis.

12.34 The Monitor believes that a semi-annual quota application process will be more manageable for Mallinckrodt than a quarterly application process, and anticipates learning more about the logistics of this change, and the sufficiency of Mallinckrodt's resources to deal with the change, in the next reporting period.

3. Direct Customer Due Diligence

12.35 Mallinckrodt's two systems for monitoring potentially suspicious direct customer orders are (1) the direct customer dashboard monitoring orders for unusual quantity, pattern, or frequency, and (2) the "OI Hold system," monitoring direct customer orders for potential violations of the Operation Injunction's provisions. If an order flags on either the direct customer dashboard or the OI Hold system, Mallinckrodt will not ship the order until the SOMT releases the hold.

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

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

12.38 Additionally, the Monitor reviews the suspicious order reports ("SORs") for a randomly chosen week each month, and a sample of any related correspondence, to confirm the CSC Specialist and a CSC Manager reviewed the flagged direct customer orders before determining whether to release them. In this reporting period, the Monitor reviewed the SORs for October, November, and December 2023, and January, February, and March 2024.

a. *Direct customer flagged orders for the fourth quarter of 2023 and the first quarter of 2024*

12.39 As the Monitor has previously reported, the CSC Specialist reviews all direct customer orders the system flags. She then determines whether to release the order after reviewing the customer's order history, conferring with the Customer Service Department regarding any changes in the customer's contracts or product needs, and contacting the customer, if necessary. A flagged order is only released after approval by both the CSC Specialist and a CSC Manager.

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

12.41 For example, in the fourth quarter of 2023, the direct customer dashboard flagged an order for an Opioid Product because of its unusual size. The CSC Specialist appropriately requested additional information from the Commercial Department because the order was inconsistent with the customer's prior ordering pattern. The Commercial Department contacted the direct customer, which confirmed the order was a mistake and cancelled the order. While it appears the customer made a mistake, if the customer had been attempting to purchase an excessive quantity of an Opioid Product, it would have been properly flagged as suspicious by the direct customer dashboard and led to further inquiry by the CSC Specialist.

12.42 The CSC Specialist and a CSC Manager released all of the other orders the direct customer dashboard flagged during the fourth quarter of 2023 and the first quarter of 2024.

b. *OI-Hold Reports for the fourth quarter of 2023 and the first quarter of 2024*

12.43 In the fourth quarter of 2023 and the first quarter of 2024, none of Mallinckrodt's direct customer orders were flagged for potential violations of the Operating Injunction.

c. *The SORs for select weeks in October, November, and December 2023 and January, February, and March 2024*

12.44 The Monitor Team reviews a SOR for one week each month to confirm all flagged orders for Opioid Products were only released after both the CSC Specialist and a CSC Manager reviewed them and concluded the order was not potentially suspicious per the relevant SOP. At times, the CSC Specialist or a CSC Manager will require additional information from the Commercial Department or the direct customer to release an order, and Mallinckrodt provides any backup documentation the CSC Specialist and / or a CSC Manager compiles along with the SOR. For each SOR, the Monitor Team also reviews that backup documentation for a sampling of the flagged orders that are released.

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

unusual quantity for the customer; or (5) order is for a new product that had to be manually entered into an item group.

12.46 In the instances where the CSC Specialist requested and received information resulting in the release of the flagged order, the SORs indicated supporting documentation was obtained from the customer or the Commercial Department. The SOMT retains those communications, which were provided to the Monitor Team for review. Based on the Monitor Team's review of a sample of such communications, it appears the SOMT properly obtained and maintained any necessary backup documentation for those orders.

d. *The Monitor's interview with the CSC Specialist concerning her review of direct customer orders*

12.47 In addition to the Monitor Team's review detailed above, the Monitor Team interviewed the CSC Specialist concerning the review process for flagged direct customer orders as well as the SORs and accompanying documentation produced during the Tenth Reporting Period.

12.48 Since the Ninth Reporting Period, CSC Manager B has replaced CSC Manager A as the SOMT member conducting the second-level review of flagged orders. The CSC Specialist informed the Monitor that CSC Manager B has received extensive training from CSC Manager A on Mallinckrodt's process for reviewing flagged direct customer orders. Although CSC Manager B has a relevant base of knowledge from her time at the DEA, the CSC Specialist further informed the Monitor that she and the CSC Senior Manager continue to work with CSC Manager B to impart relevant institutional knowledge regarding Mallinckrodt's direct customers and their ordering practices to inform the review process. The CSC Specialist reported no concerns with how the two-level review process for releasing flagged orders is operating at this time.

12.49 The CSC Specialist and the Monitor Team further discussed her rationale for releasing certain flagged orders that appeared in the SORs. These interviews with the CSC Specialist are particularly informative for the Monitor Team because the format of the SORs does not provide the Monitor with all of the data available to the SOMT on the direct customer dashboard, including the values of certain metrics the CSC Specialist analyzes when determining if a flagged order should be released.

12.50 For example, many of the flagged orders the Monitor Team and the CSC Specialist discussed were released after she and a CSC Manager determined that the volume of the customer's order was not unusual when compared to orders placed by similar customers within this segment of industry. While Mallinckrodt provided the Monitor with backup documentation explaining why that customer's volume increased, the SOR did not indicate how the CSC Specialist had compared the volume of that customer's order(s) to other customers' orders within that industry segment to determine whether it was unusual.

12.51 The CSC Specialist, and later the CSC Director in a separate interview, confirmed the Monitor Team would not be able to re-create that analysis from the SOR, which does not reflect all of the information available to the SOMT on the direct customer dashboard. As they explained, what appears on the dashboard is not fully reflected in the SORs because those reports are formatted based on DEA requirements for reporting of suspicious orders. Accordingly, the SORs provided to the Monitor largely contain only the information Mallinckrodt is required to provide to the DEA for potentially suspicious orders, in the format the DEA requires.

12.52 As a result, the Monitor Team and the CSC Director discussed whether it would be possible to provide the Monitor with documentation that more closely resembles what is

available to the CSC Specialist when she reviews flagged orders. The CSC Director informed the Monitor that he would consider what other documentation could be provided to the Monitor.

12.53 The CSC Specialist further informed the Monitor that she continues to observe direct customer orders flagged due to changing market dynamics. She has observed an increase in demand for certain of Mallinckrodt's products as a result of other manufacturers exiting the market. For example, the CSC Specialist reported several instances where Mallinckrodt was previously a direct customer's secondary supplier but its primary supplier had exited the market. As a result, those direct customers ordered larger quantities from Mallinckrodt, and their orders flagged for volume. After conferring with the Commercial Department and learning the direct customers' primary supplier had exited the market, the CSC Specialist was able to release the flagged orders. The CSC Specialist's reasoning for releasing those flagged orders comported with the explanation of the Vice President of Commercial and Strategy regarding Mallinckrodt's recent increase in net opioid sales discussed *supra* 33-38 ¶¶ 12.6-23.

e. *Mallinckrodt's direct customer due diligence visits*

12.54 As the Monitor previously reported, Mallinckrodt's *SOM Review of Direct Customer Orders* SOP requires the SOMT to conduct annual due diligence visits (either in-person or virtually) with one of the "Big Three" distributors and six other distributors. *See* Sixth Monitor Report at 38 ¶ 11.23. During the Tenth Reporting Period, the Monitor Team reviewed the SOMT's due diligence reports for five visits it conducted in 2023, the list of distributors the SOMT intends to visit in 2024, and a report of a visit conducted in 2024 triggered by review of a questionnaire raising concerns about the sufficiency of the distributor's SOM controls and awareness.

i. Mallinckrodt's 2023 due diligence visits

12.55 In the Tenth Reporting Period, the Monitor reviewed the reports prepared by the SOMT for five of the eight due diligence visits it conducted in 2023, which Mallinckrodt provided to the Monitor at the end of the Ninth Reporting Period and during the Tenth Reporting Period. (The SOMT conducted more visits than the SOP required last year, and the other three reports were provided and reviewed previously.) The reports reflect that, among other things, the members of the SOMT who attended each visit discussed and observed the distributors' physical location and security, obtained information regarding that distributors' customers, and confirmed there were no findings from the distributors' last DEA and state inspections. The reports also reflect that the SOMT members who attended each visit performed a review of the distributors' SOM procedures, including but not limited to whether those distributors: (1) had various written policies in place (*i.e.*, policies regarding onsite due diligence visits to customers); (2) evaluate relevant metrics related to their customers (*i.e.*, the ratio of controlled substance to non-controlled substances dispensed by the customer); and (3) monitored customers' purchases for common "red flags" (*i.e.*, ordering excessive quantities of a limited variety of controlled substances while ordering few, if any, other controlled substances or non-controlled substances).

12.56 ***The SOMT's Due Diligence Visit With Distributor B***. In November 2023, the SOMT conducted a due diligence visit with Distributor B and prepared a report detailing findings from the visit. The "boilerplate" portions of the completed questionnaire generally do not reveal concerns with Distributor B, with one exception. Specifically, Section 4 of the questionnaire addresses "Potential additional areas of concern," and lists 11 potential topics with "yes" or "no" checkboxes for the reviewer to select. Ten of the 11 items are checked "no," to indicate no additional concerns, but one item was checked "yes": "Distributor does not seem to

know industry practice or fails to provide meaningful reasons for an order at variance with accepted legitimate industry practice?"

12.57 A narrative section of the questionnaire reserved for summary "Observations" provides additional information. For example, this section notes that Distributor B uses a particular vendor's SOM system, and notes the vendor "has a good reputation," but expresses some "[c]oncern" as to how Distributor B "interprets or follows through."

12.58 The "Observations" section also notes a prior (September 12, 2023) conversation with Distributor B's Director of Compliance regarding a particular pharmacy of interest to the SOMT, for which the SOMT had initiated a chargeback review in May 2023. Following that discussion with Distributor B's Director of Compliance on September 12, 2023, the SOMT decided to restrict the pharmacy of interest at the September 21, 2023 SOMT meeting.

12.59 The "Observations" section of the questionnaire includes some remarks from Distributor B's Director of Compliance in the September 2023 conversation with the SOMT that appear flippant, such as the comment that Mallinckrodt is "caught up in the numbers just like DEA."

12.60 Following the November 2023 due diligence visit, the SOMT concluded there was not sufficient cause to terminate Distributor B at that time but that Distributor B would "require extra vigilance."

12.61 The SOMT continued to monitor Distributor B in light of what appear to be ongoing concerns that Distributor B did not conduct sufficient due diligence of its customers. For example, following the November 2023 due diligence visit, the indirect customer dashboard flagged several pharmacies supplied by Distributor B for unusual ordering pattern or trend concerning hydrocodone. Distributor B repeatedly failed to provide responses to the SOMT's

requests for due diligence addressing concerns regarding those pharmacies' purchases of hydrocodone. Additionally, the substance of Distributor B's responses raised additional concerns for the SOMT.

12.62 For example, in one instance, Distributor B did not appear to be conducting its own due diligence in response to Mallinckrodt's questions, but rather simply forwarding to Mallinckrodt the information Distributor B had received from the pharmacy. This was the case with a pharmacy for which the SOMT initiated a chargeback review in December 2023, and made a restriction in January 2024. To make things worse, that pharmacy's responses to questions should have raised immediate concerns with Distributor B itself, but seem not to have resulted in restriction of the pharmacy by Distributor B.

12.63 Ultimately, the SOMT concluded that Distributor B was not adequately monitoring its customers, and therefore took the unusual step of suspending controlled substances sales to Distributor B at the February SOMT meeting, approximately three months after the due diligence visit. The suspension of Distributor B is further discussed *infra* 71 ¶¶ 12.121-22.

ii. Mallinckrodt's anticipated direct customer due diligence visits for 2024

12.64 Consistent with Mallinckrodt's policy, the SOMT intends to visit one of the "Big Three" distributors and six other distributors in 2024.

12.65 Under the Audit Plan, Mallinckrodt provided the Monitor Team with a list of six of the seven distributors it intends to visit in 2024. The SOMT anticipates conducting its visit with the "Big Three" distributor in person. The SOMT has not yet determined the seventh distributor it will visit but will inform the Monitor once it makes that decision.

iii. Mallinckrodt's due diligence visit with Distributor F in 2024

12.66 Mallinckrodt conducted a due diligence visit with Distributor F based upon a review of Distributor F's customer questionnaire. Review of the questionnaire revealed that Distributor F had not fully answered the questions on the questionnaire. A meeting with Distributor F did not allay Mallinckrodt's concerns, and the SOMT concluded that Distributor F—an API customer of Mallinckrodt that supplies compounding pharmacies—could not provide sufficient assurances of maintaining adequate SOM controls, resulting in a suspension of controlled substances sales to Distributor F.

f. *Follow-up on Distributor A in Tenth Monitor Report*

12.67 As the Monitor previously reported, members of the SOMT conducted a due diligence visit with Distributor A in April 2023. During that visit, the SOMT members learned that Distributor A had restricted sales of controlled substances to certain customers, and asked if Distributor A would share the identities of those customers with Mallinckrodt. Distributor A representatives said they would confer with their legal counsel. *See* Ninth Monitor Report at 32 ¶ 10.24.

12.68 During the Tenth Reporting Period, the CSC Director and CSC Manager informed the Monitor that Distributor A had provided Mallinckrodt with lists of customers Distributor A refused to onboard or had terminated in May and November 2023.

12.69 During the next reporting period, the Monitor will inquire whether Distributor A has continued to share those customer lists with Mallinckrodt.

g. *Direct customer questionnaires*

12.70 Under the Audit Plan, each year Mallinckrodt produces a sampling of distributor customer questionnaires for the Monitor Team's review. While the Customer Service

Department receives the completed questionnaires, the SOMT is responsible for determining whether the customers' responses are satisfactory. During the Tenth Reporting Period, the Monitor Team reviewed 2023 questionnaires for three existing direct customers. While the direct customers provided answers to all of the "yes" or "no" questions and filled in other information requested by the questionnaires, none of them provided Mallinckrodt with a "a brief written description" of their SOM program, which the questionnaire directed each customer to attach.

12.71 Mallinckrodt explained to the Monitor that the SOMT had visited two of the direct customers in 2022 and the SOMT's reports from those visits contained descriptions of the customers' SOM programs. Additionally, Mallinckrodt informed the Monitor that the third direct customer's ***2024*** questionnaire did include a description of its SOM program, and that the direct customer is scheduled for a due diligence visit in May 2024.

12.72 While the Monitor appreciates that the SOMT may have determined the sufficiency of its customers' SOM programs based on other sources of information, including its interactions with longtime customers and prior due diligence visits, the questionnaire for distributor customers specifically asks that "a brief written description of [the customer's] SOM[] [program]" be attached, if the customer indicates it has a SOM program. The questionnaires presumably include this request because Mallinckrodt has determined that it is important, and perhaps even necessary, for any new or existing direct customer to provide the SOMT with a brief written description of the SOM program it ***currently*** has in place, before Mallinckrodt processes, or continues to process, the customer's orders. Accordingly, the Monitor makes the recommendation below.

New Recommendation 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.

12.73 **The Monitor has observed that not all of Mallinckrodt's distributor customers provided a brief written description of their SOM programs along with the completed questionnaires. Accordingly, the Monitor recommends that Mallinckrodt obtain a brief written description of the SOM program from any distributor customer submitting a questionnaire indicating it has an SOM program, consistent with the questionnaire's request, even if the SOMT already has that information from another source.** Mallinckrodt has agreed to accept this recommendation.

4. Downstream Registrant Due Diligence

a. *The SOMT continues to review—and restrict—an increasing number of downstream registrants annually*

12.74 The Monitor has continued to observe a significant increase in the number of downstream registrants the SOMT reviews annually, and the number of such registrants restricted. Mallinckrodt shared with the Monitor Team data reflecting that Mallinckrodt completed more reviews and restricted more downstream registrants in 2023 than it had in any of the prior four years (2019 through 2022). Moreover, based on the number of reviews Mallinckrodt has completed in the first quarter of 2024, Mallinckrodt is again on track to exceed the number of customers reviewed and restricted.

i. Data regarding reviews and restrictions

12.75 The SOMT shared data with the Monitor Team summarizing numbers of pharmacies the SOMT has reviewed and restricted annually, from 2019 through the first quarter of 2024. The Monitor Team used that data to prepare the charts below, indicating the number of

pharmacies restricted annually from 2019 to 2013, and the percentage change in the number of pharmacies reviewed and restricted during the same time period:

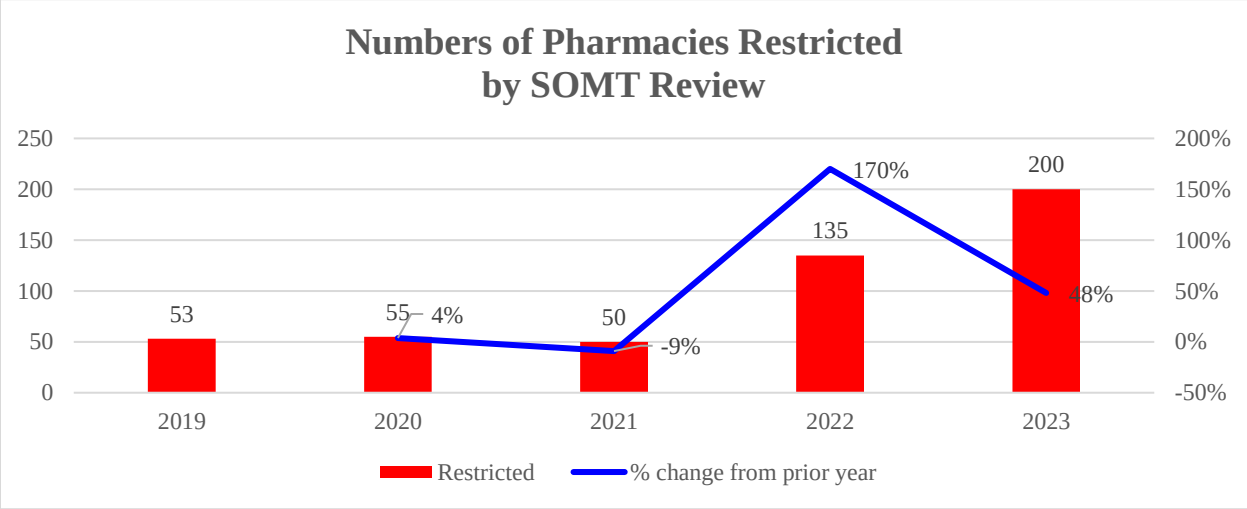

Figure 1.

12.76 As reflected in Figure 1 above, the numbers of restrictions have increased significantly over the course of the monitorship, from 50 pharmacies restricted in 2021, to 200 restricted at the end of 2023, with the biggest percentage increase in pharmacies restricted (year over year) occurring in 2022.

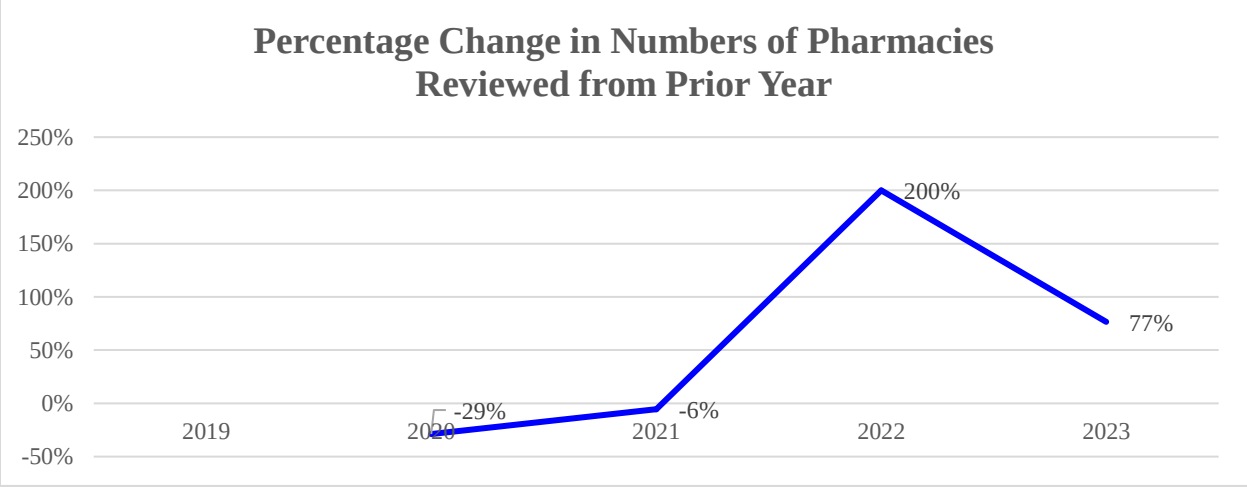

Figure 2.

12.77 The percentages of pharmacies restricted (Figure 1) roughly tracks, proportionately, the percentage change in numbers of pharmacies the SOMT has reviewed over this same timeframe, as depicted in Figure 2. Moreover, data from the first quarter of 2024, if annualized, suggests that 2024 is likely to continue the trend in increasing numbers of pharmacies both reviewed and restricted.

12.78 The Monitor attributes the increase in chargeback reviews and restrictions to two factors. First, the significant increase in chargeback reviews beginning in 2022 coincided with Mallinckrodt's implementation of the indirect customer dashboard, which significantly enhanced Mallinckrodt's SOM capabilities. Second, during the monitorship, Mallinckrodt hired two additional members of the SOMT, who are both former DEA supervisors, and replaced a departing member of the SOMT with the CSC Specialist, who has a data analytics background. As noted elsewhere in this Report, Mallinckrodt is in the process of hiring yet a third new member of the team.

12.79 Notably, although the numbers of downstream registrants reviewed over this period, as well as those restricted, have increased substantially, the proportion of restrictions of those pharmacies as a percentage of pharmacies reviewed has decreased. In other words, the ratio of pharmacies restricted to pharmacies reviewed decreased each year from 2020 through 2023. This is perhaps not surprising, and may be encouraging. During this time frame Mallinckrodt has substantially increased its SOM compliance investment both in terms of human resources and in infrastructure, through the dashboards. Meanwhile, with the advent of additional monitorships, including monitorships involving the "Big Three" distributors, and the high-profile opioid litigation and settlements, it would not be surprising if the industry is taking note of the need for significant compliance improvements, resulting in improved compliance by

pharmacies. The Monitor would expect the number of "bad actors" to decrease over time, and hence the percentage of restrictions to diminish as well. What is important, however, is that the decrease in the percentage of restrictions does not mimic a decrease in numbers of downstream registrants reviewed, and that the SOMT has increased its number of reviews five-fold over this time.

b. *Analysis of the ranking and prioritization of registrants for chargeback review and restriction*

12.80 As the Monitor Team noted in the Eighth Monitor Report, due to the manner in which the dashboard ranks and prioritizes pharmacies, it is possible for pharmacies to be flagged, and even prioritized for review, yet not ranked sufficiently high in the prioritization to be reviewed for restriction. *See* Eighth Monitor Report at 41 ¶¶ 11.38-11.43, 57 ¶ 11.81. For instance, as noted in the Eighth Monitor Report, of the 71 ***retail*** pharmacies ranked in a sample prioritization shared with the Monitor Team, only about 35 (or approximately 50%) were reviewed. And of 127 ***chain*** pharmacies ranked for review, only about 14 (or approximately 11%) were reviewed. This prompted the Monitor's recommendation (Prior Recommendation 8(b)) that Mallinckrodt determine—with the assistance of AGI, Inc. (the designer of the current dashboard) or other consultants as necessary—an appropriate and statistically defensible cutoff in the ranking and prioritization of pharmacies for chargeback reviews.

12.81 Mallinckrodt approached this issue by conducting a parallel analysis of AGI's ranking and prioritization of pharmacies as compared to the ranking and prioritization developed by CSC Manager A. In the Tenth Reporting Period, the CSC Director and CSC Manager A demonstrated this parallel analysis to the Monitor Team via Zoom. Specifically, CSC Manager A showed how the dashboard has been constructed to prioritize pharmacies for review based

upon two factors: (1) Prioritization Factor 1 is the prioritization AGI originally developed; and (2) Prioritization Factor 2 is a separate prioritization CSC Manager A developed.

12.82 Prioritization Factor 1 prioritizes all controlled substances and gives higher priority to substances with multiple "flags." But as CSC Manager A notes, this may elevate certain products in priority even though they are less subject to abuse. Consequently, orders of a buprenorphine product that is used principally for the treatment of opioid addiction (and therefore, given the opioid epidemic, may be in high demand) does not, in the view of CSC Manager A, necessarily warrant the same scrutiny that orders of oxycodone 30 mg do. Thus, under Prioritization 2, CSC Manager A gives greater weight to whether the product is a high-risk product, and to the volume of the product ordered. As a result, an order of oxycodone 30 mg that flags for volume only may be ranked higher than a buprenorphine order with multiple flags.

12.83 The CSC Director and CSC Manager A are satisfied with the results of this analysis and CSC Manager A notes that, from a resource sufficiency perspective, they have recently managed to ensure they are able to review all retail pharmacies in their prioritization over the last several months, particularly with the assistance of the CSC Specialist.

12.84 Though the SOMT did not determine an exact percentage of pharmacies prioritized for chargeback reviews that must be reviewed every month, the Monitor is satisfied with the SOMT's approach, which addresses the issue Recommendation 8(b) raised. That said, the SOMT may want to revisit the issue of statistically valid thresholds in time, as the SOMT program continues to evolve and mature. In the meantime, the SOMT continues to endeavor to ensure pharmacies are being appropriately prioritized for review, and has increased the number of pharmacies prioritized for review that are in fact reviewed, and the Monitor anticipates the

number of pharmacies reviewed each month to increase further with the addition of another CSC Manager.

c. *Development of an additional dashboard using ARCOS data and an ARCOS database of long-term historical industry data*

12.85 While data from the DEA's Automated Reports and Consolidated Ordering System ("ARCOS")[12] has been available to Mallinckrodt, and a component of Mallinckrodt's SOM program for some time, the SOMT has more recently enhanced its integration of ARCOS data into its SOM program, including by developing a third "dashboard" for ARCOS data. *See* Ninth Monitor Report at 35-36 ¶ 10.33-36 (discussing the SOMT's use of ARCOS data).

12.86 Just as ARCOS data can "give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution,"[13] ARCOS data permits companies like Mallinckrodt to

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[12] ARCOS is a data collection system to which manufacturers and distributors report their controlled substances transactions to the DEA, consistent with those registrants' regulatory reporting obligations. *See* U.S. Dep't of Justice, Drug Enforcement Admin., Diversion Control Division, "ARCOS Retail Drug Summary Reports," *available at* https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/arcos-drug-summary-reports.html (hereafter, "ARCOS Retail Drug Summary Reports") (last visited on May 9, 2024); *see also* 21 U.S.C. § 827(d)(1); 21 C.F.R. 1304.33.

As DEA has stated, "ARCOS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level," including to "hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions." *See* U.S. Dep't of Justice, Drug Enforcement Admin., Diversion Control Division, "Automation of Reports and Consolidated Orders System (ARCOS)," *available at* https://www.deadiversion.usdoj.gov/arcos/arcos.html (last visited May 8, 2024). ARCOS stores order data for the distribution of controlled substances only, and only for substance in Schedules I-IV. *See id*. The DEA can utilize this information "for determining quota, distribution trends, internal audits, and other analyses." *See* "ARCOS Retail Drug Summary Reports."

[13] U.S. Dep't of Justice, Drug Enforcement Admin., Diversion Control Division, "Automation of Reports and Consolidated Orders System (ARCOS)," *available at* https://www.deadiversion.usdoj.gov/arcos/arcos.html (last visited May 8, 2024).

analyze the data for their own surveillance and compliance purposes. Accordingly, the third "dashboard" focusing on ARCOS data supplements the existing indirect customer dashboard (which analyzes chargeback data) and direct customer dashboard (which analyzes direct customer orders).

12.87 Analysis with the use of this additional dashboard has helped to reveal additional suspect pharmacies that might not otherwise be "flagged" by the indirect customer dashboard that analyzes data for changes in volume, growth, and per capita usage (for example, if the volume does not appear significant, or there has not been significant growth in orders, but the pharmacy nonetheless warrants review for other reasons the ARCOS data reveals). As demonstrated to the Monitor Team by CSC Manager A, the ARCOS Dashboard has greatly improved Mallinckrodt's existing SOM capabilities, through the use of a number of analyses of metrics discussed below.

12.88 Additionally, Mallinckrodt is archiving the ARCOS data sets that the DEA releases every month. Because the DEA provides six months' worth of data each month, but overwrites the prior six months' worth of data, Mallinckrodt is able to retain a new month of data each month, and develop a historical database for analyzing longer-term trends. These two systems are referred to, respectively, as the "ARCOS Dashboard," and the "ARCOS Database," below.

i. Industry-wide benchmarking through the use of the ARCOS Database

12.89 With the use of industry-wide data from approximately 70,000 pharmacies, the SOMT is able to establish certain informative benchmarks. For example, it is helpful to know—and the SOMT now can know—the answers to questions like:

- what are the average percentages of pharmacies' controlled substance orders that are attributable to oxycodone and hydrocodone?

- within a particular drug family (*e.g.*, oxycodone or hydrocodone), what is the "normal" percentage for a pharmacy to order of a particular formulation of product (*e.g.*, oxycodone 30 mg as a percentage of all oxycodone ordered, or hydrocodone 10 mg as a percentage of all hydrocodone ordered)?

- how common is it for a pharmacy to order only one kind of controlled substance drug family (*e.g.*, only oxycodone), without ordering any other controlled substances in any other Schedules?

- how common is it for a pharmacy to utilize more than three suppliers for the same controlled substance?

12.90 By establishing benchmark metrics for these kinds of issues, the SOMT is able to utilize an additional set of criteria to evaluate flagged chargeback data in the indirect customer dashboard. And, in addition to this use of ARCOS data as a complement to the indirect dashboard's chargeback data, the SOMT can utilize the ARCOS data more proactively, by more efficiently querying the ARCOS Dashboard for Mallinckrodt customers, and identifying outliers based upon the sort of metrics described above.

ii. ARCOS analyses for Mallinckrodt downstream customers

12.91 ***ARCOS growth analysis.*** Where Mallinckrodt was one of several suppliers for a downstream registrant, it was previously more time consuming for Mallinckrodt to determine whether increased orders of Mallinckrodt product reflected a total increase in the pharmacy's orders, or merely a shift in orders to Mallinckrodt from some other supplier. Because ARCOS data totals all supply to a pharmacy, Mallinckrodt could determine if a pharmacy's chargeback data submitted to Mallinckrodt reflects a total increase in orders, or just an increase in Mallinckrodt orders (with orders from other suppliers going down for example), but the SOMT member conducting the chargeback review would have to run a separate query in the ARCOS database, copy the information into a chargeback review sheet, and then repeat that process for every review. Now, ARCOS data is integrated in the ARCOS Dashboard and the SOMT

member can review a downstream registrant's total purchases (as well as the other ARCOS data described below) with a simple click. This helps the SOMT more quickly identify genuine growth concerns as opposed to apparent growth driven by market demand and supply dynamics.

12.92 This analysis will be even richer in time, as the SOMT continues to warehouse incrementally more data with the release, every month, of six months' worth of historical ARCOS data.

12.93 ***ARCOS supplier number analysis.*** A familiar indicator of diversion is a pharmacy's ordering of the same controlled substance from multiple suppliers, presumably in order to evade the threshold trigger of any one of the suppliers. Without ARCOS data, the SOMT would have no transparency into the number of suppliers of product.

12.94 ***ARCOS number of drug families analysis.*** As noted above, aggregated industry-wide ARCOS data permits Mallinckrodt to determine how likely it is that a pharmacy will order only a single controlled substance family (*e.g.*, only oxycodone). As CSC Manager A is quick to recognize, this may be one factor among others that provides "probable cause" to inquire further, not evidence on its own of "guilt beyond a reasonable doubt." As a general rule, however, it is unusual for a pharmacy to order only one controlled substance without more.

12.95 ***ARCOS ratio of product formulation within drug family analysis.*** As is well known, particular product formulations are among the most highly diverted and commonly abused substances. Given the increased detail available to companies with access to ARCOS data—including now, not merely aggregated drug family volumes, but more specific formulations within families—the SOMT is now analyzing what percentage of orders for a particular drug family are attributable to high risk formulations. The SOMT knows, based upon

the voluminous industry-wide data, what "normal" or typical ratios look like, and therefore what ratios are anomalous.

12.96 ***ARCOS distributor disruption analysis.*** As has been repeatedly noted in prior Monitor reports, Mallinckrodt has had mixed results (with one notable exception involving one of the "Big Three" distributors) in obtaining the cooperation of direct customers to share with Mallinckrodt information about those customers' own restrictions of downstream registrants. Accordingly, the SOMT has developed a way to identify likely restrictions of downstream registrants, by Mallinckrodt's direct customers, through analysis of ARCOS data. The SOMT can now analyze changes in suppliers to downstream registrants, and analyze the time lag from the start of a new supplier, as a proxy for a downstream restriction. Because not all direct customers proactively inform Mallinckrodt of restrictions, the SOMT intends to use this data to approach Mallinckrodt's direct customers with requests for additional information.

d. *The SOMT's review and restriction of downstream registrants in the fourth quarter of 2023 and first quarter of 2024*

12.97 In the Tenth Reporting Period, the Monitor reviewed SOMT meeting materials and minutes for October, November, and December 2023 and for January, February, and March, 2024. The results of that review, and the Monitor's related findings from interviews with the CSC Director and CSC Managers A and B, are summarized below.

12.98 Several important themes are apparent from a review of the SOMT's meeting minutes in the Tenth Reporting Period: (1) the Monitor Team continued to observe excessive delays by Mallinckrodt's direct customers in responding to Mallinckrodt's requests for due diligence; (2) in consultation with the Monitor, Mallinckrodt agreed to resolve those open-ended due diligence requests more promptly in the event direct customers continue to delay their responses to Mallinckrodt's requests; (3) the SOMT continues its trend of reviewing and

restricting more downstream registrants annually; (4) the SOMT continues to review a greater number of chain pharmacies; (5) the SOMT continues its ad hoc restrictions of downstream registrants based on information from distributors, and to use that information to improve its own SOM indirect customer dashboard; and (6) analysis of ARCOS data corroborates the reasons Mallinckrodt has provided the Monitor for SpecGx's increased net opioid sales.

i. The Monitor Team continued to observe excessive delays by some "Big Three" distributors in responding to due diligence requests

12.99 Among the consistent themes to which the Monitor has called attention over the course of the monitorship, is the persistent practice of some of Mallinckrodt's direct distributor customers to excessively delay responses to Mallinckrodt's due diligence requests. The Monitor's observations are reflected in numerous prior reports. *See, e.g.*, Ninth Monitor Report at 41 ¶ 10.46-48 and 42 at ¶ 10.50; Eighth Monitor Report at 45-46 ¶ 11.50-52; Seventh Monitor Report at 29-30 ¶ 11.41-42; Sixth Monitor Report at 47-51 ¶ 11.48-11.55; Fifth Monitor Report at 40-41 ¶ 11.48; Fourth Monitor Report at 25 ¶ 11.14; Third Monitor Report at 24 ¶ 11.12. As elaborated upon below, this has now led to an additional Recommendation by the Monitor, which is set forth below. Mallinckrodt agreed to implement this Recommendation, and the Monitor Team has observed the initial implementation of the Recommendation in the February and March 2024 SOMT meeting minutes.

12.100 In the Tenth Reporting Period, the Monitor Team again observed this delay, and sometimes to a degree that seemed excessive. The Monitor Team shared the concern that unduly delayed responses to Mallinckrodt's requests for due diligence on downstream registrants occur against the backdrop of one or more "flags" of some kind that may suggest potential diversion. Indeed, that is, after all, the typical reason for the due diligence request.

12.101 While the Monitor recognizes that Mallinckrodt and the SOMT may not share this perspective—and, in fact, that the Monitor's perspective may be more conservative than the law requires—the Monitor has taken the conservative view that a due diligence request from the SOMT to a distributor creates at least a rebuttable presumption of possible diversion. The SOMT's perspective differs. As has been explained to the Monitor Team, the SOMT's view is not that a rebuttable presumption of diversion exists. Rather, a request for due diligence without a restriction reflects the SOMT's view that there is not a sufficient risk of diversion to warrant a restriction at the time of the due diligence request. Mallinckrodt also points to the fact that instances identified below are outliers and that, of the last approximately 904 pharmacies the SOMT reviewed for restriction (between January 1, 2022 and May 17, 2024), the vast majority—*i.e.*, over 96 percent—of its reviews were resolved within 90 days.

12.102 The Monitor nonetheless views a due diligence request as an indication of some degree of suspicion warranting a prompt response to rebut the suspicion, or else trigger restriction. To be sure, the presumption can be rebutted in any number of ways—and sometimes, even by Mallinckrodt itself, without the support or assistance of the direct customer to which the due diligence request is directed. But the Monitor shared his discomfort with what appeared to be open-ended delays with no definitive endpoint, sometimes lasting as long as nine months, with no prospect that Mallinckrodt would receive the requested due diligence in the future, and no resolution of the inquiry by Mallinckrodt. Given the Monitor's perspective and his view of the rebuttable presumption just described, the Monitor was not comfortable with this continued state of affairs, leading to the recommendation discussed further below, *infra* 68 ¶ 12.112.

12.103 For example, in October through January, delays continued to be significant, with "Big Three" distributors failing to provide substantive responses to the SOMT's requests for due

diligence sometimes for many months on end. Indeed, in some cases, the distributors initially responded, in effect, merely to say "we're looking into it," but their substantive responses remained outstanding for seven or eight months.

12.104 In other cases, the distributors failed to even acknowledge the SOMT's requests for information. For example, as reflected in the October SOMT minutes, the SOMT was still waiting on responses to due diligence requests for six different downstream registrants it had first conveyed to one of the "Big Three" distributors, Distributor C, in August, *i.e.*, approximately three months before the October SOMT meeting. At the October meeting, the SOMT restricted two of those customers.

12.105 The CSC Director and CSC Manager A informed the Monitor that they began meeting monthly with Distributor C the following month, in November 2023, and began sending the distributor a list of pharmacies in advance for discussion at those meetings. The CSC Director and CSC Manager A were optimistic these monthly meetings will lead to more timely communication between Mallinckrodt and Distributor C.

12.106 In the January SOMT minutes the delayed responses to Mallinckrodt's due diligence requests were especially apparent. Several pharmacies remained under SOMT review for periods of as long as seven, eight, nine, and even ten months by the time of the SOMT's January meeting.

12.107 ***Repeated delay relating to a particular pharmacy chain that Mallinckrodt has previously restricted after similar due diligence delays by the same "Big Three" distributor***. A particular example of distributor delay in response to Mallinckrodt's repeated requests for due diligence assistance is enlightening—and not new. In the Eighth Monitor Report, the Monitor discussed Distributor C's slow response to a request for due diligence relating to three

pharmacies, two of which were part of the same chain. *See* Eighth Monitor Report at 46 ¶ 11.51. As noted at the time, CSC Manager A (then known as the "LCSCC") took the unusual step of contacting these pharmacies directly. In contrast to Distributor C, each of the three pharmacies responded the same day, which enabled the SOMT to make a restriction of one of those pharmacies.

12.108 Of late, the incidence of pharmacies within this chain flagging for chargeback restriction review has increased, with several still awaiting an SOMT decision three to five months following the initiation of review. Unfortunately, the same pattern repeats itself: Distributor C commits to giving the chain a closer review; the SOMT continues to check back; product continues to be supplied. The minutes note that Distributor C will merely "attempt to resolve" the SOMT's questions within 90 days of receipt. Given the track record to date, this offers little reassurance that Mallinckrodt's patient waiting will reach some definite conclusion.

ii. Mallinckrodt has agreed to implement the Monitor's recommendation to more promptly resolve open-ended due diligence requests that linger due to the excessive delays of some distributors, and has begun taking steps toward that end

12.109 The Monitor has previously taken the position that it is not his place to set a "bright line" rule for when the SOMT should decide to restrict a pharmacy after a lengthy period of due diligence delay by a distributor. *See, e.g.*, Sixth Monitor Report at 48-49 ¶ 11.51. As the Monitor has previously explained, the Monitor believes the SOMT is entitled to deference in the nuanced factual determinations the SOMT must make in real time, and agrees with the CSC leadership that these decisions are a combination of "art" and "science." Furthermore, Mallinckrodt has delegated this decision making to experienced former DEA professionals whom the Monitor believes are sincerely trying to make the right "calls," which is not a simple task given Mallinckrodt's contractual obligations to supply product, the litigation risk from

prematurely restricting supply, and of course the need for patients to continue to receive medically appropriate medications in the face of market disruptions and supply shortages.

12.110 At the same time, the Monitor finds it hard to accept that delayed responses to relatively simple due diligence requests (directed to a "Big Three" distributor with presumably sophisticated SOM programs) should take as long as they often do, particularly given the Monitor's starting presumption that Mallinckrodt has made its due diligence request in the first place because of a concern for potential diversion of a controlled substance. If such a response is not obtained within some reasonable period of time, it seems to the Monitor the burden shifts back to Mallinckrodt to decide—and to decide with alacrity—whether the remaining information available to the SOMT warrants a restriction or not. Failing to act, while potentially continuing to provide a monthly supply of controlled substances to a downstream registrant flagged many months before, creates an unacceptable risk of diversion in the Monitor's view. And so, while the Monitor sees no basis for altering the position that "rules of thumb" should be made by the professionals with the experience to apply them, the Monitor did take the opportunity to remind Mallinckrodt of the risk that due diligence delays create not only for the distributors, but also at some point for Mallinckrodt, even if those delays originate with Mallinckrodt's direct customers rather than with Mallinckrodt.

12.111 Accordingly, in consultation with Mallinckrodt and its outside counsel, the Monitor obtained Mallinckrodt's commitment to address these open-ended chargeback reviews in order to resolve them, one way or another, more promptly. Specifically, the Monitor understands that Mallinckrodt will adopt a 90-day "rule of thumb"—allowing for appropriate exceptions in the judgment of the SOMT—for deciding whether to restrict a downstream customer to address continued distributors' delay in the provision of due diligence. The Monitor

anticipates that this change in approach will be documented in an updated policy, and looks forward to reviewing that policy in the next reporting period.

New Recommendation 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.

12.112 **The Monitor has observed that Mallinckrodt's direct customers do not all respond to SOMT due diligence requests sufficiently promptly, and that such open-ended requests for assistance could result in ongoing supply of controlled substances to downstream registrants even if Mallinckrodt may have concerns about the potential for diversion by those downstream registrants. Accordingly, the Monitor has recommended that Mallinckrodt independently resolve open-ended due diligence requests within a defined time frame (allowing for appropriate exceptions), and if necessary even before receiving a due diligence response if direct customers do not respond to requests sufficiently promptly. The Monitor similarly recommends that this change be documented in an appropriate SOP.** Mallinckrodt has agreed to this recommendation, which Mallinckrodt is in the process of implementing. The Monitor expects to provide an update regarding the implementation of Recommendation 10(c) in the next reporting period.

12.113 Consistent with Mallinckrodt's commitment, the Monitor Team observed a change in Mallinckrodt's approach to these delays as recently as the February and March 2024 SOMT meeting minutes.

12.114 In the February 2024 SOMT meeting minutes, there are instances where the SOMT restricted a downstream registrant before it received requested due diligence from a "Big Three" distributor. For example, the SOMT initiated a review of a downstream registrant in December 2023 and requested due diligence from Distributor C. However, before Distributor C

provided a response, "due to the context" of the information learned during the review, the SOMT restricted the downstream registrant before receiving any response from Distributor C.

12.115 The March 2024 SOMT meeting minutes reflect a continuing trend: that the SOMT has begun to make decisions about whether to restrict a downstream registrant's product supply, or to take no further action, even while the request for due diligence directed to a distributor remains pending. There were multiple instances of chargeback reviews initiated in January or February 2024, after which the SOMT sent a due diligence request, but then restricted the downstream registrant in March 2024, having not yet received a response from Distributor A, Distributor C, or Distributor D.

12.116 In other instances, it appears the SOMT is addressing much older open due diligence requests that, but for the SOMT's change in approach, might continue to remain unresolved indefinitely. Thus, for example, in March 2024 the SOMT finally restricted a downstream registrant for which it had initially requested due diligence from Distributor D in May 2023 (*i.e.*, approximately 10 months before). In other March 2024 cases, the SOMT finally restricted a downstream registrant for which it had initially requested due diligence from Distributor D in August 2023 (*i.e.*, approximately 7 months before) and restricted a downstream registrant for which it had initially requested due diligence from Distributor C in October 2023 (*i.e.*, approximately 5 months before).

12.117 These instances—where the SOMT has decided to restrict supply, even where the SOMT has not yet received a response to a due diligence request—reflect a positive development, namely the SOMT's stopping of the continued sale of what might otherwise have been diverted product, consistent with the Monitor's recommendation.

12.118 On other occasions, the SOMT has also made decisions to take no further action without having received the requested due diligence from the distributor. The CSC Director has explained that in those instances, the SOMT has concluded that there is likely an innocuous explanation for the orders, such as the SOMT's conclusion the downstream registrant of interest is either a long-term care or hospice facility. In the event the SOMT ever does receive a response to their requested due diligence, it can of course revisit the prior determination. The CSC Director advised the Monitor Team that this change in approach, although clearly in effect, has not yet been memorialized in any new or amended SOP.

12.119 Notwithstanding this recent trend, and Mallinckrodt's agreement to the Monitor's New Recommendation 10(c), the SOMT's "rule of thumb" will still permit exceptions, as the SOMT retains discretion to permit additional time for a due diligence response. For example, there were several instances documented in the March 2024 SOMT minutes (all involving pharmacies that are part of the same chain) when the SOMT decided to afford Distributor C one more month to permit a particular team to provide a due diligence response to a request Mallinckrodt made in October 2023 (*i.e.*, approximately 5 months ago). On the whole, however, it does seem that the SOMT is much more likely to restrict more promptly now than before.

iii. Mallinckrodt continues to issue ad hoc restrictions based on information from distributors, and to use that information to improve its own SOM indirect customer dashboard

12.120 As the Monitor has previously reported, the SOMT continues to restrict a greater number of downstream registrants on an ad hoc basis based on information it receives from the distributors. During an interview with the Monitor, CSC Manager A confirmed the SOMT was not only using this information to restrict Mallinckrodt's downstream registrants, but also completing a full review of each downstream registrant identified in this way to see if there was

anything suspicious about the downstream registrant that Mallinckrodt should incorporate into its dashboard and future reviews of downstream registrants, in order to further refine its SOM program.

iv. In February 2024, Mallinckrodt suspended sales to Distributor B following a due diligence visit

12.121 In February 2024, Mallinckrodt suspended sales of controlled substances to Distributor B. While Mallinckrodt has previously suspended controlled substances sales to direct customers, albeit infrequently, the suspension of such sales to Distributor B was notable given the SOMT had conducted a due diligence visit with Distributor B approximately three months prior to the restriction. As set forth in greater detail *supra* 49 ¶¶ 12.58-59, the SOMT had identified a potential area of concern regarding Distributor B's SOM program based upon a prior conversation with Distributor B's Director of Compliance in September 2023 regarding a particular pharmacy. However, the SOMT did not find sufficient cause to suspend controlled substances sales to Distributor B at that time, or at the time of the November 2023 due diligence visit, but did conclude after the due diligence visit that Distributor B would "require extra vigilance."

12.122 In the months following that visit, Distributor B's responses to the SOMT's due diligence requests not only failed to adequately address concerns regarding Distributor B's downstream customers, but Distributor B's responses affirmatively raised additional concerns for the SOMT. As a result, the SOMT voted to suspend controlled substances sales to Distributor B.

v. The SOMT's analysis of ARCOS data corroborates the explanation for SpecGx's increased net sales

12.123 As noted elsewhere in this Report, the State Attorneys General representative correctly observed, in connection with the Ninth Monitor Report, that SpecGx's net sales increased significantly in 2023. The Vice President of Commercial and Strategy provided a

persuasive and helpful explanation for that increase, as discussed in more detail *supra* 33-38 ¶¶ 12.6-23. The SOMT's observations corroborate the account of the Vice President of Commercial and Strategy. This is because, while investigating the reasons for increases in certain downstream registrants' orders through chargeback data, the SOMT has discovered that although these downstream registrants have increased their orders of Mallinckrodt's products, their total orders among all suppliers have not necessarily increased, and often remain relatively constant, based on ARCOS data. The reason for that is, consistent with the explanation of the Vice President of Commercial and Strategy, the downstream registrants have shifted their orders to Mallinckrodt and away from other potential suppliers. This makes sense, of course, given that the aggregate production quota DEA has allowed for opioids has continued to decrease. Accordingly, an increase in orders to Mallinckrodt can only be explained by a decrease in orders to other potential suppliers. Thus, this market dynamic is consistent with the account the Monitor Team received from the Vice President of Commercial and Strategy.

e. *Annual Controlled Substances Compliance Report Analysis of Highly-Diverted Controlled Substances Utilizing Chargeback Data*

12.124 The Monitor has previously reported on the comprehensive annual review of highly diverted substances, as required by the *Suspicious Order Monitoring Program Social Media and Chargeback Review of Direct Customer and Downstream Registrant* SOP. *See* Eighth Monitor Report at 40-43 ¶ 11.36-43; Fifth Monitor Report at 31-34 ¶ 11.24-29. That policy requires the "LCSCC or designee"[14] to "conduct a periodic review of Chargeback data for the prior twelve-month period and review media and publicly available information to help

[14] During the Ninth Reporting Period, Mallinckrodt changed the title of the Lead CSC Consultant ("LCSCC"). That position is now the Manager, CSC. However, with the new hire during the Ninth Reporting Period, there are now two Managers, who are referred to herein as CSC Manager A (the former LCSCC) and CSC Manager B.

identify Downstream Registrants which may pose a risk of diversion." *See* § 6.3.1. As described in the most recent Annual Review, the purpose of the analysis is to identify "trends, anomalies, and unusual patterns which may not be captured on the Downstream Customer Suspicious Order Monitoring Dashboard and could be indicative of red flags and possible downstream diversion."

12.125 This review (referred to hereafter as the "Annual Review") is separate from the routine monthly (or ad hoc) chargeback reviews, and is performed by CSC Managers A and B.

12.126 The most recent Annual Review, dated December 1, 2023, is a 38-page report titled *Annual Controlled Substances Compliance Report Analysis of Highly-Diverted Controlled Substances Utilizing Chargeback Data—FY 2023*. It was co-authored by CSC Manager A and CSC Manager B and analyzes four different dosages of hydrocodone and oxycodone—the traditionally most highly diverted products—as well as two additional dosages of hydromorphone and methadone. The latest Annual Review covers the time period from October 1, 2022 through September 30, 2023.

12.127 The introduction to the Annual Review provides information regarding the indirect dashboard for review of downstream registrants, which "became partly functional around March 10, 2022, and completely functional by June 1, 2022." The Annual Review notes that the indirect dashboard provides the reviewers (principally, CSC Managers A and B) with "various calculations for overall volume, growth, and per capita utilization of each controlled substance SpecGx manufactures," and also "flags certain pharmacies that may be purchasing a limited portfolio of controlled substances as well as pharmacies that may be utilizing an abnormal number of suppliers to obtain certain controlled substances."

12.128 More recently, the SOMT has integrated ARCOS data to reveal additional insights about potential diversion or suspicious downstream registrants. A reviewer "can now

parse out specific drug family ratios as they relate to the entire ARCOS report as well as specific formulations within a given drug family regardless of who manufactured or distributed the item. For instance, the system will analyze the percentage one drug family makes up of an entire ARCOS report." In other words, a reviewer can determine, from the ARCOS data, what portion of a pharmacy's total controlled substances orders are comprised of oxycodone products, as discussed in detail *supra* 61-62 ¶ 12.95. A reviewer can also determine what percentage of a pharmacy's oxycodone products are comprised of a specific dosage. And, of course, the availability of this industry-wide data enables the SOMT to determine, on average, what typical drug family ratios (in proportion to total controlled substances orders) or particular drug formulations (in proportion to total orders for the drug family) should be. This is helpful for benchmarking, and identifying clear outliers whose orders are not typical of the average ordering practices of most pharmacies.

12.129 The ability to query ARCOS data quickly and obtain a market-wide perspective on the ordering history of downstream registrants is particularly helpful to the SOMT because it helps to distinguish between an increase in orders from Mallinckrodt that are a result of an increase in a pharmacy's total orders, or merely an increase in the percentage of the same amount of total orders that are attributable to Mallinckrodt. Being able to make this distinction is particularly important, given that Mallinckrodt has taken market share from other market players, as noted elsewhere in this Report. *See supra* 35-36 ¶¶ 12.13-15. Thus, as the authors of the Annual Review note, an increase in a pharmacy's orders can "flag" on the indirect dashboard for growth even if this is just a product of an increase in the pharmacy's orders from Mallinckrodt, and not an increase in total orders from all suppliers. This creates false positives, or as the Annual Review authors call them, "false flags," that "take time away from the MCSC that could

have been better utilized in reviewing other potential problems." Thus, "these newly added features" to the indirect dashboard have improved the SOMT's "ability to identify other pharmacies that are in need of review that were not flagging previously on the system."

12.130 The Annual Review also notes the addition of a second CSC Manager to participate in these reviews, but observes that "[f]ull distributor cooperation and timeliness of distributor reviews remains one of the largest hurdles faced by SpecGx Compliance in making prompt and efficient decisions regarding the need for restriction," which leaves the SOMT "at the mercy of the distributors themselves to provide other relevant information in a timely manner that is crucial in making informed decisions regarding chargeback restrictions." This issue is discussed elsewhere at greater length in this Report. *See supra* 63-66 ¶¶ 12.99-108.

12.131 Finally, the Annual Review has once again served as a useful check on the accuracy of the SOMT's reviews, by confirming that some of the outliers identified in the Annual Review analysis were already reviewed by the SOMT in the normal course, while others had not been identified for review. CSC Managers A and B committed, in the Annual Review, to reviewing a portion of these unreviewed pharmacies. The Monitor Team was able to confirm some instances of follow-up review based upon the Annual Review's identification of the pharmacies' oxycodone 30 mg orders and oxycodone 15 mg orders. In the case of the top twenty customers for volume of oxycodone 15 mg orders (for all customer segments), fifteen out of the twenty pharmacies identified in the Annual Review had already been reviewed by the SOMT; a CSC Manager reviewed the ARCOS data of the remaining five pharmacies and found nothing of concern. But in the case of the top twenty customers for volume of oxycodone 15 mg orders for just independent retail pharmacies, one of the identified pharmacies not yet reviewed was reviewed and restricted.

f. *Other notable improvements to review and analysis of chargeback data*

12.132 ***Chargeback auditing report.*** CSC Manager A shared with the Monitor Team that he has developed a "chargeback auditing report" to ensure that Mallinckrodt's sales management system does not continue to process chargeback requests for sales to restricted downstream registrants.

12.133 ***Chargeback report automation.*** CSC Manager A is working with Mallinckrodt's IT Department to deploy a program that will pre-populate the review summaries CSC Managers A and B (and sometimes the CSC Specialist) prepare in connection with the SOMT's review of chargeback restrictions and reinstatement requests before each monthly meeting. If these summaries are able to be automatically populated with relevant data and information, CSC Manager A is optimistic this will significantly reduce the time necessary to prepare each review. He intends to pilot the program with state pharmacy board licensing information from Texas and Florida.

5. Other SOM-related Issues

a. *Government Communications Log*

12.134 The Operating Injunction requires Mallinckrodt to "provide full cooperation and assistance to any federal, state or local law enforcement investigations of potential diversion or suspicious circumstances involving Opioid Products." Operating Injunction § G ¶ 3. As previously reported, *see* Fifth Monitor Report at 34-36 ¶ 11.30-33, the Audit Plan requires

Mallinckrodt to produce the government communications log ("Communications Log") the SOMT maintains under the *SOM Program Review of Direct Customer Orders* SOP.[15]

i. Government inquires in the fourth quarter of 2023 and the first quarter of 2024

12.135 In assessing Mallinckrodt's compliance with the Operating Injunction's requirement to provide law enforcement assistance, the Monitor Team reviewed the entries in Mallinckrodt's Communication Log for the fourth quarter of 2023 and the first quarter of 2024 and related correspondence concerning inquiries that appear to concern Opioid Products, excluding medications typically prescribed for addiction treatment.[16]

12.136 Of the 55 government inquiries received in the fourth quarter of 2023, seven related to various Opioid Products. Of those inquiries, four were from the DEA, two were from the FDA, and one was from the Federal Bureau of Investigation. In each instance, Mallinckrodt provided a timely and appropriate response.

12.137 Of the 104 government inquiries received in the first quarter of 2024, eleven related to various Opioid Products. Of those inquiries, five were from the DEA, five were from the FDA, and one was from a state board of pharmacy. In each instance, Mallinckrodt provided a timely and appropriate response.

12.138 One of the inquiries from DEA in the first quarter of 2024 was an administrative subpoena seeking, among other things, all SORs for a direct customer and communications with

[15] Section 6.1.3 of the SOP requires Mallinckrodt to respond to routine shipping history requests from the DEA and other law enforcement agencies within 24 hours of receipt, and to document those requests. The CSC Senior Manager maintains the Communications Log.

[16] The Operating Injunction's definition of Opioid Products excludes (1) "medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as 'their indications and usage,'" and (2) methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities. *See* Operating Injunction § I.Q.

that customer regarding suspicious orders during a multi-year time period. Although the subpoena did not specifically reference the direct customer's purchase of any Opioid Product, because the SORs for that (and any) direct customer could conceivably include flagged orders for Opioid Products, the Monitor Team asked Mallinckrodt to provide additional information about its response to the subpoena. In response, Mallinckrodt's outside counsel represented that Mallinckrodt had produced, in a timely manner, all non-privileged documents responsive to that subpoena that were identified through a reasonable search. The Monitor Team will determine whether any follow-up or further review of Mallinckrodt's production is necessary in the next reporting period.

ii. *Disclosure of Government Communications to Monitor* SOP

12.139 In the Ninth Reporting Period, Mallinckrodt disclosed its receipt of subpoenas from the U.S. Attorney's Office for the Western District of Virginia discussed *infra* 92-93 ¶¶ 12.179-182. As a result of Mallinckrodt's disclosure of those subpoenas, the Monitor Team revisited the terms of Mallinckrodt's *Disclosure of Government Communications to Monitor* SOP related to the sharing of subpoenas and other requests for information from a government body with the Monitor.

12.140 Under the SOP, Mallinckrodt must inform its Legal Department of any "subpoenas, civil investigative demands, or other requests for information" directed at Mallinckrodt and related to Opioid Products that are served upon it by the federal government or any state. However, Mallinckrodt is not required to disclose its receipt of such documents to the Monitor or to share those documents with him. Rather, the SOP only requires the Legal Department to share subpoenas and other requests for information from a government body with the Monitor "upon request."

12.141 Given the SOP does not mandate the disclosure to the Monitor of subpoenas and other requests for information, the Monitor Team requested a conference with the Associate General Counsel and Mallinckrodt's outside counsel to inquire about any such subpoenas or requests that had not already been shared with the Monitor. During that conference, the Associate General Counsel and outside counsel confirmed that: (1) all subpoenas, civil investigative demands, or other requests for information directed at Mallinckrodt and potentially implicating the Operating Injunction's terms had been shared with the Monitor; and (2) Mallinckrodt would continue to share any such subpoenas and other requests for information with the Monitor ***promptly after receipt***, rather than upon request.

12.142 In order to formalize Mallinckrodt's practice of sharing such documents with the Monitor, the Monitor Team revised the Audit Plan to require Mallinckrodt to produce "[a]ll government communications, government subpoenas, civil investigative demands, government requests for information, or government lawsuits involving Mallinckrodt as a defendant, target, or subject of an investigation, that are related to the sale, promotion, distribution, or disposal of any Opioid Product." The Monitor also suggested that Mallinckrodt revise the SOP to include similar language.

b. *SOM-related TrackWise Entries*

12.143 In the Sixth Monitor Report, the Monitor recommended that any evidence of diversion risks appearing in the TrackWise inquiry and complaint logs (discussed *supra* 11-12 ¶¶ 7.11-15) be escalated by the Associate General Counsel (or her designee) to the CSC Director for his review and included in SOMT pharmacy reviews, as appropriate (*see* Prior Recommendation 6(f)). Thereafter, the Monitor amended the Audit Plan to require Mallinckrodt to provide, on a quarterly basis, copies of any inquiries elevated to the CSC Director and documents reflecting the outcome of any related investigation.

12.144 During the Tenth Reporting Period, the Monitor also conducted an independent review of the TrackWise inquiries and complaints in the fourth quarter of 2023 and the first quarter of 2024 for SOM-related entries evidencing possible diversion risks.

12.145 Since Mallinckrodt implemented Prior Recommendation 6(f), the Associate General Counsel has not identified any TrackWise entries evidencing the potential risk for diversion that would necessitate the CSC Director's review. However, she informed the Monitor that several TrackWise entries were escalated to the CSC Director, as well as to other members of management, in the fourth quarter of 2023 and the first quarter of 2024 as a matter of course. Based on the Monitor Team's review of the TrackWise data, the Monitor is satisfied that, of the ten complaints the CSC Director investigated during those quarters, the CSC Director satisfactorily investigated those complaints, despite the limited information contained in the complaints. The Monitor Team did not identify any other complaints or inquiries appearing to warrant the CSC Director's review.

c. *Distributor C Core Distribution Agreement*

12.146 After the SOMT began regular meetings with their counterparts at Distributor C in the fall of 2023, SpecGx LLC and Distributor C entered into a contract for certain branded products, which specifies how Mallinckrodt's due diligence requests to Distributor C will be handled. *See* Ninth Monitor Report at 39-40 ¶ 10.44. Given that this particular contract relates to branded products (including one branded but not promoted Opioid Product), it does not pertain to generics products, although the contract may provide the basis for applying the SOM notice and resolution provisions to additional contracts between Mallinckrodt and Distributor C for generic Opioid Products.

12.147 Mallinckrodt shared with the Monitor Team a redacted version of the contract, which is dated December 29, 2023 and became effective on January 1, 2024. The contract

contains a section titled "Suspicious Order Monitoring Notice and Resolution Process" (the "Resolution Process"), describing in some detail how Mallinckrodt and Distributor C will resolve the SOMT's due diligence requests. Under the Resolution Process, Mallinckrodt must provide written notice of any concerns regarding the ability of a customer of Distributor C "to provide effective controls against the potential diversion of Controlled Substances." Upon Distributor C's receipt of such a notice, Mallinckrodt and Distributor C are to conduct good-faith discussions about the concern(s) and exchange information to enable Mallinckrodt to conduct a due diligence review. The Resolution Process expressly provides that "[i]t is anticipated that such discussions will conclude within ninety (90) days of [Distributor C]'s receipt of [Mallinckrodt's] written notice . . . at which time [Mallinckrodt] will advise [Distributor C] whether its concerns regarding the Applicable Customer have been resolved." If Distributor C suspends or terminates distribution of Mallinckrodt's product ***to a customer of Distributor C that Mallinckrodt previously identified to Distributor C***, Distributor C agrees to provide prompt written notice of the termination to Mallinckrodt. Notably, this suggests that Distributor C, unlike one of the other "Big Three" distributors, will not proactively share with Mallinckrodt restrictions of customers that Distributor C implements on its own initiative, absent a prior request for due diligence from Mallinckrodt.

12.148 The principal benefit of this contractual language—even if it does not yet apply to generic products—is that the anticipated 90-day resolution should, in time, become the de facto benchmark to enable Mallinckrodt to restrict downstream registrants if Distributor C continues to unduly delay providing responses to Mallinckrodt's requests for due diligence. (In fact, as noted elsewhere in this Report, *see supra* 68-69 ¶¶ 12.114-15, Mallinckrodt has begun to implement

this 90-day time frame in recent decisions to restrict downstream registrants where Distributor C has still not provided a timely due diligence response.)

12.149 That said, the provisions of this contract are not as expansive as the provisions Mallinckrodt previously proposed to Distributor C (at the Monitor's recommendation) as long ago as January 2022. Indeed, in the Fourth Monitor Report, the Monitor noted:

> Mallinckrodt has implemented [the Monitor's] recommendations by sharing with its three largest distributor customers—the so-called "big three" (namely, Amerisource Bergen, Cardinal Health, and McKesson)—a letter agreement proposing revisions to Mallinckrodt's existing supply agreements in order to obtain the distributors' agreement and cooperation on a number of issues. The letter agreement . . . requires distributors to use best efforts to cooperate in detecting and preventing the diversion of controlled substances by: (1) suspending or terminating the distribution of SpecGx's controlled substances to any recipient that SpecGx informs the distributor it is restricting (per Recommendation 2(d)); (2) responding promptly to SpecGx's requests for information related to the distributor's orders, sales, and distribution of SpecGx's products (per Recommendation 2(h)); and (3) notifying SpecGx if the distributor suspends or terminates the distribution of Controlled Substances to the recipient within five days after the suspension or termination.

Fourth Monitor Report at 24 ¶ 11.13 (filed on January 19, 2022).

In contrast, Mallinckrodt was able to reach such an agreement on the above terms with one of the other "Big Three" distributors in a letter dated February 28, 2022 that was executed on April 26, 2022. *See* Sixth Monitor Report at 36 ¶ 11.18. That letter agreement has been in effect for two years, and has borne significant results. The Monitor hopes that Distributor C will agree to similar terms on a broader basis so that Mallinckrodt (and Distributor C) can realize the same compliance benefits Mallinckrodt has achieved through its agreement with Distributor E.

d. *Plans for hiring an additional CSC Manager*

12.150 Despite the fact that relevant data is more readily available and that the analysis of that data has become more automated, human resources are still required to meaningfully

interpret the voluminous information amassed by the dashboards—all of which informs the SOMT's day-to-day determinations about the supply of Mallinckrodt's products. Although Mallinckrodt has increased its deployment of human resources over time, through the hiring of CSC Managers A and B, the CSC Director advised that Mallinckrodt intends to hire a third CSC Manager this summer to provide additional data analysis assistance. The CSC Director informed the Monitor that he hopes hiring an additional CSC Manager will allow CSC Manager A, and other members of the SOMT, to perform the type of analysis underlying the Annual Review, described *supra* 72-75 ¶¶ 12.124-131, more frequently. As the Monitor has reported previously, those "deep dives" (as described by the CSC Director) give the SOMT insight into potentially concerning trends that are not readily apparent from daily review of the dashboards and have led Mallinckrodt to restrict downstream registrants that were not necessarily flagged by the indirect customer dashboard. *See, e.g.,* Eighth Monitor Report at 40-41 ¶ 11.38-40.

e. *Additional dosages of morphine sulfate (30 mg and 15 mg)*

12.151 A representative of the State Attorneys General inquired about a statement in the Ninth Monitor Report regarding what it described as a new "indication" for Mallinckrodt's morphine sulfate product. Specifically, the Ninth Monitor Report stated that "in the third quarter of 2023 Mallinckrodt released a new indication for its Morphine Sulfate Tablets in 15 mg and 30 mg dosages." Ninth Monitor Report at 48 ¶ 12.4. The representative requested additional information.

12.152 Mallinckrodt's outside counsel clarified that rather than a new ***indication***, Mallinckrodt had added two new generic ***products*** to its product catalog. Outside counsel further explained that, on August 21, 2023, Mallinckrodt had received approval for its Abbreviated New Drug Application—*i.e.*, approval to market the generic version of the product—for Morphine Sulfate Tablets Immediate Release ("IR") in 15 mg and 30 mg dosages,

and that the indication for those products was the same as the indications for the reference listed drug ("RLD"), other than the indication for pediatric use (which Mallinckrodt's generic versions of these dosages do not include). Outside counsel shared the drug label for the RLD with the Monitor Team, in comparison to the label for the Mallinckrodt products, reflecting their approved indications.

12.153 For confirmation, counsel pointed the Monitor Team to the FDA website identifying the changes in labelling over time.[17] Counsel further advised that, because generic product labels must generally track the labels of the RLD product, Mallinckrodt was in the process of submitting a supplemental application to amend its own product label, and subsequently shared the amended label with the Monitor Team.[18] Upon review, but for the difference in pediatric indication noted above, the labels do appear to be identical in terms of their indications and usage instructions.

f. *Conversations with Other Monitors*

i. Meeting with the Purdue Monitor

12.154 During the Tenth Reporting Period, the Monitor Team met with the independent Monitor of Purdue Pharma L.P. ("Purdue"), Steve Bullock (the "Purdue Monitor"), to discuss his

[17] *See* U.S. Food and Drug Admin., "Drugs@FDA: FDA-Approved Drugs" (navigate to "Approval Date(s) and History, Letters, Labels, Reviews for NDA 022207" and then "Supplements"), *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022207 (last visited Mar. 17, 2024).

[18] *See* Daily Med, SpecGx LLC label, *available at* https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8b69f67f-30b3-4982-953e-5a4b87ec6ac6 (last visited May 19, 2024).

monitorship, issues addressed in his publicly filed Sixteenth[19] and Seventeenth[20] Monitor Reports, and areas of overlap and mutual interest between the Purdue and Mallinckrodt monitorships.

12.155 ***Direct customer due diligence response times.*** The Monitor Team and the Purdue Monitor discussed the recurring issue of direct customer response times in response to requests by Mallinckrodt and Purdue for due diligence, as discussed in greater detail *supra* 63-66 ¶¶ 12.99-108. As the Purdue Monitor explained, when Purdue makes a due diligence request to a direct customer concerning a specific downstream registrant of interest, Purdue's initial request is for the direct customer to provide a response within 30 days of Purdue's request. After the initial 30 days have elapsed, Purdue may give a customer an additional 30 days. Following that 60-day period, Purdue may afford its direct customers another 15 days to provide due diligence for "good cause." If granted, Purdue concludes its due diligence review after no more than 75 days. If Purdue does not receive a substantive due diligence response satisfying its concerns by the 60th day—or 75th day if good cause exists—Purdue requests that the direct customer no longer ship its products to the downstream registrant. Critically, "good cause" requires a good-faith effort on the part of the direct customer; a cursory response that the direct customer is simply looking into the due diligence is not a legitimate response to warrant the 15 additional days.

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[19] *In re: Purdue Pharma L.P., et al.*, No. 19-23649, Dkt. 6023 (S. D. N.Y. Bankr., Nov. 20, 2023), *available at* https://www.maine.gov/ag/docs/2023.11.20%2016th%20Monitor%20Report.pdf (last visited May 8, 2024)

[20] *In re: Purdue Pharma L.P., et al.*, No. 19-23649, Dkt. 6221 (S. D. N.Y. Bankr., Feb. 20, 2024), *available at* https://www.maine.gov/ag/docs/2024.02.20%2017th%20Monitor%20Report.pdf (last visited May 8, 2024).

12.156 As noted elsewhere in this Report, Mallinckrodt has "rules of thumb" for due diligence response times, and until now has been more inclined to permit a direct customer additional time to provide due diligence. As noted above, however, the Monitor and Mallinckrodt have agreed that it is appropriate to establish more firm deadlines for the provision of due diligence in response to Mallinckrodt's requests. *See supra* 67 ¶ 12.111. Delayed provision of due diligence information has been a long-standing concern, extending as far back as the Sixth Monitor Report. *See* Prior Recommendation 6(e) (noting that Mallinckrodt should "[r]aise 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").

12.157 ***Agreements with Distributors.*** The Monitor Team noted with interest the Purdue Monitor's statement in a recent report that "[a]ll three of the principal distributors have now agreed to cease shipping Purdue controlled substances to Designated Downstream Customers, upon request made by Purdue." *See Seventeenth Report of Purdue Monitor* at 19. This statement was notable because—with the exception of its agreement with Distributor E—Mallinckrodt had not been able to secure similar agreements with the other two "Big Three" distributors, despite prior efforts, and the Monitor's Prior Recommendation 2(d) that Mallinckrodt "[u]se best efforts to ensure chargeback restrictions restrict not only chargeback payments, but also the supply of Opioid Products to a restricted pharmacy." The Monitor Team shared this development with Mallinckrodt and its counsel, for Mallinckrodt's use in further discussions with Distributors C and D.

12.158 ***Site Visits to Customers.*** The Monitor Team and the Purdue Monitor also discussed the efforts by the SOMTs of Purdue and Mallinckrodt to conduct customer site visits.

The Purdue Monitor indicated that Purdue typically has two members of its SOMT visit each of its direct customers once every three years. *Seventeenth Report of Purdue Monitor* at 11. The Purdue Monitor explained that Purdue also requires a site visit before shipping product. The Monitor Team notes that Mallinckrodt does not have a similar policy. The Purdue Monitor reports that this frequency of physical site visits helps to build the relationship between SOMT members and Purdue customers.

ii. Introduction to the Teva Monitor

12.159 On April 1, 2024, the Monitor Team met with the monitor of Teva Pharmaceuticals, Ltd. ("Teva"), Gil Soffer (the "Teva Monitor"). The Teva Monitor was appointed in connection with Teva's settlement of national opioid litigation. Like the Monitor, the Teva Monitor is charged with monitoring Teva's ongoing compliance with the injunctive relief agreed to by the settling parties and must issue reports evaluating Teva's compliance with its obligations.

12.160 During this meeting, the Monitor and the Teva Monitor introduced themselves and their respective teams. The Monitor further explained, in general terms, his methodology for auditing Mallinckrodt's compliance with its Operating Injunction terms and offered to make himself available as a resource should the Teva Monitor have any questions as the Teva monitorship progresses.

g. *Employee Departures*

12.161 During the Tenth Reporting Period, Mallinckrodt advised the Monitor Team of the departure of various employees. On occasion, the Monitor thought it would be prudent to interview certain of these employees, particularly because the departure of an employee offers an additional opportunity to obtain a candid assessment from the interviewee. As described below,

the Monitor was reassured by his interviews of two such employees in the Tenth Reporting Period.

i. Employee Departure – Senior Compliance Consultant

12.162 During the Tenth Reporting Period, Mallinckrodt's outside counsel advised the Monitor of the departure of a Senior Compliance Consultant (defined *supra* 40 ¶ 12.31 as "Employee A") at Mallinckrodt's Webster Groves Plant. The Monitor Team interviewed Employee A to discuss her experience at Mallinckrodt, her reasons for leaving the Company, and her thoughts on what if anything the Monitor Team should address or investigate further.

12.163 Employee A voluntarily retired from Mallinckrodt in March 2024 after a nearly 47-year career with the Company spanning several positions. Among other areas, Employee A had worked in her most recent role, relating to DEA compliance issues, since 1999. Previously, she had worked in procurement, where she had responsibility for ordering narcotic raw materials and applying for import permits. She also had responsibility for supplier contracts in the 1990s. In 1999, with the formation of the Company's DEA Compliance Department, she moved from a procurement focus to the DEA Compliance Department, while maintaining some responsibility for working with the Procurement Director to enter purchase orders for narcotic raw materials.

12.164 In her most recent role as Senior Compliance Consultant, Employee A's responsibilities included supporting the St. Louis plant in procuring narcotic raw materials, attending to import permits, coordinating shipments into the plant, tracking shipments into the United States, and reporting on these imports. Additionally, Employee A was responsible for reporting Mallinckrodt's ARCOS data to the DEA, which she did monthly by downloading files with order entries and inventory transactions and submitting that information to DEA.

12.165 Employee A also applied for Mallinckrodt drug quota from the DEA, issued DEA 222 Forms for any shipments leaving the Webster Groves facility, and managed the destruction, annual inventory, and year-end reports for the Webster Groves facility.

12.166 Employee A reported that her primary concern relates to issues arising from the DEA's changes to the process for requesting and obtaining quota. Employee A believed the DEA's quarterly quota request procedure (since amended) would create significant challenges for Mallinckrodt in obtaining adequate procurement quota and manufacturing quota. Additionally, she anticipated her St. Louis colleagues would struggle to manage quarterly quota requests without additional assistance, given that quota requests are tedious and detailed, and require a lot of work for Employee A's former Manager. (As noted *supra* 41-42 ¶ 12.33, the DEA rescinded the quarterly quota application requirement following the Monitor's interview with Employee A.)

12.167 Employee A said she had no personal concerns about safety or compliance issues and states she has not heard of such concerns expressed by others. She indicated that she had universally positive experiences, including supportive management. Employee A regards the addition of the CSC Director and other SOMT members with extensive DEA experience among the most positive changes to the Company's compliance efforts.

12.168 Employee A's successor is a colleague in the DEA Compliance Department who had been shadowing Employee A.

12.169 Finally, the Monitor Team asked broad questions regarding Employee A's general perception of Mallinckrodt, and whether she had ever been asked to do something she felt was wrong, illegal, or improper. Employee A said she had not, and that if anything, she believes Mallinckrodt is now more stringent than it has ever been. As to why she is leaving, Employee A

stated that the decision to retire was difficult, but she turned 65 years old in January and wanted to retire and pursue other interests while she remains healthy.

12.170 The Monitor Team invited Employee A to contact the Monitor Team in the future if she thought of anything the team did not cover in the interview.

ii. Employee Departure – Executive Director of Manufacturing Excellence and Hobart Site Director

12.171 During the Tenth Reporting Period, Mallinckrodt's outside counsel advised the Monitor of the departure of Mallinckrodt's Executive Director of Manufacturing Excellence and Hobart Site Director ("Employee B"). The Monitor Team sought an interview with Employee B to discuss his experience at Mallinckrodt, his reasons for leaving the Company (and the location responsible for manufacturing finished dose products), and what if anything the Monitor Team should address or investigate further as part of the monitorship's scope.

12.172 Employee B voluntarily departed from Mallinckrodt to pursue a new professional opportunity after having served in his last role for just over one year (from about November 2022 to February 2024). Employee B had previously worked for Mallinckrodt in a consulting capacity as well as in the capacity of an employee at different times. In the aggregate, Employee B worked for Mallinckrodt for approximately 23 years.

12.173 The Monitor Team questioned Employee B regarding his interactions with CSC and SOM in his role as Executive Director of Manufacturing Excellence and Hobart Site Director. Employee B interacted with the Director of CSC remotely and for the most part they worked together on DEA quota issues. Employee B also worked closely with the CSC Senior Manager on a daily basis.

12.174 When asked about any concerns he might have about CSC or SOM issues, Employee B said he had none. He noted there have been many positive changes at Mallinckrodt

since the early 2000s, including relating to accurate record keeping, inventories, more staff within the organization working on compliance and inventory issues, access control, and SOM programs. Employee B described the state of Mallinckrodt's CSC and SOM activity, at the time of his departure, as "at a world-class level."

h. *Internal audit reports related to DEA Requirements for controlled substances*

12.175 As the Monitor previously reported in the Seventh Monitor Report, the CSC Specialist's job responsibilities include conducting various internal audits at Mallinckrodt's Hobart, New York plant and preparing reports detailing her findings. *See* Seventh Monitor Report at 37-39 ¶ 11.63-67.

12.176 Under the Audit Plan, Mallinckrodt agreed to produce the CSC Specialist's reports relating to Mallinckrodt's compliance with DEA requirements, which are often incorporated into its internal policies. These audit reports produced to the Monitor largely relate to Mallinckrodt's record keeping obligations and its practices related to access to, and storage of, controlled substances at Mallinckrodt's facility in Hobart.

12.177 In the Tenth Reporting Period, the Monitor Team reviewed eight internal audit reports the CSC Specialist prepared in 2023. These reports generally detailed the purpose of the audit and the CSC Specialist's relevant findings and pertinent observations. All but one of the reports appear to reflect the CSC Specialist's conclusion that Mallinckrodt was already in compliance with the relevant DEA requirement(s).

12.178 In the remaining report, the CSC Specialist observed access lists for certain vaults had not been updated in accordance with internal policy. However, as the CSC Specialist noted, one of the two access lists had been updated, but was posted on the outside of the door where she could not see it when the vault door was open. The CSC Specialist's finding was based on an

old list she had observed on the inside of the door that had not yet been taken down. After the CSC Specialist spoke with the Security Officer for the relevant vaults, the old list was taken down and the access list for the other vault was updated. The Monitor is satisfied that any corrective action necessary related to these access lists was promptly taken.

i. *Update on Grand Jury Subpoena from the U.S. Attorney's Office for the Western District of Virginia*

12.179 As reported in the Ninth Monitor Report, and as Mallinckrodt disclosed in prior SEC filings, Mallinckrodt received grand jury subpoenas in 2023, in connection with a federal criminal investigation by the U.S. Attorney's Office for the Western District of Virginia. *See* Ninth Monitor Report at 49-52 ¶ 14.1-8. As also noted in the Ninth Monitor Report, Mallinckrodt and its outside counsel have kept the Monitor Team informed regarding Mallinckrodt's productions in response to the subpoenas, and have shared with the Monitor Team the cover letters related to those productions. *See* Ninth Monitor Report at 50-52 ¶ 14.3-8.

12.180 On March 12, 2024, three additional (and largely identical) grand jury subpoenas were issued to Mallinckrodt LLC, Mallinckrodt PLC, and SpecGx. The subpoenas generally relate to purchases of products, and transaction data related to those purchases, by Mallinckrodt's direct customers—*i.e.*, distributors—from July 17, 2017 to the date of production.

12.181 Subsequently, Mallinckrodt, through its outside counsel, advised the Monitor Team in April 2024 of Mallinckrodt's receipt of additional informal requests for information from the U.S. Attorney's Office for the Western District of Virginia on April 18, 2024.

12.182 Mallinckrodt, through its outside counsel, has agreed to share with the Monitor Team the cover letter accompanying any materials produced in response to supplemental requests that the U.S. Attorney's Office directed to Mallinckrodt in April 2024. The Monitor

Team will review that response to determine what aspects, if any, may be relevant to the focus of this Monitorship.

XIII. TRAINING (OI § III.K)

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

13.2 During the Tenth Reporting Period, the Monitor audited Mallinckrodt's compliance with the Operating Injunction's training requirements by reviewing whether: (1) all employees completed their Operating Injunction trainings in 2023; and (2) all employees hired during the first quarter of 2024 completed their Operating Injunction trainings. As noted below, the Monitor Team confirmed both to be true.

1. Trainings for Employees in 2023

13.3 On a quarterly basis Mallinckrodt agreed to provide a list of: (1) any new employees in the groups identified in Section 5.10 of its Compliance Report; (2) the Operating Injunction-related trainings each employee is required to complete; and (3) the dates of completion. Mallinckrodt also agreed to annually confirm all relevant employees had completed each of the Operating Injunction training's components.

13.4 In the Tenth Reporting Period, Mallinckrodt informed the Monitor that the three employees hired during the third quarter of 2023 who had not completed their live training and Operating Injunction quiz completed both requirements in the fourth quarter. *See* Ninth Monitor Report at 46 ¶ 11.10.

13.5 Mallinckrodt also informed the Monitor that all six employees hired during the fourth quarter of 2023, who were required to receive Operating Injunction training, completed each training component.

13.6 Additionally, Mallinckrodt confirmed that all relevant employees had completed each component of their training for 2023.

2. New Employee Trainings in 2024

13.7 In the Tenth Reporting Period, Mallinckrodt identified eight employees hired in the first quarter of 2024 who were required to receive Operating Injunction training. Five of these new employees completed all of the training components in the first quarter of 2024; whereas the remaining three employees completed their board service survey but had not yet attended a live training, reviewed and signed the Operating Injunction policy, or passed the Operating Injunction quiz. The Monitor will confirm that these employees have completed all of the training requirements during the next quarter.

3. Relevant Employees Whom Mallinckrodt Has Determined Are Required to Receive Operating Injunction Training

13.8 The Operating Injunction requires Mallinckrodt to provide "regular training, at least once per year, to relevant employees on their obligations imposed by this Agreement." Operating Injunction § K.1.

13.9 In Mallinckrodt's initial Compliance Report filed on October 12, 2020, the Company identified all officers, teams, and departments it had determined should receive Operating Injunctive training and represented that those employees would receive Operating Injunction training going forward.

13.10 Given Mallinckrodt's restructuring since filing that initial Compliance Report, during the Tenth Reporting Period the Monitor Team asked Mallinckrodt to identify the teams and departments that currently receive training and those teams and departments that do not.

13.11 In response, Mallinckrodt informed the Monitor that the Company had continued to train all officers, departments, and teams that were disclosed in the Compliance Report. In

addition to the employees identified in the Compliance Report, Mallinckrodt informed the Monitor that it has also required the Finance, Human Resources, and Procurement Departments to receive Operating Injunction training. With the addition of those three departments, Mallinckrodt is currently providing Operating Injunction training to all employees other than administrative assistants and manufacturing line workers.

13.12 The Monitor is satisfied that Mallinckrodt has appropriately identified the relevant employees who should receive Operating Injunction training.

4. New Interactive Third-Party Training to Replace the Live Operating Injunction Training

13.13 During the monitorship, Mallinckrodt has required all relevant employees to attend an annual live Operating Injunction training that the Compliance Department develops and presents. However, as the Monitor previously reported, Mallinckrodt informed the Monitor Team that it intended to engage a third-party vendor to provide that component of the Operating Injunction training instead. Mallinckrodt anticipates that using a vendor will allow it to conduct a one-on-one computer-based training that is more interactive than the large group trainings it has conducted to date. Indeed, both Mallinckrodt's Compliance Department and the Monitor Team agree that such interactive training is important to increase employees' engagement and participation in the training. *See* Ninth Monitor Report at 47 ¶ 11.13.

13.14 During the Tenth Reporting Period, Mallinckrodt provided the Monitor Team with a version of an interactive training prepared by a Mallinckrodt vendor on an unrelated topic, for illustrative purposes. The Monitor Team reviewed the training and concluded that the training was an appropriate model for the Operating Injunction training.

13.15 Mallinckrodt subsequently informed the Monitor Team it had engaged that vendor to develop a similar interactive Operating Injunction training, and Mallinckrodt and the vendor

held an initial project meeting in April 2024. Mallinckrodt expects the vendor to complete the new interactive training by the third quarter of 2024. Mallinckrodt further informed the Monitor Team that it has not made any changes to the Operating Injunction quizzes for 2024 because it plans to prepare any update to the quizzes in conjunction with the implementation of the interactive training.

13.16 In the next reporting period, the Monitor Team will review the new interactive training and any updated materials Mallinckrodt prepares for the training.

XIV. CLINICAL DATA TRANSPARENCY (OI § IV)

14.1 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.

14.2 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.[21] *See* First Monitor Report at 17 ¶ 64. Any research proposals submitted through Vivli will be reviewed for scientific merit by an independent review panel.

14.3 In response to the Monitor's request in the Audit Plan, Mallinckrodt confirmed there were no requests for access to this clinical data during the fourth quarter of 2023 or the first quarter of 2024.

14.4 Likewise, there were no new Mallinckrodt Opioid Products, or indications for existing products, in the fourth quarter of 2023 or the first quarter of 2024.

[21] Additional information regarding Mallinckrodt's clinical data archive is available at https://vivli.org/ourmember/specgx-llc-a-subsidiary-of-mallinckrodt-plc/ (last visited May 8, 2024).

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

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

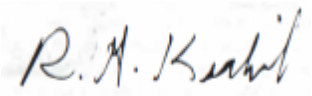
15.1 Section V of the Operating Injunction required Mallinckrodt to produce certain documents to the Settling States within nine months of October 12, 2020 (*i.e.*, on or before July 12, 2021). Mallinckrodt complied with this requirement as described in prior Monitor Reports. *See, e.g.,* Sixth Monitor Report at 69-70 ¶ 14.1-5. There are no further updates at this time.

XVI. CONCLUSION

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

* * *

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



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

EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE TENTH MONITOR REPORT DATED MAY 24, 2024[1])

I. FIRST MONITOR REPORT (4/26/2021)

No recommendations.

II. SECOND MONITOR REPORT (7/23/2021)

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
1.	**2(a)**	Modernize and enhance the SOM function using big data analytics, artificial intelligence, and automated processes and algorithms.	Implemented
2.	**2(b)**	Select one or more candidates with suitable qualifications, and with flexibility to hire from outside the Hobart, New York market, to fill the vacant role of Compliance Auditor / Analyst.	Implemented
3.	**2(c)**	Consider the sufficiency of both short-term and long-term human resource allocation in the SOM function.	Implemented and Ongoing
4.	**2(d)**	Use best efforts to ensure chargeback restrictions restrict not only chargeback payments, but also the supply of Opioid Products to a restricted pharmacy.	Implemented and Ongoing
5.	**2(e)**	Use best efforts to obtain timely provision of chargeback data from direct customers.	Implemented and Ongoing

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

6.	**2(f)**	Evaluate the feasibility of reducing the turnaround time for obtaining, analyzing, and reporting on chargeback data.	Implemented
7.	**2(g)**	After analyzing turnaround times for chargeback reviews and restrictions, amend relevant SOPs to memorialize firm timelines.	In Progress
8.	**2(h)**	Incorporate all existing data sources available to Mallinckrodt, and use best efforts to reach agreements with direct customers to provide more detailed retail data to conduct more effective chargeback reviews.	Implemented and Ongoing
9.	**2(i)**	Assess the potential value of additional factors to consider in conducting chargeback reviews.	Implemented
10.	**2(j)**	Continue actively pursuing opportunity for a public-private "clearinghouse" concept, in collaboration with the U.S. Drug Enforcement Administration and industry partners.	In Progress
11.	**2(k)**	Amend relevant SOPs to create a chargeback review task checklist, provide an audit trial, and ensure second-level review and approval.	Implemented
12.	**2(l)**	Memorialize and routinize the periodic review of (1) pharmacies reviewed but not restricted, and (2) pharmacies that are reinstated.	Implemented
13.	**2(m)**	Re-evaluate direct customer order thresholds with the assistance of Analysis Group, Inc. (AGI).	Implemented
14.	**2(n)**	Re-evaluate chargeback thresholds with the assistance of AGI.	Implemented
15.	**2(o)**	Determine whether flagging and releasing direct customer orders can be refined to better identify potentially suspicious orders, in collaboration with AGI.	Implemented
16.	**2(p)**	Implement two-level review and approval for release of flagged orders.	Implemented
17.	**2(q)**	Memorialize the confidentiality of thresholds, consistent with current practice.	Implemented
18.	**2(r)**	Establish minimum standards and criteria for conducting retail pharmacy due diligence, potentially with the advice and input of a third-party compliance consultant.	Implemented (As Later Modified)

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

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

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

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

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

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

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

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

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
29.	**6(a)**	Include explicit references to the Operating Injunction in Sales Compensation Plans for future years.	Implemented
30.	**6(b)**	Provide additional training to the Human Resources Department (by Mallinckrodt's legal counsel) to prevent consideration of improper incentives in bonus recommendations.	Implemented
31.	**6(c)**	Ensure greater consistency among direct customer audit reports, and more fulsome follow-up where necessary to obtain compliance assurances.	Implemented
32.	**6(d)**	Share with the SOMT, before each monthly meeting, CSC Director's separate tracking list of pharmacies pending due diligence review to ensure tabled pharmacies do not evade future review.	Implemented
33.	**6(e)**	Raise with the "Big Three" distributors, the persistent issue of delayed provision of due diligence, which in turn delays Mallinckrodt's chargeback restrictions, potentially affecting the diversion of Opioid Products.	Implemented and Ongoing
34.	**6(f)**	Ensure evidence of diversion risks appearing in the TrackWise inquiry and complaint logs escalated by the Associate General Counsel (or designee) is reviewed and included in SOMT pharmacy reviews, as appropriate.	Implemented

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

Section 9 – Lobbying Restrictions (OI § III.D)			Implementation Status
35.	**8(a)**	Provide annual training to Mallinckrodt's external lobbyists, focusing on the Operating Injunction's lobbying-related provisions.	Implemented
Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			
36.	**8(b)**	Determine an appropriate statistically defensible marker for the ranking and prioritization of chargeback reviews, so as to determine which, if any, flagged pharmacies present the lowest risk of diversion and therefore may not warrant review.	In Progress

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

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