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

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EIGHTH 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 Eighth Monitor Report covers the period from the filing of the Seventh Monitor Report on December 1, 2022, to the present (the "Eighth Reporting Period").[1] The Eighth Monitor Report: (1) provides an update on Mallinckrodt's implementation of the Monitor's recommendations in prior reports; (2) makes new recommendations; (3) reviews the Monitor's actions during the Eighth Reporting Period, including the review of documents and data, and interviews or meetings with Mallinckrodt employees; (4) summarizes observations from the Monitor's fact-finding; and (5) describes anticipated next steps in future reporting periods.

1.2 During the Eighth Reporting Period, the Monitor 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 the Eighth

[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. Accordingly, this Eighth Monitor Report is being submitted 180 days after the submission of the Seventh Monitor Report. The Monitor provided an interim update to both Mallinckrodt and representatives from the Ad Hoc Committee, and will continue to make himself available in future to provide similar interim updates.

[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.

Reporting Period Mallinckrodt provided over 525 files (consisting of 2.71 GB of documents and data).

1.3 A summary of the Monitor's recommendations to date, including the recommendations in this report, appears in the chart attached as **Exhibit 1**.

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

* * *

1.5 Mallinckrodt's employees, 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 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. Mallinckrodt's confirmed and now operative Plan of Reorganization incorporates the Operating Injunction. *See* Case No. 20-12522, Dkt. No. 6660-2.

[3] *See* Mallinckrodt's "Corporate Compliance" webpage, *available at* http://www.mnk.com/corporate-responsibility/corporate-compliance/ (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.

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

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. As noted above, *see* 2 ¶ 1.4 n.3, *supra*, the Sixth Monitor Report and all subsequent reports will not be filed on the Bankruptcy Court's docket. Instead, this and all other reports will continue to be publicly available through Mallinckrodt's website.

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

IV. SUMMARY OF RECOMMENDATIONS

4.1 As discussed in more detail in Sections 9 and 11, *infra*, the Monitor has made two new recommendations related to the Operating Injunction's lobbying restrictions and its

requirement to monitor and report direct and downstream customers. Mallinckrodt has agreed to implement these recommendations.[4] The recommendations are that Mallinckrodt should:

8(a) Provide annual training to Mallinckrodt's external lobbyists, focusing on the Operating Injunction's lobbying-related provisions.

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.

V. THE INTEGRITY HOTLINE

5.1 As of the date of this report, the Monitor has still not received any relevant substantive reports through the integrity hotline.

VI. BAN ON PROMOTION (OI § III.A)

6.1 Section III.A of the Operating Injunction prohibits Mallinckrodt from engaging in certain activities relating to the Promotion of Opioids,[5] 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. Promotional Review Committee ("PRC")

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

[4] These recommendations are prefaced by the number "8" to indicate they were made in the Eighth Monitor Report.

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

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

6.4 The PRC did not have any materials to review in the fourth quarter of 2022, and therefore, did not meet in that quarter. Accordingly, the Monitor did not receive or review any meeting minutes from that quarter.

6.5 The PRC met twice during the first quarter of 2023: on February 9 and March 22. During the February meeting, the PRC reviewed the print version of the 2023 Specialty Generics Product Catalog, which is discussed further below. During the March meeting, the PRC reviewed changes to the Active Pharmaceutical Ingredient ("API") Controlled Substances Product Catalog. These changes were made to update the catalog's information to reflect current products and product codes, which had not been revised since 2019.

6.6 In the Seventh Monitor Report, the Monitor noted that the PRC Chair, who is the Product Manager of Commercial, would be on leave for several months, and the Product Analyst would chair the group in her absence. In the Eighth Reporting Period, the Monitor spoke with the Product Analyst about her new role as PRC Chair. She explained that she has been a Mallinckrodt employee for nearly twenty-two years, and assumed the new role of Product Analyst in July 2022. Her duties in that role include supporting the Commercial Department by managing promotional materials, introducing new products, and organizing conference attendance. Additionally, in her role as PRC Chair, the Product Analyst supervises the approval process for promotional items in MetricStream, Mallinckrodt's internal software program that tracks the re-review and approval of promotional materials based on a two-year timetable. Prior to assuming the Chair position, the Product Analyst observed one PRC meeting on July 14, 2022.

6.7 The Monitor discussed a particular promotional item with the Product Analyst—*i.e.*, the DEA 222 Form—which is the template Mallinckrodt uses to record customer orders to ensure compliance with U.S. Drug Enforcement Administration ("DEA") regulations. In the Seventh Monitor Report, the Monitor discussed this document, which the PRC tabled for further review and discussion during the July 14, 2022 PRC meeting. The Monitor Team asked the Product Analyst about the status of this item, and why certain methadone products were pre-listed on the Form. The Product Analyst explained that distributors rarely use this document, and that addiction treatment clinics primarily use the document to place orders, since many of those customers could not place orders online. As such, the pre-listed products were "standard" products that those clinics typically ordered.

6.8 The Monitor Team raised the concern that customers other than addiction treatment facilities could potentially still use the Form to place an order, and that the pre-listed products could be perceived as implicitly promoting certain dosages of methadone tablets that do not fall within the permissible exception for addiction treatment in the Operating Injunction when promoted for non-addiction treatment. Specifically, the Operating Injunction provides an exception to the general ban on promotion—*i.e.*, it ***permits*** promotion—for products used for the treatment of Opioid Use Disorder ("OUD"). However, that exception is limited. The Operating Injunction states that:

> [t]he term "Opioid Products(s)" shall not include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their 'indications and usage'; ***methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities***; or raw materials, active pharmaceutical ingredients and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials, active pharmaceutical ingredients and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories.

See Operating Injunction § I.Q (emphasis added).

6.9 In other words, Mallinckrodt may promote 5 mg and 10 mg dosages of methadone, but only "to the extent they are sold to addiction treatment facilities." Thus, because the Operating Injunction prohibits promoting methadone 5 mg and 10 mg to non-addiction treatment facilities, the methadone 5 mg and 10 mg dosages on the DEA 222 Form could potentially be viewed as promoting these dosages to certain customers ***not*** involved in addiction treatment. Out of an abundance of caution, the Monitor shared this concern with the Product Analyst, who understood the concern. Mallinckrodt has agreed to revise the sample DEA 222 form shown in its electronic product catalog to address this issue, and will make conforming changes to future printings of paper copies of the product catalog DEA 222 Form.

2. <u>2023 Product Catalog</u>

6.10 Pursuant to the Audit Plan, Mallinckrodt provided the 2023 print version of the Specialty Generics Product Catalog. The PRC reviewed the Product Catalog on February 9, 2023 and finalized it on February 17, 2023. Mallinckrodt did not add any new products to this year's catalog, but several product categories contained new language noting that "[t]his product is subject to a Risk Evaluation and Mitigation Strategy (REMS)" and referring the customer to different websites about the REMS programs.

6.11 The Product Catalog also contained new instructions pertaining to how Mallinckrodt's customers should fill out the DEA 222 Form.

3. <u>TrackWise</u>

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

6.13 In response to a concern the Monitor raised, Mallinckrodt developed and implemented a review and auditing protocol, *Auditing Medical Information for Opioid Business Work Instruction*, that tasks the Post-Market Surveillance ("PMS") Department with reviewing customer inquiries and complaints on a monthly basis, and with evaluating the PMT's responses for compliance with the Operating Injunction.

6.14 Beginning in the Fourth Reporting Period, and on an on-going basis as part of the agreed-upon Audit Plan, the Monitor has reviewed quarterly TrackWise inquiry and complaint entries pertaining to Opioids, as well as the results of this auditing process. During the Eighth Reporting Period, the Monitor reviewed TrackWise Opioid-related data for the fourth quarter of 2022 and the first quarter of 2023.

6.15 For the fourth quarter of 2022, as noted in the Monitor'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. The Monitor's review of the data from this period did not reveal any areas of concern regarding compliance with the Operating Injunction. However, there were several entries in which the "Conclusion" column was left blank, so the Monitor was unable to assess how those calls were handled. The Monitor Team's discussion with the Senior Director of Quality regarding these entries is addressed below.

6.16 For the first quarter of 2023, the Monitor noticed an increase in TrackWise inquiries pertaining to supply issues with Mallinckrodt's fentanyl patches, with varying responses from Mallinckrodt, as well as a few additional TrackWise entries where the

"Conclusion" column was left blank. The Monitor Team's discussion with the Senior Director regarding these entries is also addressed further below.

6.17 During the Eighth Reporting Period, the Monitor also reviewed the TrackWise Audit Reports for the fourth quarter of 2022 and the first quarter of 2023. The Senior Director[6] primarily conducted these audits, including audits of both TrackWise inquiry and complaint data. According to the audit reports, and consistent with past audits, that process did not reveal any instances requiring remedial training or other corrective action for those quarters.

6.18 Previously, during an employee interview, the Monitor Team learned about Mallinckrodt's use of a third-party vendor ("Vendor 1") to handle overflow customer inquiries. *See* Fifth Monitor Report at 11 ¶ 6.9. Towards the end of the Seventh Reporting Period, in response to the Monitor's prior requests for documentation regarding the training of Vendor 1, he received a copy of the *Job Aid For Medical Information Activities of SpecGx, LLC*. The document outlined the relationship between Vendor 1 and the Product Monitoring Team, as well as Vendor 1's responsibilities. This document prompted the Monitor to inquire further about the relationship, as it appeared that Vendor 1 had a more prominent role in the product inquiry process than simply handling overflow calls, as its role had been previously described to the Monitor in an employee interview. It also explained that product complaints were to be handled by Mallinckrodt, not Vendor 1, which appeared contrary to some of the recent TrackWise data the Monitor reviewed.

[6] The Senior Director of Quality informed the Monitor that she recently trained an additional employee, the Manager of Pharmacovigilance, to assist with the TrackWise auditing process. This employee appeared as the signatory on one audit report during this reporting period.

6.19 The Monitor interviewed the Senior Director about the Monitor's review of the latest TrackWise data and the empty "Conclusion" sections, the TrackWise audit process, and the role of Vendor 1 in Mallinckrodt's PMT. She explained that all consumer calls are funneled through the same phone number, which is manned by a call center that Vendor 1 operates. Vendor 1 documents the call information and transfers it to the appropriate team within Mallinckrodt if necessary. For example, Mallinckrodt employees always handle product quality complaints. When asked by the Monitor about references to Vendor 1 in recent TrackWise Complaint data, the Senior Director explained that Vendor 1 may document and address the "lack of effect" portion of the call, but any product complaint would be handed off to Mallinckrodt's PMT. With respect to Mallinckrodt's training of this Vendor, the Senior Director confirmed that the Vendor's employees receive similar training to Mallinckrodt employees, and emphasized that there is also a training curriculum that the Vendor offers. Additionally, the Senior Director meets with Vendor 1's employees on at least a weekly basis in the normal flow of business, which helps confirm their understanding of, and compliance with, Mallinckrodt's policies and procedures.

6.20 The Senior Director also explained why some TrackWise entries lacked a "Conclusion" section in the reports provided to the Monitor. She indicated that there is a thirty-day cycle for the investigation and closure of all product complaints. This is triggered when the complaint is entered into TrackWise. From there, an email is sent to the plant where the product was manufactured, instructing the site to begin an investigation into the complaint. As such, even though the thirty-day cycle may not have been completed when the TrackWise reports were compiled for the Monitor, all complaints are eventually concluded within that timeframe, unless they require elevation pursuant to a Mallinckrodt policy. Additionally, the PMT tracks the

closure time on a monthly basis to ensure their internal requirements are being met, and to assess any complaint trends that appear over time, so they can be addressed and / or improved. This assessment process includes monthly meetings with the manufacturing sites to address investigation closures and product quality trends. Going forward, Mallinckrodt has agreed to adjust the timing of its provision of TrackWise reports to the Monitor, such that they will be produced thirty days after the close of a quarter in order to reflect the "Conclusion" of complaints.

6.21 Finally, the Senior Director discussed fentanyl patch supply chain constraints resulting in an increase in TrackWise inquiries. Specifically, she explained that one of Mallinckrodt's vendors discontinued a non-pharmacological component in the patch. Consequently, Mallinckrodt had been unable to find a new source for this component. As a result, Mallinckrodt had fewer patches available for the market, which led to inquiries from consumers. When these inquiries began, Mallinckrodt was unsure when the patches would be available again, and therefore had different responses to the consumers. However, now that Mallinckrodt has a better understanding of that issue, they have a standard formal response on this topic.

6.22 Based on the Monitor's review of the underlying TrackWise data and the audit reports for the fourth quarter of 2022 and first quarter of 2023, as well as his discussion with the Senior Director of Quality, it appears that the TrackWise entries and audits are being conducted in a manner consistent with the Work Instruction and the Operating Injunction.

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

7.1 Section III.B.1 of the Operating Injunction states that "Mallinckrodt shall not provide financial incentives to its sales and marketing employees or discipline its sales and

marketing employees based upon sales volume or sales quotas for Opioid Products." Accordingly, the Monitor's Audit Plan requires Mallinckrodt, annually, to produce to the Monitor updates to Mallinckrodt's sales compensation plans. Mallinckrodt produced to the Monitor, on or about April 6, 2023 (when finalized by the company), updated sales compensation information for 2023.

7.2 These materials included the 2023: (1) API Sales Compensation Guidelines for independent contractors; (2) API Sales Compensation Plan ("SCP"); (3) Guidelines for the Award of Discretionary Bonuses to API Contract Staff; (4) Guidelines for the Award of Discretionary Bonuses to API Staff; (5) SCP for Addiction Treatment National Account Managers; (6) SCP for Generics National Accounts; and (7) generally applicable Terms and Conditions for the various SCPs for business units of SpecGx. Items 1-5 in the above list, although reviewed by the Monitor Team, are not within the scope of the Operating Injunction, which excludes both APIs and addiction treatment medications from the definition of "Opioid Products." *See* Operating Injunction § I.Q.

1. <u>Monitor Recommendation 6(a) Implemented</u>

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

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

7.4 Similarly, under a section titled "Employee Performance," the document makes clear that "[n]ot successfully meeting" certain "criteria . . . may impact [an employee's] plan

and/or bonus compensation," including "[a]dherence to applicable laws, the Company Code of Conduct, policies, procedures and guidelines," and "***adherence to and compliance with the requirements of the Operating Injunction.***" (Emphasis added) A similar condition exists for the SCPs of the Generics National Accounts Team, the Addiction Treatment National Account Manager, and the API contractor and sales personnel.

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

> Through your participation in the Plan, you agree that if a court of proper jurisdiction determines that you: (a) knowingly participated in any criminal misconduct in connection with your employment with Mallinckrodt or (b) were aware, other than from public information, of acts or omissions of another person in connection with Mallinckrodt's commercial practices in selling opioids that you knew at the time were fraudulent or criminal and that you failed to report to Mallinckrodt or to law enforcement, then you will forfeit any rights to payment under this agreement and, if requested by Mallinckrodt, you will repay all amounts paid to you under this Plan.

7.6 In early February 2023, Mallinckrodt provided the Monitor with the standards for performance bonuses for 2023. For each category of employees, there were numerous requirements to receive performance bonuses, each of which included "Adherence and Compliance with the Operating Injunction." Each contract or full-time employee must be in compliance with certain requirements in order to receive a bonus.

2. <u>The Sales Compensation Plans Appear Compliant With The OI</u>

7.7 Despite the general prohibition on providing financial incentives to sales and marketing employees, the Operating Injunction "does not prohibit financial incentives (*e.g.*, customary raises or bonuses) based on the performance of the overall company or Mallinckrodt's generics business, as measured by EBITDA, revenue, cash flow or other similar financial metrics." Operating Injunction § III.B.1. Thus, the Generics National Accounts Team SCP

awards bonuses based upon a weighted calculation of two elements: (1) first, SpecGx achieving Targeted Net Sales and Financial Net Contribution Margin (which accounts for 80% of the weighting); and (2) second, Individual Management by Objectives ("MBO") Achievements (which accounts for 20% of the weighting). This incentive, based in part upon the overall sales performance of Mallinckrodt's generics business, is permitted under the Operating Injunction.

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

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

8.2 As detailed in Mallinckrodt's Compliance Report, the Specialty Generics Grant and Sponsorship Approval Committee ("SGGSAC" or "the Committee") reviews and approves third-party requests for grants and sponsorships to ensure compliance with the Operating Injunction. *See* Mallinckrodt Compliance Report § 5.4. During the Eighth Reporting Period, the Monitor reviewed the minutes of eight SGGSAC meetings, which took place on October 27, 2022,[7] December 21, 2022, January 18, 2023, February 1, 2023, February 8, 2023, February 17, 2023, March 1, 2023 and March 16, 2023, as well as three addendums to prior meetings. The Monitor also reviewed the accompanying third-party funding Request Forms and any related materials the Committee considered in reviewing each request.

[7] The October 27, 2022 meeting consisted of an email review and vote on two sponsorship requests, but the members of the SGGSAC did not actually meet to discuss the items.

8.3 Most of the Committee's activity during the fourth quarter of 2022 took place during the December 2022 meeting, in which the Committee approved six funding requests. However, despite the high volume of requests and this being the only time the Committee met for discussion during the quarter, only three of five Committee members were in attendance.[8] Given the infrequency of their meetings, the Monitor encourages the Committee to choose dates on which the entire Committee can attend and participate in the discussion. This is particularly important for meetings such as the December 2022 meeting, where three different requestors appeared before the Committee to explain the background of the organizations under consideration and the purpose of their funding request.

8.4 The SGGSAC considered eight requests for funding during the fourth quarter of 2022, totaling approximately $100,000. This was a significant increase in funding from the prior quarter. The Committee approved six of those requests. One request was rescinded due to the "lack of booth availability" at the time of review, and one request was tabled for further review upon receipt of a historical or current agenda. The majority of these requests related to Mallinckrodt's addiction treatment products and the Company's growing business in that space.

8.5 The SGGSAC also considered twelve requests for funding during the first quarter of 2023. Given the volume of these requests, the Monitor will summarize just some of the more noteworthy requests:

(1) Four requests discussed during the February 2 and February 8, 2023 meetings pertained to sponsorships of events organized by group purchasing organizations ("GPOs") – Asembia's 2023 Summit, Minnesota Multistate Contracting Alliance for Pharmacy's Infuse 2023 Vendor Trade Show, Premier, Inc.'s Breakthroughs 23, and Managed Health Care Associates, Inc. 2023 Business Summit. These requests stood out to the

[8] One of the members, the Associate General Counsel, was out on a scheduled leave of absence. However, the meeting minutes noted that the General Counsel attended the December 2022 SGGSAC meeting on her behalf.

Monitor because they did not have a direct connection to the addiction treatment space, as is typical for many requests reviewed by the Committee over the last several years. Attendance at these events provides Mallinckrodt with an opportunity to discuss products and company information with the GPO's customers. Two of the requests were tabled for further review due to a lack of detail in the agenda or the lack of a final agenda, and one request was denied due to listed agenda topics that could potentially discuss opioids and the treatment of pain. The Monitor welcomes the Committee's cautious review and approval of these sponsorships.

(2) On January 18, 2023, the Committee reviewed and approved a request for a Legislative Reception Sponsorship for the North Carolina Biosciences Organization 2023 Legislative Reception. The Director of Government Affairs submitted the request, noting for the Committee that he attended the same event last year. However, that Director also voted on his own request as a Committee member. Given that the Committee is only comprised of five members, and noting the relative weight each vote carries in such a small group, the Monitor encourages Committee members to recuse themselves from voting upon their own requests to avoid the appearance of any conflicts.

(3) In the March 1, 2023 meeting, the Director of Government Affairs again submitted his own request for a sponsorship to attend the National Commission on Correctional Healthcare Spring Conference. However, this time, the Director chose to abstain from voting because he planned to attend the event himself. The Monitor encourages this recusal practice for all similar requests submitted by a Committee member over which the member might vote, regardless of whether the member will attend the event at issue.

8.6 In the Fifth and Sixth Monitor Reports, the Monitor discussed a new procedure implemented by Mallinckrodt, by which the Integrity & Compliance Department completes a first-level review of sponsorship / grant requests for potential violations of the Operating Injunction before they are sent to the full Committee. During the first quarter of 2023, this review mechanism flagged a request for a $1,750 sponsorship to fund an exhibit booth at the American Society of Addiction Medicine 54th Annual Conference - Innovations in Addiction Medicine and Science. The Integrity & Compliance Manager denied the request outright, noting that the conference agenda titles and descriptions appeared to promote the use of Opioids in

different pain settings, and therefore could violate the Operating Injunction. The Monitor is encouraged to see this review process working efficiently and successfully.

8.7 The Monitor also noted that the Committee continues to implement his recommendation that the SGGSAC finalize conditional approvals of requests by ensuring that the Committee's full approval upon receipt of the current year's materials is noted in the minutes of future meetings or, if deliberations took place over email, that such correspondence is appended to the original meeting minutes. For example, on November 8, 2022, the Committee added an addendum to the August 31, 2022 meeting minutes indicating that the final agenda for the Opioid Treatment Providers of Georgia "Real Help Real Hope: How Can We Access You?" conference was reviewed and approved. The Committee also added an addendum on January 16, 2023, noting its receipt of a final agenda for the GSMS 2023 STAR Summit and subsequent unanimous approval of the request.

8.8 During this reporting period, the Monitor also reviewed updated training materials reflecting the changes to the SGGSAC Standard Operating Procedure ("SOP") and Funding Request Form discussed in the Sixth Monitor Report. *See* Sixth Monitor Report at 21 ¶ 8.3. These materials noted the increased responsibilities of funding requestors and the new first-level review of funding requests implemented by the Integrity & Compliance Department, among other changes.

8.9 During the next reporting period, as part of the agreed-upon Audit Plan, the Monitor will continue to review a list of any grants and sponsorships awarded or rejected by the SGGSAC, along with any accompanying Request Forms and underlying materials, and the minutes of any SGGSAC meetings on a quarterly basis. The Monitor will continue to work with

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

IX. LOBBYING RESTRICTIONS (OI § III.D)

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

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

9.3 During the Eighth Reporting Period, pursuant to the Audit Plan, the Monitor received and reviewed the results of the Government Affairs Team's fourth quarter 2022 and first quarter 2023 audit of Mallinckrodt's external state and federal lobbyists' public disclosure reports under the *Lobbying Certification and Activity Review* SOP. These reports, completed by the Director of Government Affairs, detail the states where lobbyists conduct their work, the applicable state or federal disclosure report filing schedule, links to the online filing location of the disclosure reports, and an assessment of whether the activities reported comport with the Operating Injunction. In the audit reports reviewed during this reporting period, the Director of Government Affairs did not identify any concerns or potentially violative activity. However, the Monitor Team noted that those audit reports revealed that—with only one exception—all of the

federal lobbying contracts were not renewed for the upcoming year. Thus, there is only one federal lobbying firm working on Mallinckrodt's behalf in 2023.

9.4 Under the Audit Plan, the Monitor also receives a list of bills that Mallinckrodt's internal and external lobbyists reported lobbying for or against on the company's behalf every quarter. According to the list, there were no additional bills lobbied for or against in the third or fourth quarters of 2022. The disclosure for the first quarter of 2023 revealed lobbying activity on four bills in Missouri, two bills in New York, and one bill in Illinois. The Monitor Team reviewed each of these bills and discussed several of them with Mallinckrodt's external state lobbyists, as detailed further below.

9.5 During the Eighth Reporting Period, the Monitor Team also conducted a "spot check" of the public lobbying disclosure reports Mallinckrodt's external lobbyists filed in order to: (1) confirm that Mallinckrodt obtained Certifications from all lobbyists working on its behalf; (2) review the external lobbyists' areas of advocacy and confirm their activity complied with the Operating Injunction; and (3) confirm the accuracy of Mallinckrodt's review under the *Lobbying Certification and Activity Review* SOP. This review revealed that the Monitor had not received individual Certifications for five lobbyists doing work on Mallinckrodt's behalf. In response to the Monitor Team's inquiry, the Director of Government Affairs confirmed Mallinckrodt had those Certifications on file and produced them to the Monitor. Accordingly, the Monitor Team has confirmed that Mallinckrodt has a Certification for each lobbyist working on its behalf.

9.6 This review also revealed some lobbying activity performed by Mallinckrodt's Illinois lobbyists ("Lobbying Firm IL"). Specifically, Lobbying Firm IL's public reports

disclosed expenditures and noted that the lobbyists took Illinois legislators out to dinner to discuss policy issues on Mallinckrodt's behalf in November 2022.

1. Interviews With External Lobbyists

9.7 As discussed in the Seventh Monitor Report, Mallinckrodt's list of bills produced for the second quarter of 2022 appeared to show an increase in lobbying activity in Massachusetts, Missouri, and New York. During the Eighth Reporting Period, the Monitor Team met with representatives from Mallinckrodt's external lobbyist firms for Massachusetts, Missouri, and Illinois to discuss their work on Mallinckrodt's behalf.[9]

9.8 Mallinckrodt's lobbyist from a lobbying firm acting in Massachusetts ("Lobbying Firm MA") explained that he primarily focuses on monitoring and opposing legislation regarding the taxation of opioids and opioid manufacturers.[10] While the Monitor Team noted that the Operating Injunction created an express allowance for lobbying against opioid taxes (*see* Operating Injunction § III.D.4.a), it was not clear to the Monitor Team that the Massachusetts lobbyist had a strong understanding of the Operating Injunction's other lobbying provisions. When asked to describe his understanding of its lobbying restrictions, the lobbyist explained that his general sense was that Mallinckrodt produces raw materials for pharmaceuticals as well as generic versions of opioids and other medications, and that his "representation of them is limited to things that would infringe on their ability to do that," such as opposing taxation legislation.

[9] The Monitor Team chose to speak with lobbyists from these states based upon review of the lobbyists' publicly filed disclosure reports and the legislative bills Mallinckrodt disclosed during this reporting period. The Monitor Team previously spoke with Mallinckrodt's lobbying firm from New York in April 2022, and plans to have a second conversation with that firm during the next reporting period.

[10] This response aligned with the list of Massachusetts bills produced by Mallinckrodt to the Monitor, which primarily related to the taxation of opioids or creating certain assessments on opioid manufacturers.

When prompted by the Monitor Team, he confirmed he was "generally aware" of the restrictions on advocating for increased prescriptions of opioids, but that it had never come up in his work on Mallinckrodt's behalf in Massachusetts. Similarly, he explained that legislation limiting access to non-opioid pain treatments had never been "put on the table" in Massachusetts, so he has never lobbied on that issue on behalf of Mallinckrodt or any other client.

9.9 Despite the lobbyist's lack of familiarity with the Operating Injunction's lobbying-related provisions, it is probably highly unlikely, in the current political environment, for any legislation to be proposed that promotes opioid prescribing or limits access to non-opioid alternative treatments—much less for a company's lobbyists to promote such legislation. Consequently, given public awareness of the opioid abuse epidemic, and the acute risks (reputational, legal, and otherwise) to industry participants from promoting opioid use, it may be that a lobbyist's lack of familiarity with these prohibitions is of only modest concern. At the same time, the Monitor takes the lobbying prohibitions seriously, and believes Mallinckrodt does too. It is therefore important—as discussed further below—that Mallinckrodt ensure its lobbyists are acting with full appreciation for the Operating Injunction's prohibitions and that they receive training on them.

9.10 The Monitor Team also spoke with a lobbyist for Lobbying Firm IL. He explained that his firm is not doing any active lobbying on Mallinckrodt's behalf, and is primarily monitoring bills for Mallinckrodt's situational awareness. With respect to the Illinois bill disclosed in Mallinckrodt's first quarter 2023 legislative list, the lobbyist explained that the bill related to incarcerated individuals' access to MAT, and that his firm had engaged in informational conversations with legislators and the governor's office, but the bill never ripened into legislation. The Monitor Team also inquired about the November 2022 dinner with

legislators that his firm previously disclosed. The lobbyist explained the dinner was an introductory meeting with new members of the state legislative body, which was disclosed out of an abundance of caution. Finally, the Monitor Team asked the Illinois lobbyist to explain his understanding of the Operating Injunction's lobbying prohibitions in his own words, and he answered that the document was "pretty clear on its face" in its provisions relating to opioids, and his goal was to "make sure we are not going out of bounds" and keep records of any "hard lobbying" done on Mallinckrodt's behalf. Similar to the Monitor Team's discussion with the Massachusetts lobbyist, this answer did not make clear that the Illinois lobbyist had a strong understanding of the Operating Injunction's lobbying provisions.

9.11 The Monitor Team also spoke with Mallinckrodt's lobbyist from a lobbying firm acting in Missouri ("Lobbying Firm MO"). She explained that her primary lobbying priorities for Mallinckrodt are bringing production of API back to the United States, and increasing access to MAT for the incarcerated. In order to communicate these priorities, she met with Missouri state legislators in person to explain Mallinckrodt's positions and outline the benefits of those positions. With respect to MAT, she explained that she gave a general handout to legislators detailing how access to MAT is economically beneficial and has reduced recidivism and opioid deaths in other states. The Monitor Team subsequently requested and reviewed a copy of this handout, and found it to be clear, informative, and compliant with the Operating Injunction.

9.12 The Missouri lobbyist appeared to have a clear understanding of the Operating Injunction's lobbying restrictions, and noted that she is a "cautious lobbyist" who tries to avoid ever getting "close to the line" of impermissible lobbying activity. She explained that she shared any new bills pertaining to Mallinckrodt's policy priorities with the Director of Government Affairs prior to taking any action on Mallinckrodt's behalf. The Missouri lobbyist also walked

the Monitor Team through each bill listed on Mallinckrodt's disclosure to the Monitor for the second quarter of 2022, as well as the bills she was currently advocating on Mallinckrodt's behalf. These bills did not directly relate to opioids and instead addressed issues such as economic development and allocation of the state budget. Finally, the Monitor Team asked why she had not disclosed any lobbying expenditures on Mallinckrodt's behalf for the last two years. She explained that expenditures or gifts to legislators were made illegal in Missouri in 2020, although lobbyists are still required to make these expenditure disclosures to the state. Thus, there were no disclosures to be made in these more recent years.

* * *

New Recommendation 8(a). Provide annual training to Mallinckrodt's external lobbyists, focusing on the Operating Injunction's lobbying-related provisions.

9.13 **The Monitor Team's interaction with the external lobbyists suggested that although the lobbyists are aware of the Operating Injunction generally, there would be value in providing annual training for Mallinckrodt's lobbyists, akin to the internal training Mallinckrodt has already conducted for its own employees (specifically the Government Affairs Team) to ensure greater familiarity with the specific lobbying prohibitions. Mallinckrodt could relatively easily adapt its existing training materials for external lobbyists, in order to ensure these lobbyists keep the Operating Injunction's prohibitions "front of mind." The training could be conducted by Mallinckrodt's Compliance Manager and observed by Mallinckrodt's Director of Government Affairs. Mallinckrodt has agreed to implement this recommendation.**

2. <u>Interviews With Mallinckrodt's Government Affairs Team</u>

9.14 The Monitor Team met with the Director of Government Affairs to discuss the current structure and operation of the Government Affairs Team given corporate restructurings

over the past year, as well as the extent of Mallinckrodt's lobbying activities over the last several quarters, including the information disclosed by its Illinois lobbyists. The Director outlined Mallinckrodt's current state-level policy priorities that make up the bulk of its advocacy activity—*i.e.*, increasing access to MAT, and opposing taxes on prescription drugs and drug manufacturers. According to the Director, these priorities have remained consistent for the last several years. The Director noted Mallinckrodt's limited position with regard to opioid taxes and that he is vigilant in ensuring Mallinckrodt's opposition to these taxes does not run afoul of the Operating Injunction's other lobbying restrictions.

9.15 Additionally, the Director provided an updated description of the process for reviewing the external lobbyists' public reports under the *Lobbying Certification and Activity Review* SOP. He emphasized that Mallinckrodt does not lobby in any way "to expand the opioid market," so his review is primarily concerned with ensuring that lobbyists acting on behalf of their other clients (*i.e.*, clients other than Mallinckrodt, perhaps on topics that could be inconsistent with the Operating Injunction requirements and prohibitions) do not make disclosures that combine permissible activity on behalf of Mallinckrodt with impermissible activity on behalf of the lobbyists' other clients, and ensuring that "technical lines" have not been crossed. The Director was aware of the Illinois lobbying activity disclosed in November 2022, and explained that Lobbying Firm IL was discussing increased access to addiction treatment medication with legislators generally over dinner, but was not discussing a specific bill, so there was no bill to list in Mallinckrodt's quarterly disclosure to the Monitor for the last quarter of 2022.

9.16 The Monitor Team also met with the Vice President of Government Affairs & Patient Advocacy to discuss Mallinckrodt's current federal policy priorities, and its decision to

reduce its number of federal lobbying firms from three to one. He explained that this reduction is entirely related to budgetary concerns and cost-cutting measures.

9.17 As to Mallinckrodt's current federal policy priorities, the Vice President discussed how these priorities had not significantly changed since he last met with the Monitor Team in September 2021. His work remains primarily focused on the issue of re-shoring domestic pharmaceutical manufacturing to reduce manufacturing reliance on other countries. According to the Vice President, Mallinckrodt supports two separate mechanisms for accomplishing this goal: (1) fortifying domestic manufacturing infrastructure, and (2) passing economic legislation that makes the American manufacturing market competitive with other countries, through incentives such as reimbursements and tax credits. He emphasized that this domestic manufacturing issue is the only area that Mallinckrodt has asked its federal lobbying firm to engage on at this time. Accordingly, Mallinckrodt's current federal policy priorities and accompanying lobbying activity appear to comply with the Operating Injunction.

3. Mallinckrodt's Consideration of the Potential Deregulation of Methadone

9.18 During the Eighth Reporting Period, Mallinckrodt raised an issue with the Monitor Team regarding a national conversation about whether to deregulate methadone so as to permit dispensing of methadone in pharmacies, as opposed to limiting such dispensing to specialized methadone clinics known as opioid treatment programs ("OTPs"). Mallinckrodt and its counsel sought the Monitor's views as to whether a particular position by Mallinckrodt could violate the Operating Injunction's lobbying provisions.

9.19 Currently, only an OTP can dispense methadone to treat addiction. To access the drug, most patients must undergo frequent drug tests, participate in counseling sessions, demonstrate they have experienced opioid addiction for at least a year, and show up in person at a methadone clinic each day to receive a single dose. Mallinckrodt explained that, although the

company had taken no official position on the issue, it wanted to know if the Monitor believed engaging on this topic could run afoul of the Operating Injunction's prohibition on lobbying against the enactment of any regulation that supports "evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for" opioid use disorder ("OUD"). *See* Operating Injunction § III.D.2.g.

9.20 The Monitor conducted his own independent research to determine whether there is an "evidence-based" consensus favoring either deregulation or continued regulation of dispensing methadone to treat OUD through OTPs. After consulting different contacts and reviewing relevant literature, the Monitor concluded that there is presently no clear consensus on the deregulation issue.[11] Accordingly, the Monitor shared with Mallinckrodt that he could not conclude definitively, at this time, that advocating for or against deregulation of methadone would constitute lobbying against an "evidence-based treatment option," in violation of the Operating Injunction.[12] He also requested that Mallinckrodt keep the Monitor Team updated if Mallinckrodt decides to take a formal position on this issue. Mallinckrodt agreed to do so, and to date has not taken a formal position.

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[11] *Compare* STAT News, "Top U.S. addiction researcher calls for broad deregulation of methadone" *available at* https://www.statnews.com/2022/11/16/nora-volkow-nida-broad-deregulation-methadone/ (last visited May 24, 2023) *with* STAT News, "Providers of methadone treatment say a big increase in access could backfire" *available at* https://www.statnews.com/2022/11/03/providers-of-methadone-treatment-say-a-big-increase-in-access-could-backfire/ (last visited May 24, 2023).

[12] The Monitor does note that the Substance Abuse and Mental Health Services Administration ("SAMHSA") has recently issued guidance to OTPs and clinicians relating to an extension of COVID-era flexibility for take-home dosages of medication for treatment of OUD. *See* SAMHSA, "Methadone Take-Home Flexibilities Extension Guidance," *available at* https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance (last visited May 24, 2023). Undoubtedly, research on the results of this flexibility, and the benefits weighed against the risks of diversion, will inform future policy making in this area.

9.21 During the next reporting period, as part of the agreed-upon Audit Plan, the Monitor will continue to review the results of Mallinckrodt's quarterly audits of its lobbyists' public disclosure reports and related materials, and conduct interviews with its lobbyists as needed.

X. BAN ON CERTAIN HIGH DOSE OPIOIDS (OI § III.E), BAN ON PRESCRIPTION SAVINGS PROGRAMS (OI § III.F), BAN ON PROVIDING OPIOID PRODUCTS DIRECTLY TO PHARMACIES OR HEALTHCARE PROVIDERS (OI § III.G.4), GENERAL TERMS (OI § III.H), AND COMPLIANCE WITH ALL LAWS AND REGULATIONS RELATING TO THE SALE, PROMOTION, AND DISTRIBUTION OF ANY OPIOID PRODUCT (OI § III.I)

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

10.2 As noted in the Fourth Monitor Report, Mallinckrodt's Associate General Counsel executed the first updated annual certification under the Audit Plan on January 5, 2022, providing certain certifications regarding Mallinckrodt's compliance with these provisions.

Those certifications are set forth in greater detail in Paragraph 10.5 of the Second Monitor Report.

10.3 Pursuant to the Audit Plan, *see* 1 ¶ 1.2, *supra*, SpecGx's Vice President / General Counsel, on behalf of Mallinckrodt LLC, Mallinckrodt Enterprises LLC, and SpecGx LLC, re-certified Mallinckrodt's compliance with these provisions of the Operating Injunction on January 17, 2023.

10.4 The January 17, 2023 Certification did not include certain provisions related to the Operating Injunction's Ban on Prescription Savings Programs. *See* Operating Injunction § III.F.1-3. Accordingly, on February 8, 2023, the Vice President / General Counsel certified that, since January 1, 2022, Mallinckrodt did not:

(1) offer or provide financial support to any third parties that offer any coupons, discounts, rebates or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (e.g., free trial prescriptions) for any Opioid Product (*see* OI § III.F.1-2); or

(2) directly or indirectly assist patients, Health Care Providers, or providers regarding the claims and/or prior authorization process required for third-party payors to approve claims involving any Opioid Product (*see* OI § III.F.3).

10.5 The Monitor intends to include these certificates related to the Ban on Prescription Savings Programs in the 2024 certification.

10.6 In the event Mallinckrodt becomes aware of any violations of the above-referenced provisions of the Operating Injunction or the Vice President / General Counsel's representations in the most recent certification in the interim, Mallinckrodt has agreed to promptly inform the Monitor.

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

11.1 In the Eighth Reporting Period, the Monitor continued his assessment of Mallinckrodt's compliance with Section III.G of the Operating Injunction. Specifically, the Monitor: (1) obtained updates from Mallinckrodt and its outside counsel regarding the status of Mallinckrodt's implementation of the Monitor's recommendations related to suspicious order monitoring ("SOM") in prior reports; (2) continued his review of data and documents provided in response to the Audit Plan; and (3) conducted follow-up interviews with the Director of Controlled Substances Compliance ("CSC") and the Lead CSC Consultant (the "LCSCC").

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

1. Documents Reviewed During the Eighth Monitoring Period

11.3 Mallinckrodt timely produced all SOM-related documents requested under the Audit Plan for the fourth quarter of 2022 and the first quarter of 2023. 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.

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

(1) the SOMT Team ("SOMT") meeting materials and minutes for December 2022 and January, February, March, and April 2023;

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

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

(4) data regarding the DEA's procurement quota for oxycodone and hydrocodone from 1995 to 2022, and Mallinckrodt's procurement and manufacturing quota for oxycodone and hydrocodone from 2019 to 2022;

(5) the Government Communications logs for the fourth quarter of 2022 and first quarter of 2023 and related correspondence;

(6) sales data for highly diverted Opioid Products;

(7) direct customer flagged order data;

(8) select suspicious order reports and related correspondence for flagged direct customer orders in January, February, March, and April 2023;

(9) TrackWise inquiries and complaints raising potential diversion concerns;

(10) the SOMT's report of a due diligence visit to a distributor customer;

(11) the *Annual Controlled Substances Compliance Report Analysis of Highly-Diverted Controlled Substances Utilizing Chargeback Data* prepared by the LCSCC;

(12) recent complaints filed by the U.S. Department of Justice against AmerisourceBergen and Rite Aid, alleging violations of the Controlled Substances Act;

(13) Mallinckrodt's letter to a "virtual distributor" and API direct purchaser; and

(14) statistics regarding the SOMT's review of downstream registrants using the indirect customer dashboard.

2. Direct Customer Due Diligence

a. *Direct customer flagged orders*

11.5 During the Eighth Reporting Period, the Monitor Team reviewed the number of direct customer orders Mallinckrodt flagged as suspicious in the fourth quarter of 2022 and the first quarter of 2023. The Monitor Team also reviewed the related documentation for a selection of flagged orders released in January, February, March, and April 2023.

11.6 In the fourth quarter of 2022 and the first quarter of 2023, all orders the direct customer dashboard flagged as potentially suspicious were released after review by both the CSC Auditor / Data Analyst and the LCSCC.

11.7 As indicated in prior Monitor Reports, *see*, *e.g.*, Sixth Monitor Report at 34 ¶ 11.12, the Monitor Team requested backup documentation for flagged orders that were ultimately shipped. Mallinckrodt provided the suspicious order reports ("SORS") and related documentation for certain weeks in January, February, March, and April 2023.

11.8 As the Monitor has previously reported, the direct customer dashboard flags orders that are potentially suspicious based on frequency, volume, or item share (*i.e.*, the percentage a product makes up of (1) the customer's total purchases and (2) other customers' purchases of that product). The SORS for selected weeks indicated the CSC Auditor / Data Analyst and LCSCC released each order after determining: (1) the customer's aggregate monthly orders did not represent an unusual quantity when compared to orders placed by similar customers within this segment of industry; (2) the customer's aggregate monthly orders did not represent an unusual share when compared to orders placed by similar customers within this segment of industry; (3) the customer's aggregate monthly orders did not represent an unusual volume when compared to orders placed by similar customers within this segment of industry; and (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.

11.9 The LCSCC explained to the Monitor Team that he and the CSC Auditor / Data Analyst make those determinations based on their: (1) knowledge of current customers' ordering practices over the past eighteen months, or, for new customers, their knowledge of similar

customers' purchasing practices; (2) review of the contracts provided by the customers to the commercial department; and / or (3) analysis of the data for similar customers that is available through the direct customer dashboard.

11.10 When necessary, the CSC Auditor / Data Analyst or another member of the SOMT contacted the customer for additional information. In the instances where the CSC Auditor / Data Analyst requested and received information resulting in the release of the flagged order, the SORS indicated supporting documentation was obtained from the customer. 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.

b. *Direct customer sales data*

i. Mallinckrodt's annual sales data

11.11 In January 2023, the Monitor Team reviewed Mallinckrodt's 2022 sales data for hydrocodone, oxycodone, and all Opioid Products by volume, by industry segment (*i.e.*, the type of customer, whether a national wholesale distributor, independent retailer, etc.), and by dollars, and compared this data to Mallinckrodt's sales in 2021 and 2020. A summary of this review is provided in the paragraphs below.

11.12 ***Hydrocodone 10/325 mg***. The volume of Mallinckrodt's hydrocodone 10/325 mg sold decreased from 2020 to 2021 (by about 4-5%), and increased between 2021 and 2022 (by about 3-4%). Notably, among the three product formulations likely to be abused, hydrocodone sales alone increased in 2022. The CSC Director and LCSCC attribute the increase in Mallinckrodt's hydrocodone sales to supply issues in the marketplace (for example, the shutdown of one supplier's plant, resulting in a shift of customer demand to Mallinckrodt), as opposed to an increase in market demand. Indeed, the amount of hydrocodone 10 mg

manufactured across the industry has not increased overall, because the DEA continues to decrease the production quota for this product each year (*see infra*).

11.13 ***Oxycodone 15 mg.*** The volume of oxycodone 15 mg sold between 2020 and 2021 increased (by about 7-9%), but decreased significantly from 2021 to 2022 (by about 9-11%).

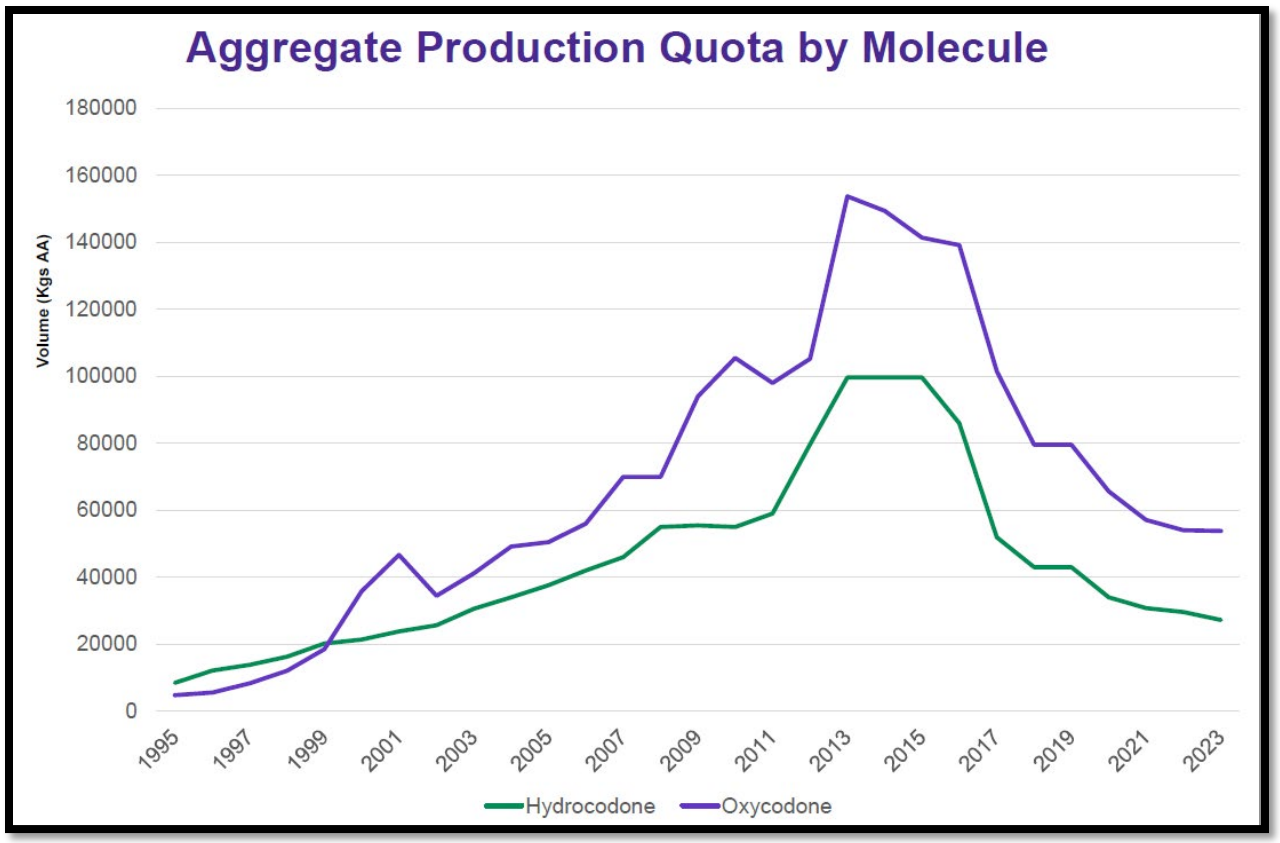
11.14 ***Oxycodone 30 mg***. The volume of oxycodone 30 mg sold between 2020 and 2021 decreased significantly (by about 7-9%), and decreased further still from 2021 to 2022 (by about 13-14%). Due to these decreases, in 2022 Mallinckrodt only sold 79% of the quantity of oxycodone 30 mg it had sold just two years before.

* * *

11.15 All told, between 2021 and 2022 Mallinckrodt's sales of all Opioid Products decreased by both volume and value, following a slight increase in volume of sales from 2020 to 2021.

ii. Changes in DEA quota over time

11.16 The Monitor Team also reviewed the DEA's aggregate production quotas, by molecule, for hydrocodone and oxycodone. As the CSC Director indicated, the DEA's production quota, for both hydrocodone and oxycodone, has decreased every year since 2019, following significant decreases since approximately 2017, as reflected in the chart below.



11.17 Since 2019, Mallinckrodt's hydrocodone ***procurement*** quota (*i.e.*, the amount the DEA allots to Mallinckrodt for potential manufacture and sale) has decreased year after year between 2019 and 2022. However, its hydrocodone ***manufacturing*** quota (*i.e.*, the amount of API the DEA permits Mallinckrodt to manufacture for sale) rose between 2019 and 2021, and decreased significantly in 2022.

11.18 In contrast, since 2019, Mallinckrodt's oxycodone ***procurement*** quota rose year after year between 2019 and 2022. Mallinckrodt's ***manufacturing*** quota for oxycodone decreased between 2019 and 2020, and then rose in 2021, and remained the same in 2022.

c. *Government Communications Log*

11.19 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.

11.20 As previously reported, *see* Fifth Monitor Report at 34 ¶ 11.30 to 36 ¶ 11.33, 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.[13]

11.21 In assessing Mallinckrodt's compliance with that provision, the Monitor Team reviewed Mallinckrodt's Communication Logs for the fourth quarter of 2022 and the first quarter of 2023.

11.22 Of the 51 government inquiries in the fourth quarter of 2022, only one related to an Opioid Product. Based on the Communications Log, it appears the SOMT appropriately responded to the subpoena sent by the FBI.

11.23 In order to further assess Mallinckrodt's responsiveness to government inquiries, in the Eighth Reporting Period, the Monitor also requested copies of the communications referenced in the Communications Log for any Opioid Products.

11.24 For the first quarter of 2023, the Monitor Team reviewed the Communications Log and the related communications. Of the 66 government inquiries during that quarter, only 3 related to Opioid Products. In each instance, the DEA requested information, which Mallinckrodt provided by telephone or email in a timely manner.

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

11.25 ***Prior Recommendation 2(t).*** The Monitor previously recommended that Mallinckrodt "establish[] regularly scheduled interactions with direct customers." Accordingly, Mallinckrodt revised its *Suspicious Order Monitoring Program Review of Direct Customer*

[13] 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.

Orders SOP to require the SOMT to conduct due diligence visits with one of the "Big Three" and at least six other direct customers every year. *See* Sixth Monitor Report at 38 ¶ 11.23.

11.26 Pursuant to the Audit Plan, in January 2023, Mallinckrodt informed the Monitor it intended to conduct due diligence visits with one of the "Big Three" distributors and six other distributors in 2023, in accordance with its *SOM Program Review of Direct Customer Orders* SOP. The Monitor Team will review the SOMT's reports from these visits as they are finalized.

11.27 ***Prior Recommendation 6(c)***. In reviewing the reports prepared in connection with the SOMT's due diligence visits in 2022, the Monitor Team observed certain inconsistencies between the reports and some instances where the information derived from the audit seemed to warrant follow-up, but additional information was not provided. Accordingly, in the Sixth Monitor Report the Monitor recommended that Mallinckrodt ensure greater consistency among direct customer audit reports, and conduct more fulsome follow-up where necessary to obtain compliance assurances. *Id.* at 39 ¶ 11.27 to 40 ¶ 11.29.

11.28 During the Eighth Monitoring Period, the Monitor Team reviewed the *Controlled Substance Compliance/Suspicious Order Monitoring Specialty Pharmacy Review* prepared by the LCSCC for a mail order pharmacy customer that the CSC Director and LCSCC visited in November 2022. The LCSCC's report was thorough and contained detailed observations. The Monitor Team did not observe any responses that required additional follow-up.

11.29 The Monitor Team will continue to assess Mallinckrodt's compliance with Recommendation 6(c) as it reviews the LCSCC's reports from the SOMT's due diligence visits in 2023.

e. *Mallinckrodt's termination of its relationship with the API purchaser referenced in prior reports*

11.30 As previously noted in the Fourth Monitor Report (filed in January 2022), Mallinckrodt restricted a "virtual distributor" and direct purchaser of API (the "Purchaser") in connection with the Purchaser's orders of levorphanol in 2021. *See* Fourth Monitor Report at 43 ¶ 11.62 to 46 ¶ 11.66. Subsequently, Mallinckrodt was reassured by the Purchaser's agreement to certain compliance measures, which were memorialized in an "Amended and Restated API Supply Agreement," for the supply of the levorphanol tartrate API. Specifically, the Purchaser agreed to, among other things: (1) retain experienced outside regulatory counsel; (2) retain a third-party compliance consultant for two years (during which time Mallinckrodt, and the Monitor, would be able to review quarterly compliance reports); and (3) replace its prior third-party logistics ("3PL") vendor with a particular "Big Three" distributor well known to Mallinckrodt (the "Distributor").

11.31 Mallinckrodt ultimately decided to terminate its relationship with the Purchaser, due to Mallinckrodt's belief that the Purchaser had breached material terms of the Amended and Restated API Supply Agreement. Thus, Mallinckrodt terminated its relationship with the Purchaser by letter dated February 16, 2023, and advised the Monitor Team of this decision.

11.32 At the time of Mallinckrodt's termination of its relationship with the Purchaser, the Purchaser had not yet made any additional orders from Mallinckrodt. And for this reason, neither Mallinckrodt nor the Monitor had yet received any third-party compliance reports on behalf of the Purchaser.

3. <u>Downstream Registrant Due Diligence</u>

11.33 In parallel with its direct customer due diligence efforts, Mallinckrodt continues to conduct due diligence on downstream registrants, also referred to as its indirect customers.

11.34 A summary of the volume of these reviews, restrictions, and reinstatements—as previously defined in prior reports—is provided below:

	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023
Chargeback reviews	66	61	63	74	79
Chargeback restrictions	49	43	15	28	42
Chargeback reinstatements	3	3	5	3	6
Chargeback reinstatements denied	3	1	0	0	0

11.35 The increased volume for review naturally raises a question regarding resource sufficiency. Indeed, the Monitor has previously discussed the double-edged effect of Mallinckrodt's improved surveillance—*i.e.*, the benefits of a rich source of data, and the burdens from having to continually analyze the data efficiently, and under resource constraints. *See* Seventh Monitor Report at 27 ¶ 11.33; Sixth Monitor Report at 42 ¶ 11.36. The assistance of the CSC Auditor / Data Analyst is of course helpful, but as elaborated upon below, Mallinckrodt's effectiveness at mining data has, ironically, made a strong case for additional human resources to be deployed in the SOM effort. Specifically, while the Monitor has previously noted his agreement with Mallinckrodt's prioritization of retail pharmacies in indirect dashboard reviews, *see* Seventh Monitor Report at 27 ¶ 11.34, the CSC Director and LCSCC are cognizant of the relatively small percentage of pharmacy chains being reviewed in comparison to reviews of retail pharmacies, and have indicated their agreement in the value of additional human resources to monitor the chains that the indirect customer dashboard flags. Indeed, while chains traditionally may be viewed as lower risk than retail pharmacies, the allegations in a recent U.S. Department of Justice complaint against one such chain, as discussed below, is a reminder that this segment

of the industry is not immune from risk. Accordingly, the Monitor has—in the words of the Seventh Monitor Report—continued in this reporting period to assess whether Mallinckrodt has adequate resources to effectively and efficiently manage the increasing volume of chargeback reviews. Those observations are discussed *infra* (*see* 41 ¶ 11.40 to 43 ¶ 11.43).

a. *The LCSCC's annual chargeback review*

11.36 The Monitor previously reported on the LCSCC's comprehensive review of chargeback data for highly diverted substances, as required by the *Suspicious Order Monitoring Program Social Media and Chargeback Review of Direct Customer and Downstream Registrant* SOP. *See* Fifth Monitor Report at 31 ¶ 11.24 through 34 ¶ 11.29. As previously noted, that policy requires the "LCSCC or designee" to "conduct a periodic review of Chargeback data for the prior twelve-month period and review media and publicly available information to help identify Downstream Registrants which may pose a risk of diversion." *See* § 6.3.1. This review, referred to hereafter as the "Annual Review," is separate from the LCSCC's routine monthly (or ad hoc) chargeback reviews.

11.37 The LCSCC's most recent Annual Review, dated January 10, 2023, is a twenty-six-page report titled *Annual Controlled Substances Compliance Report Analysis of Highly-Diverted Controlled Substances Utilizing Chargeback Data*. It is co-authored with the CSC Auditor / Data Analyst, and addresses six products (hydrocodone 10/325 mg, oxycodone 30 mg, oxycodone 15 mg, morphine sulphate (15 mg, 30 mg, 60 mg, 100 mg, and 200 mg formulations), and fentanyl 100 mcg). It covers the time period from October 1, 2021 through September 30, 2022. (The prior report discussed in the Fifth Monitor Report covered the time frame from November 2020 through October 2021.)

11.38 The Monitor Team noted, during the course of its review of SOMT meeting minutes during the Eighth Reporting Period, *see infra* 44 ¶ 11.46 (discussing SOMT meeting

minutes), that a substantial number of chargeback restrictions resulted from the LCSCC's identification of suspicious downstream registrants through the analysis conducted to generate the Annual Report. The Monitor Team was curious why these suspicious pharmacies were not identified in the usual course through the LCSCC's routine review of flagged chargeback requests in the indirect customer dashboard. As the CSC Director and LCSCC explained, the indirect dashboard prioritizes pharmacies for review based upon a ranking of all pharmacies in Mallinckrodt's chargeback review database. Thus, for example, a pharmacy that triggers multiple flags (as opposed to just one) may be ranked higher in the prioritization list for the LCSCC's review. Consequently, although the suspicious pharmacies identified through the LCSCC's annual review may well be flagged for a single metric on the indirect dashboard (*e.g.*, for only growth, or only volume), those pharmacies will not necessarily be prioritized for review if they do not combine multiple flags on the indirect dashboard (*e.g.*, for growth ***and*** volume).

11.39 In sum, the great success from Mallinckrodt's deployment of a sophisticated data analytics tool has nonetheless revealed—through the LCSCC's Annual Review—that certain pharmacies warrant restriction even if the dashboard does not prioritize them for review. In other words, though the dashboard's capabilities are impressive, it appears that the dashboard still leaves suspect pharmacies that merit restriction without review. If there is a lesson to take away from this, perhaps it is that the sophistication of data analytics does not yet offer (if it ever will) a complete substitute for human intelligence.

11.40 The Monitor Team followed up with the CSC Director and LCSCC to better understand this phenomenon, and to confirm the Monitor Team's understanding of this potential shortcoming in the indirect dashboard. The Monitor Team also requested that the CSC Director and LCSCC provide an analysis of the pharmacies that are flagged, yet not reviewed in a

particular month. Through those discussions, the Monitor Team was able to confirm their understanding that, due to the manner in which the dashboard ranks and prioritizes pharmacies, it is possible for flagged pharmacies to be flagged, and even prioritized for review, yet not be ranked sufficiently high in the prioritization to be reviewed for restriction. Indeed it is some of those very pharmacies (although perhaps not all of them) that the LCSCC has effectively detected in his Annual Review. By way of example, the analysis the CSC Director and LCSCC shared included a pharmacy in Texas that was marked for prioritized review, was in the 99th percentile by ranking of registrant type (*i.e.*, a retail pharmacy), had a "prioritization status" of 100, a "prioritization factor" of 710, a "high risk percent" of 100, and was nonetheless initially not selected for review.

11.41 To be sure, under the resource constraints all businesses face, it is impossible to review every downstream registrant flagged for a chargeback review, and how to prioritize those reviews is a complicated question. But under present circumstances, the deployment of just two employees—the LCSCC and the CSC Compliance Auditor / Data Analyst—may not be sufficient to adequately review a statistically defensible sample of flagged, ranked, and prioritized pharmacies.

11.42 For instance, of the 71 retail pharmacies ranked in a sample prioritization shared with the Monitor Team, only about 35 (or approximately 50%) were reviewed. But the situation is even starker in the case of chain pharmacies, for which 127 pharmacies were ranked for review, of which only about 14 (or approximately 11%) were reviewed. The emphasis on retail pharmacies does make sense, given that established chains' compliance programs are likely to be more robust. And so, in deploying resources, Mallinckrodt's decision to emphasize the retail pharmacies is reasonable. But as the U.S. Department of Justice's allegations against Rite Aid in

a recent civil complaint demonstrate (discussed elsewhere in this Report, *see infra* 59 ¶ 11.86 to 61 ¶ 11.91), chains still warrant careful scrutiny. Where precisely Mallinckrodt sets its threshold for ranking and reviewing pharmacies is an important issue for Mallinckrodt to decide. As noted in the recommendation below, the Monitor recommends that Mallinckrodt establish such a statistical threshold to determine which pharmacies must be reviewed, and which need not be reviewed, according to Mallinckrodt's risk assessment.

11.43 During the course of finalizing this Report—and while considering a recommendation for Mallinckrodt to consider the possible need for additional human resources to assist in managing the growing volume of chargeback reviews and flagged downstream registrants—Mallinckrodt and its counsel informed the Monitor Team that Mallinckrodt had already decided to hire an additional employee with experience akin to that of the LCSCC in order to conduct additional downstream registrant reviews. The Monitor welcomes this development, and believes it will increase the volume of reviews the current SOMT is able to handle in a timely fashion. The Monitor looks forward to an update on Mallinckrodt's hiring for this position in the Ninth Reporting Period.

* * *

New Recommendation 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.

11.44 **For the foregoing reasons, the Monitor recommends 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. The Monitor defers to Mallinckrodt and its consultants and counsel regarding what might be a reasonable and**

appropriate risk tolerance, mindful that no system is capable of a review of every pharmacy. Mallinckrodt has agreed to implement this recommendation.

b. *The SOMT's review and restriction of downstream registrants*

11.45 In the Eighth Reporting Period, the Monitor reviewed SOMT meeting materials and minutes for December 2022, as well as for January, February, March, and April of 2023. The results of those reviews, and the Monitor's related findings from interviews with the CSC Director and LCSCC, are summarized below.

i. December 2022 SOMT meeting

11.46 As noted in the summary chart below, the December 2022 minutes reflect consideration of 22 pharmacies for potential chargeback restrictions,[14] of which 3 were restricted. An additional 2 pharmacies were reviewed for reinstatement, and reinstated.

December 2022 SOMT Meeting		
New chargeback[15] restriction reviews	9 reviewed	2 restricted
Old chargeback restriction reviews	9 reviewed	1 restricted
No action recommended to SOMT	4 recommended	4 accepted
Chargeback reinstatement reviews	2 reviewed	2 reinstated

[14] The SOMT considers restrictions based on customers' and downstream registrants' purchase of any controlled substances, and these metrics reflect the number of downstream registrants under review for purchases of both Opioid Products and non-Opioid Products.

[15] "New" chargeback restriction reviews include downstream registrants the SOMT reviewed for the first time in the month of the current SOMT meeting. "Old" chargeback restriction reviews include: (1) review of downstream registrants that were reviewed in a prior month, but remained under review pending the SOMT's final determination in the month of the current SOMT meeting; (2) review of downstream registrants that had been scheduled for re-review during the month of the current SOMT meeting; and (3) restrictions issued earlier in the month on an ad hoc basis.

11.47 ***Increased responsiveness and cooperation from two of the "Big Three" distributors***. As noted in the Seventh Monitor Report, one of the "Big Three" distributors ("Distributor A") signed a letter agreement with certain commitments Mallinckrodt had requested regarding handling of suspicious orders and chargeback restriction requests. Specifically, Distributor A agreed to: (1) terminate supply to customers Mallinckrodt identifies as posing a diversion risk; (2) inform Mallinckrodt of Distributor A's restriction of downstream registrants; (3) respond to Mallinckrodt's requests for information; and (4) submit timely chargeback requests. *See* Seventh Monitor Report at 23 ¶ 11.19. Distributor A has continued to be responsive to the LCSCC's requests for information and has continued to proactively inform Mallinckrodt when Distributor A restricted a customer on its own initiative.

11.48 For example, in December 2022, Distributor A informed the LCSCC of its concerns with a particular pharmacy's diversion controls. As a direct result of the information Distributor A shared, the SOMT voted to restrict the pharmacy, which neither Mallinckrodt's SOMT nor its indirect customer dashboard had previously identified.

11.49 Additionally, the Monitor Team observed that another one of the "Big Three" distributors ("Distributor B") was more responsive to the LCSCC's requests. For example, on three occasions, Distributor B responded to the LCSCC's requests within four days or less. As a result of Distributor B's more timely cooperation, the SOMT was able to more efficiently review and, in some cases, restrict pharmacies.

11.50 As the Monitor previously reported, when distributors do not respond promptly, the SOMT's reviews often take longer to complete. *See*, *e.g.*, Seventh Monitor Report at 29 ¶ 11.41 to 30 ¶ 11.42. Lack of cooperation and timely responses from distributors are a significant impediment to Mallinckrodt's ability to expeditiously complete chargeback

investigations and restrictions. The consequences of such delay are potentially serious, including the possible continued diversion of controlled substances.

11.51 Indeed, on three occasions in December, the LCSCC took the unusual step of directly contacting the pharmacy under review, because the same "Big Three" distributor ("Distributor C") failed to provide any information in response to his inquiries. In contrast, all three pharmacies responded to the LCSCC's inquires the same day of the inquiry, one of which (as noted immediately below), the SOMT restricted.

11.52 The LCSCC's review of each of those three pharmacies began in September, and the SOMT did not contact them directly until November, after waiting for responses from Distributor C that Mallinckrodt never received. Naturally, Distributor C's failure to respond significantly delayed the SOMT's ability to determine whether to restrict the customer. And, in one of those three instances, the SOMT ultimately restricted the customer. The SOMT undoubtedly could have restricted the customer even earlier with Distributor C's cooperation.

11.53 ***The SOMT's restriction of a pharmacy after a second media alert involving misconduct by a rogue employee.*** As previously reported, the Monitor discussed with the CSC Director whether further review might be warranted in cases involving misconduct by rogue employees. *See* Fourth Monitor Report at 40 ¶ 11.52. The Monitor was concerned, at the time, that not continuing to review such pharmacies might fail to reveal a pattern of systemic misconduct by such a pharmacy. The CSC Director and LCSCC explained that the SOMT does not typically restrict a pharmacy simply because a rogue employee is disciplined or prosecuted for diverting Opioid Products, but will consider restricting such a pharmacy if the information they receive indicates that one employee's problematic misconduct is not isolated. The Monitor

was persuaded by the CSC Director's explanation that the SOMT would be able to reevaluate the need for a restriction in the event of any repeated misconduct at the pharmacy.

11.54 In November 2022, the SOMT received a media alert for a pharmacy indicating that an employee was arrested for theft of several narcotics including oxycodone and hydrocodone. The SOMT's records, including the Tracking Spreadsheet, reflected that Mallinckrodt had previously received a media alert for the same pharmacy in 2018 relating to the suspension of the owner's pharmacy license and his arrest. The pharmacist-owner later pleaded guilty to one count of misdemeanor unlawful dispensing.

11.55 Because the second media alert evidenced a recurring pattern of diversion at that pharmacy, and the SOMT was concerned about the pharmacy's inability to prevent diversion, the SOMT voted to restrict it. This event provides the Monitor with additional reassurance that the SOMT's approach efficiently balances the need for continued surveillance with the administrative cost of continually monitoring pharmacies with isolated misconduct that in many cases may not recur.

11.56 ***Six of the fourteen chargeback reviews identified in the December minutes were initiated because of the LCSCC's Annual Review.*** As discussed *supra*, the LCSCC conducted his Annual Review for 2022, and identified six pharmacies warranting further review by the SOMT because they were either top chargeback customers or were high volume purchasers of oxycodone and / or hydrocodone. None of those pharmacies had been prioritized for review by the indirect customer dashboard. While the SOMT ultimately voted not to restrict four of those pharmacies (the other two were tabled for further review pending receipt of additional due diligence), for the reasons described *supra*, the LCSCC's Annual Review is a valuable tool in identifying potential occurrences of diversion that may evade the direct and indirect customer

dashboards' detection. This shows, as noted above, that while machine-driven data analysis is an important component of any SOM program, the algorithms are not a substitute for human review and analysis.

ii. January 2023 SOMT meeting

11.57 As noted in the summary chart below, the January 2023 minutes reflect consideration of 31 pharmacies for potential chargeback restrictions, of which 13 were restricted. An additional 2 pharmacies were reviewed for reinstatement, and reinstated.

January 2023 SOMT Meeting		
New chargeback restriction reviews	12 reviewed	1 restricted
Old chargeback restriction reviews	14 reviewed	12 restricted
No action recommended to SOMT	5 recommended	5 accepted
Chargeback reinstatement reviews	2 reviewed	2 reinstated

11.58 ***Continued proactive reporting by one "Big Three" distributor, combined with a media alert, led to the SOMT's restriction of multiple pharmacies.*** On December 19, 2022, the SOMT learned through a media alert that DEA served an order to show cause on a California pharmacy due to its alleged filling of online prescriptions for ADHD medication. The LCSCC's investigation revealed that this California pharmacy is associated with six other pharmacies. The same day as the media alert, Mallinckrodt learned from Distributor A that it had restricted eight related pharmacies, including the California pharmacy (one of which did not have a DEA number and so could not be restricted). The SOMT followed Distributor A in restricting all seven pharmacies with active DEA registrations.

11.59 Another example of the value of proactive intelligence received from Distributor A is the SOMT's restriction of a Florida pharmacy on January 18, 2023. The SOMT learned of the pharmacy through Distributor A, which advised Mallinckrodt that Distributor A had conducted due diligence on the pharmacy and, based upon a conversation with the Pharmacist-In-Charge, had concluded that it had "concerns regarding the pharmacy's ability to provide effective controls against potential diversion of controlled substances." The LCSCC discovered that this particular pharmacy was using as many as four different distributors to order some controlled substances. The SOMT restricted this customer as well.

11.60 Given their position in the supply chain, in particular the proximity of the "Big Three" distributors to downstream pharmacies—and Mallinckrodt's inability to obtain and analyze dispensing data—distributors' proactive sharing of intelligence is invaluable to Mallinckrodt's SOM efforts. These alerts have led to numerous restrictions that Mallinckrodt might not otherwise have initiated, contributing to the prevention of further potential diversion.

11.61 ***Continued delay by one "Big Three" distributor in response to due diligence requests prompted the SOMT's restriction.*** The SOMT continues to experience delay in Distributor C's response to the SOMT's requests for due diligence. For example, on December 8, 2022, the LCSCC initiated a review of a Kentucky pharmacy based upon a flag for hydrocodone 10/325 mg volume. After consulting ARCOS data, the LCSCC observed that this pharmacy's order volume is "more than twice the combined volume of the next 3 largest pharmacies." On December 8, 2022, the LCSCC sent an email inquiry to Distributor C regarding this pharmacy, but as of January 10, 2023, had still not received a response. The SOMT voted to restrict this pharmacy as well.

11.62 Similarly, the SOMT commenced a review of an Indiana pharmacy in September 2022, but as of January 2023 had still received no response from Distributor C. Consequently, the SOMT voted to restrict the pharmacy.

11.63 ***Additional chargeback restrictions arising from the LCSCC's Annual Review.*** As was the case in January, the Monitor Team noted the LCSCC's identification of a number of downstream registrants for chargeback restriction review, due to the LCSCC's Annual Review—one in Texas, and the other in Georgia. The SOMT voted to restrict the Texas pharmacy. The SOMT is continuing to review the Georgia pharmacy (which is the highest purchaser of hydrocodone in the state of Georgia), pending receipt of a compliance report from a third-party compliance vendor.

iii. February 2023 SOMT meeting

11.64 As noted in the summary chart below, the February 2023 minutes reflect consideration of 33 pharmacies for potential chargeback restrictions, of which 15 were restricted. An additional 2 pharmacies were reviewed for reinstatement, and reinstated.

February 2023 SOMT Meeting		
New chargeback restriction reviews	6 reviewed	1 restricted
Old chargeback restriction reviews	22 reviewed	14 restricted
No action recommended to SOMT	5 recommended	5 accepted
Chargeback reinstatement reviews	2 reviewed	2 reinstated

11.65 ***The SOMT continues to restrict pharmacies on an ad hoc basis when appropriate.*** In February, there was an unusually large number of ad hoc reviews due to media alerts, information received from distributors, the LCSCC's Annual Review, ***and*** the indirect

customer dashboard. Based on the Monitor Team's observations, the SOMT does not typically restrict pharmacies flagged by the indirect customer dashboard until the monthly meeting. However, in February, the SOMT restricted multiple pharmacies, following ad hoc review.

11.66 Two of those pharmacies were flagged for an unusual ordering pattern or trend because they were purchasing oxycodone from more than five distributors, which is an indicator of potential diversion. Through his investigation, the LCSCC determined both pharmacies were also purchasing significantly more oxycodone than nearby chain and independent pharmacies. When the LCSCC shared his findings with two of the pharmacies' distributors, they both discontinued sales to the pharmacies. The SOMT then issued ad hoc restrictions as well.

11.67 A third pharmacy flagged for unusual ordering pattern or trend for oxycodone was also restricted on an ad hoc basis. In conducting the pharmacy's chargeback review, the LCSCC observed that the pharmacy's oxycodone purchases totaled 98 percent of the total volume of its ARCOS-reportable purchases. Once the LCSCC informed the pharmacy's distributor, Distributor B, of his findings, Distributor B began investigating the pharmacy and notified the LCSCC it had restricted the pharmacy. The SOMT then issued a restriction that same day.

11.68 ***Mallinckrodt issued a significant number of restrictions on an ad hoc basis based on information received form Distributor A.*** The unusually large number of pharmacies restricted in February on an ad hoc basis was also due to cooperation from Distributor A. Distributor A proactively identified 8 pharmacies it had restricted in January, which Mallinckrodt restricted in February.

11.69 The CSC Director and LCSCC informed the Monitor that Distributor A continues to update the SOMT as to all of the pharmacies it restricts throughout the month.

iv. March 2023 SOMT meeting

11.70 As noted in the summary chart below, the March 2023 minutes reflect consideration of 31 pharmacies for potential chargeback restrictions, of which 13 were restricted. An additional pharmacy was reviewed for reinstatement, and reinstated.

March 2023 SOMT Meeting		
New chargeback restriction reviews	13 reviewed	0 restricted
Old chargeback restriction reviews	16 reviewed	11 restricted
No action recommended to SOMT	2 recommended	2 accepted
Chargeback reinstatement reviews	1 reviewed	1 reinstated

11.71 ***Distributor A continues to proactively share pharmacy restrictions with Mallinckrodt, assisting Mallinckrodt in conducting additional restrictions.*** Consistent with the pattern observed in the most recent months, as discussed above, Distributor A provided Mallinckrodt with notice of 10 pharmacies that the distributor restricted in January. In March, this accounted for almost all of Mallinckrodt's restrictions.

v. April 2023 SOMT meeting

11.72 As noted in the summary chart below, the April 2023 minutes reflect consideration of 43 pharmacies for potential chargeback restrictions, of which 17 were restricted.

April 2023 SOMT Meeting		
New chargeback restriction reviews	14 reviewed	4 restricted
Old chargeback restriction reviews	22 reviewed	13 restricted
Chargeback reinstatement reviews	0 reviewed	0 reinstated

No action recommended to SOMT	7 recommended	7 accepted

11.73 ***The LCSCC'S analysis of ARCOS data continues to result in restrictions.*** In April, the LCSCC continued to review ARCOS data as part of the chargeback review process, and the SOMT issued several restrictions based on his findings. Indeed, the SOMT restricted four pharmacies that were flagged by the indirect customer dashboard for unusual purchasing pattern or trend. Each of those pharmacies' purchases of oxycodone made up 90% or more of the total volume of their ARCOS-reportable purchases, and three of those pharmacies' purchases of oxycodone totaled 94% or more.

11.74 ***Mallinckrodt's tracking of pharmacies under review continues to be a valuable tool in preventing potential diversion.*** As the Monitor Team previously reported, the SOMT maintains a Tracking Spreadsheet of all pharmacies that have been reviewed or are under review. In April, the SOMT restricted two pharmacies whose chargeback reviews were first initiated months before. Both pharmacies were flagged by the indirect customer dashboard based on the per capita volume of their purchases of methylphenidate. While methylphenidate is not an Opioid Product, the restrictions described below demonstrate the benefit of maintaining a Tracking Spreadsheet to ensure pharmacies scheduled for review at a later date are actually re-reviewed and restricted when appropriate.

11.75 Mallinckrodt reviewed the first pharmacy in July 2022. The LCSCC contacted Distributor C, requesting information regarding the pharmacy's filling of a high number of methylphenidate prescriptions from a local practitioner. The LCSCC did not receive a substantive response. In October 2022, the SOMT decided not to restrict and instead waited for a response from Distributor C and continued to monitor the volume of the pharmacy's purchases through ARCOS. In April 2023, when the SOMT re-reviewed the pharmacy, the LCSCC

observed an increase in the volume of its purchases, which had still not been explained by Distributor C. As a result, the SOMT restricted the pharmacy.

11.76 The second pharmacy was initially reviewed in August 2022. Based on the LCSCC's due diligence explaining, in part, the higher per capita volume of purchases in the county where the pharmacy was located when compared to average for the state, the SOMT voted to re-review the pharmacy again in six months. At the April 2023 meeting, because the LCSCC observed an increase in the pharmacy's purchase of methylphenidate, and because Distributor C failed to respond to the LCSCC's request for additional information, the SOMT voted to restrict the pharmacy.

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

a. *The U.S. Department of Justice lawsuits against AmerisourceBergen and Rite Aid*

i. *United States v. AmerisourceBergen*

11.77 On December 29, 2022, the U.S. Department of Justice filed a civil complaint against AmerisourceBergen Corporation and its subsidiaries (collectively, "ABC"), alleging violations of the Controlled Substances Act.[16] In its own press release issued the same day as the filing of the Complaint, ABC emphatically denied the government's allegations.[17] Mallinckrodt

[16] *United States v. AmerisourceBergen Corporation et al,* Dkt. No. 1, 22-cv-05209 (Dec. 29, 2022) ("ABC Compl."), *available at* https://www.justice.gov/opa/press-release/file/1559811/download (last visited Feb. 6, 2023); *see also* Press Release, U.S. Dep't of Justice, *Justice Department Files Nationwide Lawsuit Against AmerisourceBergen Corp. and Subsidiaries for Controlled Substances Act Violations* (Dec. 29, 2022), *available at* https://www.justice.gov/opa/pr/justice-department-files-nationwide-lawsuit-against-amerisourcebergen-corp-and-subsidiaries (last visited Feb. 6, 2023).

[17] *See* Press Release, AmerisourceBergen, *AmerisourceBergen Response to the Department of Justice Complaint – An Inevitable Outcome of Regulatory and Enforcement Outsourcing* (Dec. 29, 2022), *available at*

learned of the Complaint through Mallinckrodt's Google alerts. That lawsuit remains pending as of the filing of this Report.

11.78 The Monitor Team read the Complaint with interest, and with an eye toward what lessons the Monitor Team and Mallinckrodt might draw from the government's allegations. Specifically, the Complaint alleges compliance failures in connection with various pharmacies and distributors referenced anonymously in the Complaint. The Monitor Team inquired with Mallinckrodt regarding the descriptions of these entities and whether Mallinckrodt could identify them as either direct or indirect customers. The Monitor Team was interested to know whether these entities, if they could be identified, were among those restricted as a result of Mallinckrodt's SOM program, and if so whether any of the entities were reinstated. The Monitor Team discussed the possible identities of a number of pharmacies and other entities with the CSC Director and LCSCC. Ultimately, they shared that there were no new entities they could identify that the SOMT has not already reviewed.

11.79 In any event, a number of themes arise from the government's allegations in the ABC Complaint and reinforce and amplify observations the Monitor has made in his monitorship of Mallinckrodt: (1) SOM variables that could be applied independently (*i.e.*, disjunctively) may underestimate or under-identify risks when applied in combination (*i.e.*, conjunctively); (2) despite the great value from technological advances that make data aggregation and analysis even more powerful and insightful, this cannot substitute for the role of human intelligence, requiring sufficient human resources to benefit from the rich data available for analysis; and (3)

https://www.amerisourcebergen.com/newsroom/executive-perspectives/response-to-doj (last visited Feb. 6, 2023).

commercial / sales employees should not have improper influence over independent SOM compliance and due diligence. These topics are elaborated upon below.

11.80 ***Disjunctive vs. conjunctive flagging.*** The ABC Complaint alleges that ABC developed a SOM system that flagged orders that were ***both*** unusual due to their size ***and*** pattern, even though the applicable DEA regulation is most naturally read to require the flagging of suspicious orders based upon unusual size, pattern, ***or*** frequency.[18] Naturally, conjoining two variables, rather than treating them as disjunctive flags, had the effect of decreasing the number of ABC's flags. The ABC Complaint describes this as a "dual trigger" requirement that "flagged only controlled-substances orders that failed two or more of . . . three thresholds."[19] But "[o]rders that exceeded only the . . . threshold due to their unusual size or only the . . . threshold due to their substantially abnormal pattern were not flagged by [ABC's system] and instead automatically shipped to customers without reporting to DEA."[20] Consequently, the ABC Complaint alleges that "by design, [ABC's system] allowed orders that ABC's own algorithms had identified as being of unusual size or deviating substantially from a normal pattern to ship without any review or opportunity for reporting to DEA."[21]

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[18] The regulation speaks of three different kinds of orders, not a single order exhibiting three different characteristics. *See* 21 C.F.R. 1301.74(b) ("The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. ***Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.***") (emphasis added).

[19] ABC Compl. at 30 ¶ 185.

[20] *Id.* at 30 ¶ 186.

[21] *Id*. at 30 ¶ 187.

11.81 To be very clear, the Monitor does not suggest that this same problem exists in exactly the same way in Mallinckrodt's SOM system, as far as the Monitor Team is aware (much less that Mallinckrodt has designed a system to achieve this effect intentionally, as alleged in the ABC Complaint). But the allegations in the ABC Complaint present an opportunity for refinement and continued assessment of Mallinckrodt's ranking and prioritization of pharmacies in chargeback reviews for downstream registrants, as discussed elsewhere in this Report. *See supra* 40 ¶ 11.38 to 43 ¶ 11.43. And, as noted, the Monitor Team has observed a somewhat similar issue in the manner in which Mallinckrodt's indirect customer dashboard appears to rank higher (and therefore prioritize for review), pharmacies with combinations of multiple flags, while pharmacies with single flags are ranked lower and therefore may ultimately not be reviewed.

11.82 ***Resource allocation sufficiency.*** The ABC Complaint alleges that even when suspicious orders were flagged, "grossly insufficient" human review resulted in "cursory, if not non-existent reviews."[22] Specifically, the Complaint alleges that "ABC's underfunding . . . meant that the Diversion Control team—the . . . unit with primary responsibility for suspicious order reviews and reporting—was grossly understaffed"[23] because, although it "was responsible for reviewing tens of thousands or hundreds of thousands of orders per year . . . for a significant part of the relevant period, [it] had only around five or six dedicated order reviewers, and even those employees were able to spend only a portion of each workday reviewing flagged orders."[24]

[22] *Id.* at 33, 35.

[23] *Id.* at 35 ¶ 224.

[24] *Id.* at 35 ¶ 227 to 36 ¶ 228.

11.83 Again, the Monitor does not suggest that an identical problem exists with Mallinckrodt's SOM system. (And, given Mallinckrodt's different position to ABC in the supply chain, Mallinckrodt's volume of direct orders and chargeback reviews are undoubtedly significantly smaller.) Nonetheless, the general issue of human resource allocation is always relevant, because any surveillance system could always benefit from additional personnel.

11.84 The Monitor Team has discussed this issue with Mallinckrodt before, including when the indirect customer dashboard was deployed. The success of that system, and its generation of new leads for review of downstream registrants raises, again, a question of whether SpecGx has sufficient "hands on deck" to conduct the necessary analysis. In prior discussions, the CSC Director has shared the view that the SOMT had sufficient resources at the time, and was confident, given Mallinckrodt's investment in the sophisticated "big data" analytics dashboard platforms that, in the event additional resources were necessary, the CSC Director would be able to obtain them. The CSC Director noted that he regularly meets with his supervisor to review and discuss resource allocation. For the reasons noted elsewhere in this report, increased volume of chargeback reviews, including the possibility that some may not be reviewed due to the prioritization of flagged chargeback reviews, suggested the time was ripe to reassess the sufficiency of human resource allocation for conducting these reviews. Indeed, Mallinckrodt anticipated this and shared with the Monitor Mallinckrodt's plan to hire an additional employee of a rank and with experience equivalent to the current LCSCC.

11.85 ***Involvement of commercial / sales personnel in due diligence.*** The ABC Complaint alleges that ABC utilized sales personnel in order to conduct some due diligence activities, such as in-person visits to pharmacies, even though these employees were

simultaneously incentivized to grow the business, creating a conflict of interest.[25] In contrast, Mallinckrodt's commercial / sales personnel are not relied upon to conduct due diligence. At most, they are consulted in the event the SOMT is conducting due diligence, and only in order to understand the reasons for increased customer sales and related market dynamics.[26]

ii. *United States v. Rite Aid*

11.86 Not long after the ABC Complaint, on March 13, 2023, the U.S. Department of Justice intervened in a civil False Claims Act case brought against Rite Aid Corporation and its subsidiaries (collectively, "Rite Aid").[27] Once again, the Monitor Team read this Complaint with an eye toward what lessons the Monitor Team, and Mallinckrodt, might draw from the Complaint's allegations.

11.87 The Rite Aid Complaint alleges that "Rite Aid filled prescriptions for powerful opioid painkillers, such as oxycodone, fentanyl, and other highly diverted controlled substances

[25] *Id.* at 22 ¶ 129-32.

[26] Furthermore, after discussion with the Monitor, the PRC ceased the practice of allowing commercial / sales personnel to evaluate promotional materials. And, as noted in the Sixth Monitor Report, under the *Specialty Generics Grant & Sponsorship Approval Committee* SOP (effective June 21, 2022), "to reduce the risk of the appearance of improper influence, the new SOP provides that sales, commercial, finance, and marketing team members may no longer serve as voting members of the Committee." Sixth Monitor Report at 21 ¶ 8.3.

[27] *United States ex rel. White et al. v. Rite Aid Corporation et al.,* Dkt. No. 38, 21-cv-01239-CEF (Mar. 13, 2023) ("Rite Aid Compl."), *available at* https://www.justice.gov/opa/press-release/file/1573956/download (last visited May 7, 2023); *see also* Press Release, U.S. Dep't of Justice, *United States Files Complaint Alleging that Rite Aid Dispensed Controlled Substances in Violation of the False Claims Act and the Controlled Substances Act* (Mar. 13, 2023), *available at* https://www.justice.gov/opa/pr/united-states-files-complaint-alleging-rite-aid-dispensed-controlled-substances-violation (last visited May 7, 2023).

that were unlawful and medically unnecessary," and thereby "significantly contributed to this country's opioid crisis."[28] As further alleged in the Complaint, the allegedly

> unlawful prescriptions for controlled substances included prescriptions for "trinities," a widely known dangerous combination of an opioid, benzodiazepine, and muscle relaxant, desirable by drug abusers because of the increased euphoric effect of taking them together; "early fills" of fentanyl and oxycodone prescriptions before a prior prescription for the same drug had run out, which is a clear sign of overutilization; prescriptions for extremely high doses and excessive quantities of opioids that fed opioid dependence and addiction; and prescriptions written by prescribers who Rite Aid's own pharmacists had repeatedly identified as writing illegitimate prescriptions with no medically valid purpose.[29]

11.88 Of particular note, the Complaint also alleges that Rite Aid ignored "warnings from its distributor about the amount of drugs, in particular oxycodone, ordered for outlier Rite Aid stores."[30] In sum, the Department of Justice alleges that Rite Aid either submitted, or caused to be submitted, false or fraudulent prescriptions, for payment by federal healthcare programs, resulting in the submission of false claims.

11.89 The Monitor Team called to Mallinckrodt's attention a list of dozens of Rite Aid stores listed in an exhibit to the Complaint, which are allegedly implicated. Mallinckrodt may find value in cross-referencing this list as part of its ongoing SOM activities.

11.90 For the most part, the allegations against Rite Aid may be less directly relevant to Mallinckrodt, given Rite Aid's position in the supply chain as a direct dispenser of controlled substances. Nonetheless, the Rite Aid Complaint does echo a familiar theme from the Department of Justice's Complaint against AmerisourceBergen—namely, the risks from insufficient human resource allocation. For example, the Rite Aid Complaint notes that "Rite

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[28] Rite Aid Compl. at 2 ¶ 3.

[29] *Id*. at 2-3 ¶ 5.

[30] *Id*. at 4 ¶ 10.

Aid assigned only one Government Affairs employee to review all of the tickets submitted to Rite Aid [*i.e.*, reports regarding suspicious activity] by pharmacists nationwide. From February 2013 through February 2018, that employee was a pharmacy technician."[31] Thus, as in the case of the AmerisourceBergen Complaint, the government's theory is that having too few "hands on deck" increases the risk of diversion from the failure to detect and address suspicious orders.

11.91 For this reason, as elaborated upon elsewhere in this Report, the Monitor Team has called to the attention of Mallinckrodt's SOMT the numbers of flagged downstream registrant chargeback requests that are presently identified, but not addressed through the indirect customer dashboard. *See supra* 40 ¶ 11.38 to 43 ¶ 11.43.

b. *Other SOM-related updates under the Audit Plan*

11.92 Mallinckrodt provided a number of miscellaneous updates under the Audit Plan in the fourth quarter of 2022 and the first quarter of 2023.

11.93 ***Mallinckrodt's list of independent consultants for reinstatement requests***. In 2023, Mallinckrodt ceased its practice of providing a list of independent consultants to direct customers and / or downstream registrants for potential use in compliance due diligence and reinstatement reviews. Mallinckrodt does not presently intend to resume this practice in the future.

11.94 ***Mallinckrodt's media search terms.*** Pursuant to the Audit Plan, in January 2023, Mallinckrodt informed the Monitor it had not made any changes to the list of search terms used for social media reviews of direct customers and downstream registrants previously provided to the Monitor in April 2022.

[31] *Id*. at 52-53 ¶ 161.

11.95 ***The Operating Injunction hold list for direct customer orders.*** During the fourth quarter of 2022 and the first quarter of 2023, there were no direct customer orders flagged for potential violations of the Operating Injunction. *See* Seventh Monitor Report at 21 ¶¶ 11.9-11.10 (discussing the operating injunction hold list for orders potentially in violation of the Operating Injunction).

11.96 ***SOM-related TrackWise Entries.*** In the Sixth Monitor Report, the Monitor recommended that any evidence of diversion risks appearing in the TrackWise inquiry and complaint logs (discussed *supra*) 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 (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. For the first quarter of 2023, Mallinckrodt informed the Monitor there were no such TrackWise inquiries.

XII. TRAINING (OI § III.K)

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

12.2 During the Eighth Reporting Period, the Monitor audited Mallinckrodt's compliance with the Operating Injunction's training requirements by: (1) confirming all employees completed each component of the Operating Injunction training in 2022; (2) confirming all employees hired during the quarter of 2023 completed their Operating Injunction trainings; (3) reviewing the 2023 training materials; and (4) interviewing the Integrity & Compliance Manager of SpecGx.

1. 2022 Employee Trainings

12.3 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.

12.4 In the Eighth Reporting Period, Mallinckrodt informed the Monitor that two new employees hired in the fourth quarter of 2022, who were required to receive Operating Injunction training, completed each training component before the end of the year.

12.5 Mallinckrodt also confirmed that all but one SpecGx employee had completed all components of the Operating Injunction training in 2022. That employee was added to the list of employees who must receiving training in December 2022 and received his live training in February 2023.

2. Trainings for New Employees in the First Quarter of 2023

12.6 Mallinckrodt identified five employees hired in the first quarter of 2023. Each of these new employees reviewed and signed the Operating Injunction policy, completed the board service survey, attended a live training, and passed the Operating Injunction quiz. Two employees completed all of the training components in the first quarter of 2023, and the remaining three employees began their trainings in the first quarter but completed them in the second quarter.

3. 2023 Training Materials

12.7 As the Monitor previously reported, Mallinckrodt tests its employees' understanding of the Operating Injuncting in two ways: (1) by posing hypothetical scenarios in live trainings, and asking whether a practice is "permissible" or "impermissible" under the

Operating Injunction; and (2) requiring employees to pass an Operating Injunction quiz that includes multiple choice, true or false, and fill in the blank questions related to the different sections of the Operating Injunction. Mallinckrodt updated its live trainings and quizzes for 2023 and provided those materials to the Monitor for his review in February, before Mallinckrodt started its live trainings for 2023. Specifically, Mallinckrodt produced: (1) the master PowerPoint for the Operating Injunction for Opioids Business Training Sessions; (2) all of the hypothetical scenarios posed during the live trainings for Mallinckrodt's different departments that receive Operating Injunction training and the answers to those questions; and (3) the Operating Injunction Quiz Questions for those departments.

a. ***Quiz questions and hypothetical scenarios from live trainings***

12.8 While the format of the 2023 materials was largely similar to the 2022 materials, there were changes to both the hypothetical scenarios and quiz questions from the prior year. For example, with respect to the quizzes, the Monitor Team observed that all of the questions in six of the eight sections changed, which included the quiz questions on the Operating Injunction's Ban on Promotion and Ban on Funding / Grants to Third Parties sections. As the Monitor observed when he attended the live trainings, those are both areas where employees tend to ask more questions. As to the quiz questions related to the Operating Injunction's Lobbying Restrictions, two of three questions changed. Understandably, the only section where the quiz questions did not change was the section related to the Operating Injunction's straightforward Ban on Certain High Dose Opioids.

12.9 Likewise, Mallinckrodt made changes to the hypothetical scenarios posed during the live trainings and included additional scenarios as well. As previously reported, each department's live trainings include three to six hypothetical scenarios. For 2023, these

hypothetical scenarios focused on the Operating Injunction's provisions related to promotion, third-party support, financial incentives, lobbying, and manufacture of high dose Opioids.

12.10 After reviewing the 2023 training materials, the Monitor Team interviewed the Integrity & Compliance Manager of SpecGx and discussed their observations with her. She informed the Monitor that Mallinckrodt made changes to the questions based on, among other things, questions that arose from scenarios that occurred in the past year and the Monitor's observations and recommendations. Mallinckrodt also wanted to test its employees on additional components of the Operating Injunction.

b. *The live training PowerPoint presentations*

12.11 Other than changes to the hypothetical scenarios, there were minimal changes to the PowerPoint presentation used in the different departments' live trainings. The slides were updated to reflect changes to any relevant standard operating procedures, and Mallinckrodt added a section on the Operating Injunction's requirements regarding Clinical Data Transparency.

12.12 Additionally, in an effort to convey to employees Mallinckrodt's "tone from the top," the 2023 live trainings included a slide with a message from the Executive Vice President and Head of SpecGx regarding the monitorship, the Operating Injunction, and compliance generally. In the past, the Executive Vice President and Head of SpecGx was able to attend all of the live trainings and impart that message himself. This year he was unable to attend all of the trainings due to scheduling, and so the slide imparted that message.

12.13 The Executive Vice President and Head of SpecGx's message emphasized Mallinckrodt's commitment to its compliance with the Operating Injunction and employees' integral role in, and responsibility for, the company's compliance.

12.14 As of this report, all employees who receive Operating Injunction training had completed their live trainings.

12.15 In the next reporting period, the Monitor plans to attend certain live training sessions for newly hired employees to further assess their efficacy in training employees on the Operating Injunction's requirements.

XIII. CLINICAL DATA TRANSPARENCY (OI § IV)

13.1 Section IV of the Operating Injunction requires Mallinckrodt to share certain clinical data related to its Opioid Products through a third-party data archive that makes such information available to Qualified Researchers with a bona fide scientific research proposal.

13.2 As the Monitor previously reported, Mallinckrodt contracted with the company Vivli Inc. ("Vivli") to make such data available, and Mallinckrodt has advised the Monitor that all of the data required to be shared under Section IV is available through that platform.[32] Any research proposals submitted through Vivli will be reviewed for scientific merit by an independent review panel.

13.3 In response to the Monitor's request in the Audit Plan, *see supra* 1 ¶ 1.2, Mallinckrodt confirmed there were no requests for access to this clinical data or any new Mallinckrodt Opioid Products, or indications for existing products, during the fourth quarter of 2022 or the first quarter of 2023.

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

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

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

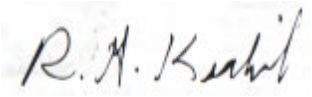
14.1 Section V of the Operating Injunction required Mallinckrodt to produce certain documents to the Settling States within nine months of October 12, 2020 (*i.e.*, on or before July 12, 2021). Mallinckrodt complied with this requirement is described in prior Monitor Reports. *See, e.g.*, Sixth Monitor Report 69 ¶ 14.1 to 70 ¶ 14.5. There are no further updates at this time.

XV. CONCLUSION

15.1 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.

* * *

15.2 Wherefore, the undersigned Monitor respectfully submits this Eighth Monitor Report.



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

EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE EIGHTH MONITOR REPORT DATED MAY 30, 2023[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.	In Progress
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.	In Progress
5.	**2(e)**	Use best efforts to obtain timely provision of chargeback data from direct customers.	In Progress

[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.	In Progress
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.	In Progress (No Restricted Direct Customers Have Been Reinstated)

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.	In Progress
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.	In Progress
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 (MAY 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.	In Progress
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