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

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NINTH 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 Ninth Monitor Report covers the period from the filing of the Eighth Monitor Report on May 30, 2023, to the present (the "Ninth Reporting Period").[1] The Ninth Monitor Report: (1) provides an update on Mallinckrodt's implementation of the Monitor's recommendations in prior reports; (2) reviews the Monitor's work during the Ninth Reporting Period, including the Monitor Team's review of documents and data, and interviews and meetings with Mallinckrodt employees; (3) summarizes observations from the Monitor's fact-finding; and (4) describes anticipated next steps in future reporting periods.

1.2 During the Ninth Reporting Period, the Monitor once again assessed Mallinckrodt's compliance with the Operating Injunction by reviewing documents Mallinckrodt produced in response to the Monitor's Audit Plan[2] requests and ad hoc requests, and by conducting interviews. In response to the Audit Plan and the Monitor's ad hoc requests, during the Ninth Reporting Period Mallinckrodt provided over 517 files (consisting of 5.49 GB of documents and data).

[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 Ninth Monitor Report is being submitted 180 days after the submission of the Eighth Monitor Report.

[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.

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

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

1.5 During the Ninth Reporting Period, Mallinckrodt, through its outside counsel, informed the Monitor that it entered into a Restructuring Support Agreement ("RSA") in anticipation of initiating voluntary prepackaged Chapter 11 proceedings in the U.S. Bankruptcy Court for the District of Delaware. Mallinckrodt advised that it was considering initiating bankruptcy proceedings for the second time in three years when its bondholders asked Mallinckrodt to consider not making a scheduled payment of $200 million to the Opioid Master Disbursement Trust II (the "Opioid Trust") that had been due on June 16, 2023. Mallinckrodt filed a Form 8-K with the Securities and Exchange Commission ("SEC") on June 5, 2023, with this disclosure.

1.6 Subsequently, Mallinckrodt initiated Chapter 11 proceedings, and on October 10, 2023, the U.S. Bankruptcy Court confirmed Mallinckrodt's Plan of Reorganization (the "Plan"). According to Mallinckrodt, the Plan positioned the Company to emerge from Chapter 11 proceedings by the end of the year. Upon emergence,[4] Mallinckrodt stated that the Plan would

[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.

[4] On November 15, 2023, Mallinckrodt's outside counsel informed the Monitor Team that the Company announced that it successfully emerged from bankruptcy.

reduce Mallinckrodt's total funded debt by approximately $1.9 billion and provide Mallinckrodt with additional financial flexibility to meet its business obligations to customers, partners, vendors, suppliers and employees.

1.7 Under the RSA, Mallinckrodt will make one final $250 million payment to the Opioid Trust, in addition to the $450 million previously paid, to support the Opioid Trust's mission to address the U.S. opioid crisis and fund addiction treatment. Previously, pursuant to the agreement reached in Mallinckrodt's prior bankruptcy proceedings, Mallinckrodt had agreed to pay $1.7 billion to the Opioid Trust in exchange for settling pending opioid-related claims. As such, the new RSA represents a $1 billion reduction in payments to the Opioid Trust. Nonetheless, the Opioid Trust supported the RSA and Mallinckrodt's financial restructuring Plan.

1.8 Mallinckrodt's outside counsel advised the Monitor that these developments will not interfere with the Monitor's ongoing monitorship work in any way, and Mallinckrodt's obligations under the Operating Injunction remain in full force and effect. From the Monitor's perspective, the second bankruptcy proceeding has not altered Mallinckrodt's commitment to compliance with the Operating Injunction, or its compliance in fact.

* * *

1.9 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[5] 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.

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

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

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

[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.

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 supra* 2 ¶ 1.4 n.3, 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.

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

IV. THE INTEGRITY HOTLINE

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

4.2 During the Ninth Reporting Period (on or about August 25, 2023), SpecGx's Associate General Counsel informed the Monitor Team that Mallinckrodt had received a report to the Hotline that was mistakenly categorized as relating to the Operating Injunction. Upon determining that the report had no connection to the Operating Injunction, the Associate General Counsel corrected the report categorization and advised the Monitor Team to disregard the report. However, the Monitor Team advised the Associate General Counsel that the Monitor Team actually did not receive the report. The Associate General Counsel agreed to look into the matter and, in any event, to manually forward any such reports to the Monitor Team in the future. The Associate General Counsel subsequently explained that Mallinckrodt discovered an

issue with the selection process for Integrity Hotline reports—*i.e.*, namely, that a reporter was required to select both "Specialty Generics" and "Operating Injunction" for the Monitor to receive a notification. The Associate General Counsel advised that this error was corrected, so the Monitor Team should receive a notification of a hotline report anytime "Operating Injunction" is selected from the menu in the future. The Associate General Counsel subsequently input a test report to confirm the issue had been addressed, which was properly received by the Monitor Team.

4.3 On or about September 6, 2023, the Associate General Counsel shared a copy of a report that the Integrity & Compliance Manager submitted to test the Integrity Hotline system. Upon further inquiry from the Monitor Team about the frequency of such testing, the Associate General Counsel advised that this was the first test report submitted since the system's launch in May 2021. The Associate General Counsel further explained that the testing was prompted by Mallinckrodt's internal two-year review process for most of its policies and standard operating procedures ("SOPs"), including its Operating Injunction Policy.

4.4 Aside from the two mock hotline reports discussed above, as of the date of this Report the Monitor has still not received any relevant substantive reports relating to the Operating Injunction through the Integrity Hotline.

V. BAN ON PROMOTION (OI § III.A)

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

1. Promotional Review Committee ("PRC")

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

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

5.4 The PRC did not meet in the second quarter of 2023 because the PRC did not have any promotional materials to review. Therefore, the Monitor did not receive or review any meeting minutes from that quarter.

5.5 The PRC met once in the third quarter of 2023, on July 13, 2023. During this meeting, the PRC reviewed the revised website version of the Specialty Generics Product Catalog. Specifically, this version of the catalog was updated to address the Monitor's concern, raised in the Eighth Monitor Report, regarding the pre-listed methadone products contained in the sample DEA 222 Form in the catalog. *See* Eighth Monitor Report at 7-8 ¶¶ 6.7-6.9. Mallinckrodt agreed to address this concern by revising the DEA 222 form in subsequent versions of the Product Catalog, and did so during the Ninth Reporting Period.

2. TrackWise

5.6 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 in an internal database called "TrackWise."

5.7 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 Director of Post-Market Surveillance, or the Director's designee, with reviewing customer inquiries and complaints on a monthly basis, and with evaluating the PMT's responses for compliance with the Operating Injunction.

5.8 Beginning in the Fourth Reporting Period, and on an on-going basis as part of the agreed-upon Audit Plan, the Monitor has received and reviewed quarterly TrackWise inquiry and complaint entries pertaining to Opioids, as well as the results of this auditing process. During the Ninth Reporting Period, the Monitor Team reviewed TrackWise Opioid-related data for the second quarter of 2023. For the first time, TrackWise data logged by Mallinckrodt's third party call vendor was provided as well, in separate spreadsheets.

5.9 For the second quarter of 2023, like prior reviews, many TrackWise inquiries pertained to the composition of Mallinckrodt's Opioid Products, such as whether the products contain allergens (*e.g.*, gluten), while TrackWise complaints generally encompassed areas such as defects in patch adhesives, broken or missing tablets, or other product quality issues. Further, as discussed in the Eighth Monitor Report, there continued to be an increase in TrackWise inquiries pertaining to supply issues with Mallinckrodt's fentanyl patches.

5.10 During its review of the TrackWise inquiry data for June 2023, the Monitor Team noticed that a call-taker appeared to answer a question about a non-Mallinckrodt product: "Hydrocodone 325." The call-taker initially told the caller that the product was not manufactured by SpecGx, but nonetheless proceeded to answer additional questions. As noted further below, the Monitor Team discussed this inquiry with the Manager of Pharmacovigilance. *See infra* 11 ¶ 5.14 (noting that the caller's next question pertained to a Mallinckrodt product, as identified by the national drug code the caller referenced, and therefore, it was appropriate for

the call-taker to answer questions about the Mallinckrodt product's active ingredients and how it is prescribed).

5.11 During the Ninth Reporting Period the Monitor also reviewed the TrackWise Audit Reports for the second quarter of 2023. From this review, the Monitor noticed that the Senior Director, Quality was no longer conducting the audits. Instead, the audits were performed by the Manager of Pharmacovigilance,[6] including audits of both TrackWise inquiry and complaint data. According to the resulting audit reports, and consistent with past audits, the process did not reveal any instances requiring remedial training or other corrective action for the second quarter of 2023.

5.12 Given the change in personnel overseeing the TrackWise Audit Reports, the Monitor spoke with the Manager of Pharmacovigilance to gain a better understanding of her auditing process and her awareness of the relevant TrackWise policies and procedures, as well as the specific call pertaining to "Hydrocodone 325." The Manager explained that she is a licensed pharmacist, and has worked at Mallinckrodt for approximately six years. She described her daily job duties, including reviewing product adverse events with an emphasis on patient safety and escalating issues to management as needed, as well as her new role conducting audits of TrackWise data pertaining to Opioids. She explained that her audit process involves sorting the data by codes, analyzing trends, and confirming inquiries and complaints are appropriately escalated.

[6] This change is consistent with information provided to the Monitor during the last reporting period, in which the Senior Director, Quality informed the Monitor that she recently trained an additional employee, the Manager of Pharmacovigilance, to assist with the TrackWise auditing process.

5.13 When the Monitor Team asked the Manager of Pharmacovigilance what might raise a concern for her in the data, she mentioned that her review seeks to confirm whether the call-takers: (1) offered information to the patient that is appropriate, accurate and complete, including referring the patient to the package insert for the product; (2) directed the patient to their prescriber and health care provider for specific treatment questions; (3) provided appropriate literature to health care professionals upon request; and (4) did not engage in any promotion of Opioids or the Treatment of Pain. The Monitor is satisfied with these priorities, as stated by the Manager of Pharmacovigilance, and is reassured that the Manager is aware of the need to conduct a thoughtful and thorough monthly review of TrackWise data in accordance with Mallinckrodt's policies and procedures.

5.14 As for the June 2023 call pertaining to "Hydrocodone 325," the Manager explained that the caller initially asked about a non-Mallinckrodt product. However, the caller's next question pertained to a Mallinckrodt product, as identified by the national drug code the caller referenced. Accordingly, it was appropriate for the call-taker to answer questions about the Mallinckrodt product's active ingredients and how it is prescribed. The Manager agreed that if the caller had only asked about a non-Mallinckrodt product, the call-taker should not have provided any additional information, but that providing information under the circumstances was appropriate.

5.15 Based on the Monitor's review of the underlying TrackWise data and the audit reports for the second quarter of 2023, as well as his discussion with the Manager of Pharmacovigilance, it appears the TrackWise entries and audits are being conducted in a manner consistent with the Work Instruction and the Operating Injunction.

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

6.1 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 last produced to the Monitor (on or about April 6, 2023) updated sales compensation information for 2023. The Monitor looks forward to receiving updated sales compensation information for 2024, and will review and evaluate those materials, upon receipt.

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

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

1. SGGSAC

7.2 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 this reporting period, the Monitor reviewed the minutes of five SGGSAC meetings, which took place on April 13, April 27, May 30, June 21, and June 29, 2023, as well as several addenda to prior meeting minutes. Additionally, the Monitor reviewed the accompanying third party funding Request Forms, and

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

7.3 At the outset, the Monitor noted in his review of the meeting minutes that one of the members of the Committee, the Vice President of Clinical Development, was no longer listed as present or excused. After inquiring, the Monitor Team learned from the Integrity & Compliance Manager that this individual no longer worked for Mallinckrodt and that the open position on the Committee would be filled by his replacement, a new hire to the Company, once the new hire has been briefed on his role on the Committee.

7.4 The SGGSAC considered fifteen requests for sponsorships during the second quarter of 2023, totaling approximately $50,000. Most of these requests related to Mallinckrodt's addiction treatment products and the Company's growing business in that space, as well as opportunities for Mallinckrodt to connect with its customers in a variety of settings. Given the volume of these requests, below is a summary of just some of the most noteworthy requests:

(1) On May 30, 2023, the Committee reviewed a request for a small exhibitor fee for the North Carolina Association for the Treatment of Opioid Dependency, 2023 Best Practices in Opioid Treatment: Voices for Recovery event. In its review of this request, the Committee noted several session topics were listed as "coming soon" and one session topic was titled "Nursing – Fentanyl; A Complete Overview." Accordingly, the Committee felt additional information was required to decide on funding, and therefore placed the request on hold. If the Committee receives more information, this will be documented on an addendum to the meeting minutes, reflecting a denial or approval of the

request, and this information will be shared with the Monitor.[7]

(2) Also on May 30, 2023, the Committee reviewed and approved a request for exhibit fees and a sponsorship of the American Correctional Association's 153rd Congress of Corrections. Mallinckrodt's Director of Government Affairs & Patient Advocacy abstained from voting because he intended to attend the event.[8] This is consistent with the Monitor's prior comments on the desirability for Committee members not to vote on their own sponsorship requests to avoid any appearance of a conflict of interest. *See* Eighth Monitor Report at 17 ¶ 8.5(2). The Monitor appreciates the Committee's efforts.

(3) On June 21, 2023, the Committee reviewed a funding request for the RxSS 2023 Supplier Strategy Summit. According to Mallinckrodt, RxSS is a buying group with customers that consist of grocery store chains and small Pharmacy Benefit Managers. RxSS is also a customer of Mallinckrodt and a distributor of SpecGx's products. Based on the information provided to the Committee at the time, sessions at the Summit included an overview of pharmaceutical market trends and panel discussions on challenges and opportunities for the attendees. The Committee determined that it needed more information to evaluate these events, and placed the request on hold for further review. As noted above, it is the Monitor's understanding and expectation that, if the Committee receives more information, this will be documented on an addendum to the meeting minutes, reflecting a denial or approval of the request, and this information will be shared with the Monitor.

7.5 The SGGSAC also considered one request for a $150,000 grant to the Legal Action Center in the second quarter of 2023. According to its website, the Legal Action Center

[7] Mallinckrodt's outside counsel advised that the Company produced the Q3 2023 SGGSAC data to the Monitor, which reflects the outcome of these requests. The Monitor Team will review and summarize this data during the next reporting period.

[8] Consistent with the Monitor's comments, the Director of Government Affairs & Patient Advocacy also abstained from voting on one of his own requests, for the Biotechnology International Convention, during the April 27, 2023 SGGSAC meeting.

uses legal and policy strategies to fight discrimination, build health equity, and restore opportunity for people with arrest and conviction records, substance use disorders, and HIV or AIDS. According to Mallinckrodt, this grant supports its generics business because this organization helps improve patient access to medication-assisted treatment in the criminal justice system and helps improve access to Medicaid coverage after release. The Committee reviewed the request form and Statement of Work ("SOW"), and voted unanimously to approve the grant request.

7.6 The Monitor reviewed the SOW associated with the grant to the Legal Action Center, and noted that the SOW did not contain any language regarding the Operating Injunction and its provisions. However, the Monitor noted that he had previously received lobbyist certifications from this organization's Director / President, as well an additional employee, in which these employees agreed to abide by the Operating Injunction's terms pertaining to lobbying activities.

7.7 Furthermore, Mallinckrodt's Integrity & Compliance Manager confirmed that the Legal Action Center will be required to sign a Letter of Agreement that outlines compliance obligations under the Operating Injunction, pursuant to Mallinckrodt's funding policies, prior to releasing any grant money. Mallinckrodt subsequently produced this Letter of Agreement, signed by the Legal Action Center, to the Monitor. The Letter contained definitions, conditions, and prohibitions on the use of the grant money that tracked the Operating Injunction's funding provisions. Accordingly, the Monitor concludes that this grant complies with the terms of the Operating Injunction.

7.8 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 and addenda of any SGGSAC meetings on a quarterly basis. The Monitor will continue to work with Mallinckrodt to ensure the SGGSAC is operating consistently with Section III.C of the Operating Injunction as it relates to awarding grants and sponsorships to third parties.

2. Community Charitable Giving Program

7.9 During this reporting period, the Monitor Team spoke with Mallinckrodt's Director of Sustainability & Social Impact, who shared that one of her job duties is managing Mallinckrodt's Community Charitable Giving Program ("CCGP" or "Program"). She explained that, in her capacity as the manager of the Program, Mallinckrodt's website maintains a link for donation-seekers to access a portal through which they may submit a request for funding. The Director conducts an initial review of these requests, and either denies them immediately because they do not align with the Company's mission, or escalates them for further review by the Vice President of Government Affairs. When asked why a request might be denied automatically, the Director responded that the CCGP focuses on communities where Mallinckrodt has a footprint, so many requests are denied automatically based upon location. Further, the Program's two main priorities are (1) health and wellness and (2) STEM education, so requests may be denied if they do not align with those priorities. The Director also explained that she evaluates requests based upon comprehensive information that must be submitted by the requestor, including the grant application and tax status of the entity, as well as her own research utilizing websites such as Charity Navigator.

7.10 The Monitor Team reviewed the CCGP homepage on Mallinckrodt's website. The webpage lists Mallinckrodt's "strategic areas of giving," which aligned with the funding priorities outlined by the Director. The webpage also outlined the grant application requirements and types of grant requests Mallinckrodt would not fund, including discriminatory organizations,

partisan political organizations, religious groups, for-profit organizations, and individuals. Notably, the Operating Injunction and its funding restrictions were not mentioned anywhere on the webpage.

7.11 The Monitor Team inquired how the Director evaluates these requests in light of the Operating Injunction. The Director explained that she was familiar with the provisions banning the funding of anything related to the Treatment of Pain and Promotion of Opioids, and those requests would either be denied outright or forwarded to SpecGx's Integrity & Compliance Department for further review. When asked if she ever received any requests touching on those topics, she estimated that she received one or two from individuals submitting requests to the portal, and they were automatically denied.

7.12 Mallinckrodt suggested the Monitor Team speak with the Vice President of Government Affairs & Patient Advocacy for further clarification. Accordingly, the Monitor Team spoke with the Vice President and discussed his role in overseeing donation requests received through the CCGP webpage. He confirmed that this Program is focused on two specific funding priorities, as explained by the Director of Sustainability & Social Impact: (1) STEM education and (2) health and wellness. As such, many of these requests come from the same STEM education-focused organizations each year. When a request is received, the Vice President and Director will consult with one another, before making informal recommendations to Company leadership. When asked how these decisions were navigated in light of the Operating Injunction, the Vice President explained that everyone involved in the review and approval process was trained on the Operating Injunction and well-versed in its funding restrictions. Therefore, any donation requests that touched upon controlled substances or the Treatment of Pain would trigger a "red flag" and likely be denied outright. Nonetheless, it gives

the Monitor Team some pause that there is apparently a separate and parallel funding mechanism—independent of the SGGSAC—that seems not to be subject to the SGGSAC's comprehensive review and approval process. The Monitor will further address this in the next reporting period.

VIII. LOBBYING RESTRICTIONS (OI § III.D)

8.1 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.

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

8.3 During the Ninth Reporting Period, pursuant to the Audit Plan, the Monitor received and reviewed the results of the Government Affairs Team's second and third quarter 2023 audits 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 & Patient Advocacy, detail the states covered by the external lobbying firms encompassed in the review, the applicable state or federal disclosure report filing schedule, and an assessment of whether the activities reported comply with the Operating Injunction. They also provide links to the online filing location of the disclosure reports. Like the last several

audit reports, the second and third quarter 2023 audit reports did not identify any concerns or potentially violative activity.

8.4 Under the Audit Plan, the Monitor also receives a list of bills that Mallinckrodt's external lobbyists reported lobbying for or against on the company's behalf during the reporting period. The disclosure for the second quarter of 2023 revealed lobbying activity on two bills in Massachusetts, two in New York, [9] one in North Carolina, and one at the federal level. The disclosure for the third quarter of 2023 revealed lobbying activity only on two bills at the federal level. The Monitor Team reviewed each of these bills and discussed some of them with Mallinckrodt's external state and federal lobbyists, as detailed further below.

1. Interviews With External Lobbyists

8.5 As previously discussed in the Eighth Monitor Report, Mallinckrodt's list of bills produced for the last several quarters appeared to show an increase in lobbying activity in New York. During the Ninth Reporting Period, the Monitor Team spoke with a representative from Mallinckrodt's external lobbyist firm that covers New York lobbying ("NY Lobbyist"). The Monitor previously spoke with the NY Lobbyist in April 2022.

8.6 The NY Lobbyist reviewed with the Monitor Team each bill he has worked on over the last several quarters on Mallinckrodt's behalf. He explained that many of the bills were part of legislative packages, and that he was communicating the pharmaceutical industry's general position on the package, but listed the bills on his public disclosures for each company out of an abundance of caution. With respect to bills Mallinckrodt actively opposed, several

[9] With respect to Massachusetts and New York, Mallinckrodt listed two bills for each state. However, in both states, the bills were identical pieces of legislation moving on parallel tracks through the two legislative bodies in those states (*i.e.*, the House and Senate or Assembly). As such, as a practical matter, Mallinckrodt engaged in lobbying activity on one identical legislative initiative in each state during the second quarter of 2023.

were "advanced notice" bills, which required pharmaceutical companies to file notice in advance of any drug price increase, regardless of the amount, and pay a variable registration fee based upon the timing. He further explained that a narrower version of this bill passed through the legislature this year and was awaiting the Governor's signature. Currently, the NY Lobbyist is working on economic development projects pertaining to Mallinckrodt's facility in Hobart, New York. Based on the Monitor Team's legislative review and its discussion with the NY Lobbyist, these advocacy topics do not appear to implicate the Operating Injunction's lobbying restrictions.

8.7 As discussed in the Eighth Monitor Report, Mallinckrodt reduced its federal lobbying firms from three to one for budgetary reasons. The Monitor Team spoke with a representative of the remaining federal lobbying firm ("Federal Lobbyist") to discuss her work on Mallinckrodt's behalf at the national level. The Federal Lobbyist informed the Monitor Team she has been with her federal lobbying firm for the last twenty years, and currently co-leads the healthcare group, where she has approximately twelve to fifteen other clients in the healthcare space. She has advocated on Mallinckrodt's behalf since 2016, and most of her work for the company in recent years has been focused on industrial base expansion, meaning working with the federal government to build up and incentivize domestic manufacturing. All of her work is directed and overseen by Mallinckrodt's Vice President of Government Affairs & Advocacy, whom she speaks with regularly each week.

8.8 When asked to describe her understanding of the Operating Injunction's lobbying restrictions, the Federal Lobbyist stated she cannot lobby on Opioid-related issues, meaning "policies that would impact the sale, pricing, or distribution of Opioids," and cannot promote Opioids in any way. Therefore, with respect to legislation pertaining to Opioids, such as Opioid

taxes, she monitors the legislation and reports back to Mallinckrodt, but does not actively engage in any lobbying on the topic. [10]

8.9 The Monitor Team also inquired how the Federal Lobbyist ensures that her advocacy work for other healthcare clients does not run afoul of the Operating Injunction's lobbying restrictions that apply to Mallinckrodt. She explained that Mallinckrodt's Vice President of Government Affairs & Patient Advocacy, as a long-standing client, has the right to block any new clients that may generate a conflict of interest. Further, she explained that many of her healthcare clients do not engage individually on "sticky" issues, like drug pricing. Instead, they engage as an industry through their trade associations, rather than through their individual lobbyists. Finally, the Federal Lobbyist explained her understanding that her other pharmaceutical clients do not make Opioid Products. Based on this discussion, the Monitor Team was satisfied that the Federal Lobbyist understands her obligations under the Operating Injunction.

8.10 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 additional interviews with its lobbyists as needed.

[10] When the Monitor mentioned that the Operating Injunction allows for lobbying with respect to Opioid taxes, the Federal Lobbyist explained that she recently learned, through a training led by Mallinckrodt, that there was a little more "flexibility" in the Operating Injunction's lobbying restrictions than she initially thought. However, she preferred to "err on the side of caution," and therefore would never engage on an issue without running it by the Vice President of Government Affairs & Patient Advocacy first.

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

8.11 In the Eighth Monitor Report, the Monitor recommended Mallinckrodt provide annual training to Mallinckrodt's external lobbyists, focusing on the Operating Injunction's lobbying-related provisions, akin to the internal training Mallinckrodt has already conducted for its own employees, specifically the Government Affairs Team. Mallinckrodt agreed to the recommendation and implemented external lobbyist training accordingly.

8.12 During the Ninth Reporting Period, both the NY Lobbyist and the Federal Lobbyist informed the Monitor Team that they recently attended an Operating Injunction training led by Mallinckrodt's Integrity & Compliance Manager. Mallinckrodt later shared with the Monitor Team a copy of a PowerPoint presentation entitled "Operating Injunction for Specialty Generics Opioid Business: Contract Lobbyist Awareness Training," dated August 11, 2023, along with a spreadsheet tracking its lobbyists' attendance. The training was offered three times in August 2023, and one makeup session was offered in October 2023. The presentation reviewed the Operating Injunction's lobbying restrictions, and included hypothetical lobbying scenarios for the group to discuss regarding whether particular conduct was permissible or impermissible. Finally, the training reminded the contract lobbyists of the requirement that they each sign a Lobbyist Certification, and ended with time for questions.

8.13 Both Lobbyists independently praised the training, and emphasized how helpful the scenario discussion section of the training was to clarify and deepen their understanding of the Operating Injunction's lobbying restrictions. Both Lobbyists felt comfortable asking questions and engaging in the discussion. Accordingly, the Monitor believes *Recommendation 8(a)* has been satisfactorily implemented. The Monitor Team will continue to monitor future similar trainings.

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

8.14 During this reporting period, Mallinckrodt produced its 2022 Sustainability Report, which describes the company's key activities and initiatives to advance its Environmental, Social, and Governance program in 2022. The Monitor was particularly interested in the Governance section, which emphasized Mallinckrodt's commitment to good governance and a culture of integrity and responsibility throughout the organization. In this section, the Sustainability Report referenced the Operating Injunction and its restrictions, and provided a link to the Monitor's past reports. The same section discussed Mallinckrodt's commitment to "responsible lobbying" with the goal of advocating "for policies and positions that protect and expand patient access to innovative therapies, support medical innovation and a competitive marketplace, and advance principles of good corporate citizenship, including diversity, equity and inclusion."

8.15 The Governance section of the 2022 Sustainability Report also discussed Mallinckrodt's contributions to political candidates and other political groups through the Mallinckrodt LLC Political Action Committee ("MNKPAC"). The Monitor Team reviewed donations made by MNKPAC to date for the year 2023. In 2023, MNKPAC has given approximately $20,000 to various political candidates and political groups of both major national parties (*i.e.*, Democrats and Republicans). From the Monitor Team's review of the websites of these individuals and groups, none of the candidates or groups appear to advocate for positions implicating the Operating Injunction's provisions.

8.16 Finally, this section of the 2022 Sustainability Report linked to Mallinckrodt's *Policy on U.S. Political Contributions and Lobbying Activities*. This policy outlined Mallinckrodt's political advocacy priorities, as well as its guidelines when considering political candidates for donations by MNKPAC. Notably, however, the Policy does not reference the

Operating Injunction's lobbying and funding restrictions. The Monitor encourages Mallinckrodt to review this Policy and to consider whether revisions may be warranted to cross-reference Mallinckrodt's lobbying-related obligations under the Operating Injunction.

IX. 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)

9.1 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).

9.2 As noted in the Fourth and Eighth Monitor Reports, Mallinckrodt's Associate General Counsel and Vice President / General Counsel executed annual certifications under the Audit Plan in January 2022 and January 2023 respectively, providing certain certifications regarding Mallinckrodt's compliance with these provisions.

9.3 Consistent with the Audit Plan, *see supra* 1 ¶ 1.2, the Monitor anticipates an appropriate representative of SpecGx will re-certify Mallinckrodt's compliance with these provisions of the Operating Injunction in January 2024.

9.4 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.

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

10.1 In the Ninth 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 interviews with the Director of Controlled Substances Compliance ("CSC"), the Lead CSC Consultant (the "LCSCC") who is now known as one of two CSC Managers ("CSC Manager A"), and the newly hired second CSC Manager ("CSC Manager B").

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

1. Documents Reviewed During the Ninth Monitoring Period

10.3 Mallinckrodt timely produced all SOM-related documents requested under the Audit Plan for the second and third quarters of 2023. Mallinckrodt also timely produced all

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

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

(1) SOMT meeting materials and minutes for May, June, July, August, and September 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) the Government Communications logs for the second and third quarters of 2023 and related correspondence;

(5) sales data for highly diverted Opioid Products;

(6) direct customer flagged order data;

(7) selected suspicious order reports ("SORs") and related correspondence for flagged direct customer orders in May, June, July August, and September 2023;

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

(9) the SOMT's reports of due diligence visits to distributor customers;

(10) reports prepared by third party consultants for the terminated virtual distributor referred to in prior reports (*see, e.g.*, Eighth Monitor Report at 38 ¶¶ 11.30-11.32);

(11) the federal grand jury subpoenas Mallinckrodt received from the U.S. Attorney's Office for the Western District of Virginia, and Mallinckrodt's filings with the SEC reporting its receipt of those subpoenas; and

(12) The *Disclosure of Government Communications to Monitor* SOP.

2. Direct Customer Due Diligence

10.5 As the Monitor previously reported, Mallinckrodt has two systems for monitoring potentially suspicious direct customer orders. The first system is the direct customer dashboard that monitors orders for unusual quantity, pattern, or frequency. The second system, referred to as the "OI Hold system," monitors direct customer orders for potential violations of the Operation Injunction's provisions.

10.6 Mallinckrodt's OI Hold system places an automatic hold on an order if: (1) a customer that is not a DEA registrant places an order for a controlled substance; (2) the customer's industry segment (*e.g.*, retail pharmacy) is not authorized to purchase an Opioid Product (*see* OI § G.4); or (3) a customer only authorized to place orders for addiction treatment Opioids places an order for a non-addiction treatment Opioid. If an order flags on both systems—*i.e.*, both the direct customer dashboard and the OI Hold system—it will not ship until the SOMT releases both holds.

10.7 Each quarter, the Monitor Team reviews: (1) a report showing all of the flagged orders for Opioid Products during that period, by product, along with any backup documentation compiled by the Specialist, CSC ("CSC Specialist") as part of her due diligence; and (2) a report showing any orders flagged due to an OI Hold.

10.8 Additionally, the Monitor reviews the SORs for a randomly chosen week each month and a sample of any related correspondence to confirm the CSC Specialist completed her review of all of the flagged direct customer orders before determining whether to release them. In this reporting period, the Monitor reviewed the SORs for May, June, July, August, and September 2023.

a. *Direct Customer Flagged Orders for Q2 and Q3 2023*

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

10.10 Typically, almost all of the flagged direct customer orders are released after the CSC Specialist's and CSC Manager A's review. However, in the second quarter of 2023, the direct customer dashboard flagged two orders that, upon review, Mallinckrodt ultimately cancelled for the reasons discussed below.

10.11 ***First***, the direct customer dashboard flagged a methadose order in a larger amount than the customer typically ordered. Upon further inquiry, the CSC Specialist determined that the customer ("Clinic A") was attempting to supply a sister clinic ("Clinic B") that had recently changed its address. As Clinic B had not yet received its new Controlled Substance Ordering System ("CSOS") Certificate, it could not order methadose.[11] And since Clinic A did not have the necessary prior authorization from the DEA to distribute the methadose it ordered from Mallinckrodt to any another location, Mallinckrodt's Customer Service Department cancelled the order.

[11] "A CSOS Certificate is a digital identity issued by the DEA's CSOS Certification Authority (CSOS CA) that allows for electronic ordering for Schedule I and II (as well as III-V) controlled substances. A CSOS Certificate is the digital equivalent of the identification information contained on a DEA Form-222." *DEA Diversion Control Division, E-Commerce Program, About CSOS Certificates, available at* https://www.deaecom.gov/qanda.html#001%20001 (last visited Oct. 26, 2023).

10.12 ***Second***, in May 2023 the DEA published a notice of its intent to revoke the registration of one of Mallinckrodt's distributor customers ("Distributor A"), which would become effective within 30 days. As a result of that notice, Mallinckrodt decided to suspend all sales to Distributor A. When the customer attempted to place an order, both the direct customer dashboard and the OI Hold system discussed *infra* flagged the order, and it was cancelled by the Customer Service Department. This summer, the U.S. Court of Appeals for the Fifth Circuit granted Distributor A's request to stay entry of DEA's license revocation, pending the Fifth Circuit appeal. After Distributor A informed Mallinckrodt of the stay, the SOMT asked Distributor A to provide a third party compliance report to be considered for reinstatement. After reviewing the report, concurring with the findings therein, and further conferring with Distributor A, the SOMT reinstated Distributor A for the period of the stay.

10.13 While the vast majority of the flagged orders are released after the CSC Specialist's review, the above-described two cancelled orders show that this process is still a necessary part of Mallinckrodt's efforts to prevent diversion.

10.14 In the third quarter of 2023, the CSC Specialist and CSC Manager A released all of the orders the direct customer dashboard flagged.

b. *OI-Hold Reports for Q2 and Q3 2023*

10.15 Two subsequent orders Distributor A placed were flagged on the OI Hold report for the second quarter of 2023 because the SOMT had restricted Distributor A.

10.16 In the third quarter of 2023, two distributors' orders were flagged because their information was incorrect in Mallinckrodt's system. For the first distributor, the distributor was inaccurately characterized in Mallinckrodt's system as a retail pharmacy, and the order was cancelled. For the second distributor, Mallinckrodt's system did not reflect that the customer

could lawfully purchase certain controlled substances it ordered. After the CSC Specialist determined the hold was incorrectly placed on the order, it was released.

10.17 These examples in both the second and third quarters illustrate the importance of Mallinckrodt's multiple systems for flagging potentially suspicious orders for review based on different criteria.

c. *The SORs for May, June, July, August, and September 2023*

10.18 The SORs for selected weeks in this reporting period show that the CSC Specialist and CSC Manager A 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.

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

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

10.20 ***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. During the Ninth Reporting Period, Mallinckrodt provided reports from its visits with two distributors during the second quarter of 2023, Distributor A and Distributor B.

10.21 For the visit with Distributor A, Mallinckrodt's CSC Director, CSC Senior Manager, CSC Manager A, Director of Global Security, and CSC Specialist attended. They were joined by four representatives of Distributor A: the Director of Compliance and other individuals engaged in compliance, customer due diligence and site visits, and customer onboarding.

10.22 For the visit with Distributor B, one of the "Big Three" distributors, Mallinckrodt's Director of CSC and CSC Manager A attended. They were joined by five representatives of Distributor B: a Manager of IT Analytics, Manager of Customer Relations, Manager of CS Investigations, Regulatory Counsel, and VP of Regulatory Affairs.

10.23 The written reviews of these visits covered consistent topics. In some instances, however, the reports did not contain referenced attachments. Mallinckrodt subsequently provided these to the Monitor Team for review. For instance, the review of Distributor B indicated an attachment to the review addressing compliance obligations as a result of "any form of monitorship, court-ordered, or agreed upon compliance obligations." Similarly, the review of

Distributor A referenced an attached list of licensing in various states. Having now received them, the Monitor will review these attachments in the next reporting period.

10.24 Consistent with the Monitor's recommendation, the Mallinckrodt representatives who met with Distributor A learned that Distributor A has restricted sales of controlled substances to customers and the Mallinckrodt representatives asked if Distributor A would share the identity of those customers with Mallinckrodt. Distributor A representatives said they would confer with their legal counsel. In the next Reporting Period the Monitor will seek follow-up in this regard.

3. Downstream Registrant Due Diligence

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

	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023
Chargeback reviews	63	74	79	103	150
Chargeback restrictions	15	28	42	42	59
Chargeback reinstatements	5	3	6	6	3
Chargeback reinstatements denied	0	0	0	2	3

10.26 As noted in the Eighth Monitor Report, an increased volume of chargeback reviews raised a natural question regarding resource allocation sufficiency. For instance, the Monitor Team learned, in the Eighth Reporting Period that, due to the manner in which the dashboard ranks and prioritizes pharmacies, it is possible for pharmacies to be flagged, and even

prioritized for review, yet not be ranked sufficiently high in the prioritization to be reviewed for restriction. This was, in part, an issue of resource allocation sufficiency, given that only two employees—CSC Manager A and the CSC Specialist—were conducting chargeback reviews. As discussed in greater detail below, SpecGx's hiring of an additional CSC Manager will undoubtedly help in this regard.

10.27 ***Prior Recommendation 8(b).*** The resource allocation challenge is related to a different issue (which was the subject of *Recommendation 8(b)*), namely whether Mallinckrodt is reviewing a statistically valid sample of the flagged and prioritized pharmacies, while leaving others of presumably lower risk on the proverbial "cutting room floor"—*i.e.*, unreviewed. For instance, as noted in the Eighth Monitor Report, of the 71 ***retail*** pharmacies ranked in a sample prioritization shared with the Monitor Team, only about 35 (or approximately 50%) were reviewed. And of 127 ***chain*** pharmacies ranked for review, only about 14 (or approximately 11%) were reviewed. This prompted the Monitor's recommendation 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. This recommendation remains pending implementation at this time, although Mallinckrodt has informed the Monitor Team that the SOMT is presently conducting parallel analyses of different approaches to ranking and prioritization. The Monitor looks forward to the final results of this analysis and what the SOMT identifies to strengthen the existing ranking and prioritization.

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

10.28 In the Ninth Reporting Period, the Monitor reviewed SOMT meeting materials and minutes for May, June, July, August, and September 2023. The results of that review, and

the Monitor's related findings from interviews with the CSC Director and CSC Manager A,[12] are summarized below.

i. SOMT meeting materials and minutes for May 2023

10.29 As noted in the summary chart below, the May 2023 minutes reflect consideration of 29 pharmacies for chargeback restrictions, of which 11 were restricted, and 5 pharmacies for chargeback reinstatement, of which 3 were reinstated.

May 2023 SOMT Meeting		
New chargeback[13] restriction reviews	14 reviewed	10 restricted
Older chargeback restriction reviews	7 reviewed	1 restricted
No action recommended to SOMT	8 recommended	8 accepted
Chargeback reinstatement reviews	5 reviewed	3 reinstated

10.30 ***The SOMT's review of more chain pharmacies.*** In May, the SOMT conducted chargeback reviews of several chain pharmacies. As the Monitor previously reported, the SOMT has typically prioritized conducting chargeback reviews for independent pharmacies, which may

[12] As discussed *supra* 25 ¶ 10.1, during the Ninth Reporting Period Mallinckrodt changed the title of the Lead Controlled Substances Compliance Consultant ("LCSCC"). That position is now the Manager, CSC. And, with the new hire during the Ninth Reporting Period discussed in this report, there are now two Managers, referred to herein as CSC Managers A and B.

[13] If the SOMT has considered a pharmacy for a chargeback restriction prior to the SOMT meeting that month, and resolves how to address the pharmacy before the SOMT meeting (*e.g.*, an ad hoc review prompted by a media alert), the Monitor Team regards this as a new chargeback restriction. Thus, for example, if the SOMT reviewed a pharmacy for restriction following the April 2023 SOMT meeting, and resolved what to do with the pharmacy before the May 2023 SOMT meeting, this is counted as a new chargeback review. "Older chargeback reviews" refers to chargeback review initiated in a prior month that are being reviewed by the SOMT for follow-up.

be more likely to have less extensive and sophisticated SOM programs compared to bigger retailers.

10.31 While chains traditionally may be viewed as posing less risk than smaller independent retail pharmacies, the allegations in a recent U.S. Department of Justice complaint against one such chain, as discussed in the Eighth Monitor Report, remind us that the large chain retail segment of the industry is not entirely immune from risk. *See* Eighth Monitor Report at 39 ¶ 11.35, 59 ¶ 11.77 to 61 ¶ 11.91.

10.32 Although the SOMT has always conducted chargeback reviews for both types of downstream customers, in May 2023 the Monitor observed that the SOMT conducted even more reviews of chain pharmacies than in prior months. The CSC Director and CSC Manager A informed the Monitor that they expect this trend to continue because Mallinckrodt has now hired an additional SOMT member, as discussed *infra*. With the addition of that new team member, the SOMT plans to conduct even more reviews of all types of pharmacies flagged by the indirect customer dashboard. s

10.33 ***The indirect customer dashboard remains a sophisticated tool in Mallinckrodt's prevention of diversion, and it is still evolving.*** As the Monitor has previously reported, the indirect customer dashboard compiles a variety of valuable data sources, including Mallinckrodt's chargeback data and publicly available information from the Automated Reports and Consolidated Ordering System ("ARCOS").[14] The dashboard analyzes that data and flags

[14] ARCOS is a data collection system in which manufacturers and distributors report their controlled substances transactions to the DEA. *See* U.S. Department of Justice, DEA, Diversion Control Division, "ARCOS Retail Drug Summary Reports," *available at* https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/#:~:text=Automated%20Reports%20and%20Consolidated%20Ordering,Drug%20Enforcement%20Administration%20(DEA) (last visited on Nov. 27, 2023).

indirect customers for the SOMT's review based upon, among other things, the potentially suspicious growth, volume, or unusual purchase pattern or trend of the orders of Mallinckrodt products; per capital utilization of a controlled substance; and ARCOS data (such as the number of distributors from whom the pharmacy purchases a controlled substance, and the total number of different controlled substances the pharmacy purchases). Based upon these metrics, the indirect customer dashboard ranks and prioritizes the pharmacies that are flagged for the SOMT's review.

10.34 Recently, the SOMT incorporated additional data into the indirect customer dashboard—a tab reflecting the growth of the ARCOS volume for any product an indirect customer purchases. While the indirect customer dashboard does not incorporate ARCOS volume in ranking and prioritizing indirect customers for review, the SOMT can now easily consult this data through the indirect customer dashboard while conducting chargeback reviews.

10.35 Each of the metrics the indirect customer dashboard analyzes and the other data sources it incorporates provides important information in combating diversion. For example, in May 2023 the SOMT restricted six pharmacies flagged for three different metrics, and Mallinckrodt conducted chargeback reviews for additional pharmacies flagged based on other metrics as well. Thus, as the May 2023 SOMT meeting minutes reflect, the breadth of the information analyzed allows Mallinckrodt to detect potential diversion in a multitude of ways. Moreover, the SOMT's recent adjustments to the indirect customer dashboard allow the SOMT to more efficiently conduct chargeback reviews.

10.36 For example, by incorporating the ARCOS growth metric, the SOMT can determine whether a registrant's increased ordering of a product from Mallinckrodt could be the result of rational market dynamics as opposed to diversion. Thus, if a registrant's orders from

Mallinckrodt increase because, for instance, another source of supply has left the market, that would of course increase demand for Mallinckrodt's product for reasons having nothing to do with diversion. And so, this metric enables the SOMT to spend less time reviewing pharmacies that flag for suspicious growth if it can be determined that its increased proportion of purchases through Mallinckrodt is due to supply constraints to that pharmacy.

10.37 The CSC Director and CSC Manager A are also in the process of making changes to how the indirect customer dashboard prioritizes pharmacies for review. For example, they have decided to allocate less weight in the prioritization calculation to chargeback reviews for addiction-treatment drugs, while adding more weight to higher risk products. The SOMT is in the process of testing the new prioritization model by running the old model and the new model side by side, and the Monitor looks forward to further discussing the results of this test with the CSC Director and CSC Manager A in the next reporting period.

10.38 In sum, the indirect customer dashboard has continued to evolve based on its real-world application over the past year. The CSC Director's and CSC Manager A's efforts to further hone the usefulness of the indirect customers' dashboard data output appears to be resulting in meaningful improvements in the efficiency and effectiveness of the chargeback review process, and the Monitor hopes the SOMT continues to proactively make adjustments in the future as necessary.

ii. SOMT meeting materials and minutes for June 2023

10.39 As noted in the summary chart below, the June 2023 minutes reflect consideration of 45 pharmacies for chargeback restrictions, of which 19 were restricted, and 2 pharmacies for chargeback reinstatement, of which 1 was reinstated.

June 2023 SOMT Meeting		
New chargeback restriction reviews	29 reviewed	19 restricted
Older chargeback restriction reviews	4 reviewed	0 restricted
No action recommended to SOMT	12 recommended	12 accepted
Chargeback reinstatement reviews	2 reviewed	1 reinstated

10.40 ***The SOMT continues to restrict pharmacies based on available ARCOS data***. As discussed *supra*, the indirect customer dashboard incorporates available ARCOS data, including the number of distributors supplying a particular drug family to each indirect customer, the indirect customer's total ARCOS purchases, and the growth of each indirect customer's ARCOS purchase for a drug family. The SOMT uses this data not only to flag indirect customers for review but also to conduct chargeback reviews. For example, the SOMT may compare an indirect customer's total reportable purchases for a drug family to nearby pharmacies' purchases of the same drug family to assess the reasonableness of the amount purchased by the indirect customer given its size and the number of competing pharmacies in the area.

10.41 Often, as was the case in June, the SOMT's chargeback restrictions are premised on ARCOS data. For example, in June, the SOMT restricted 6 indirect customers on an ad hoc basis based on ARCOS data. The SOMT also conducted chargeback reviews for four other indirect customers that were flagged for an unusual purchasing pattern or trend because ARCOS revealed oxycodone compromised 90 percent or more of their total reportable drug purchases, ultimately restricting three of those indirect customers. The SOMT restricted two more indirect

customers based on the high percentage of their purchases of hydrocodone compared to their total ARCOS reportable purchases.

10.42 These restrictions further demonstrate the value of sharing information to potentially prevent diversion and make a case for requiring companies across the supply chain to publicly report certain information regarding purchases of opioid products (as well as other products with a likelihood of diversion). Indeed, the Monitor previously recommended that Mallinckrodt continue to pursue establishing a public-private "clearing house" for such information. *See* Exhibit 1, *Prior Recommendation 2(j)*. Based upon discussions during the Ninth Reporting Period, Mallinckrodt is willing to explore potential involvement in the clearinghouse established in the "Big Three" monitorship.

iii. SOMT meeting materials and minutes for July 2023

10.43 As noted in the summary chart below, the July 2023 minutes reflect consideration of 36 pharmacies for chargeback restrictions, of which 8 were restricted, and 2 pharmacies reviewed for chargeback reinstatement, of which 0 were reinstated.

July 2023 SOMT Meeting		
New chargeback restriction reviews	18 reviewed	8 restricted
Older chargeback restriction reviews	7 reviewed	0 restricted
No action recommended to SOMT	11 recommended	11 accepted
Chargeback reinstatement reviews	2 reviewed	0 reinstated

10.44 ***Improvement in sharing of information by one "Big Three" distributor.*** The Monitor Team learned from the CSC Director and CSC Manager A that the sharing of information from one of the Big Three distributors ("Distributor C") improved in the Ninth

Reporting Period, with agreement reached to meet with SOM counterparts at Distributor C on a monthly basis. Nonetheless, better and more timely communication from Distributor C is still needed. The Monitor hopes that this relationship will deepen to the point that Distributor C, like another Big Three distributor ("Distributor B"), can proactively share intelligence with Mallinckrodt before Mallinckrodt requests it. By way of example, in April 2023 the SOMT restricted a particular pharmacy in Florida after Mallinckrodt learned from Distributor B that Distributor B had restricted the pharmacy due to concerns about the pharmacy's drug diversion controls. Mallinckrodt restricted the pharmacy after contacting Distributor C but receiving no information. Subsequently, in May 2023, only after the pharmacy sought reinstatement, Mallinckrodt learned that Distributor C had actually already restricted the customer in February 2023. Knowing that information earlier could have averted Mallinckrodt's continued supply of a suspicious pharmacy for several months.

iv. SOMT meeting materials and minutes for August 2023

10.45 As noted in the summary chart below, the August 2023 minutes reflect consideration of 58 pharmacies for chargeback restrictions, of which 18 were restricted, and 3 pharmacies for chargeback reinstatement, of which 3 were reinstated.

August 2023 SOMT Meeting		
New chargeback restriction reviews	31 reviewed	18 restricted
Older chargeback restriction reviews	8 reviewed	0 restricted
No action recommended to SOMT	19 recommended	19 accepted
Chargeback reinstatement reviews	3 reviewed	3 reinstated

10.46 ***Length of time for review of chargebacks***. As previously discussed, the Monitor recommended that Mallinckrodt 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 in this review process and what, if anything, can (or should) be done to reduce them. *See* Exhibit 1, *Prior Recommendation 4(a)*; *see also* Fourth Monitor Report at 31 ¶ 11.27. Mallinckrodt implemented that recommendation and thus, has been tracking the time required at each phase of chargeback review since at least the Fourth Monitor Report in a "Tracking Spreadsheet."

10.47 As the Monitor has subsequently discussed at some length, *see* Sixth Monitor Report at 51-55, the Monitor refrained from making a specific recommendation regarding the advisable time frame for any particular stage of the review process, and has deferred to Mallinckrodt the decision of what appropriate internal "rule of thumb" it may wish to use. Nonetheless, following review of the Tracking Spreadsheet from August, the Monitor Team noted—and raised with the CSC Director and CSC Manager A—that it seemed there had been some lengthening beyond the 60-day timeframe that Mallinckrodt has allowed for distributors to respond to an inquiry for due diligence. The CSC Director and CSC Manager A explained that if a distributor responds with some indication that its investigation is ongoing, Mallinckrodt is inclined to permit that process to unfold, even if it requires more than 60 days.

10.48 While the Monitor is still of the view that Mallinckrodt should decide what threshold to adopt for permitting time for the distributors' responses, the SOMT is encouraged to keep a close eye on the Tracking Spreadsheet for delays by the distributors that may be unreasonable in order to determine whether Mallinckrodt should decide to restrict a downstream registrant without further information from the distributor. By way of example, the August

SOMT meeting minutes reflect discussion of a particular pharmacy that Mallinckrodt decided to restrict after three months without a response to a due diligence request directed to "Big Three" Distributor B. This delay was surprising, given the normally proactive approach of Distributor B.

v. SOMT meeting materials and minutes for September 2023

10.49 As noted in the summary chart below, the September 2023 minutes reflect consideration of 60 pharmacies for chargeback restrictions, of which 28 were restricted, and 2 pharmacies for chargeback reinstatement, of which 1 was reinstated.

September 2023 SOMT Meeting		
New chargeback restriction reviews	35 reviewed	25 restricted
Older chargeback restriction reviews	14 reviewed	3 restricted
No action recommended to SOMT	11 recommended	11 accepted
Chargeback reinstatement reviews	2 reviewed	1 reinstated

10.50 ***Deferral to newly established monthly meetings with Distributor C***. As noted above, Mallinckrodt has arranged to confer monthly with Distributor C. In the September SOMT meeting minutes there are many instances in which the SOMT deferred a final decision on a chargeback restriction review to the October meeting with Distributor C. The Monitor Team will review the October SOMT minutes in the next reporting period with interest to determine whether the monthly meetings with Distributor C are helping to reduce the delayed response time from Distributor C to requests for information from Mallinckrodt.

4. Other SOM-related Issues

a. *Government Communications Log*

10.51 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.

10.52 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.[15]

10.53 In assessing Mallinckrodt's compliance with that provision, the Monitor Team reviewed Mallinckrodt's Communication Logs for the second and third quarters of 2023 and related correspondence concerning inquiries that appear related to Opioid Products, excluding medications typically prescribed for addiction treatment.[16]

10.54 Of the 48 government inquiries in the second quarter of 2023, four related to fentanyl and oxycodone products and one concerned a chargeback restriction. Of those five inquires, four were from the DEA and one was from a state police department. In each instance, Mallinckrodt provided a timely and appropriate response.

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

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

10.55 Of the 49 government inquiries in the third quarter of 2023, two related to morphine sulfate oral solution and oxycodone products. Of those two inquires, one was from the DEA and one was from a county sheriff's office. In each instance, Mallinckrodt provided a timely and appropriate response.

b. *SOM-related TrackWise Entries*

10.56 In the Sixth Monitor Report, the Monitor recommended that any evidence of diversion risks appearing in the TrackWise inquiry and complaint logs (discussed *supra* 8-10 ¶¶ 5.6-5.15) be escalated by the Associate General Counsel (or her designee) to the CSC Director for his review and included in SOMT pharmacy reviews, as appropriate (*see Prior Recommendation 6(f)*). Thereafter, the Monitor amended the Audit Plan to require Mallinckrodt to provide, on a quarterly basis, copies of any inquiries elevated to the CSC Director and documents reflecting the outcome of any related investigation.

10.57 For the second and third quarters of 2023, Mallinckrodt informed the Monitor there were no such TrackWise inquiries.

c. *Hiring of new SOM personnel*

10.58 As noted above, *see supra* 35 ¶ 10.32, Mallinckrodt hired an additional CSC Manager ("CSC Manager B") who began work on or about September 9, 2023. As was the case with the most recent prior CSC Manager hire (referred to as "CSC Manager A"), CSC Manager B comes to Mallinckrodt after having served as a Diversion Group Supervisor for the DEA. CSC Manager B most recently served in that capacity in the DEA Office in San Antonio, Texas, where she worked for approximately 18 years.

10.59 CSC Manager B explained that she has spent her initial weeks at Mallinckrodt assisting CSC Manager A in conducting chargeback reviews of downstream registrants, and has also assisted with direct customer order reviews. She has also begun to attend monthly SOMT

meetings. CSC Manager B appears competent and engaged, and given her extensive investigatory experience with supervised registrants, is a welcome addition to the SOMT.

XI. TRAINING (OI § III.K)

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

11.2 During the Ninth Reporting Period, the Monitor audited Mallinckrodt's compliance with the Operating Injunction's training requirements by reviewing whether all employees hired during the second and third quarters of 2023 completed their Operating Injunction trainings. Additionally, as noted immediately below, the Monitor Team surveyed a series of Town Hall meetings to evaluate the "tone from the top" conveyed in these meetings regarding the Monitorship and the Operating Injunction.

1. Town Halls

11.3 During the Ninth Reporting Period, the Monitor Team received and reviewed recordings of all Mallinckrodt's internal quarterly Town Hall meetings held between May 2021 and April 2023.

11.4 During these Town Hall meetings, in addition to discussing general topics pertaining to the business, Mallinckrodt and SpecGx leadership spoke positively about the Operating Injunction and the importance of complying with its terms. The leadership team explained to employees that the monitorship has not "hamstrung" Mallinckrodt in any way—instead, it has resulted in Mallinckrodt's "best in class" and industry-leading SOM program. Further, the leadership team explained that monitorships are a positive development for the pharmaceutical industry as a whole, and they welcomed the opportunity for other companies to rise to the standard Mallinckrodt has set during its monitorship.

11.5 By way of limited example, Mallinckrodt's Chief Executive Officer attended a recent in-person Town Hall in April 2023 at Mallinckrodt's Hobart, New York facility. He told employees the Operating Injunction helps prevent misuse of their Opioid Products and "makes sure we do things the right way."

11.6 Thus, the Monitor is satisfied that Mallinckrodt's leadership is continuing to set an appropriate "tone from the top" that emphasizes the benefits of the Operating Injunction and ongoing compliance with its terms.

2. Trainings for New Employees in Second and Third Quarters of 2023

11.7 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.

11.8 In the Ninth Reporting Period, Mallinckrodt informed the Monitor that twelve of the fifteen employees hired in the second and third quarters of 2023, who were required to receive Operating Injunction training, completed each training component.

11.9 Specifically, Mallinckrodt identified nine employees hired in the second 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. Seven employees completed all of the training components in the second quarter of 2023, and the remaining two employees began their trainings in the second quarter but completed them in the third quarter.

11.10 Mallinckrodt identified six employees hired during the third quarter of 2023. Three 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. The remaining three employees signed the policy and completed the survey. However, these three employees were scheduled for live training during the fourth quarter of 2023, and therefore, did not yet complete the Operating Injunction quiz that follows the live training. The Monitor will confirm that these employees have completed all of the training requirements during the next quarter.

11.11 During this reporting period, the Monitor planned to attend certain live trainings sessions for newly hired employees to further assess the efficacy of such training of employees on the Operating Injunction's requirements. However, after further consideration, the Monitor determined that attending the smaller group sessions typical for new employees would be less effective than attending training sessions with the larger annual group that are scheduled to take place in the next reporting period. Additionally, the Monitor will continue to confirm that all Mallinckrodt employees complete their Operating Injunction training and review the relevant materials during the next reporting period.

11.12 Additionally, in the next reporting period, the Monitor will review any updated materials Mallinckrodt prepares for employee annual trainings in 2024.

3. New Third Party Training Under Consideration for Operating Injunction Training

11.13 Mallinckrodt and its counsel have advised the Monitor Team that for the annual training on the Operating Injunction scheduled for the first quarter of 2024, the company is considering utilizing a third party vendor to conduct a more interactive training, rather than the large group trainings it has conducted to date. As explained to the Monitor Team, Mallinckrodt's Compliance Department believes that such interactive training is important. (The Monitor Team agrees, and has noted the need to ensure participation previously. *See* Sixth

Monitor Report at 65-66 ¶¶ 12.5-12.8.) The new training medium anticipates one-on-one computer-based training. In light of the significant expense of such training, Mallinckrodt has committed to demonstrating such training for the Monitor Team before committing to this new approach. Assuming the new approach is adopted, the Monitor Team will review the training upon implementation.

XII. CLINICAL DATA TRANSPARENCY (OI § IV)

12.1 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.

12.2 As the Monitor previously reported, Mallinckrodt contracted with Vivli Inc. ("Vivli") to make such data available, and Mallinckrodt has advised the Monitor that all of the data required to be shared under Section IV is available through that platform.[17] Any research proposals submitted through Vivli will be reviewed for scientific merit by an independent review panel.

12.3 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 during the second or third quarters of 2023.

12.4 Likewise, there were no new Mallinckrodt Opioid Products, or indications for existing products, in the second quarter of 2023. However, in the third quarter of 2023 Mallinckrodt released a new indication for its Morphine Sulfate Tablets in 15 mg and 30 mg dosages. Through its Associate General Counsel, Mallinckrodt informed the Monitor that

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

Mallinckrodt performed a bioequivalence study with respect to these new indications and provided information about the study to Vivli to upload to the existing public platform, as the Operating Injunction requires.

12.5 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.

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

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

XIV. MALLINCKRODT'S RECEIPT OF FEDERAL GRAND JURY SUBPOENAS IN NINTH REPORTING PERIOD

14.1 During the Ninth Reporting Period, Mallinckrodt and its subsidiaries received two federal grand jury subpoenas from the U.S. Attorney's Office ("USAO") for the Western District of Virginia relating to its controlled substances business. The first was directed to SpecGX LLC, Mallinckrodt plc, and Mallinckrodt LLC. SpecGx alone received a second subpoena directed to its Custodian of Records. In both instances Mallinckrodt advised the Monitor Team of the receipt of these subpoenas. Mallinckrodt also publicly disclosed the receipt of the subpoenas in its filings with the SEC.

14.2 On or about August 22, 2023, Mallinckrodt received the first federal grand jury subpoena from the USAO dated August 16, 2023. Mallinckrodt reported its receipt of the

subpoena publicly in its Form 8K filing with the SEC on August 28, 2023 (under Item 7.01 of that filing).[18] The disclosure states, in relevant part:

> On August 22, 2023, the Company received a grand jury subpoena from the U.S. Attorney's Office for the Western District of Virginia ("USAO") seeking production of data and information for the time period from July 17, 2017 to the present, including information and data relating to the Company's reporting of suspicious orders for controlled substances, chargebacks and other transactions, and communications between the Company and the U.S. Drug Enforcement Administration ("DEA") regarding those issues. The Company's legal representatives discussed the intended scope of the subpoena and initial timeline with the USAO on August 24, 2023.
>
> The Company is in the process of responding to the subpoena and intends to cooperate in the investigation and share information with the USAO about the operating injunction under which the Company's Specialty Generics segment has been operating since October 2020 and which was agreed to by 50 state and territory attorneys general and entered by the U.S. Bankruptcy Court for the District of Delaware ("operating injunction"). Among other things, the operating injunction provides that Specialty Generics must retain an independent monitor to evaluate and audit compliance with the operating injunction. R. Gil Kerlikowske, former Director of the Office of National Drug Control Policy and former Commissioner of U.S. Customs and Border Protection, currently serves as the monitor and issues periodic reports on Specialty Generics' compliance program, which can be found on the Company's web site at https://www.mallinckrodt.com/corporate-responsibility/corporatecompliance/.
>
> The Company believes that Specialty Generics is in compliance with its obligations through its industry-leading compliance program for controlled substances. Prior to the existing operating injunction, Specialty Generics operated under a compliance-related memorandum of understanding with DEA established in July 2017 that expired in July 2020.

14.3 Mallinckrodt's outside legal counsel informed the Monitor Team of Mallinckrodt's receipt of the grand jury subpoena. The Monitor Team subsequently discussed with Mallinckrodt's outside counsel, with the state Attorneys General, and with the USAO itself, the implications for the Monitorship of a parallel U.S. Department of Justice investigation that

[18] The filing is available on Mallinckrodt's website here: https://ir.mallinckrodt.com/static-files/4a137382-21fb-4ecd-b195-50467f0f0ca1.

(1) apparently addresses overlapping subject matter covered in the Operating Injunction and (2) will continue concurrently with the monitorship.

14.4 The Monitor advised the state Attorneys General of the subpoena (through a representative member of the coalition of states), and met, via Zoom, with a group of those state Attorneys General on September 27, 2023. These included representatives of the states of Kentucky, New York, North Carolina, Pennsylvania, Tennessee, and Wisconsin.

14.5 The Monitor Team learned of the second grand jury subpoena served upon SpecGx from the same USAO, dated September 27, 2023. This subpoena seeks a narrower set of information. Mallinckrodt disclosed its receipt of this subpoena in its Form 10Q filing with the SEC on November 7, 2023.[19] The filing notes Mallinckrodt's view that it "believes that Specialty Generics is in compliance with its obligations through its industry-leading compliance program for controlled substances," and "is in the process of responding to the subpoenas and intends to cooperate in the investigation."

14.6 Mallinckrodt's Form 10Q filing also notes that on October 11, 2023, Mallinckrodt's outside counsel "met with the USAO to, among other things, share information with the USAO about the operating injunction under which the Company's Specialty Generics segment has been operating since October 2020 and which was agreed to by 50 state and territory attorneys general and entered by the Bankruptcy Court."

14.7 On October 23, 2023, the Monitor's counsel met with a representative of the USAO, via Zoom. During that meeting the Monitor's counsel explained the potential for overlap, and the interest of the Monitor Team in "deconflicting" with the USAO investigation,

[19] The filing is available on Mallinckrodt's website here: https://ir.mallinckrodt.com/static-files/0fde7cba-ec2d-49b2-bc4f-a0bddc119270.

due to the concern that witnesses may be chilled in their discussions with the Monitor Team in light of the pending USAO investigation. Representatives of the USAO were understanding of the Monitor's counsel's concerns, and said they would try to take them into account.

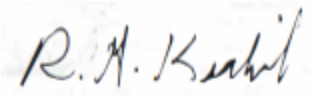
14.8 The Monitor Team has requested that Mallinckrodt and its counsel share with the Monitor Team copies of the cover letters accompanying Mallinckrodt's productions in response to the subpoenas, in lieu of copies of the productions to the USAO themselves, so that the Monitor Team can be apprised of the contents of those productions and what, if any, materials the Monitor Team may wish to review. Mallinckrodt and its counsel have agreed to this request. Accordingly, as of the date of this Report, the Monitor Team has received three production cover letters dated October 6, October 23, and October 31, 2023.

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 Ninth Monitor Report.



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

EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE NINTH MONITOR REPORT DATED NOVEMBER 27, 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.	Implemented and Ongoing
4.	**2(d)**	Use best efforts to ensure chargeback restrictions restrict not only chargeback payments, but also the supply of Opioid Products to a restricted pharmacy.	Implemented and Ongoing
5.	**2(e)**	Use best efforts to obtain timely provision of chargeback data from direct customers.	Implemented and Ongoing

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

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

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

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

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

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

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

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

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

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

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
29.	**6(a)**	Include explicit references to the Operating Injunction in Sales Compensation Plans for future years.	Implemented
30.	**6(b)**	Provide additional training to the Human Resources Department (by Mallinckrodt's legal counsel) to prevent consideration of improper incentives in bonus recommendations.	Implemented
31.	**6(c)**	Ensure greater consistency among direct customer audit reports, and more fulsome follow-up where necessary to obtain compliance assurances.	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.	Implemented and Ongoing
34.	**6(f)**	Ensure evidence of diversion risks appearing in the TrackWise inquiry and complaint logs escalated by the Associate General Counsel (or designee) is reviewed and included in SOMT pharmacy reviews, as appropriate.	Implemented

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

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