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

December 1, 2022

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SEVENTH 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:

1. EXECUTIVE SUMMARY

1.1 This Seventh Monitor Report covers the period from the filing of the Sixth Monitor Report on September 1, 2022, to the present (the "Seventh Reporting Period"). The Seventh Monitor Report: (1) provides an update on Mallinckrodt's implementation of the Monitor's recommendations in prior reports; (2) reviews the Monitor's actions during the Seventh Reporting Period, including the review of documents and data, and interviews or 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 A summary of the Monitor's recommendations to date appears in the chart attached as **Exhibit 1**.

1.3 During the Seventh Reporting Period, the Monitor reviewed Mallinckrodt's compliance with the Operating Injunction by reviewing documents Mallinckrodt produced in response to the Monitor's Audit Plan requests and ad hoc requests, visiting Mallinckrodt's manufacturing facility in Hobart, New York, and conducting interviews.

1.4 As described in the Fourth Monitor Report, *see* Fourth Monitor Report at 2 ¶ 1.3, 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"). In response to the Audit Plan and the Monitor's

ad hoc requests, during the Seventh Reporting Period Mallinckrodt provided over 136 files (consisting of 697 MB of documents and data).

1.5 ***Mallinckrodt's emergence from bankruptcy and resolution of opioid litigation.*** As previously reported, Mallinckrodt's emergence from bankruptcy established an Effective Date—*i.e.*, "the date on which the Chapter 11 Plan goes effective."[1] This Effective Date: (1) permits the settling states (*i.e.*, the 50 state signatories to the Restructuring Support Agreement[2]) to enforce the terms of the Operating Injunction in each of the states;[3] (2) permits the Monitor to file reports every 180 days, rather than every 90 days;[4] and (3) means, practically, that Monitor Reports are shared with Mallinckrodt and the seven states on the Ad Hoc Committee of governmental entities (the "Ad Hoc Committee"),[5] but are no longer filed with the Bankruptcy Court. (The reports, along with all prior reports, are instead posted on

[1] *See* Operating Injunction § I.H.

[2] The Restructuring Support Agreement is filed as Exhibit A to Docket No. 128 of Case No. 20-12522.

[3] *See* Operating Injunction § II.C (stating that, "[a]fter the Effective Date, [the Operating Injunction's injunctive terms are] enforceable in state court in each of the Settling States").

[4] *See id.* VI.B.2.b ("The frequency of Monitor Reports may decrease to every 180 days after the Effective Date").

[5] As previously noted, *see* Second Monitor Report at 24 ¶ 11.2 n.11, the Ad Hoc Committee consists of (1) seven States and (2) the court-appointed Plaintiffs' Executive Committee (the "PEC") in the multi-district litigation captioned *In re National Prescription Opiate Litigation*, Case No. 17-md-02804, MDL No. 2804 (N.D. Ohio) (the "MDL"). The seven states on the Ad Hoc Committee are part of a group of 50 states that are signatories to the Restructuring Support Agreement filed as Exhibit A to Docket No. 128 of Case No. 20-12522.

Mallinckrodt's website, where they are publicly available.[6]) 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.

1.6 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, the Eighth Monitor Report will be submitted 180 days after the submission of the Seventh Monitor Report—*i.e.*, on May 30, 2023. The Monitor has made clear, however, that he is happy to continue to provide quarterly updates to any interested party, or to respond to questions on an ad hoc basis more frequently, as he has done over the course of nearly two years in the monitorship to date.

1.7 ***The Monitor's visit to Mallinckrodt's Hobart, New York facility.*** The Monitor and members of his team were able to conduct a site visit and meeting with Mallinckrodt personnel on September 22-23, 2022, at Mallinckrodt's Hobart, New York facility. This visit is discussed in more detail below. *See infra*, Section 11.

* * *

1.8 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 defined below.

[6] *See* Mallinckrodt's "Corporate Compliance" webpage, *available at* http://www.mnk.com/corporate-responsibility/corporate-compliance/ (listed under "Operating Injunction" drop-down).

2. THE OPERATING INJUNCTION

2.1 On October 12, 2020, Mallinckrodt and the Settling States agreed to the Mallinckrodt Injunctive Relief Draft Term Sheet. *See* Case No. 20-12522, Dkt. No. 128, Ex. 2. The Court adopted an amended and final Term Sheet on January 8, 2021 (referred to herein as the "Operating Injunction" or "OI"). *See* Adv. Pro. No. 20-50850, Dkt. No. 196-1. A copy of the Operating Injunction is attached as Exhibit 1 to the First, Second, and Third Monitor Reports. Mallinckrodt's confirmed and now operative Plan of Reorganization incorporates the Operating Injunction. *See* Case No. 20-12522, Dkt. No. 6660-2.

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

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

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

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

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

3. 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. The Sixth Monitor Report is publicly available through Mallinckrodt's website. *See* page 3 ¶ 1.5, *supra*.

4. SUMMARY OF RECOMMENDATIONS

4.1 The Monitor is not making any new recommendations this reporting period. Prior recommendations are discussed herein and set forth in the accompanying **Exhibit 1**.

5. THE INTEGRITY HOTLINE

5.1 As of the end of the Seventh Reporting Period, the Monitor has still not received any relevant substantive reports through the integrity hotline.

6. BAN ON PROMOTION (OI § III.A)

6.1 Section III.A of the Operating Injunction prohibits Mallinckrodt from engaging in certain activities relating to the Promotion of Opioids,[7] Opioid Products, products used for the treatment of Opioid-induced side effects, and the Treatment of Pain in a manner that directly or indirectly encourages the utilization of Opioids or Opioid Products.

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

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

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

6.4 The PRC met once in the third quarter of 2022.[8] The Product Manager of Commercial, who chairs the PRC, led the meeting.[9] The meeting was conducted via videoconference and lasted approximately thirty minutes. The Monitor reviewed the minutes of this meeting as well as the promotional item the PRC considered.

6.5 In reviewing the meeting minutes, the Monitor noted that only three standing PRC members were present: the Product Manager, the Compliance Manager, and the Lead Medical Affairs Specialist. Five Standing Core PRC members were absent. Given that this was the only PRC meeting of the quarter, the Monitor would have expected to see the majority of the members in attendance. The Monitor encourages the PRC to schedule its meetings at a time when a majority of its members can attend, particularly given the relative infrequency of these meetings, and encourages all PRC members to prioritize their attendance to the extent reasonably practicable.

6.6 At its July meeting, the PRC reviewed and considered the Drug Enforcement Administration ("DEA") Form-222, the template Mallinckrodt uses to record customer orders to ensure compliance with DEA regulations. To provide additional guidance as to the form's purpose and to answer questions, the Director of Controlled Substances Compliance ("CSC") attended the PRC meeting as a subject matter expert.[10] The Director suggested revisions to the

[8] Pursuant to its operating charter, the PRC meets on an as-needed basis. The third quarter 2022 meeting was held on July 14, 2022.

[9] Also present to observe the meeting was the Product Analyst, who will chair the PRC on an interim basis in the coming months while the Product Manager of Commercial is out on a scheduled leave of absence. The Monitor looks forward to speaking with the Product Analyst about her new role as interim Chair of the PRC during the next reporting period.

[10] The benefit of having a subject matter expert available to offer guidance on a unique promotional item further supports the Monitor's suggestion that PRC members prioritize meeting attendance.

order form, including the addition of a product's strength to the item name/description field to better align with DEA regulations. Additionally, the Compliance Manager reported a number of proposed changes on behalf of an absent PRC member. Because incorporation of these proposed changes and completion of the Legal Department's review would require additional time, the PRC deferred further deliberation on the item until a later date. The Monitor looks forward to reviewing a revised version during the next reporting period.

6.7 In the Second Monitor Report, the Monitor detailed his interviews of members of Mallinckrodt's Product Monitoring Team ("PMT") as well as his review of Mallinckrodt's policies related to post-market communications with patients and caregivers. The Monitor described the PMT's operation of a call center for fielding and responding to customer questions and complaints, and the logging of those calls in an internal system called TrackWise. He also noted the absence of a formalized process for periodic review and auditing of the TrackWise logs to confirm that the PMT's responses to customer questions and complaints are consistent with the Operating Injunction and Mallinckrodt's existing policies and procedures.

6.8 In response to this concern, Mallinckrodt developed and implemented a review and auditing protocol, *Auditing Medical Information for Opioid Business Work Instruction*, that tasked the Director of Post-Market Surveillance ("PMS"), or her designee, with reviewing customer inquiries on a monthly basis and with evaluating the PMT's responses for compliance with the Operating Injunction.

6.9 Beginning in the Fourth Reporting Period, and on an on-going basis as part of the agreed-upon Audit Plan, the Monitor receives and reviews TrackWise complaint and inquiry entries pertaining to Opioid Products, as well as the results of this auditing process, on a quarterly basis. Many TrackWise ***inquiries*** pertain to the composition of Mallinckrodt's Opioid

Products, such as whether the products contain gluten or similar allergens, while TrackWise ***complaints*** generally concern product defects such as faulty patch adhesives, broken or missing tablets, or other product quality issues.

6.10 During the Seventh Reporting Period, the Monitor reviewed the TrackWise Audit Reports for the third quarter of 2022. The audits were conducted by the Senior Director of Quality, and included reviews of both TrackWise inquiry and complaint data. According to the resulting reports, the auditor determined that PMT call-takers fielded, logged, and elevated complaints and inquiries in a manner consistent with the Operating Injunction and the company's internal processes.[11]

6.11 During this reporting period, the Monitor also reviewed the updated *TrackWise Complaint Entry and Processing Work Instruction*, which he received at the end of the prior reporting period. The new version includes changes to the existing coding system for logging complaints into TrackWise as well as additional guidance for call taker elevation of complaints to other departments for further review.

6.12 Based on the Monitor's review of the underlying TrackWise data and the audit reports for the third quarter of 2022, as well as the updated *TrackWise Complaint Entry and Processing Work Instruction,* it appears the TrackWise entries and audits are being conducted in a manner consistent with the work instruction and the Operating Injunction.

[11] As detailed in the last several Monitor Reports, the December 21, 2021 TrackWise audit revealed that a call-taker, working for a third-party vendor, responded to a customer inquiry related to a non-Mallinckrodt Opioid Product. According to the former Director of Post Market Surveillance, who conducted the audit, Mallinckrodt provided the call-taker and the vendor's other employees with remedial training on the Operating Injunction to ensure similar errors did not reccur. At the close of this reporting period, following the Monitor's renewed request for the materials covered in the remedial training, Mallinckrodt informed the Monitor that the training consisted of a review of a third-party vendor "Job Aid." The Monitor intends to request and review that document in the next reporting period.

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

7.1 Section III.B.1 of the Operating Injunction states that "Mallinckrodt shall not provide financial incentives to its sales and marketing employees or discipline its sales and marketing employees based upon sales volume or sales quotas for Opioid Products." However, the same Section permits Mallinckrodt to create more holistic financial incentives, even if Opioid Products are included: "Notwithstanding the foregoing, this provision does not prohibit financial incentives (*e.g.*, customary raises or bonuses) based on the performance of the overall company or Mallinckrodt's generics business, as measured by EBITDA, revenue, cash flow or other similar financial metrics."

7.2 As discussed in the Sixth Monitor Report, the Monitor recommended that Mallinckrodt's legal counsel provide additional training to the Human Resources Department to prevent consideration of improper incentives in bonus recommendations (*see* ***Recommendation 6(b)***). Mallinckrodt provided that training on November 14, 2022. The Monitor Team reviewed the PowerPoint slides used during the training. The slides provided additional education to Mallinckrodt's Human Resources personnel regarding the Operating Injunction's requirements concerning permissible financial incentives and included appropriate hypothetical scenarios to test their understanding of those requirements and their impact on the calculation of employees' bonuses. Accordingly, the Monitor is comfortable that Mallinckrodt has implemented Recommendation 6(b).

7.3 The Audit Plan requires Mallinckrodt, annually, to produce to the Monitor updates to its sales compensation plans. Mallinckrodt produced to the Monitor, on or about April 8, 2022 (when it was finalized by the company), updated sales compensation information for 2022. The Monitor looks forward to receiving updated sales compensation plans for 2023,

and will again review these materials to confirm Mallinckrodt's continued compliance with the above-quoted provisions of the Operating Injunction and implementation of Recommendation 6(a).

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

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

8.2 As detailed in Mallinckrodt's Compliance Report, the Specialty Generics Grant and Sponsorship Approval Committee ("SGGSAC" or "the Committee") reviews and approves third-party requests for grants and sponsorships to ensure compliance with the Operating Injunction. *See* Mallinckrodt Compliance Report § 5.4.[12] During the Seventh Monitoring Period, the Monitor reviewed the minutes of five SGGSAC meetings, which took place from July 20, 2022 to September 14, 2022, as well as the accompanying third-party funding Request Forms, and any related materials the Committee considered in determining whether to approve or deny a specific request.

8.3 The SGGSAC considered five requests for funding during the third quarter of 2022, totaling approximately $10,000. The majority of these requests related to Mallinckrodt's addiction treatment products and the expansion of the company's role in that space. The Committee approved all five requests. Based on the Monitor's review of these requests and the

[12] In August of 2021, as detailed in the Fourth Monitor Report, the SGGSAC's duties expanded to include the review and approval of funding requests related to conference registration fees. *See* Fourth Monitor Report at 14 ¶ 8.7.

underlying materials, it appears that Mallinckrodt is operating in a manner consistent with the Operating Injunction in its funding of third-party requests.

8.4 In the Sixth Monitor Report, the Monitor noted that under the new *Specialty Generics Grant & Sponsorship Approval Committee* SOP, in those instances where an event's agenda or speaker schedule is unavailable at the time a funding request is submitted, the requestor can submit the prior year's agenda or other historical data, provided that the requestor supplements the request by submitting the current year's materials in a timely manner. Accordingly, the Monitor suggested that the SGGSAC should close the loop on these conditional approvals by ensuring that the Committee's full approval upon receipt of the current year's materials is noted in the minutes of future meetings or, if deliberations took place through email, that such correspondence is appended to the original meeting minutes. In reviewing the SGGSAC minutes from this quarter, the Monitor observed that this suggestion was implemented. For example, the meeting minutes for the March 11, March 25, and August 10 meetings were each amended to include an addendum dated September 14, 2022. The meeting addenda reflect the SGGSAC's receipt and review of a final agenda as well as the Committee's final approval of the pending request.

8.5 The Monitor also reviewed the newly-revised *Specialty Generics Grant & Sponsorship Approval Committee* Charter, which became effective on June 21, 2022. The new Charter included several noteworthy changes. First, the SGGSAC meeting frequency was increased from "annually and on an ad hoc basis as needed" to "biweekly and on an ad hoc basis as needed" to permit more frequent and timely review of funding requests. Additionally, while the previous Charter allowed the SGGSAC to reach decisions via email, the new Charter provides that "the SGGSAC should meet in person/virtually and reserve e-mail decisions for

extraordinary circumstances." Finally, the composition of the group has significantly changed. The number of Standing Core Members was reduced from eleven to five, and is comprised of representatives from key disciplines, such as Government Affairs, Regulatory Affairs, and Integrity & Compliance. These changes also formalize recently amended provisions of the Committee's SOP which exclude sales, commercial, finance, and marketing team members from serving as voting members of the Committee. Instead, personnel from those departments will now serve as Presenters and Ad Hoc Committee Members.

8.6 During this reporting period, Mallinckrodt's Integrity & Compliance Team notified the Monitor of a potential issue relating to a pending sponsorship request. The request, submitted by the Director of Government Affairs (a Standing Core Member), sought a $25,000 sponsorship of the National Commission on Correctional Health Care's ("NCCHC") annual conference.[13] The Request was conditionally approved during the SGGSAC's June 17, 2022 meeting after the Committee reviewed the previous year's conference agenda and similar materials. The updated agenda, submitted in late September, revealed that the conference included three sessions related to the treatment of pain.[14]

8.7 The Monitor evaluated the updated conference agenda and other supplemental materials including background information about the NCCHC and the other conference sponsors to assess whether the company's support of the conference would violate the Operating

[13] In the Sixth Monitor Report, the Monitor observed that the company's practice of permitting SGGSAC members to submit and vote to approve their own funding requests warranted additional consideration. *See* Sixth Monitor Report at 24-25 ¶ 8.8. The Monitor will continue to engage with the company as to the propriety of this practice during the next reporting period.

[14] The sessions were titled: Managing Wound Pain and Inflammation to Promote Healing, Chest Pain Protocols and Evolving ECG Standards, and Primary Care for Hip Pain and Other Orthopedic Issues.

Injunction. This review revealed that the conference's main focus was best practices in correctional facility healthcare (rather than sales) and that Mallinckrodt's participation was intended to expand its presence in the addiction treatment space (rather than increasing Opioid sales).[15] Based upon this review, the Monitor concluded that the sponsorship did not violate the Operating Injunction, and communicated such to Mallinckrodt.

8.8 During the next reporting period, as part of the agreed-upon Audit Plan, the Monitor will continue his quarterly review of the SGGSAC's work flow including its meeting minutes, funding requests and related materials. The Monitor will also continue engaging with Mallinckrodt to ensure that the SGGSAC is operating in a manner consistent with Section III.C of the Operating Injunction as it relates to awarding grants and sponsorships to third-parties.

9. LOBBYING RESTRICTIONS (OI § III.D)

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

9.2 In the Fifth Reporting Period, Mallinckrodt implemented the *Lobbying Certification and Activity Review* SOP which formalizes the process by which the Government Affairs team, on a quarterly basis, reviews its external lobbyists' public disclosure reports and record the results of that review contemporaneously.

[15] The Operating Injunction specifically contemplates and allows for such a review by the Monitor. *See* Operating Injunction § III.C.10 ("Mallinckrodt will be in compliance with Sections III.C.2 and III.C.3 with respect to support of an individual Third Party to the extent that the Independent Monitor or the Settling States determines that such support does not increase the risk of the inappropriate use of Opioids and that Mallinckrodt has not acted for the purpose of increasing the use of Opioids.").

9.3 During the Seventh Reporting Period, pursuant to the Audit Plan, the Monitor received and reviewed the results of the Government Affairs team's second and third quarter 2022 audit of Mallinckrodt's external state and federal lobbyists' public disclosure reports. These audit reports, completed by the Director of Government Affairs, list the external lobbying firms reviewed, the applicable state or federal disclosure report filing schedule, links to the online filing location of the disclosure reports, and an assessment of whether the activities reported comport with the Operating Injunction. As detailed in the second and third quarter 2022 audit reports, the Director of Government Affairs did not identify any concerns or potentially violative activity.[16] Similarly, the Monitor's own review of the reported activity and underlying legislation revealed that Mallinckrodt's external lobbyists are operating in a manner consistent with the Operating Injunction.

9.4 Pursuant to the Audit Plan, the Monitor also received and reviewed a list of legislative bills that Mallinckrodt's external lobbyists reported having lobbied for or against on the company's behalf in the second quarter of 2022.[17] In the last reporting period, the Monitor suggested that Mallinckrodt specify the company's position on each bill as such information would permit the Monitor to better assess whether Mallinckrodt's advocacy on these items comports with the Operating Injunction. Mallinckrodt implemented this suggestion and produced a list that included a statement of whether its external lobbyists' activities were conducted in support of or in opposition to each piece of proposed legislation.

[16] In the Sixth Monitor Report, the Monitor suggested that the audit report itself be amended to include additional detail about the process undertaken to complete the review. Sixth Monitor Report at 27 ¶ 9.5. The second and third quarter reports were revised in a manner consistent with the Monitor's suggestion.

[17] According to the Director of Government Affairs, there were no additional bills lobbied for or against in the third quarter of 2022.

9.5 The second quarter of 2022 disclosure reports appeared to reflect an uptick in Mallinckrodt's state lobbying activity. Specifically, Mallinckrodt's external lobbyists reported activity on five proposed bills in the first quarter of 2022 and sixteen in the second quarter. The majority of the second quarter's lobbying activity occurred in three states: Massachusetts, Missouri, and New York.[18]

9.6 The Monitor met with the Director of Government Affairs to discuss Mallinckrodt's lobbying activities, particularly regarding initiatives Mallinckrodt opposed (through its lobbyists). The Director explained that while there was a recent increase in the number of bills reported in its lobbyists' disclosure reports, it did not correlate to an actual increase in the company's lobbying activity or depth of engagement with certain measures. He distinguished Mallinckrodt's activity in opposition to proposed legislation in Massachusetts and New York, for example, from the company's efforts to record its nuanced position on California's proposed lockable vial legislation in the first half of 2022,[19] which included submission of correspondence to a number of key legislators. The Director confirmed that the company did not undertake nearly the same effort or expense as most of the lobbying activity occurred during committee hearings in which a large number of proposed bills were considered

[18] The Missouri legislation concerned corporate tax credits and appropriations to state agencies and did not relate to Opioids. However, in New York and Massachusetts, Mallinckrodt opposed several measures including legislation that would enhance local control of prescription drug pricing and impose taxes on opioid manufacturers to compensate victims of Opioids, a position Mallinckrodt is permitted to take pursuant to the Operating Injunction. *See* Operating Injunction § III.D.4.a. (stating that Mallinckrodt is not prohibited from "[l]obbying against the enactment of any provision of any state, federal, municipal, or county taxes, fees, assessments, or other payments").

[19] The Monitor's review of Mallinckrodt's lobbying activity in relation to the California legislation is discussed in the Sixth Monitor Report. *See* Sixth Monitor Report at 27-28 ¶¶ 9.6-9.7.

simultaneously. Based upon this meeting and the Monitor's review of the audit materials and proposed legislation, it appears that Mallinckrodt's lobbying activities are being conducted in a manner consistent with the Operating Injunction.

9.7 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.

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

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

10.2 As noted in the Fourth Monitor Report, Mallinckrodt's Associate General Counsel executed the first updated annual certification under the Audit Plan on January 5, 2022, providing certain certifications regarding Mallinckrodt's compliance with these provisions. Those certifications are set forth in greater detail in Paragraph 10.5 of the Second Monitor Report.

10.3 Pursuant to the Audit Plan, *see* 1 ¶ 1.4, *supra*, the Monitor will request that Mallinckrodt's General Counsel re-certify its representations regarding these provisions of the Operating Injunction in January 2023.

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

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

11.1 In the Seventh Reporting Period, the Monitor continued his assessment of Mallinckrodt's compliance with Section III.G of the Operating Injunction. Specifically, the Monitor: (a) obtained updates from Mallinckrodt and its outside counsel regarding the status of Mallinckrodt's implementation of the Monitor's SOM-related recommendations in prior reports; (b) continued his review of data and documents provided in response to the Audit Plan; (c) conducted follow-up interviews with the CSC Director, the Lead CSC Consultant (the "LCSCC"), the CSC Senior Manager, the CSC Auditor / Data Analyst, and the Director of Security for the Hobart, New York facility; and (d) toured Mallinckrodt's manufacturing facility in Hobart and met with Mallinckrodt executives and employees during that site visit.

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

1. Documents the Monitor Reviewed During the Seventh Monitoring Period

11.3 Mallinckrodt timely produced all SOM-related documents requested under the Audit Plan for the third quarter of 2022 and in response to the Monitor's ad hoc requests.

11.4 In auditing Mallinckrodt's compliance with the Operating Injunction's SOM-related provisions, the Monitor reviewed the following: (1) SOMT meeting materials and minutes for August, September, and October 2022; (2) the spreadsheet of all direct and indirect customers the SOMT has evaluated for restriction and / or reinstatement (the "Tracking Spreadsheet"); (3) the Government Communications log ("Communications Log") and related correspondence; (4) sales data for highly diverted Opioid Products; (5) direct customer flagged order data; (6) internal audit reports; (7) correspondence with the DEA regarding restriction and reinstatement of downstream registrants; (8) TrackWise inquiries and complaints raising potential diversion concerns; and (9) direct customer questionnaires.

2. Direct Customer Due Diligence

a. *Direct customer flagged orders in Q3 2022*

11.5 As discussed in the Sixth Monitor Report, Mallinckrodt produced lists of flagged direct orders of Opioid Products for the Monitor's review. *See* Sixth Monitor Report at 31-34 ¶¶ 11.5-11.12. During the site visit to Mallinckrodt's Hobart, New York manufacturing facility on September 22, 2022, the Monitor discussed the flagged order monitoring process with the CSC Auditor / Data Analyst. She reported no incidents since the Sixth Reporting Period when a flagged order was restricted from shipment. She noted that Mallinckrodt's sales team has been investing effort in building relationships with direct customers, and that this puts Mallinckrodt in

a better position to identify valid reasons for orders that vary from usual patterns in terms of timing or volume.

11.6 The Monitor reviewed the data concerning flagged orders for the third quarter of 2022. The data was consistent with the CSC Auditor / Data Analyst's account and did not indicate any deviation from the applicable SOP or any unusual order being flagged. The data covered 167 orders with 25,999 product lines, of which 8,986 lines were flagged.[20] No lines were restricted from shipment. The CSC Auditor / Data Analyst reported that in each instance where an order was flagged, the Mallinckrodt team was able to verify that the order was appropriate for shipment. The CSC Auditor / Data Analyst works closely with the LCSCC to determine whether to release a flagged order, often through direct outreach to the customers. They also use the Mallinckrodt sales team's familiarity with market conditions and customer ordering patterns as an additional resource. The CSC Auditor / Data Analyst stated that an increase in the customer's patient base is a common explanation for an increase in order quantity or frequency, both of which can result in an order being flagged.

11.7 As indicated in the Sixth Monitor Report, *see* Sixth Monitor Report at 34 ¶ 11.12, the Monitor Team requested backup documentation for flagged orders that were ultimately shipped. Mallinckrodt provided documentation on select orders, and the descriptions of the circumstances leading to each order indicated that the decision to ship was appropriate.

b. *Direct customer sales data*

11.8 Mallinckrodt provided the Monitor Team with reports on direct sales of hydrocodone 10/325 mg, oxycodone 15 mg, and oxycodone 30 mg for the third quarter of 2022.

[20] The Sixth Monitor Report discusses the distinction between orders and lines at page 31 ¶ 11.5.

These reports broke the sales data down by product and customer segment. The Monitor reviewed the data in these reports and determined that it is consistent with the data in prior sales reports he reviewed.

c. *Operating Injunction Hold List*

11.9 As discussed in the Sixth Monitor Report, Mallinckrodt produced data concerning orders flagged and held because they did not comply with the requirements of the Operating Injunction. *See* Sixth Monitor Report at 34 ¶¶ 11.13-14. The Monitor team reviewed this data, which concerned two orders, and discussed it with the CSC Senior Manager.

11.10 The CSC Senior Manager stated that the two orders on the hold list had been flagged because the customer had been mischaracterized in Mallinckrodt's ordering system as not being authorized to order Opioids under the terms of the Operating Injunction. The CSC Senior Manager reviewed the customer profile, confirmed that the customer was in fact authorized to order the products at issue, and authorized them for shipping.

d. *Government Communications Log*

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

11.12 During a site visit to Mallinckrodt's Hobart, New York manufacturing facility on September 22, 2022, the Monitor discussed the Communications Log with the CSC Senior Manager. She reported no unusual communications since the Sixth Monitoring Period. She

noted that many of the inquiries she had noted during that time involved confirming shipment amounts to particular customers in response to DEA requests.

11.13 The Monitor reviewed the Communications Log covering the third quarter of 2022, which consists almost entirely of shipping verification requests, and also almost entirely relates to Methadose, an Opioid that can treat both chronic pain and also addiction. Based upon this review, there was nothing remarkable from the Communications Log in the Seventh Reporting Period.

e. *Flagged Order SOP*

11.14 Mallinckrodt revised its *Suspicious Order Monitoring Program Review of Direct Customer Orders* SOP in August 2022. The Monitor Team reviewed the updated SOP, which includes, among its substantive changes: (1) revisions to the procedures for direct customer checklist distribution and review; and (2) review of direct customer checklist responses.

f. *Revised direct customer questionnaires*

11.15 As the Monitor previously reported, Mallinckrodt agreed to, and has since implemented, the Monitor's recommendation to revise Mallinckrodt's direct customer questionnaires (for new customers and renewing customers)[21] to yield helpful, actionable, and verifiable information (***Recommendation 2(s)***). *See* Fourth Monitor Report at 36-38 ¶¶ 11.40-45. The Fourth Monitor Report also discussed, in detail, the recommended changes to one such direct customer questionnaire—namely, the *Suspicious Order Monitoring Questionnaire for Distributor Customers* (the "Distributor Questionnaire"). *See* Fourth Monitor Report at 37-38 ¶¶ 11.42-45. At the time, Mallinckrodt also agreed to update its questionnaires for other kinds of direct customers.

[21] Existing customers must submit the questionnaire annually.

11.16 Mallinckrodt has now shared with the Monitor updated questionnaires for (1) Analytical Lab / Research customers; (2) DATA-Waived Opioid Treatment customers; (3) Manufacturer customers; (4) Narcotic Treatment Program customers; and (5) Pharmacy customers. These updates are based upon the changes to the Distributor Questionnaire.

11.17 Having reviewed these five new questionnaires, the Monitor is satisfied they seek appropriate due diligence from each type of customer, including but not limited to information concerning the customers' ownership, employees, and business practices; DEA registration and inspections; state licenses and accreditations; compliance with relevant laws; and policies and procedures related to controlled substances.

g. *Recommendations related to direct customers in prior reports*

11.18 ***Prior Recommendations 2(d), 2(e), and 2(h).*** The Monitor recommended that Mallinckrodt use best efforts to reach agreement with direct customers on various anti-diversion efforts. *See* Second Monitor Report at 28-29, 32-33.

11.19 To that end, Mallinckrodt entered a letter agreement with one of the "Big Three" distributors amending Mallinckrodt's existing supply agreement in order to obtain the distributor's agreement and cooperation on a number of issues. As described in the Sixth Monitor Report at 36 ¶ 11.18, the distributor agreed to terminate supply of SpecGx product to any customer that Mallinckrodt "informs the Distributor, in writing, raises a substantial risk of diversion of controlled substances from legitimate channels" (per ***Recommendation 2(d)***). The distributor further agreed to promptly: (1) inform Mallinckrodt of its suspension or termination of any downstream registrant; (2) respond to "reasonable requests" for information (per ***Recommendation 2(h)***); and (3) submit chargeback requests (per ***Recommendation 2(e)***).

11.20 Mallinckrodt's letter agreement with that customer was based on a proposed letter agreement described in detail in the Fourth Monitor Report at 24 ¶ 11.13 to 25 ¶ 11.14.

11.21 While Mallinckrodt has been unable to reach a similar agreement with either of the other two "Big Three" distributors, it intends to propose the same letter agreement to additional distributor customers in 2023.

11.22 ***Prior Recommendation 5(b)***. In the Fifth Monitor Report, the Monitor recommended that restricted direct customers undertake substantial compliance reforms before Mallinckrodt reinstates them. Since agreeing to adopt that recommendation, Mallinckrodt has not reinstated any direct customers. *See* Fifth Monitor Report at 41 ¶ 11.49.

11.23 Mallinckrodt also informed the Monitor that, since April 2022 Mallinckrodt has not sold any API to the API Purchaser referred to in the Fourth Monitor Report that was required to undertake substantial compliance efforts, including retaining a third-party compliance consultant and sharing compliance reports with Mallinckrodt regularly, before it could be reinstated. *See* Fourth Monitor Report at 43-45 ¶¶ 11.62-11.66. As the API Purchaser has not purchased any API from Mallinckrodt since April 2022, the API Purchaser has not sold any Opioid Products produced with Mallinckrodt's API, and its third-party consultant has not yet conducted an audit of the API Purchaser's sales. Mallinckrodt agrees to inform the Monitor when it receives compliance reports from the API Purchaser.

11.24 ***Prior Recommendation 6(c).*** In the Sixth Monitoring Period, the Monitor reviewed the audit reports prepared in connection with Mallinckrodt's visits to its direct customers. While the audit reports were thorough, the Monitor observed certain inconsistencies among the reports. *See* Sixth Monitor Report at 39-40 ¶¶ 11.27-29. As a result, the Monitor recommended that, in future reports, Mallinckrodt ensure greater consistency among direct customer audit reports and document more fulsome follow-up questions where appropriate.

11.25 The Monitor has had the opportunity to review additional direct customer audit reports in the Seventh Monitor Period, including a report regarding the review of a "Big Three" distributor ("Distributor 1"), a secondary generics distributor ("Distributor 2"), and a large mail-order pharmacy ("Pharmacy 1") that does not provide chargeback data to Mallinckrodt.

11.26 ***Audit report relating to Distributor 1.*** On November 10, 2022, Mallinckrodt's CSC Director conducted a site visit at Distributor 1. According to the audit report, completed on November 16, 2022, among other things, the Director revisited the issue addressed in prior Monitor Reports regarding Mallinckrodt's request that distributors inform Mallinckrodt when a distributor stops supplying a pharmacy for suspicious order monitoring-related reasons. According to the audit report, Distributor 1 declined to provide this information due to legal concerns, including the potential to be accused of "colluding" with a manufacturer to restrict a customer's supply. Distributor 1 was not persuaded by the Director's observation that other distributors had agreed to provide such information.

11.27 ***Audit report relating to Distributor 2.*** On September 19, 2022, Mallinckrodt's CSC Director, CSC Senior Manager, its LCSCC, and its CSC Auditor / Data Analyst conducted a video interview with Distributor 2. According to the audit report, completed on November 2, 2022, one of the representatives of Distributor 2 requested that Mallinckrodt regularly provide a running list of restricted pharmacies, as the periodic notices from Mallinckrodt are hard to track. Additionally, Distributor 2 wants to be able to cross-reference such a list against the names of potential new customers. Although Distributor 2 could create such a list from the regular updates Mallinckrodt distributes, Mallinckrodt agreed to provide Distributor 2 with such a list. According to the CSC Director, Distributor 2 is not the first direct customer to make such a request, and Mallinckrodt is happy to provide the list.

11.28 ***Audit report relating to Pharmacy 1.*** On November 4, 2022, Mallinckrodt's CSC Director and LCSCC conducted a site visit at Pharmacy 1 that was completed on November 7, 2022. Pharmacy 1 is a mail order pharmacy that, according to the audit report, "contracts with health insurance providers and pharmacy benefit managers to provide captive mail order pharmacy services to . . . customers in all 50 states and US territories." Pharmacy 1 is among a small group of Mallinckrodt's direct customers that do not submit chargeback requests to Mallinckrodt, and for whom Mallinckrodt therefore does not have chargeback data with which to conduct due diligence. Although Pharmacy 1 does conduct a Prescription Drug Monitoring Program ("PDMP") review of every order it fills, because it is dispensing to the end users (who are a limited universe of patients whose insurance plans provide for mail-order dispensing), the PDMP data is of limited use to Mallinckrodt's anti-diversion efforts. For now, Mallinckrodt's effort to compensate for the lack of chargeback data include audits of this kind with direct customers who do not make chargeback requests.

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

11.29 In parallel with its direct customer due diligence efforts, Mallinckrodt continues to conduct due diligence on downstream registrants, also referred to as indirect customers. A summary of updates on these efforts is provided below.

a. *The indirect customer dashboard*

11.30 As previously noted, the SOMT's implementation of the indirect dashboard, along with Mallinckrodt's hiring of the LCSCC and the CSC Auditor / Data Analyst, has significantly enhanced Mallinckrodt's surveillance capabilities for both direct customers and downstream registrants.

11.31 As the Monitor reported in the Sixth Monitor Report, in just the first two quarters of 2022, he observed a dramatic increase in the effectiveness of Mallinckrodt's indirect customer

surveillance based on the increase in the volume of chargeback reviews conducted, volume of resulting restrictions, and volume of reinstatements. *See* Sixth Monitor Report at 42 ¶ 11.36.

11.32 The third quarter data Mallinckrodt provided the Monitor offers further evidence of the results of Mallinckrodt's enhanced surveillance abilities, reflecting the increased volume of reviews the SOMT completed each month and the restrictions the SOMT imposed. For example, as depicted in the chart below, the SOMT continues to conduct a significant number of chargeback reviews each quarter:

	Q1 2022	Q2 2022	Q3 2022
Chargeback reviews	66	61	63
Chargeback restrictions	49	43	15
Chargeback reinstatements	3	3	5

11.33 The Monitor and the LCSCC have discussed the challenge this improved surveillance creates—namely, how to effectively manage the significant increase in the number of pharmacies flagged, and chargeback reviews the LCSCC conducts monthly. *See* Sixth Monitor Report at 42 ¶ 11.36. The LCSCC is training the CSC Auditor / Data Analyst to assist with the chargeback review process, which should help to maintain a high level of surveillance. (Indeed, the September SOMT meeting materials and minutes reflect that the CSC Auditor / Data Analyst has already initiated chargeback reviews, under the LCSCC's supervision.)

11.34 Since the indirect customer dashboard was implemented, the LCSCC has—appropriately, in the Monitor's view—prioritized review of independent pharmacies, where there may be a greater potential for diversion, over other kinds of downstream customers, such as pharmacy chains. The LCSCC anticipates additional assistance from the CSC Auditor / Data Analyst will enable the LCSCC and the SOMT to conduct more reviews generally, including

reviews of chain pharmacies. In fact, the September SOMT meeting materials and minutes reflect review of both independent and chain pharmacies.

11.35 In future reporting periods, the Monitor will continue to assess whether Mallinckrodt has adequate resources to effectively and efficiently manage the increasing volume of chargeback reviews.

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

11.36 In the Seventh Reporting Period, the Monitor reviewed SOMT meeting materials and minutes for August, September, and October 2022. The results of that review, and the Monitor's related interviews with the CSC Director and LCSCC, are summarized below. At the Monitor's request, the Monitor has obtained these meeting minutes more promptly of late, within just weeks of the SOMT meetings.

i. SOMT meeting materials and minutes for August 2022

11.37 ***The SOMT's follow up reviews for pharmacies previously flagged for review but ultimately not restricted.*** The SOMT's meeting minutes and materials reflect that the SOMT reviewed four pharmacies identified for follow-up review in prior meetings (and in the Tracking Spreadsheet) in August as scheduled. The CSC Director's continual updates to the Tracking Spreadsheet, which he now circulates to the SOMT before meetings, helps ensure that downstream registrants flagged for follow up review, or tabled by the SOMT, do not evade further review (*see* ***Recommendation 6(d)***).

11.38 For three of those four pharmacies, the SOMT determined no further follow up was needed. However, for one of those pharmacies, the SOMT determined it was appropriate to follow up on its request for additional due diligence from the pharmacy's distributor. The SOMT had previously requested that due diligence because the distributor's explanation regarding the reason for the pharmacy's higher than expected ratio for the sale of controlled

substances, including oxycodone, to non-controlled substances did not adequately address the SOMT's concerns.

11.39 The SOMT first requested clarification from that distributor in May 2022, but as of August 2022, had not received any response. Unfortunately, this instance reflects yet another example of one of the "Big Three" distributors failing to provide relatively basic due diligence information about a customer in a timely manner. The Monitor has noted this lapse repeatedly in prior reports, most recently in the Sixth Monitor Report. *See* Sixth Monitor Report at 47-49 ¶¶ 11.48-11.51.

11.40 ***The SOMT, once again, learns of a distributor's restriction of a pharmacy months after the fact.*** In August, the SOMT continued to promptly restrict downstream registrants based upon ad hoc reviews. The SOMT restricted one such pharmacy that was under follow-up review after the LCSCC learned the pharmacy's distributor (one of the "Big Three"), had restricted the downstream registrant ***two months earlier***. The LCSCC only learned of the restriction because he requested due diligence from the distributor. If the SOMT had been promptly informed of the distributor's restriction, the SOMT would likely have restricted the pharmacy well before the August meeting. As the Monitor has previously reported, this situation is not uncommon. But unlike a delayed response to Mallinckrodt's request for due diligence, the failure of a large distributor to alert others in the supply chain to a restriction is harder to understand.

11.41 ***The distributors' delayed responses to due diligence requests.*** In August, the Monitor continued to observe a pattern concerning two of the "Big Three" distributors' delayed responses to due diligence requests in the case of at least five pharmacies. Generally, those distributors either respond to due diligence relatively quickly or not at all. As the Monitor has

previously reported, the SOMT's ability to monitor its downstream registrants is greatly enhanced by the timely receipt of information from the distributors, who have far greater insight into their direct customers than Mallinckrodt. The Monitor hopes Mallinckrodt's and the distributors' continued discussions regarding this issue will lead to greater cooperation in the future. *See* ***Recommendation 6(e).***

11.42 The Monitor interviewed the CSC Director and LCSCC in person during the Hobart site visit to discuss the August SOMT meeting and other issues. The CSC Director and LCSCC share the Monitor's view that the SOMT's ability to review pharmacies quickly is hindered by delay on the part of some distributors in timely responding to Mallinckrodt's requests, and that this delay in turn keeps pharmacies under the SOMT's review for longer than necessary. The CSC Director continues to discuss this issue with two of the "Big Three" distributors, and had another meeting with one of the two in November (*see* ***Recommendation 6(e)***).

11.43 The CSC Director also noted that the SOMT would also benefit from more timely access to ARCOS data. Unfortunately, ARCOS data is not updated in real time—the data is only available with a two-month time lag. They noted that an industry-wide clearing house (as the Monitor has previously recommended, *see* ***Recommendation 2(j)***) would address this problem.

ii. SOMT meeting materials and minutes for September 2022

11.44 ***The SOMT continues to review more pharmacies each month.*** As noted above, *see supra* 26 ¶ 11.30, the indirect customer dashboard and the CSC Auditor / Data Analyst's assistance have enabled the LCSCC (and SOMT), to review more downstream registrants each month. In September, the SOMT reviewed as many as 36 downstream registrants for potential restriction. By comparison, the SOMT considered restricting just 14 downstream registrants in August, and 12 in July. Although the increased number of downstream registrants reviewed in

September is attributable, in part, to the backlog of pharmacies for which the LCSCC actually initiated review in June and July, the Monitor continues to observe a positive increase in SOMT activity, which is likely attributable both to human resources and technology changes.

11.45 ***The indirect dashboard has enhanced the SOMT's review of non-Opioid Product purchases by downstream registrants.*** The LCSCC uses the indirect dashboard to initiate chargeback reviews for both Opioid Products ***and*** non-Opioid Products (*i.e.*, all controlled substances), based upon volumes, frequencies, or patterns that are statistically notable. This includes, for example, analysis of a downstream registrant's chargeback data in terms of absolute volume, per capita volume, and growth (*i.e.*, percentage increase in dosage units ordered) in order to compare a downstream registrant's purchases to others' comparable purchases. The Monitor has observed an increase in the number of downstream registrant chargeback reviews based upon sales of non-Opioid Products, such as amphetamine salts.

11.46 ***One of the "Big Three" distributors shows some improvement in the timeliness of its responses to due diligence requests.*** In September, the Monitor continued to observe instances when two of the "Big Three" distributors that have not signed the letter agreement referenced above, *see supra* 24 ¶ 11.19, took two months or longer to respond to a request for due diligence from Mallinckrodt, or simply did not respond to requests for information at all.

11.47 In one such instance, when one of the "Big Three" distributors never responded, Mallinckrodt waited three months before ultimately restricting the downstream registrant under review. Without the benefit of that distributor's information regarding its own customer, it cannot be said whether Mallinckrodt would have restricted the downstream registrant sooner or not restricted them at all. Either way, the distributor's failure to provide the information Mallinckrodt requested hindered the SOMT's ability to efficiently conduct the chargeback

review. The Monitor has previously discussed with Mallinckrodt whether a one- or two-month outer limit would be appropriate to wait for due diligence before a restriction is made. The Monitor appreciates that these are fact-dependent decisions, and so, as noted in the Sixth Monitor Report, ultimately defers to the SOMT's best judgment as to when to impose a restriction after a sustained period of no response to a due diligence request. *See* Sixth Monitor Report at 48 ¶¶ 11.50-11.51.

11.48 However, the Monitor also observed instances when those two distributors responded to Mallinckrodt's due diligence requests more promptly than in the past. The LCSCC and CSC Director confirmed that at least one of those two distributors has been more responsive of late.

11.49 While the two "Big Three" distributors do not typically respond as quickly as the smaller distributors, who have fewer customers and typically respond within days of the LCSCC's request, the Monitor is hopeful that the companies' ongoing discussions (*see* ***Recommendation 6(e)***) will result in improved due diligence response times for the "Big Three" distributors.

iii. SOMT meeting materials and minutes for October 2022

11.50 In the October SOMT meeting, the team considered 15 pharmacies for potential restriction, none for reinstatement, 3 for which the LCSCC had recommended no action, and 8 that required follow-up from prior reviews.[22]

[22] Section 6.4.3 of the *Suspicious Order Monitoring Program Media & Chargeback Reviews of Direct Customers and Downstream Registrants* SOP requires that the LCSCC's recommendation of "no action necessary" following a chargeback restriction review, must be approved by the CSC Director or designee and documented. The SOMT agreed with each of the LCSCC's no-action recommendations.

11.51 ***Chargeback restriction reviews.*** Of the 15 pharmacies reviewed for potential restriction, the vast majority involved non-Opioid Products as defined in the Operating Injunction, including amphetamines and benzodiazepines: amphetamine salts 30 mg; a dosage defined in the indirect customer / downstream registrant dashboard as "Amphetamine High Risk 20 mg"; mixed amphetamine salts; methylphenidate; and temazepam. Of the 15 pharmacies, only about 4 were reviewed for opioid-related prescribing. And of the 15, the SOMT decided to restrict 6 (of which just 1, acetaminophen/codeine, was an Opioid Product), with the remainder subject to future follow-up and review or deemed not to warrant any action at all.

11.52 The increased consideration of non-Opioid Products for restriction may be attributable to the fact that, as noted above, the indirect dashboard flags all controlled substances (not just Opioid Products) for potential restriction. Additionally, the CSC Director and LCSCC noted that certain market dynamics—specifically, a reduction in the number of suppliers of amphetamine salts—may explain an increased demand for this product from Mallinckrodt customers. Specifically, the LCSCC noted that dashboard "flags" for this product have generally resulted from ***growth*** in quantity ordered from Mallinckrodt, rather than increases in total ***volume*** of orders from all suppliers. In other words, a pharmacy's ordering from Mallinckrodt may have increased (accounting for growth over prior orders) and yet their total order volume for the product may nonetheless remain unchanged if the pharmacy is merely shifting their source of supply from one supplier to Mallinckrodt. Accordingly, comparisons to competitors within a geographic area is useful to determine whether growth may also mean the pharmacy's total volume ordered has increased as well. The LCSCC provided a specific example of similarly situated pharmacies, both under chargeback restriction review, and both with similar growth in orders, where one pharmacy in Tennessee was not restricted because its order volume did not

depart drastically from other competitors in the area, while the second pharmacy in Mississippi was restricted because its total order volume was substantially different than local competitors.

11.53 ***Media reviews.*** As a result of Media Alerts, the SOMT reviewed an additional 5 pharmacies, and restricted them all.

11.54 ***Notable third-party due diligence report.*** The Monitor noted with interest the SOMT's review of a particular pharmacy, for which the SOMT minutes indicate an initial chargeback review on January 18, 2021, following a Media Alert to federal court action restricting the pharmacy's dispensing of Opioids. A requirement of that pharmacy's resolution with the U.S. Department of Justice is that the pharmacy undergo 6-month reviews for the three years following the federal court action. According to the SOMT meeting minutes, on September 30, 2021, the SOMT voted to reinstate the pharmacy pending the SOMT's receipt of compliance reports. The minutes state that on September 28, 2022, the LCSCC reached out to the pharmacy to obtain the most recent review, and reviewed the review that same day. The review concluded that the pharmacy was fully compliant with the restrictions imposed in a consent order. Consequently, the SOMT voted to continue to review the pharmacy and the third-party consultant's compliance reports. The report of July 20, 2022 (which covered the time frame from December 1, 2021 through May 31, 2022) is thorough and detailed. And the third-party reviewer evidently has been accepted by the U.S. Attorney's Office for the Northern District of Ohio. The Monitor has suggested to Mallinckrodt that this particular compliance report could serve as a helpful yardstick for the work of other third-party consultants.

4. Other SOM-related issues

a. *SOM-related TrackWise inquiries*

11.55 As discussed above in Paragraphs 6.9 to 6.12, the Monitor received and analyzed data from TrackWise complaints and inquiries.

11.56 Although the TrackWise Work Instruction, *TrackWise Complaint Entry and Processing*, does not contemplate auditing of complaint data, the CSC Senior Manager has taken the initiative to incorporate that process into her monthly auditing protocol. Inquiries and complaints are assessed by call-takers and identified for elevation to management and other departments pursuant to the *Elevated Issue Management Notification Process* SOP, which the Monitor discussed in the Sixth Monitor Report. *See* Sixth Monitor Report at 13-14 ¶ 6.13. Under the SOP, calls documented with specific product codes must be elevated to more senior management for further review. Using the product codes in TrackWise, the CSC Senior Manager audits those complaints to determine whether the PMT responded appropriately. The primary focus of the TrackWise audit process the CSC Senior Manager implements is the call-taker's compliance with the Operating Injunction and the company's policies for call handling.

b. *TrackWise assessment during the Seventh Monitoring Period*

11.57 During a site visit to Mallinckrodt's Hobart, New York manufacturing facility on September 22, 2022, the Monitor Team discussed its review of TrackWise records and Mallinckrodt's processing and auditing of TrackWise inquiries and complaints with the CSC Senior Manager.

11.58 The CSC Senior Manager explained that when any TrackWise inquiry or complaint comes from a telephone call, the Mallinckrodt quality team ascertains as much information as possible concerning the product involved and the nature of the issue. The call-takers have medical backgrounds and a written decision tree that guides the process for elevating any complaint or inquiry indicating potential diversion of Opioid Products.

11.59 Based upon the applicable procedures and decision tree, the call-takers elevate any report involving potential diversion to the CSC Senior Manager, the Director of Security, and senior Quality Management personnel. The TrackWise software alerts the CSC Senior

Manager with emails to prompt an investigation of the root cause of any diversion-related complaint. The CSC Senior Manager has been reviewing complaints from Mallinckrodt customers for ten years and reported that she cannot recall a single instance in which diversion by a Mallinckrodt employee was identified as the root cause of any complaint. She estimated she receives roughly three complaints per month through TrackWise that indicate the possibility of diversion of Opioid Products.

11.60 The CSC Senior Manager recounted the example of an investigation that TrackWise complaints prompted, arising from a pharmacy chain in Colorado, previously discussed in the Sixth Monitor Report. *See* Sixth Monitor Report at 59 ¶ 11.80. Those complaints all indicated that pills were missing from bottles of the oxycodone 5 mg product. The investigation identified the root cause from review of a closed circuit television video recording by the Packaging SME, Security Director, and CSC Senior Manager. The video indicated that there had been a brief malfunction of bottle-filling equipment on the production line. Some bottles tipped over. A line operator set them upright and allowed them to continue along the line without realizing that some pills had fallen out of the bottles. This was contrary to established procedures, but did not indicate diversion. The video footage confirmed that line operators disposed of all pills that had fallen in accordance with established procedures.

11.61 The CSC Senior Manager also discussed the fact that Mallinckrodt retains samples of every lot of Opioid Product it produces, so that it can run comparative analyses between the test samples returned from the field due to complaints against the retained samples. In some instances, this testing process can confirm that a particular product was properly manufactured and not adulterated at the time it was shipped from the Mallinckrodt facility. The CSC Senior Manager noted that this testing process commonly takes place for complaints

concerning morphine oral solution. She also explained that it is not uncommon for Mallinckrodt to receive complaints from long-term care facilities that a bottle of morphine oral solution has been diluted or is missing product. The testing can confirm that dilution or diversion took place after shipment.

11.62 The Monitor Team also reviewed TrackWise inquiry and complaint data for the period from July through September of 2022. This review indicated that inquiries and complaints that could indicate potential diversion of Opioid Products are being handled in accordance with the applicable review and auditing protocol. Furthermore, none of these complaints appeared unusual.

c. *Internal audits / process reviews at the Hobart, New York facility*

i. The Monitor's interview with the CSC Auditor / Data Analyst

11.63 As discussed in the Sixth Monitor Report, one of the responsibilities of the CSC Auditor / Data Analyst is conducting various internal audits or "process reviews."[23] *See* Sixth Monitor Report at 63-64 ¶¶ 11.94-11.95. During a visit to Mallinckrodt's Hobart, New York manufacturing facility on September 22, 2022, the Monitor Team discussed this process with the CSC Auditor / Data Analyst.

11.64 She reported that she conducts several different types of process reviews, all focused on compliance with DEA requirements (as opposed to FDA compliance, which is audited separately by other Mallinckrodt personnel). The reviews the CSC Auditor / Data

[23] The Monitor Team and Mallinckrodt representatives have discussed whether these reviews are more appropriately called "audits" or "process reviews." As noted below, the work product from these reviews is reports titled "Audits," and the CSC Auditor / Data Analyst is responsible for them. Although for the Monitor's purposes the difference is largely semantic, this Report adopts Mallinckrodt's terminology and refers to these activities as "reviews," except, for example, where the reports themselves are described as "audit" reports.

Analyst conducts largely relate to Mallinckrodt's record keeping obligations and its practices related to access to, and storage of, controlled substances at Mallinckrodt's facility in Hobart. The focus of these reviews includes: (1) security and access control for cages containing Opioid Products; (2) security of lab facilities processing Opioid Products; (3) security and access control for vaults containing products that Mallinckrodt retains for potential testing in response to customer complaints or inquiries ("retained samples"); and (4) documentation of responses to security incidents.

11.65 There are separate labs at the Hobart facility that are part of this process review and the CSC Auditor / Data Analyst conducts the reviews with a checklist. Her review of responses to security incidents is limited to ensuring that adequate documentation exists in the file relating to each incident, rather than auditing the responses to the incidents themselves. All of the CSC Auditor / Data Analyst's findings are summarized in what are called "audit" reports.

ii. The audit reports

11.66 During the Seventh Reporting Period, Mallinckrodt provided the Monitor with six reports that are self-described "internal audit" draft reports that the CSC Auditor / Data Analyst prepared in 2022: (1) the ***12F Vault Sample Audit*** (described as "an internal audit of 12F sample totes confirming controlled substances compliance on inventory and inventory documentation"); (2) the ***QC Stability Chamber Audit*** (described as "an internal audit of the QC Stability Chambers to ensure proper handling and documentation of controlled substances and their records"); (3) the ***MOA Audit*** (described as an "internal audit against the MOA to ensure the corporation continues to be in compliance"); (4) the ***12 F Vault, 12 F Cage, 12B Vault, and 12B Cage Audit*** (described as "an internal audit of the vaults and cages in both 12F and 12B . . . to ensure that products are stored properly as per the controlled substances compliance regulations"); (5) the ***Analytical Sciences Lab Audit*** (described as an "Audit for Controlled

Substance Compliance in the Analytical Sciences Lab," with "Random samples . . . selected by audit team and traced start to last step"); and (6) the ***Cage and Vault Access Audit*** (described as "An audit of the access lists located at each cage and vault to ensure that all lists were up to date").

11.67 These reports generally detailed the purpose of the review, relevant findings, pertinent observations, and recommended corrective action. With the exception of one report, each of the reports the Monitor reviewed reflect conclusions by the auditor (*i.e.*, the CSC Auditor / Data Analyst, and in certain instances a second auditor) that Mallinckrodt was already in compliance with the relevant DEA requirement(s) or had taken any necessary corrective action to achieve compliance as of the date of the report. One report indicated that the Quality Control Department was in the process of determining whether any corrective action was necessary. The CSC Auditor / Data Analyst confirmed that subsequent corrective action was taken.

iii. The timing and frequency of the reviews

11.68 The Monitor had a follow-up interview with the CSC Auditor / Data Analyst regarding her reports and the frequency of the reviews, as it was not clear to the Monitor from the reports how often each of the reviews is conducted.

11.69 The CSC Auditor / Data Analyst informed the Monitor that she conducts at least four reviews a year in accordance with the relevant Work Instruction, although she may also conduct additional ad hoc reviews. As a result, not every type of review is conducted each year, but Mallinckrodt tries to conduct each kind of review within a two- to three-year rotation. The CSC Auditor / Data Analyst and the CSC Senior Manager maintain a spreadsheet tracking when the reviews are conducted.

11.70 The CSC Auditor / Data Analyst explained there is not an exact schedule for the reviews because they do not want the department being inspected to prepare for the review

beforehand. While the Monitor understands Mallinckrodt's need for flexibility as to when the reviews are conducted, he suggests that the CSC Auditor / Data Analyst and CSC Senior Manager consider a more formal *internal* schedule, which would not be shared with any other department, to ensure each type of review is conducted at a regular interval. The Monitor also suggests including the dates of the prior reviews as an addendum or attachment to each report, so the reviewer can quickly reference when prior reviews were conducted.

11.71 Mallinckrodt agreed to produce all reports the CSC Consultant / Analyst prepares related to compliance with DEA requirements in future under the Audit Plan.

iv. The possible need for additional guidance on procedures for conducting the internal process reviews

11.72 The Monitor observed that, with the exception of one checklist and a Work Instruction for conducting lab process reviews (neither of which the Monitor has received), there appears to be little guidance for the CSC Consultant / Analyst as to how to conduct the reviews. To be sure, some of the reviews are simpler than others (*e.g.*, the cage access review, which apparently merely requires confirmation regarding personnel with access to the cage) but others may be less straightforward, and however simple the audits may be, Mallinckrodt should review whether there is a need for routine processes to be documented to ensure consistency and comparability over time, without sacrificing the element of surprise that the CSC Senior Manager and CSC Auditor / Data Analyst wish to preserve.

d. *Mallinckrodt's updated Google Alerts continue to identify relevant information concerning diversion of controlled substances*

11.73 As previously reported, in response to the Monitor's recommendation that the SOMT consider ways to make its media reviews more effective in combatting Opioid Product diversion (*see* ***Recommendation 2(u)***), Mallinckrodt refined and updated its Media Monitoring Search Terms. *See* Sixth Monitor Report at 56-57 ¶¶ 11.71-76. Mallinckrodt's use of Google

Alerts generated by search terms have successfully identified relevant publicly available information about diversion, including information in press releases from the U.S. Department of Justice. *Id.*

11.74 During the Seventh Monitoring Period, the Monitor continued to test the effectiveness of Mallinckrodt's Google searches on an ad hoc basis by inquiring with Mallinckrodt regarding media coverage about which the Monitor had independently learned. For example, on October 17, 2022, the U.S. Department of Justice issued a press release regarding a civil law suit the United States initiated against a Florida pain clinic and associated individuals. In that case, the judge issued a temporary restraining order prohibiting the pain clinic, its operators, and one of its doctors from administering, dispensing or distributing any controlled substances, including opioids.[24]

11.75 The Monitor inquired with Mallinckrodt whether (a) Mallinckrodt's Google Alert had captured the press release, or (b) Mallinckrodt had any relationship with the clinic. In response, Mallinckrodt's Associate General Counsel informed the Monitor that Mallinckrodt's Google Alert did alert the SOMT to the press release, and that there is no relationship between Mallinckrodt and the clinic.

11.76 As Mallinckrodt's Google Alerts have captured each of the press releases the Monitor has independently identified to date, it appears that the Google Alerts continue to be effective in capturing relevant information for the SOMT's review.

[24] *See* Press Release, U.S. Dep't of Justice, "Federal Court Issues Temporary Restraining Order Prohibiting Tampa-Area Clinic from Distributing Opioids and Other Prescription Drugs" (Oct. 17, 2022), *available at* https://www.justice.gov/opa/pr/federal-court-issues-temporary-restraining-order-prohibiting-tampa-area-clinic-distributing.

e. *Hobart, New York facility security*

11.77 During the Monitor's visit, he toured the Hobart plant, gaining valuable insight into Mallinckrodt's production and packaging of pharmaceuticals, including Opioid Products. He learned more about both the site's security and safety protocols.

11.78 The Monitor also learned about the plant's physical security during his interview with the Director of Security, who is a member of the SOMT. The Director of Security is a former DEA agent with over two decades of direct experience in combatting diversion of controlled substances.

11.79 The Monitor learned about Mallinckrodt's efforts to make the site even more secure since the Director joined the company, including Mallinckrodt's investment of over $2 million in, and its deployment of, high definition cameras, which the Director believes are a significant deterrent to employee theft. Indeed, since those cameras were deployed, the company has not identified any employee diverting, or attempting to divert, controlled substances. The Monitor also noted Mallinckrodt's use of security personnel (who are not contractors, but rather Mallinckrodt employees, many of whom work for Mallinckrodt part time while also employed in local law enforcement positions), protocols, and searches to prevent and deter diversion of product from the Hobart facility.

11.80 The Director also explained Mallinckrodt's approach to drug screening of employees, at the time of hire, at random intervals, or for cause.

12. TRAINING (OI § III.K)

12.1 Mallinckrodt's training of employees on the Operating Injunction and related obligations and prohibitions is described generally in the Monitor's prior reports. *See e.g.*, Fifth Monitor Report at 42 ¶ 12.1 and 43-44 ¶ 12.6; Fourth Monitor Report at 49 ¶ 13.1.

12.2 During the Seventh Reporting Period, the Monitor audited Mallinckrodt's compliance with the Operating Injunction's training requirements by: (1) reviewing the list of newly hired employees and the trainings they completed, which Mallinckrodt produced under the Audit Plan; and (2) continuing to explore ways to increase employee engagement during the live trainings with the Compliance Manager and Associate General Counsel.

1. Employee Trainings During the Third Quarter

12.3 As part of the agreed-upon Audit Plan referenced above, *see supra* 1 ¶ 1.4, on a quarterly basis Mallinckrodt has 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. As of October 6, 2022, Mallinckrodt identified three newly hired or promoted employees in the third quarter of 2022, all of whom have completed each component of their Operating Injunction training.

12.4 Additionally, all of the six new employees in the second quarter completed their Operating Injunction quizzes.

2. The Operating Injunction Quiz Pass Rate

12.5 As the Monitor previously reported, Mallinckrodt's Operating Injunction training consists of four components, including a quiz. After attending the Operating Injunction live trainings, employees must complete quizzes testing their retention of the information conveyed during those trainings and understanding of the Operating Injunction's requirements generally. *See* Fifth Monitor Report at 43-44 ¶ 12.6. Participants must take the Operating Injunction quiz within 14 days of the live training. To earn a passing grade, participants are given three chances to answer 8 out of 10 questions correctly.

12.6 The Monitor has attempted to determine the percentage of employees who pass the quiz on the first attempt, but Mallinckrodt has said that this data is unavailable. Mallinckrodt can only determine a pass / fail result for the quiz, and because the quiz locks and requires higher level approval for a fourth attempt at passing the quiz, Mallinckrodt can infer that no one has needed to take the quiz more than three times.

3. Future Training Efforts

12.7 In the Sixth Monitor Report, the Monitor shared observations relating to Mallinckrodt employee engagement in training. *See* Sixth Monitor Report at 65-66 ¶¶ 12.3-12.6. In response, Mallinckrodt has said that it believes the "thumbs up / thumbs down" function is a simple and effective measure of employee engagement, but is exploring other WebEx functions with its IT Department.

12.8 Relatedly, Mallinckrodt presently does not plan to re-introduce in-person trainings, but does plan to continue to conduct live remote trainings. This approach is due to Mallinckrodt's need to train a large number of employees (nearly 200) in numerous business functions, in multiple locations and time zones, some of them in the United Kingdom and Japan. Consequently, Mallinckrodt views remote live trainings as an efficient alternative to in-person trainings.

12.9 Finally, Mallinckrodt advises that training materials for 2023 will be available for review by the Monitor during the next reporting period.

13. CLINICAL DATA TRANSPARENCY (OI § IV)

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

13.2 As the Monitor previously reported, Mallinckrodt contracted with the company Vivli Inc. ("Vivli") to make such data available, and Mallinckrodt has advised the Monitor that all of the data required to be shared under Section IV is available through that platform.[25] Any research proposals submitted through Vivli will be reviewed for scientific merit by an independent review panel.

13.3 In response to the Monitor's request in the Audit Plan, *see supra* 1 ¶ 1.4, Mallinckrodt confirmed there were no requests for access to this clinical data during the third quarter of 2022.

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

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

14.1 Section V of the Operating Injunction required Mallinckrodt to produce certain documents to the Settling States within nine months of October 12, 2020 (*i.e.*, on or before July 12, 2021). As noted in the Second and Fourth, Monitor Reports, Mallinckrodt complied with this requirement by reviewing documents for redaction of information in accordance with Section V.B of the Operating Injunction and producing these documents and the associated redaction logs to the Minnesota Attorney General's Office on July 12, 2021. Additional information on Mallinckrodt's compliance with Section V of the Operating Injunction is available in prior Monitor Reports. *See, e.g.*, Sixth Monitor Report 69-70 ¶¶ 14.1-14.5. There are no further updates at this time.

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

15. OTHER ISSUES OF NOTE

15.1 As discussed in the Sixth Monitor Report, the Monitor learned from Mallinckrodt's Chief Compliance Officer of Mallinckrodt's annual risk assessment of the SpecGx business. During the Seventh Reporting Period, the Monitor received and reviewed policies and procedures pertaining to this annual risk assessment, as well as the results of an annual Risk Assessment Survey, and SpecGx's 2022 Risk Mitigation Plan stemming from those results.

15.2 SpecGx's risk assessment policies include a *Risk Assessment Internal Review and Mitigation Policy* SOP, as well as a separate *Risk Assessment Internal Review and Mitigation Policy*. As these documents explain, Mallinckrodt annually identifies areas of risk, which it then incorporates into an anonymous survey of select employees, who assign numerical values to different areas of business activity risk based upon three variables: ***impact*** ("estimated impact on or harm to the business/function if a harmful event were to occur"), ***likelihood*** ("how likely or probable the activity will occur during the ordinary course of business"), and ***control*** ("the level of control in place when an activity is performed"). The survey results are analyzed, and used to generate a ranking of top ten areas of risk on a color-coded ("heat map") matrix, and compliance audit and monitoring work plans for particular departments. The Compliance Department works with the various functions to design a compliance monitoring plan for these top ten listed areas for the upcoming year, which are summarized in a Risk Mitigation Plan.

15.3 Several business areas identified in the 2022 Risk Mitigation Plan mention compliance with the Operating Injunction as a factor contributing to increased risk in those areas: (1) Social Media; (2) arrangements with third-party Distributors, Wholesalers, etc.; and (3)

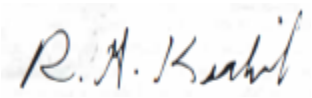
Pharmacovigilance Contact Centers for Adverse Event Reporting. This makes sense given the interplay between those areas and various aspects of Section III of the Operating Injunction.

16. CONCLUSION

16.1 Based upon the Monitor's work to date, Mallinckrodt continues to provide helpful assistance to the Monitor in the exercise of his duties and, in the Monitor's view, is in compliance with the Operating Injunction. The Monitor looks forward to continuing on this path in the next reporting period and beyond.

* * *

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



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

EXHIBIT 1

MALLINCKRODT MONITORSHIP – SUMMARY OF RECOMMENDATIONS
(AS OF THE SEVENTH MONITOR REPORT DATED DECEMBER 1, 2022)[26]

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

No recommendations.

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

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

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

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

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

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

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

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

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

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

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
27.	**5(a)**	Revise the Due Diligence Questionnaire to inquire about relevant persons' criminal backgrounds.	Implemented
28.	**5(b)**	Require restricted direct customers to undertake substantial compliance reforms before reinstatement can occur.	In Progress (No Restricted Direct Customers Have Been Reinstated)

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

Section 11 – Monitoring and Reporting of Direct and Downstream Customers (OI § III.G)			Implementation Status
29.	**6(a)**	Include explicit references to the Operating Injunction in Sales Compensation Plans for future years.	In Progress (Will Not Be Implemented Until 2023)
30.	**6(b)**	Provide additional training to the Human Resources Department (by Mallinckrodt's legal counsel) to prevent consideration of improper incentives in bonus recommendations.	Implemented
31.	**6(c)**	Ensure greater consistency among direct customer audit reports, and more fulsome follow-up where necessary to obtain compliance assurances.	In Progress
32.	**6(d)**	Share with the SOMT, before each monthly meeting, CSC Director's separate tracking list of pharmacies pending due diligence review to ensure tabled pharmacies do not evade future review.	Implemented
33.	**6(e)**	Raise with the "Big Three" distributors, the persistent issue of delayed provision of due diligence, which in turn delays Mallinckrodt's chargeback restrictions, potentially affecting the diversion of Opioid Products.	In Progress
34.	**6(f)**	Ensure evidence of diversion risks appearing in the TrackWise inquiry and complaint logs escalated by the Associate General Counsel (or designee) is reviewed and included in SOMT pharmacy reviews, as appropriate.	Implemented