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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re	**Chapter 11**
ENDO INTERNATIONAL plc, *et al.*,	**Case No. 22-22549 (JLG)**
Debtors.[1]	**(Jointly Administered)**

NOTICE OF FILING OF FINAL REPORT OF THE MONITOR

PLEASE TAKE NOTICE that R. Gil Kerlikowske, as duly appointed Monitor for Endo International plc, *et al*., hereby files the Final Monitor Report attached hereto as **Exhibit A**.

Dated: April 19, 2024
Pittsburgh, PA

SAUL EWING LLP

/s/ Joe Valenti
Joe Valenti

[1] The last four digits of Debtor Endo International plc's tax identification number are 3755. Due to the large number of debtors in these chapter 11 cases, a complete list of the debtor entities and the last four digits of their federal tax identification numbers is not provided herein. A complete list of such information may be obtained on the website of the Debtors' claims and noticing agent at https://restructuring.ra.kroll.com/Endo. The location of the Debtors' service address for purposes of these chapter 11 cases is: 1400 Atwater Drive, Malvern, PA 19355.

Exhibit A

Final Monitor Report

FINAL REPORT OF R. GIL KERLIKOWSKE, INDEPENDENT COURT-APPOINTED MONITOR FOR ENDO INTERNATIONAL PLC ET AL. RELATED TO CASE NO. 22-22549 (JLG), A CHAPTER 11 PROCEEDING IN THE UNITED STATES BANKRUPTCY COURT FOR THE SOUTHERN DISTRICT OF NEW YORK[1]

April 19, 2024

[1] Due to the large number of debtors in these Chapter 11 cases, a complete list of the debtor entities is not provided herein. A complete list of such information may be obtained on the website of the Debtors' claims and noticing agent at https://restructuring.ra.kroll.com/Endo.

TABLE OF CONTENTS

Page

FINAL MONITOR REPORT

Comes now, R. Gil Kerlikowske, as duly appointed Monitor for Endo International plc and its related debtor entities in Case No. 22-22549 (JLG) in the United States Bankruptcy Court for the Southern District of New York (collectively, "Endo"), and reports as follows:

1. EXECUTIVE SUMMARY

1.1 This Final Monitor Report covers the period from the date of the Initial Monitor Report filed on March 16, 2023 to the present (the "Final Reporting Period"). This Final Monitor Report: (1) keeps the same organization and numbering as the Initial Monitor Report; (2) incorporates prior sections by reference for the sake of brevity when those sections remain current without need for change or supplementation; (3) rewrites sections that warrant updating; (4) adds new sections at later numbers where additional information beyond the Initial Monitor Report is required; (5) notes the Monitor's actions during the Final Reporting Period, including the review of documents and data and the use of interviews or meetings with Endo employees and relevant third parties; (6) summarizes observations from the Monitor's fact-finding; (7) confirms Endo's implementation of the recommendations from the Initial Monitor Report; and (8) explains certain additional recommendations (and confirms Endo's implementation thereof during the Final Reporting Period) regarding the requirements outlined in the Voluntary Operating Injunction ("VOI").

1.2 The Initial Monitor Report is incorporated herein by reference.

1.3 The Initial Monitor Report is incorporated herein by reference.

1.4 The Initial Monitor Report is incorporated herein by reference.

1.5 The Initial Monitor Report is incorporated herein by reference.

1.6 The Initial Monitor Report is incorporated herein by reference.

1.7 The Initial Monitor Report is incorporated herein by reference.

1.8 The Initial Monitor Report is incorporated herein by reference.

1.9 During the Final Reporting Period, the Monitor reviewed Endo's compliance with the VOI by examining documents Endo produced voluntarily, requesting specific documents from Endo and similarly examining them, conducting independent research within public records, viewing and posing questions during demonstrations of specific algorithms and software used for compliance purposes, and conducting virtual interviews (including supplemental interviews of people previously interviewed in person) of approximately ten Endo employees and five third-party witnesses that work with Endo in some capacity.

1.10 The Monitor and members of his team were able to interview the Endo employees and the two third-party lobbying / regulation-monitoring firms that Endo has used for federal issues over the past several years. These interviews are discussed in more detail below. *See infra*, Section 8.

1.11 For several hours on July 19, 2023 and September 12, 2023, the Monitor and members of his team were able to engage with Endo's DEA Compliance Team and Endo's key software vendor to view and discuss the suspicious-order-monitoring system and Endo's continuing efforts to enhance the data available in that system. The Monitor also provided (and Endo accepted) recommendations in real-time to the DEA Compliance Team to support the goal of bolstering analytic capabilities, improving documentation, and implementing an appropriate schedule for ongoing internal review (and, if necessary, adjustments) of relevant compliance policies, procedures, and practices. These activities are discussed in more detail below. *See infra,* Section 10.

1.12 Endo's employees, counsel, consultants, and vendors are responsive, cooperative, and helpful to the Monitor. Based on the information reviewed to date, the Monitor believes that Endo has complied in good faith and in all material respects with the terms and conditions of the VOI. The Monitor's engagement is necessarily limited in time, scope, and cost by the terms of the VOI, thus leading to the risk-based approach and tailored focus areas discussed below. Nothing herein is meant to be relied on by any party as a guarantee of Endo's full compliance with the VOI but rather this Final Monitor Report serves as an independent examination and audit of key areas of Endo's operations.

2. THE VOLUNTARY OPERATING INJUNCTION

2.1 The Initial Monitor Report is incorporated herein by reference.

2.2 The Initial Monitor Report is incorporated herein by reference.

2.3 The Initial Monitor Report is incorporated herein by reference.

2.4 The Initial Monitor Report is incorporated herein by reference.

3. SUMMARY OF RECOMMENDATIONS

3.1 The Monitor previously recommended that Endo's Executive Director of Government and External Affairs ensure that federal lobbying disclosures prepared by its lobbying firms are accurate. While Endo was implementing this recommendation, Endo eliminated that position altogether. The Monitor updated his recommendation to call for Endo's Legal Department to take responsibility for these lobbying disclosures, which indeed were amended and will be verified in the future by Endo's Legal Department. *See infra,* Section 8.6.

3.2 The Monitor previously recommended that Endo's DEA Compliance Team continue to work with the vendor of its order-analysis system on a periodic basis to determine whether the system's algorithms are suited to identify potentially suspicious orders, considering any unique characteristics of Endo's business. This recommendation is incorporated into Endo's

policies and procedures, and the Monitor also met with the vendor to confirm full implementation of this ongoing (*i.e.*, periodic in the future) course of action. *See infra*, Sections 10.10 & 10.21.

3.3 The Monitor previously recommended that Endo prohibit any existing customer who has not updated its response to Endo's annual customer due diligence questionnaire within the last 12 months from receiving controlled substances, with such prohibition to be lifted upon successful submission and thorough review of a complete response. Moreover, the Monitor recommended that Endo review and consider whether additional information should be requested by the questionnaire. Endo has fully implemented both of these recommendations, as verified by the Monitor's policy reviews and by the Monitor's own participation in updating the questionnaire. *See infra*, Section 10.10.

3.4 The Monitor previously recommended that Endo review the databases to which Endo's DEA Compliance Team has direct access and consider providing direct access to a third-party informational database. In particular, the Monitor recommended that Endo's DEA Compliance Team have access to a database containing information about whether current or potential customers (direct or downstream) or healthcare providers have valid DEA registrations, whether their licenses are up to date, whether they have any sanctions placed against them, and whether they are included on the HHS Office of the Inspector General's exclusion list. The Monitor also recommended that Endo's DEA Compliance Team have access to any relevant data available to Endo's Customer Operations Team. Endo has fully implemented this recommendation and demonstrated its operational use to the Monitor. *See infra*, Sections 10.13, 10.15, 10.18, & 10.21.

4. GENERAL PROVISIONS (VOI § III.A); BAN ON CERTAIN HIGH DOSE OPIOIDS (VOI § III.B); MISCELLANEOUS PROVISIONS (VOI § III.I); COMPLIANCE WITH LAWS RELATING TO OPIOIDS (VOI § III.J)

4.1 The Initial Monitor Report is incorporated herein by reference.

4.2 The Initial Monitor Report is incorporated herein by reference.

4.3 The Initial Monitor Report is incorporated herein by reference.

4.4 The Initial Monitor Report is incorporated herein by reference.

4.5 The Initial Monitor Report is incorporated herein by reference.

4.6 The Initial Monitor Report is incorporated herein by reference.

4.7 The Initial Monitor Report is incorporated herein by reference.

4.8 The Monitor is not aware of any violations of the VOI Subsections discussed in Section 4 of this Report. Endo agreed that, if it became aware of any violation of the above referenced provisions of the VOI or inaccuracies in the Endo Chief Financial Officer's representations in the most recent certifications, Endo would promptly inform the Monitor. At no point during the Monitorship has Endo notified the Monitor of any violations of the above-referenced provisions of the VOI or inaccuracies in the Chief Financial Officer's representations in the most recent certification.

4.9 Endo has not notified the Monitor of any inquiries or subpoenas received that indicate an investigation into violations committed by Endo during the Monitorship, and Endo has advised that none have been received. For the avoidance of doubt, Endo indeed disclosed—and the Monitor indeed is independently aware of—prior and recently resolved government investigations and related litigation involving Endo that relate to Endo's conduct in 2018 or earlier. Yet, all such investigations and litigations are beyond the scope of this Monitorship, which focuses on Endo's operations from 2022 onward (albeit using historical information as noted where applicable).

4.10 The Monitor investigated whether Endo was subject to any disciplinary actions during the Monitorship. The Monitor reviewed documents from Endo, conducted independent

public-records searches, and interviewed Endo employees, with all of these sources indicating that Endo was not subject to any disciplinary action with respect to any conduct since the beginning of the Monitorship. The Monitor reviewed drafts of the updated policies that Endo provided to confirm Endo's certifications regarding the content of those policies. The Monitor made specific suggestions and recommendations, all of which were addressed or otherwise adopted by Endo and incorporated into the final versions of the policies.

5. BAN ON PROMOTION (VOI § III.C)

5.1 The Initial Monitor Report is incorporated herein by reference.

5.2 The Initial Monitor Report is incorporated herein by reference.

5.3 The Initial Monitor Report is incorporated herein by reference.

5.4 The Initial Monitor Report is incorporated herein by reference.

5.5 The Initial Monitor Report is incorporated herein by reference.

5.6 The Initial Monitor Report is incorporated herein by reference.

5.7 The Initial Monitor Report is incorporated herein by reference.

5.8 During the Initial Reporting Period, Endo's Vice President of Patient Access, Value, and Pricing also explained that Endo's Customer Service Operations Team receives compliance training each year to not answer medical questions (including, without limitation, questions related to Opioid Products). Questions related to health and safety are routed to Endo's Medical Team. During the Final Reporting Period, the Monitor received and reviewed the Customer Service Operations Team's workflow and training materials. In short, the Monitor confirmed that adverse event, product quality, and medical questions are all routed to Endo's Medical Team. Endo's Customer Service Operations Team otherwise answers questions about availability, pricing, supply constraints, and order status, all of which is permissible under the VOI

as basic order-taking and order-management functions rather than Promotion. Patients that call Endo are directed back to their pharmacies or healthcare providers (in accordance with the VOI).

5.9 The Initial Monitor Report is incorporated herein by reference.

5.10 The Initial Monitor Report is incorporated herein by reference.

5.11 The Initial Monitor Report is incorporated herein by reference.

5.12 The Initial Monitor Report is incorporated herein by reference.

5.13 The Monitor reviewed Endo's training procedures and documentation for relevant new and existing employees. This review included policies and procedures (relating to promotional materials, non-promotional materials, communication of medical information, interactions with healthcare providers, communications with certain compendia, publications, independent medical education grants, commercial sponsorships, charitable contributions, and investigator-initiated research) that were revised to incorporate provisions reflecting Endo's VOI commitments. As part of their training, relevant employees are required to review policies related to the functional areas in which they work and certify their compliance. The Monitor is satisfied in all respects with the training materials and compliance policies currently in effect.

6. NO FINANCIAL REWARD OR DISCIPLINE BASED ON VOLUME OF OPIOID SALES (VOI § III.D)

6.1 The Initial Monitor Report is incorporated herein by reference.

6.2 The Initial Monitor Report is incorporated herein by reference.

6.3 The Initial Monitor Report is incorporated herein by reference.

6.4 The Initial Monitor Report is incorporated herein by reference.

6.5 The Initial Monitor Report is incorporated herein by reference.

6.6 The Initial Monitor Report is incorporated herein by reference.

6.7 The Initial Monitor Report is incorporated herein by reference.

6.8 The Monitor reviewed Endo's compensation policies and procedures, including updated standard operating procedures. The Monitor also interviewed Endo's Senior Director of Customer Operations, who oversees the team that handles customer management and supply. Endo's Customer Operations Team essentially handles order taking and order management while liaising with other Endo teams focused on DEA compliance, supply-chain management, contracting, pricing, and shipping. This review and interview confirmed that Endo employees are not given bonuses or otherwise specially compensated for Opioid sales. Indeed, Endo's Customer Operations Team only spends a small portion of its time handling Opioid orders, which are placed by known returning customers who typically only have issues related to backorders. The volume, speed, profit margin, or customer satisfaction relating to Opioid sales is not part of any specific Customer Operations Team grading criteria (and it is a negligible portion of overall grading criteria, such as total orders (of all products) handled or average order-processing time). The Monitor also reviewed Endo's training procedures for relevant new and existing employees and found that the training is consistent with the VOI. The Monitor also interviewed members of Endo's DEA Compliance team about its training and compensation practices and confirmed that team members are never pressured to release (or compensated for releasing) a pended order.

7. BAN ON FUNDING/GRANTS TO THIRD PARTIES (VOI § III.E)

7.1 The Initial Monitor Report is incorporated herein by reference.

7.2 The Initial Monitor Report is incorporated herein by reference.

7.3 The Initial Monitor Report is incorporated herein by reference.

7.4 The Monitor also interviewed Endo's now-former Executive Director of Government and External Affairs, who explained that Endo has a Political Action Committee ("PAC") that is funded by voluntary employee contributions and not corporate funds. Endo's PAC did not give contributions in 2022 or 2023. As the Monitorship was winding up, Endo's PAC

began to consider donations to candidates from both major political parties. During these last few months of the Monitorship, a total of $290,000 to 75 different candidates and/or their affiliated PACs is scheduled or proposed for contributions by Endo's PAC in this manner. Given the lack of PAC activity for much of the Monitorship, and the separate lobbying restrictions discussed below, the Monitor concludes that this area is not a significant concern for a Third-Party funding issue under this Subsection.

7.5 The Executive Director also explained that the Endo Philanthropic Committee ("EPC") provides support to not-for-profit organizations. He explained that the EPC provides support for patient assistance to independent third-party organizations operating in compliance with all requirements and guidance of federal laws and regulations that govern charitable patient assistance programs. This entity independently establishes eligibility criteria and does not disclose to Endo prescriber or patient identifiable data. Endo may also sponsor organizations after confirming that the sponsorship would not result in Endo becoming a primary source of funds for the organization. The Monitor reviewed Endo's most recent policy on charitable contributions, which has been amended to include that Endo does not provide charitable contributions in a manner that violates the VOI with respect to Opioid businesses. Under the amended policy, Endo also does not provide charitable contributions to promote or educate about Opioids and related products. Similarly, Endo does not contribute to other organizations that advocate for increased Opioid access or advocate against measures to limit Opioid access, consistent with the VOI. The Monitor's review of a random sampling of the EPC's supported organizations did not reveal any violations of the VOI.

7.6 The Initial Monitor Report is incorporated herein by reference.

7.7 The Initial Monitor Report is incorporated herein by reference.

7.8 Endo's Chief Financial Officer also certified that Endo's Conflict of Interest policy was revised to require officers and management-level employees (vice president-level or above) to disclose their outside affiliations on an annual basis. The Monitor reviewed the revised policy and related disclosures and did not find any violations of the VOI prohibitions within these materials or within limited independent research in this area. Notably, Endo board members (non-officer and non-employee directors) are not bound by this section of the VOI, and their disclosures (made for other purposes) are beyond the scope of the Monitorship.

7.9 The Initial Monitor Report is incorporated herein by reference.

7.10 The Monitor has reviewed documentation related to the EPC, its makeup, its policies, and its procedures as described above in Section 7.5. The Monitor also reviewed information regarding affiliations of each of Endo's officers and management-level employees. The Monitor also reviewed training materials for new and existing employees that require every U.S. employee to read and sign the Opioid Settlement Agreement Commitments Legal Policy. The Monitor reviewed Endo training records, which indicated that all relevant new Endo hires since the policy was first rolled out in February 2023 have completed their read-and-sign of the policy.

8. LOBBYING RESTRICTIONS (VOI § III.F)

8.1 The Initial Monitor Report is incorporated herein by reference.

8.2 The Initial Monitor Report is incorporated herein by reference.

8.3 The Initial Monitor Report is incorporated herein by reference.

8.4 The Initial Monitor Report is incorporated herein by reference.

8.5 The Initial Monitor Report is incorporated herein by reference.

8.6 Before the Initial Monitor Report, Endo's then-but-now-former Executive Director of Government and External Affairs had pointed out that recent disclosures of one of the federal

firms seem to suggest that Endo was Lobbying for or against issues related to Opioids as recently as the second quarter of 2022. That former Executive Director had explained that Endo has not Lobbied for or against laws related to Opioids or Opioid Products in recent years. He credibly stated that the federal disclosures that suggest otherwise were a mistake on the part of Endo's third-party Lobbying firm. He explained that the disclosure forms are often pre-populated from the last report, which makes it easy for outdated information to remain on forms. These disclosures have since been amended by the firm, and copies have been provided to the Monitor. The former Executive Director explained that he did not previously have a policy of reviewing the third-party disclosures, but he indicated that he would do so in the future. He also explained that he had made these third-party Lobbying firms aware of the terms in the VOI. During the Final Reporting Period, Endo eliminated the Executive Director's position (and reduced its Lobbying spend) as part of its restructuring plan. Upon learning that the third-party Lobbying firms would still work on behalf of Endo but under the direction of Endo's Legal Department, the Monitor updated his prior recommendation to ensure that the Legal Department would implement a policy and practice of reviewing third-party Lobbying disclosures. Endo accepted this recommendation. During the Final Reporting Period, the Monitor interviewed the Assistant General Counsel about the updated policy. Likewise—and to account for a specific concern that had been raised by the Opioid Claimants Committee after the Initial Monitor Report—the Monitor interviewed representatives (the Senior Vice President of Government Affairs and the Public Affairs Director, respectively) of Endo's two third-party federal Lobbying firms. Both third-party Lobbying firms credibly stated that they had not engaged in Lobbying for Endo related to Opioids for several years and further confirmed that they have amended prior Lobbying reports that contained inaccurate information that simply auto-populated year after year. Both third-party Lobbying firms also demonstrated

substantial familiarity with the VOI and otherwise independently corroborated statements given by Endo employees regarding how Lobbying issues were handled in the past, are addressed at present, and will be addressed in the future.

8.7 Both the former Executive Director and the representatives from the third-party Lobbying firms confirmed that Endo's lobbying expenditures on its "no activity reports" submitted during the Monitorship period are related to monitoring federal regulatory activity and the status and text of draft bills; they are not Lobbying.

8.8 During the Initial Reporting Period, the Executive Director confirmed that he was the only person employed at Endo who was responsible for Lobbying, unless he specifically requested that someone from another department be present to discuss a particular issue (for example, a medical expert to explain how a particular drug works). Since his departure, Endo has not hired (and does not presently plan to hire) a replacement for that position, instead having all Lobbying directed by third-party firms working at the direction of Endo's Legal Department or employees designated and overseen by Legal. At no point during the Monitorship period has Endo engaged in any Lobbying activities covered by the VOI.

8.9 The Initial Monitor Report is incorporated herein by reference.

8.10 The Monitor reviewed Endo's policies and procedures related to Lobbying, including Endo's new procedures for review of external Lobbyists' public disclosure reports, and a copy of all training materials related to Lobbying. Endo confirmed that its Legal Department will be reviewing third-party Lobbyists' public disclosure reports in the future before filing. The Monitor also met with Endo's internal and third-party Lobbyists to ensure that errors in previous disclosures were corrected and that third-party Lobbyists are familiar with the VOI and its requirements related to Lobbying.

9. BAN ON PRESCRIPTION SAVINGS PROGRAMS (VOI § III.G)

9.1 The Initial Monitor Report is incorporated herein by reference.

9.2 The Initial Monitor Report is incorporated herein by reference.

9.3 The Initial Monitor Report is incorporated herein by reference.

9.4 The Initial Monitor Report is incorporated herein by reference.

9.5 The Monitor reviewed Endo's updated Standard Operating Procedures ("SOPs") related to this Subsection. The Monitor also reviewed documentation related to Endo's training procedures for relevant new and existing employees that encompass this Subsection of the VOI. The Monitor found that the amended SOPs and training policies and procedures comply with the VOI.

10. MONITORING AND REPORTING OF DIRECT AND DOWNSTREAM CUSTOMERS (VOI § III.H)

10.1 The Initial Monitor Report is incorporated herein by reference.

10.2 The Initial Monitor Report is incorporated herein by reference.

10.3 The Initial Monitor Report is incorporated herein by reference.

10.4 The Initial Monitor Report is incorporated herein by reference.

10.5 The Initial Monitor Report is incorporated herein by reference.

10.6 The Monitor reviewed Endo's policies and procedures related to suspicious order monitoring ("SOM"), interviewed every current member of its DEA Compliance Team (up to and including the Senior Director), viewed Endo's order analysis system, analyzed underlying algorithms and workflows, and reviewed all pended U.S. orders for Opioid Products from Endo from September 2022 to February 2024.

10.7 The DEA Compliance Team is comprised of the following employees, up to and including the Senior Director:

(a) Senior Director. The Initial Monitor Report is incorporated herein by reference.

(b) Senior Manager. The Initial Monitor Report is incorporated herein by reference.

(c) Four compliance associates. One compliance associate was previously interviewed who continues to provide assistance as needed to the DEA Compliance team. Specifically, this associate is available during particularly busy periods or when other DEA Compliance Team members are on scheduled leave to review pended orders. Three additional team members were brought on to Endo's DEA Compliance Team in Spring 2023 in an effort to both expand the DEA Compliance Team and fill empty positions (one compliance associate—previously interviewed by the Monitor—departed Endo since the Initial Monitor Report). Despite being relatively new to Endo's DEA Compliance Team, the three associates bring a range of expertise relevant to the field of DEA compliance. One associate has extensive experience in state government and therefore is familiar with navigating policies and regulations. She also has a background in fact development and investigations. This associate's primary focus at Endo is state licensing, but she is also cross-trained to investigate pended orders. The second associate has a legal and compliance background, having previously worked as a paralegal at Endo to assist with managing Opioid litigation. This associate primarily focuses on investigation of pended orders on the DEA Compliance Team. The third associate was an analyst for fifteen years for a healthcare company and has extensive experience with DEA compliance, namely combing through and processing data and related

information in licensing, state disciplinary actions, and federal sanctions. At Endo, this associate primarily focuses on investigations of pended orders.

10.8 The Initial Monitor Report is incorporated herein by reference.

10.9 The Initial Monitor Report is incorporated herein by reference.

10.10 The Monitor reviewed the SOPs that apply to Endo's customer due diligence program. These SOPs were updated in response to the Monitor's feedback in the Initial Monitor Report (*see* Sections 10.7(d) and 10.10 of the Initial Monitor Report, incorporated herein by reference except where otherwise outdated or inconsistent with the Final Monitor Report). The SOPs reviewed and updated included the DEA Compliance Customer Due Diligence Program; the Due Diligence Questionnaire on New and Existing Accounts; Action on Pended Order Accounts and Electronic Analysis of Orders; and Analyzing Customer Specific Data from Third-Party Sources. The updates are in line with the Monitor's prior (and often confidential) recommendations. The Monitor also has confidence that Endo will periodically review pended-order decisions and SOPs in an appropriate manner going forward using its internal periodic review process.

10.11 ***Investigating pended orders***.

(a) Once the order-analysis system pends an order, the DEA Compliance Team investigates the order by taking numerous compliance-industry-standard steps (*e.g.*, reviewing the customer's ordering history or gathering additional information about the customer or order at issue from a variety of sources). As noted in the Initial Monitor Report, the Monitor's independent review of the DEA Compliance Team investigations from September through November of 2022 showed that two-thirds of the pended Opioid orders were cleared after internal investigation only. The remaining orders were cleared only after a

DEA Compliance Team member obtained and analyzed additional external information. Notably, instances exist where a fuller investigation of one order that gathers external information (such as public data from the FDA's Drug Shortages Database) allows informed internal decision-making on similarly-situated pended orders. For this Final Monitor Report, the Monitor independently reviewed pended orders and DEA Compliance Team investigations from June 2023 to February 2024 and found trends to be consistent to those described in the Initial Monitor Report. The Monitor reviewed Endo's specific procedures that guide the DEA Compliance Team's investigation/decision-making and specific investigative files that demonstrate the documented application of those procedures to investigations in practice. In implementing the Monitor's recommendations from the Initial Monitor Report, the DEA Compliance Team has prioritized the importance of maintaining an adequate documentary record that uses specific and unique language to explain changes in order behavior rather than relying on form language. Consistent with the Monitor's recommendations provided in the Initial Monitor Report, the DEA Compliance Team also checks (and now more specifically documents) DOJ and FDA alerts (among other sources) to independently verify information provided by customers.

(b) All of the DEA Compliance employees interviewed stated that they did not feel pressure to approve orders.

(c) Multiple Endo presentations credibly demonstrated (and independent Monitor review of 2022 Q4 Opioid order records and pended-order alerts confirmed) that 1-3% of all orders for Opioid Products are pended, which is in line with compliance- and pharma-industry trends seeking to both manually review potentially suspicious orders but also avoid needless consumption of resources on "white noise" that is easily justified. The Senior

Director of DEA Compliance and the Senior Manager of Customer Due Diligence & State Licensing on the DEA Compliance Team both stated in multiple interviews that Endo has not had any Suspicious Orders of Opioid Products to report to the DEA since they began their current positions with Endo in 2018. The Senior Manager explained that Endo's three Opioid Products make up a small part of their product portfolio and are sold primarily to a small group of known wholesale customers.

10.12 The Initial Monitor Report is incorporated herein by reference.

10.13 ***Review of third-party information databases***. Third-party information databases exist that provide a central resource for information about whether a current or potential customer (direct or downstream) or healthcare provider has a valid registration, whether their licensure is up to date, whether they have any sanctions placed against them, and whether they are included on the HHS Office of the Inspector General's exclusion list. Prescription, ordering, and related data may also be included. In the Initial Monitor Report, the Monitor noted that members of Endo's DEA Compliance Team expressed a desire to have more access to a database that more centrally compiles such information to streamline their investigations. The Monitor then recommended that Endo review the databases to which the DEA Compliance Team has direct access and consider obtaining and providing additional access as warranted. For this Final Monitor Report, the Monitor again interviewed members of Endo's DEA Compliance Team, which confirmed that additional databases have been obtained and used to assist with review of pended orders. Likewise, these interviews and a system demonstration in front of the Monitor also confirmed that the data issues previously disclosed in Section 10.15 were remedied and remain in working order.

10.14 The Initial Monitor Report is incorporated herein by reference.

10.15 The Initial Monitor Report is incorporated herein by reference.

10.16 ***Oversight***. As noted in the Initial Monitor Report, each member of Endo's DEA Compliance Team confirmed that they are in regular communication with each other and their supervisors; meet monthly in person; and see every order that is pended by the order analysis system. The Senior Director also stated that he sees every justification to release a pended order, and he has never disagreed with the Senior Manager about whether to release an order. However, in the Initial Monitor Report, it was observed that the DEA Compliance Team had no formal or informal auditing policy related to their SOM procedures and they do not review one another's decisions to release a pended order unless one of the associates requests assistance. Shortly before the release of the Initial Monitor Report, Endo added its SOM program to its annual enterprise risk assessment review. Since then, Endo's internal oversight is ongoing.

10.17 ***Training***. Former and current DEA Compliance associates described different training experiences. Among the forms of training received were on-the-job training, attending pharma-compliance-industry conferences, DEA training when available, and membership in umbrella organizations (along with related publications and peer networking) consisting of personnel from different companies involved in monitoring Suspicious Orders. As discussed in the Initial Monitor Report, the Monitor recognized each of these forms of training as beneficial but noted a desire to understand how and when a relevant employee will receive such training. Since the Initial Monitor Report, the Monitor interviewed Endo's DEA Compliance team regarding its new-employee onboarding and continuing education practices. Members of Endo's DEA Compliance team reported receiving both in-person and virtual training and are in regular communication with each other as part of day-to-day activities, as well as when any questions or issues arise. Endo's DEA Compliance team members also acknowledged receiving outside training by participating in annual pharma/compliance industry conferences. Likewise, they also

credibly reported that they stay current on industry trends by periodically reviewing trade publications and alerts released by the Department of Justice. Endo's DEA Compliance team members stated that they were familiar with the VOI and stayed abreast of (and, in some cases, worked on) updates to policies and procedures related to suspicious order monitoring. The Monitor also was involved in reviewing the Endo DEA Compliance Team's revised standard operating procedures related to customer-specific data, pended orders, and due diligence and offered suggestions regarding those policies, all of which were addressed by Endo. Further details need not be provided publicly to maintain the security of such procedures, but the Monitor is satisfied in all respects with the training materials and compliance policies currently in effect.

10.18 The Initial Monitor Report is incorporated herein by reference.

10.19 The Initial Monitor Report is incorporated herein by reference.

10.20 The Initial Monitor Report is incorporated herein by reference.

10.21 The Monitor has reviewed sales figures, pended orders, investigations, and release justifications related to Opioid Products. As part of its inquiry into other aspects of Endo's SOM program, the Monitor met with Endo's third-party order analysis system vendor to better understand the algorithm used to pend orders, how the algorithm can be customized and retuned based on customer behavior, and training provided by that vendor to Endo's DEA Compliance Team (and other users of the same software throughout the pharma/compliance industry). The Monitor also attended a demonstration of the software used by Endo's DEA Compliance Team to evaluate pended orders by visually depicting data, allowing access to historical factors, enabling custom reports, and offering other functions to support robust analysis. As discussed above in Sections 10.7 and 10.10, Endo's DEA Compliance Team has grown over the course of the Monitorship, and relevant SOPs have been updated in line with Monitor recommendations. Endo

has implemented specific training on the applicable software/modules used and continues to have Endo-vendor retunement meetings on a periodic basis to mitigate the risks of potentially problematic orders not being pended in the first place by the algorithm.

11. CLINICAL DATA TRANSPARENCY (VOI § IV)

11.1 The Initial Monitor Report is incorporated herein by reference.

11.2 The Initial Monitor Report is incorporated herein by reference.

11.3 The Initial Monitor Report is incorporated herein by reference.

11.4 Endo has not identified any new Endo-Sponsored Studies on its website or non-public clinical data related to any Opioid Products since the beginning of the Monitorship.

11.5 The Monitor reviewed Endo's compliance risk assessment template related to this Section of the VOI, including Collaborative Research Arrangement/Studies, Compendia, Health Economics and Outcome Research, and Publications. According to Endo's self-certification and the Monitor's independent spot-check reviews of Endo-Sponsored Studies, there have been no new clinical trials related to any Opioid Products since the beginning of the Monitorship.

11.6 Overall, Endo has self-certified its compliance with this area of the VOI, and the Monitor has not independently found any evidence to call that self-certification into question. The Monitor believes that Endo is in compliance with Section IV of the VOI.

12. THE ETHICS HOTLINE

12.1 The Initial Monitor Report is incorporated herein by reference.

12.2 The Initial Monitor Report is incorporated herein by reference.

12.3 The Initial Monitor Report is incorporated herein by reference.

12.4 The Initial Monitor Report is incorporated herein by reference.

12.5 The Initial Monitor Report is incorporated herein by reference.

12.6 Although the Initial Monitor Report and each of the Monitor's interactions with Endo employees and vendors welcomed direct confidential contact to address any concern, no Endo employee (or member of the public) has contacted the Monitor or the Monitor's counsel to raise any concerns in this reporting period.

12.7 During the Monitorship, Endo committed to providing the Monitor with any complaints related to Opioid Products or VOI compliance within two business days of receipt. According to Endo's self-certification and the Monitor's independent spot-check reviews of hotline complaints received during the Monitorship, no such Opioid/VOI complaints were received during the Monitorship.

13. CONCLUSION

13.1 Based upon the Monitor's work to date, Endo has provided helpful assistance to the Monitor in the exercise of his duties and, in the Monitor's view, is in substantial compliance with the VOI during this reporting period.

* * *

13.2 Wherefore, the undersigned Monitor respectfully submits this Final Monitor Report.

/s/ R. Gil Kerlikowske
R. Gil Kerlikowske
Gil Kerlikowske L.L.C.