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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 INITIAL REPORT OF THE MONITOR

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

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[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.

Dated: March 16, 2023
Pittsburgh, PA

SAUL EWING LLP

/s/ Joe Valenti
Joe Valenti

Exhibit A

First Monitor Report

INITIAL 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]

March 16, 2023

[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

INITIAL 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 Initial Monitor Report covers the period from the date the Monitor's Work Plan, defined below, was finalized on December 16, 2022 to the present (the "Initial Reporting Period"). This Initial Monitor Report: (1) notes the Monitor's actions during the Initial Reporting Period, including the review of documents and data and the use of interviews or meetings with Endo employees; (2) summarizes observations from the Monitor's fact-finding; (3) makes certain recommendations regarding the requirements outlined in the Voluntary Operating Injunction, defined below; and (4) describes anticipated steps to cover in the next reporting period.

1.2 During the Initial Reporting Period, the Monitor reviewed Endo's compliance with the Voluntary Operating Injunction by examining documents Endo produced voluntarily, requesting specific documents from Endo and similarly examining them, conducting independent research within public records, visiting Endo offices, and conducting in-person or virtual interviews of approximately ten Endo employees.

1.3 The Monitor and a member of his team had a kick-off meeting on December 7, 2022 at Endo's outside counsel's office in New York. Endo's Senior Vice President and Chief Compliance Officer, Senior Vice President and Associate General Counsel, Vice President and Assistant General Counsel, and Senior Director for DEA Compliance and State Licensing attended the meeting, which was productive and informative. At that meeting, Endo provided an overview

of its businesses, its U.S. operations related to opioids, and its suspicious order monitoring program. It also provided a number of documents for the Monitor's review.

1.4 The Monitor and members of his team were able to conduct a site visit and meeting with Endo personnel on February 2, 2023, at Endo's Woodcliff Lake, New Jersey office. This visit is discussed in more detail below. *See infra*, Section 10.

1.5 Endo's employees, counsel, and consultants are responsive, cooperative, and helpful to the Monitor. Based on the information reviewed to date, the Monitor believes that Endo is making a good-faith effort to comply with the terms and conditions of the Voluntary Operating Injunction, as defined below.

1.6 Endo has certified to the Monitor — and an independent review of both FDA records and Endo's product list confirms — that it sells its products in the United States through two entities: Endo Pharmaceuticals Inc. and Par Pharmaceutical, Inc., both of which are virtual manufacturers and do not have manufacturing or distribution DEA registrations. Endo Pharmaceuticals Inc. currently virtually manufactures one Opioid Product[2]: Percocet. Par Pharmaceutical, Inc. currently virtually manufactures two Opioid Products: Endocet and Buprenorphine HCl Injection (with only the Buprenorphine HCl Injection being directly manufactured by a DEA registrant that is related to Endo – Par Sterile Products, LLC).

1.7 Further, while Endo also sells other controlled substances, the Monitor notes that his focus is limited to the Opioid Products — though on occasion larger datasets or procedures covering all controlled substances are examined for their relevance to Opioid Products.

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

1.8 The Monitor's engagement is necessarily limited in time, scope, and cost by the terms of the Voluntary Operating Injunction, 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 Voluntary Operating Injunction but rather this Initial Monitor Report serves as an independent examination and audit of key areas of Endo's operations to date.

2. THE VOLUNTARY OPERATING INJUNCTION

2.1 On November 16, 2022, the Honorable James L. Garrity, Jr., in the United States Bankruptcy Court for the Southern District of New York issued an Order Granting Debtors' Motion for a Preliminary Injunction Pursuant to Section 105(a) of the Bankruptcy Code. *See* Case No. 22-22549 (JLG), Dkt. No. 63, attached hereto at **Exhibit 1**. That Order attached and entered a Voluntary Operating Injunction ("VOI") through which Endo agreed to retain R. Gil Kerlikowske as an independent monitor to monitor Endo's compliance with the VOI's terms.

2.2 The operative sections of the VOI, for purposes of the monitorship, are Sections III (Injunctive Relief) and IV (Clinical Data Transparency).

2.3 Section III (Injunctive Relief) consists of the following subsections: (1) general provisions (VOI § III.A); (2) a ban on making high-dose opioids (*id*. § III.B); (3) a ban on opioid promotion (*id*. § III.C); (4) a prohibition on financially rewarding or disciplining Endo employees based on the volume of opioid sales (*id*. § III.D); (5) a ban on opioid-related funding/grants to third parties (*id*. § III.E); (6) lobbying restrictions (*id*. § III.F); (7) a ban on opioid prescription savings programs (*id*. § III.G); (8) monitoring and reporting of direct and downstream opioid customers (*id*. § III.H); (9) miscellaneous terms (*id.* § III.I); and (10) compliance with all laws and regulations relating to the sale, promotion, and distribution of any opioid product (*id.* § III.J).

2.4 Section IV (Clinical Data Transparency) consists of the following subsections: (1) Endo-Sponsored data to be shared (*id*. § IV.A) and (2) creation and management of a third-party data archive (*id*. § IV.B).

3. SUMMARY OF RECOMMENDATIONS

3.1 The Monitor recommends that Endo's Executive Director of Government and External Affairs ensure that federal lobbying disclosures prepared by its lobbying firms are accurate, as discussed in more detail in Section 8.6, below.

3.2 The Monitor recommends 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 suspicious orders, considering any unique characteristics of Endo's business, as discussed in more detail in Section 10.10(d), below.

3.3 The Monitor recommends 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 recommends that Endo review and consider whether additional information should be requested by the questionnaire. This recommendation is discussed in more detail in Section 10.10(a), below.

3.4 The Monitor recommends that Endo review the databases to which the DEA Compliance Team has direct access and consider providing direct access to a third-party informational database containing aggregated downstream order and licensing data, as well as directly providing its DEA Compliance Team with any relevant data available to its Customer Operations Team. This recommendation is discussed in more detail in Section 10.13, below.

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 General Provisions state that Endo shall not make any written or oral statement about Opioids or Opioid Products that (1) is false, misleading, deceptive, unfair, or unconscionable; (2) states that any product with an FDA-approved indication for the "relief of pain" or "management of pain" should be used in combination with Opioids to improve efficacy in the Treatment of Pain; or (3) states that Opioids or Opioid Products have approvals, characteristics, uses, benefits, or qualities that they do not have.

4.2 The Ban on Certain High Dose Opioids prohibits Endo from manufacturing, Promoting, or distributing any Opioid Product that exceeds 30 milligrams of oxycodone per pill. For the sake of clarity, it is important to note that this provision does not apply to injectable Opioid Products used primarily in hospice, hospital, or other inpatient settings.

4.3 In relevant part, the Miscellaneous Provisions at VOI § III.I contain a requirement for Endo to regularly train relevant new and existing employees on the VOI's application to their roles in addition to a number of provisions related to conflicts that may arise between the VOI and federal/state laws or requests for information directed to Endo from relevant government entities regarding its Opioid Products.

4.4 The section regarding Compliance with Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid or Any Opioid Product requires Endo to comply with applicable laws, including state controlled substances acts and related regulations; the Federal Controlled Substances Act and related guidance from the DEA; the Federal Food, Drug, and Cosmetic Act; FDA Guidances; state consumer protection laws; and state laws and regulations related to opioid prescribing, distribution, and disposal.

4.5 Endo certified to the Monitor that:

(a) None of the Opioid Products sold by Endo exceed 30 milligrams of oxycodone per pill;

(b) Endo has a number of policies that prohibit it from including – in promotional materials, non-promotional materials, communications of medical information, interactions with healthcare providers, communications with certain compendia, and publications – the following types of statements:

(i) "Any statement that promotes or encourages the use of Opioids or Opioid Products."

(ii) "Any statement that promotes or encourages the use of products for the treatment of Opioid-induced side effects unless the promotion concerns a product's indication to reverse overdose and/or treat opioid addiction and is done in a manner that does not associate the product with Opioids or Opioid Products."

(iii) "Any statement that any product with an FDA-approved indication for the "relief of pain" or "management of pain" should be used in combination with Opioids to improve efficacy in the Treatment of Pain."

(iv) "Any statement about Opioids or Opioid Products that is false, misleading, deceptive, unfair or unconscionable."

(v) "That Opioids or Opioid Products have approvals, characteristics, uses, benefits, or qualities that they do not have."

(c) Endo has not identified any written or oral statements made by it about Opioids or Opioid Products since the VOI went into effect that it believes are false, misleading, deceptive, unfair, or unconscionable.

(d) Endo has not identified any provision of the VOI that is in conflict with federal or relevant state law or regulation such that Endo cannot comply with both the law or regulation and the provision of the VOI. In the event Endo identifies such a conflict during the term of the monitorship, Endo shall inform the Monitor promptly; and

(e) Endo has revised its policies to reflect that employees are prohibited from acting in a manner that is inconsistent with the commitments Endo has voluntarily agreed to follow with respect to Opioids, Opioid Products, products indicated for the use of Opioid-induced side effects, or the Treatment of Pain.

4.6 The Monitor reviewed Endo's product list (as well as FDA records and publicly available research and promotional materials) to confirm that Endo does not offer High Dose Opioids.

4.7 The Monitor likewise examined materials provided by Endo and independently found in the public sphere to confirm that Endo does not promote its Opioid Products, let alone in a false or misleading manner. Indeed, extensive internal procedures and related training exist to ensure that Endo's only statements on Opioid Products are from approved FDA labels. In addition, health and safety questions related to Opioid Products are directed to Endo's Medical Affairs or Medical Information groups (rather than any sales personnel).

4.8 The Monitor is not aware of any violations of the VOI Subsections discussed in Section 4 of this Report. In the event Endo becomes aware 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, Endo has agreed to promptly inform the Monitor.

4.9 Endo has not notified the Monitor of any inquiries or subpoenas received that indicate an investigation into violations by Endo, and Endo has advised that none have been received.

4.10 The Monitor is continuing to investigate whether Endo has been subject to any disciplinary actions since the date of the VOI. The Monitor also continues to review the updated policies that Endo has provided to confirm Endo's certifications regarding the content of those policies as well as to suggest any potential updates to those policies.

5. BAN ON PROMOTION (VOI § III.C)

5.1 The VOI contains extensive terms prohibiting Endo from engaging in the Promotion of Opioids or Opioid Products, including through sales representatives, speaking engagements, educational program sponsorship, control or sponsorship of media accounts, creation or distribution of materials or internet advertisements, use of search engine optimization or other techniques to make Opioids or Opioid Products more accessible to the public online, dissemination of unbranded information that links to branded information, or Promotion of the concept that pain is undertreated in a manner that encourages use of Opioids or Opioid Products.

5.2 However, Endo may do the following:

(a) Have a website or distribute materials that includes basic, approved information about its products or that is required by law to be stated;

(b) Respond to unsolicited requests by healthcare providers that is consistent with the FDA's guidelines;

(c) Respond to unsolicited requests from patients by directing them to their healthcare providers and making no further statements or directions;

(d) Provide information about Opioids or Opioid Products and their pricing sufficient to identify the product for ordering purposes;

(e) Provide information on co-pay assistance and managing pain for end-of-life and/or cancer-related pain;

(f) Provide rebates, discounts, and other customary pricing adjustments to DEA-registered customers and contracting intermediaries; and

(g) Sponsor required accredited continuing medical education programs provided by third parties, in which the third party is responsible for content without Endo's participation.

5.3 The VOI also prohibits Endo from engaging in Promotion of products for the treatment of Opioid-induced side effects unless it concerns reversing overdoses, treating addiction, or does not associate the product with Opioids or Opioid Products.

5.4 Lastly, the VOI prohibits Endo from engaging in Promotion of the Treatment of Pain in a manner that encourages use of Opioids; Promoting the concept that pain is undertreated in a manner that encourages use of Opioids; or disseminating Unbranded Information that contains links to branded information about Opioid Products.

5.5 Endo has certified to the Monitor that:

(a) Endo does not Promote, and has not Promoted since 2016, any of its Opioid Products to healthcare professionals in the United States;

(b) Endo terminated its entire U.S. pain sales force in 2017, including full-time employees and contract sales representatives responsible for promoting Opioids or Opioid Products in the United States; and

(c) Endo withdrew one of its branded Opioid Products, OPANA® ER, from the market in 2017 and discontinued research and development of new Opioid Products.

5.6 ***Interview with the Vice President of Patient Access, Value, and Pricing***. The Monitor interviewed Endo's Vice President of Patient Access, Value, and Pricing. This Vice President confirmed that Endo does not market its Opioid Products at all. He further has not had an Opioid-related question in a year-and-a-half in his current role. In addition, since 2017, his teams have been aware of restrictions voluntarily imposed by Endo that prohibit the Promotion of Opioids and Opioid Products.

5.7 This Vice President noted that Endo provides rebates, discounts, and other customary pricing adjustments to DEA-registered customers and contracting intermediaries that are specifically allowed under the VOI. He credibly explained that any discounts or rebates offered by Endo for any of its Opioid Products are those that are consistent with industry custom and practice.

5.8 This Vice President also explained that Endo's Customer Service Operations Team receives compliance training each year to not answer medical questions (including, but not limited to, questions related to Opioid Products). Questions related to health and safety are routed to Endo's Medical Team. The Monitor has requested the Customer Service Operations Team's workflow and training materials.

5.9 This Vice President also credibly stated that Endo employees do not (1) discuss billing or payment related to Opioid Products with office managers at physicians' offices, (2) have any Opioid-related programs such as insurance pre-approval or prior-authorization programs, or (3) provide free samples of Opioid Products. The Monitor's review of Endo policies, procedures, and other employee statements further support these statements.

5.10 The Monitor independently reviewed Endo's product catalog and online materials related to its three Opioid Products: Percocet, Endocet, and Buprenorphine HCl Injection. This

research confirmed that Endo does not Promote Percocet, Endocet, or Buprenorphine HCl Injection. Indeed, the only information available on Endo's website is information permitted by the VOI, such as the full prescribing information and a link to the Opioid Analgesics REMS website. Independent searches on popular search engines and private engagement on popular social-media platforms also did not reveal the existence of Endo-sponsored advertising or other promotional materials related to Opioids.

5.11 Lastly, the Monitor reviewed Endo's compliance risk assessment template, which reviews policies, procedures, spend, third-party involvement, oversight, risk override, risk mitigation, and training in several key areas related to this Subsection of the VOI, including Co-Promotion Events[3]; Co-advertising; Email Communication of Sales Reps; HCP Meals, Gifts, and Hospitality; Interactions with Patients; Items of Value / Promotional Items; Patient Access and Market Access Interactions; Medical Field Personnel Interactions; Medical Information Requests; Product Samples; Promotional Detailing / Product Coaching; Social Media, Speaker Programs & Other Learning Activities; Speaker Training; and Sponsorships.

5.12 Given the aforementioned independent investigative steps and the attendant self-certification by Endo, the Monitor finds that adequate oversight exists to identify inadvertent Promotion by Endo of Opioids or Opioid Products.

5.13 The Monitor is still investigating how and whether Endo's training procedures for relevant new and existing employees encompass this Subsection of the VOI and has requested training documentation to that end. The Monitor has also requested an interview with another Endo employee regarding these issues and ongoing production of any updated standard operating procedures.

[3] These area titles are provided within the compliance risk assessment template itself.

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

6.1 Endo is prohibited from incentivizing or disciplining its sales and marketing employees based upon sales volume or sales quotas for Opioid Products. Endo is also prohibited from offering or paying any remuneration (including any kickback, bribe, or rebate) directly or indirectly to or from any person in return for the prescribing, sale, or use of an Opioid Product.

6.2 Endo's Chief Financial Officer certified to the Monitor that Endo terminated its entire U.S. pain sales force in 2017 and, since that time, no other sales or marketing employees have received financial incentives based on sales volume for Opioid Products. He also certified that Endo's Incentive Compensation for Field Sales Personnel policy states that "[n]o [i]ncentive [c]ompensation or any other financial incentives may be based upon sales volume or sales quotas for Opioid Products."

6.3 The Monitor also interviewed Endo's Director of Incentive Compensation and Sales Planning, who confirmed that Endo does not offer any field incentive compensation for sales of Opioid Products. He explained that, since Endo disbanded its pain salesforce in 2017, it has not had any field representatives responsible for Opioid sales.

6.4 This Director further explained that Endo currently only Promotes six products – four branded products and two sterile injectable products – none of which are Opioid Products. Field incentive compensation is based only on the sales of these products, and inquiries or sales related to products outside of these six Promoted products and their corresponding specific specialty areas are handled outside of the field sales teams.

6.5 The Director explained that the eligibility for field incentive compensation is limited. In particular, only sales representatives, regional mangers or directors, and national directors are eligible for field incentive compensation. In addition, field incentive compensation

is based on sales of specific products to specified healthcare providers, and sales of other products are not considered in the calculation of field incentive compensation.

6.6 The Monitor also conducted independent research using open-source intelligence databases to confirm that Endo does not advertise rebates or deals related to Opioids or Opioid Products.

6.7 The Monitor also reviewed Endo's compliance risk assessment template, which reviews policies, procedures, spend, third-party involvement, oversight, risk override, risk mitigation, and training in key areas related to this Subsection of the VOI, including HCP Consulting Arrangements and Incentive Compensation.

6.8 The Monitor has requested compensation policies and procedures, including ongoing production of any updated standard operating procedures. The Monitor has requested an interview with a relevant Endo employee with experience in Opioid order-taking/order-processing, wholesaler relations/chargebacks, human resources, and compensation to understand how those employees are trained, evaluated, and compensated. The Monitor is also still investigating how and whether Endo's training procedures for relevant new and existing employees encompass this Subsection of the VOI and has requested training documentation to that end.

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

7.1 This Subsection prohibits Endo from:

(a) Directly or indirectly providing financial support or In-Kind Support to any Third Party for Promotion of or education about Opioids, Opioid Products, products indicated for the treatment of Opioid-induced side effects, or the Treatment of Pain;

(b) Creating, sponsoring, or providing support to any medical society or patient advocacy group that primarily engages in conduct that Promotes Opioids, Opioid Products, or the Treatment of Pain;

(c) Providing links to any Third Party website or materials or otherwise distributing materials created by a Third Party for the purpose of Promoting Opioids, Opioid Products, products indicated for the treatment of Opioid-induced side effects, or the Treatment of Pain;

(d) Using, assisting, or employing any Third Party to engage in any activity that Endo itself would be prohibited from engaging in pursuant to the VOI;

(e) Entering into any contract or agreement with any person or entity or otherwise attempting to influence any person or entity in such a manner that has the purpose or reasonably foreseeable effect of limiting the dissemination of information regarding the risks and side effects of using Opioids;

(f) Compensating or providing In-Kind Support to Health Care Providers (other than Endo employees) or organizations to advocate for formulary access or treatment guideline changes for the purpose of increasing access to any Opioid Product through third-party payers; and

(g) Allowing an officer or management-level employee (vice president-level or above) of Endo to concurrently serve as a director, board member, employee, agent, or officer of another entity that primarily engages in conduct that Promotes Opioids or Opioid Products.

7.2 The Monitor has independently researched, using open source intelligence databases, Endo's public-facing policies regarding funding and support to Third Parties, links to Third Party websites, and distribution of materials created by a Third Party. The Monitor could not find any evidence demonstrating that Endo is engaging in the prohibited actions related to those items.

7.3 Given that the VOI prohibits Endo from contracting with a Third Party to do indirectly what it is prohibited from doing directly, the Monitor interviewed the Vice President of Patient Access, Value, and Pricing regarding agreements with third parties such as direct customers. During the interview, the Vice President confirmed that Endo does not contract with direct customers to do indirectly what Endo is prohibited from doing. To the extent that a direct customer of Endo takes independent action in contravention of the VOI, Endo neither condones nor controls such action – and it is thus beyond the scope of the Monitor's inquiry. However, Endo's suspicious order monitoring policies and procedures, discussed in Section 10, *infra*, allow Endo to gain some insight into its direct and downstream customers' compliance programs and history and further allow Endo to pend or stop filling orders that could violate the VOI.

7.4 The Monitor also interviewed Endo's Executive Director of Government and External Affairs, who explained that Endo has a Political Action Committee ("PAC"), which has not given donations for the last two years. Given the lack of PAC activity (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 guidance and requirements 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 has requested documentation related to any organizations to which Endo has extended grants, sponsorships, or other support since the Monitorship began.

7.6 Lastly, the Executive Director explained that, although Endo provides support for patient assistance programs and patient advocacy organizations, none of the programs or organizations are related to Opioids or Opioid Products.

7.7 Endo's Chief Financial Officer certified to the Monitor that Endo's policies related to Independent Medical Education ("IME") Grants, U.S. Commercial Sponsorships, and U.S. Charitable Contributions prohibit the Company from providing funding for Promotion or education about Opioids, Opioid Products, Opioid-induced side effects, or the Treatment of Pain, unless the funding is required by law.

7.8 The Chief Financial Officer also certified that Endo's Conflict of Interest policy is being revised to require officers and management-level employees (vice president-level or above) to disclose their outside affiliations on an annual basis. While the collection of these disclosures remains in progress, the Monitor has reviewed ones that are available to date and has not found any violations of the VOI prohibitions within the disclosures or within limited independent research in this area.

7.9 The Monitor also notes that Endo's compliance risk assessment template addresses this Subsection of the VOI, including the review of Charitable Contributions and Corporate Giving, Collaborative Research Arrangement / Studies, Health Economics and Outcome Research, IME Grants, Interactions with Government Officials and Third Parties Outside the US, Investigator-Sponsored Research Grants, Market Research, Materials Review and Use of Materials, Medical or Commercial Congresses, Promotional Detailing/Product Coaching, Speaker Programs & Other Learning Activities, Speaker Training, and Sponsorships.

7.10 The Monitor has requested documentation regarding the requests for funding or support from Third Parties, any funding or support given to Third Parties since the beginning of the Monitorship, the makeup of any committee that oversees or approves funding or support to Third Parties, and policies and procedures related to funding or support to Third Parties. The Monitor has also requested information regarding outside affiliations of each of Endo's officers and management-level employees. Lastly, the Monitor is still investigating how and whether Endo's training procedures for new and existing employees encompass this Subsection of the VOI and has requested training documentation to that end.[4]

8. LOBBYING RESTRICTIONS (VOI § III.F)

8.1 This Subsection prohibits Endo from Lobbying for the enactment of any federal, state, or local legislative or regulatory provision that encourages or requires Health Care Providers to prescribe Opioids or sanctions Health Care Providers for failing to prescribe Opioids or failing to treat pain with Opioids; or pertains to the classification of any Opioid or Opioid Product as a scheduled drug under the Controlled Substances Act.

8.2 Moreover, Endo is prohibited from Lobbying against the enactment of any federal, state, or local legislative or regulatory provision that supports the following (including without limitation any third-party payment or reimbursement supporting the following):

[4] The Monitor notes that Endo has licensed certain patents covering extended-release oxymorphone to Impax Laboratories, Inc. ("Impax") pursuant to a patent litigation settlement agreement between the entities entered into in 2010, as amended in 2017 (the "License Agreement"). Under the License Agreement, Impax pays Endo a certain percentage of its profits from its sales of the extended-release oxymorphone in exchange for a license to use Endo's patent. The License Agreement demonstrates that Endo does not control whether Impax chooses to sell extended-release oxymorphone, the amount of extended-release oxymorphone sales made by Impax, or the methods by which that product is promoted, sold, or monitored through Impax. Endo and Impax are subject to ongoing federal enforcement litigation and media scrutiny in these matters that pre-date the VOI. This issue is beyond the scope of the Monitor's engagement.

(a) The use of non-pharmacologic therapy or non-Opioid pharmacologic therapy to treat chronic pain over or instead of Opioid use;

(b) The use or prescription of immediate release Opioids instead of extended release Opioids when Opioid use is initiated;

(c) The prescribing of the lowest effective dose of an Opioid;

(d) The limitation of initial prescriptions of Opioids to treat acute pain;

(e) The prescribing and other means of distribution of naloxone to minimize the risk of overdose;

(f) The use of urine testing before starting Opioid use and annual urine testing when Opioids are prescribed;

(g) Evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for OUD; or

(h) The implementation or use of Opioid drug disposal systems.

8.3 Lastly, Endo must provide notice of these Lobbying prohibitions to all employees engaged in Lobbying; incorporate the prohibitions into trainings provided to Endo employees engaged in Lobbying; and certify that it has provided such notice and trainings to Endo employees engaged in Lobbying.

8.4 The Monitor independently reviewed federal disclosures related to Endo's lobbying and interviewed Endo's Executive Director of Government and External Affairs.

8.5 Federal disclosures for the last several years indicate that Endo engaged two third-party Lobbying firms to lobby on its behalf. By summarizing the reported spend on the federal disclosures for Endo International and Endo Pharmaceuticals, the Monitor observed that, in total, Endo has spent approximately $2,200,000 on federal lobbying since 2019 (the last full year before

the COVID-19 pandemic). Endo's disclosures also indicate that Endo continues to make expenditures related to lobbying on "no activity reports." Notably, these disclosures list numerous issues that are beyond the scope of the VOI (often because they do not involve Opioids and/or because they do not involve influencing law but rather monitoring law).

8.6 The Executive Director of Government and External Affairs 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. The Executive Director 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 Executive Director explained that he did not previously have a policy of reviewing the third-party disclosures, but that he will do so in the future. He also explained that he has made these third-party Lobbying firms aware of the terms in the VOI.

(a) Monitor's recommendation. The Monitor recommended that the Executive Director ensure that future disclosures by firms lobbying on Endo's behalf be reviewed for accuracy. Endo accepted this recommendation and is in the process of working with its third-party Lobbying firms regarding their disclosures, past and present.

8.7 The Executive Director also 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 The Executive Director confirmed that he is the only person employed at Endo who is responsible for Lobbying, unless he specifically requests that someone from another department be present to discuss a particular issue (for example, a medical expert to explain how a particular drug works).

8.9 The Assistant General Counsel for Endo confirmed that Endo's Lobbying activities are not included in Endo's current compliance risk assessment process because they are under the oversight of Endo's Legal department, they are considered low risk, and the Company does not seek to influence Opioid-related laws.

8.10 The Monitor has requested Endo's policies and procedures related to Lobbying, including Endo's forthcoming procedures for review of external lobbyists' public disclosure reports, and a copy of all training materials related to Lobbying.

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

9.1 This Subsection prohibits Endo from directly or indirectly offering any discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient's co-payment or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product. Endo may not provide any financial support to any Third Party that engages in the foregoing conduct, nor may it assist patients, Health Care Providers, or pharmacies regarding the claims or prior authorization process required for third-party payors to approve claims involving any Opioid Product.

9.2 The Monitor's interview of Endo's Vice President of Patient Access, Value, and Pricing confirmed that no such programs are offered to end users or Health Care Providers for Opioid Products. Only industry-standard chargebacks for distributors exist.

9.3 Endo's Chief Financial Officer also certified to the Monitor that Endo:

(a) Has not operated a patient support program or any similar program that offers discounts or rebates to reduce or eliminate the cost of its Opioid Products to patients since 2017;

(b) Does not directly operate any patient support programs or otherwise offer patients coupons, rebates, or other financial support to patients for any of its Opioid Products; and

(c) Has policies and procedures in place that prohibit it from offering financial support that has the effect of reducing or eliminating the cost of prescription for any of its Opioid Products. For example, Endo's U.S. Charitable Contributions to Independent Charity Patient Assistance Programs policy states that the "Company shall not provide Charitable Contributions to an Independent Charity PAP that primarily engages in conduct that Promotes or educates about Opioids, Opioid Products, products indicated for the use of Opioid-induced side effects, or the Treatment of Pain." It also provides that a charitable contribution made by Endo shall not result in "funding of an Opioid Product."

9.4 The Monitor conducted research using open source intelligence databases regarding Endo's prescription savings programs, coupons, rebates, and free trials. The Monitor did not find any evidence that Endo is engaging in the conduct prohibited under this Subsection. Indeed, publicly available materials confirm what multiple Endo employees have stated during interviews: that Endo does not market Opioid Products and specifically does not offer these types of consumer-facing programs for Opioids or Opioid Products.

9.5 The Monitor will request continuing production of standard operating procedures related to this Subsection. The Monitor is also still investigating how and whether Endo's training

procedures for relevant new and existing employees encompass this Subsection of the VOI and has requested training documentation to that end.

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

10.1 This Subsection of the VOI requires that Endo operate an effective monitoring and reporting system in compliance with 21 C.F.R. § 1301.71(a), 21 C.F.R. §1301.74(b), 21 U.S.C. § 823(d), and Section 3292 of the SUPPORT for Patients and Communities Act that shall include processes and procedures that:

(a) Use all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer;

(b) Use all reasonably available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product; and

(c) Use all information that Endo receives that bears upon a direct customer's or a downstream customer's diversion activity or potential for diversion activity, including reports by Endo's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media.

10.2 Endo may not provide to any direct customer an Opioid Product to fill an order identified as a Suspicious Order unless Endo investigates and finds that the order is not suspicious.

10.3 Moreover, upon request of the Attorney General or controlled substances regulatory agency of a Participating State (unless otherwise required by law), Endo must report to such requesting State entity any direct customer or downstream customer in such State identified as part of the monitoring required above and any customer relationship in such State terminated by Endo relating to diversion or potential for diversion.

10.4 Similarly, upon request, Endo is required to promptly provide reasonable assistance to law enforcement investigations of potential diversion or suspicious circumstances involving Opioid Products in the United States.

10.5 Lastly, Endo agreed in the VOI that it would refrain from providing an Opioid Product directly to a retail pharmacy or Health Care Provider.

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, preliminarily analyzed underlying algorithms and workflows, and reviewed all pended U.S. orders for Opioid Products from Endo from September through November of 2022.

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

(a) Senior Director. The Senior Director has held management-level positions related to DEA compliance for at least the last twenty years and was independently verified as a licensed pharmacist in good standing. He is responsible for overseeing the DEA Compliance Team, state licensing, and any activities involving the DEA. The Monitor has no concerns about the Senior Director's competency to serve in his role.

(b) Senior Manager. The Senior Manager, who reports to the Senior Director, was hired specifically to serve as Endo's SOM "expert." She has extensive experience across the spectrum of DEA compliance, including order monitoring, site visits/inspections, surveillance, establishing production quotas, inventory management, physical security, and theft/loss reporting. She is also a committee member in the National Association of Drug Diversion Investigators (NADDI) and National Association of State Controlled Substances Authorities (NASCSA),

through which she advocates for issues related to anti-diversion. The Senior Manager splits her time equally between DEA compliance and state licensing. The Monitor has no concerns about the Senior Manager's competency to serve in her role.

(c) Two compliance associates. Both associates on the DEA Compliance Team are relatively new to the field of DEA compliance. One has been in her role since November of 2020. She does not have any prior experience in DEA compliance, although she has more than ten years of regulatory experience in the healthcare industry and a bachelor's degree in biology. Her primary responsibility is to review and release pended orders for all of Endo's U.S. orders. She is assisted by a second associate who started in her role in December of 2022 and has no prior DEA compliance experience (though she has been in the pharmaceutical industry for twenty-five years). This second associate splits her time between reviewing pended orders, when asked, and another unrelated department within Endo. Given the ongoing supervision and training provided by the Senior Manager, the Monitor is supportive of this continued expansion and training of Endo's DEA Compliance team at this time.

(d) The Senior Director of DEA Compliance noted that Endo Pharmaceuticals Inc. has been a "virtual manufacturer" since its founding in 1997 and Par Pharmaceutical, Inc. became a "virtual manufacturer" in 2021. As such, neither entity is currently a DEA registrant. The Monitor continues to review contracts and interview Endo employees but has not found anything to date to contradict the claims that these two entities have properly outsourced their manufacturing and distribution, such that they do not ever take physical possession of controlled substances and indeed have DEA-registered contracted manufacturers[5] and distributors (both their

[5] For Percocet and Endocet, Endo has a manufacturing contract with Strides Pharma Science Limited, which is a third-party contract manufacturing organization. For Buprenorphine HCl Injection, an Endo debtor entity has a manufacturing contract with Par Sterile Products, LLC,

shippers and their wholesalers) assume sole responsibility for physical security of relevant facilities and packages.

10.8 For security and operational-integrity reasons, many of the observations that follow are kept vague in this public report.

10.9 Endo's SOM procedures regarding its direct customers (all wholesalers licensed by the DEA as distributors) include performing due diligence of direct customers and investigating potentially suspicious orders, which are discussed in more detail below.

10.10 ***Customer due diligence.*** Endo's standard operating procedures explain, and the Senior Manager of DEA Compliance confirmed, that every direct customer must be cleared through a process of due diligence before Endo will sell Opioid Products to it. This due diligence consists of distributing customer questionnaires, conducting site visits, monitoring every customer's orders through a third-party order analysis system, conducting manual investigation of orders automatically pended by that third-party system, reviewing alerts from the Department of Justice regarding relevant indictments, and analyzing internal and third-party informational databases for relevant customer data.

(a) Distributing customer questionnaires. Endo's customer questionnaires demand information about a customer's basic contact information, ownership/management, business operations, expected order volume, state licensure and DEA registration status, disciplinary actions, and SOM program and inquire into whether they have been convicted of a crime related to controlled substances. The Senior Director and Senior Manager of the DEA Compliance Team review the form for potential updates on an annual basis and revise as necessary.

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which is also an Endo debtor entity and also manufactures controlled substances for an unaffiliated third party.

The Senior Manager and a DEA Compliance Team associate confirmed that distributing and collecting questionnaires is handled solely by the DEA Compliance Team, which requires all sections of the form to be completely filled out. New customers must provide a complete response to the questionnaire before they can purchase controlled substances from Endo. Existing customers must provide a complete response once during every 12-month period to continue to order controlled substances from Endo. The DEA Compliance Team sends the annual questionnaire in the first quarter of every year and requests a response within three months, reiterating that every customer must provide a complete response annually. The Senior Manager reported that they have several customers who routinely fail to provide responses within the three-month timeframe, after which Endo threatens to cut them off from ordering. Answers on the questionnaire are independently verified by Endo where possible, and Endo credibly reports that no relevant customers have misrepresented information (*e.g.*, DEA license status).

(i) *Monitor's recommendation.* Because the customer questionnaire is an important information-gathering tool that is quite useful when timely and accurately completed, and because Endo's current procedures allow its customers to avoid such completion for up to nine months without consequence, the Monitor recommends that Endo prohibit customers who have not provided a complete response within the last 12 months from ordering controlled substances. Essentially, each customer must complete Endo's due diligence questionnaire at least once every 12-month period. To allow the Monitor to further analyze this area within the Monitorship Period, the Monitor also requests that Endo review its questionnaire within the next 60 days and advise the Monitor of any expected changes before Endo's next annual distribution of it.

(b) Internet searches. Endo's standard operating procedures also state that DEA Compliance associates will conduct internet searches regarding its customers to confirm

whether there have been any disciplinary actions against the customer or whether they are located in an area of high risk.

(c) Conducting site visits. The Senior Manager of DEA Compliance explained that she is responsible for conducting site visits to all of Endo's direct wholesale customers. Site visits consist of analyzing the local area in which the customer operates; inquiring into and observing the customer's security procedures; inquiring into areas of known risk; obtaining a list of the customer's major customers and related sales data; and gathering other relevant documentation. The Senior Manager is able to conduct approximately forty visits per year, including all new customers for that year, and aims to visit every customer at least once every two years, although she has not yet reached that goal. The DEA Compliance Team will be adding and training an additional employee who will also be responsible for conducting site visits.

(d) Monitoring orders. Orders are initially pended by Endo's order-analysis software, which uses algorithms to determine whether an order's size, pattern, or frequency (or combination thereof) may be outside of a customer's ordering pattern. The software uses a visual and numerical scale to illustrate how far a particular order deviates from the customer's usual ordering pattern overall as well as in each relevant metric to facilitate human review. When the system pends an order for human review, every member of the DEA Compliance Team (up to and including the Senior Director) receives an alert about the order. The third-party vendor's algorithm is developed based on an analysis of Endo's sales data for each customer. Notably, the third-party vendor is a reputable industry provider that also has access to broad datasets across the industry, making its algorithms quite formidable, especially when monitoring for retail diversion trends. The software includes the ability to adjust the algorithms or add specific rules to further tailor a risk-based approach. While members of the DEA Compliance Team had cogent explanations for

the lack of certain adjustments (*e.g.*, eschewing auto-approve or max-limit rules in favor of more conservative algorithms), other specific suggestions or comments were not as readily explained or shown to have been fully considered (*e.g.*, auto-review rules for a key customer currently under public DEA scrutiny).

(i) *Monitor's recommendation*. The Monitor recommends that the DEA Compliance Team continue to work with the vendor of its order-analysis system to determine whether the system's algorithms are suited to identify suspicious orders, considering any unique characteristics of Endo's business (particularly the wholesaler nature of its customers and its sensitivity to nationwide drug shortages), and to adjust the order-analysis algorithm to accommodate those unique characteristics.

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). The Monitor's independent review of the DEA Compliance Team investigations from September through November of 2022 shows 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.

(b) 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. While the Monitor was generally satisfied with the process, the Monitor has discussed additional considerations with Endo regarding the qualitative factors considered and the independence of the external information obtained (*e.g.*, de-emphasizing information received directly from a customer in favor of independently obtained information collected through Endo observations, DOJ/FDA databases, etc.). The Monitor has also discussed the level of detail contained within investigative files with the DEA Compliance Team to ensure an adequate documentary record.

(c) All of the DEA Compliance employees interviewed stated that they did not feel pressure to approve orders. The Senior Manager and one of the associates both credibly asserted the maxim that "Sales doesn't drive SOMs." Both associates understood that the Customer Operations Team had no authority over them.

(d) 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 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 only to a small group of known wholesale customers.

10.12 ***Department of Justice alerts***. The Senior Manager of DEA Compliance receives alerts from the Department of Justice regarding indictments relevant to the federal Controlled

Substances Act, which may include DEA regulatory orders suspending shipments of controlled substances to particular entities or individuals. Through a review of these alerts, the DEA Compliance team may identify alerts that contain allegations regarding potential CSA violations involving direct and downstream customers. Endo will consider this information to determine whether a customer should be suspended or if any further action needs to be taken.

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. Members of the DEA Compliance Team expressed a desire to have more access to a database that more centrally compiles such information to streamline their investigations..

(a) Monitor's recommendation. The Monitor recommends that Endo review the databases to which the DEA Compliance Team has direct access, and consider providing direct access to the third-party databases discussed in Section 10.13, above.

10.14 ***Downstream customer data.*** Endo's SOM procedures also include receipt of downstream customer data, which the DEA Compliance Team analyzes if the downstream customer is the subject of an alert from the Department of Justice or associated with a pended order. The Senior Manager explained Endo obtains downstream customer data in the following ways:

(a) A third-party order tracking system that allows Endo to see:

(i) detailed transactions of product flowing to and from distribution centers;

(ii) supply levels of product based on a snapshot of downstream customers' inventory from a previous day's transactions;

(iii) downstream customers' purchasing history, and

(iv) chargeback requests from direct customers, which occur when a direct customer sells Endo's product at a discount from the price at which Endo sold it and has a right under its agreement with Endo to request a refund of the difference between the price at which the direct customer bought the drug from Endo and the price at which the direct customer sold the drug to its own customer. Although the Senior Manager stated that "not many" of Endo's customers participate in the chargeback program, for those that do, the requests may provide the DEA Compliance Team with insight into volume of sales to downstream customers; and

(b) Downstream-customer lists provided by direct customers, typically at site visits.

10.15 In December 2022, Endo disclosed that, throughout 2022, its third-party order analysis system had not been properly loading all of the above downstream customer data. As a result, the data listed in 10.14(a) related to Endo's only branded Opioid Product, Percocet, was not available to the DEA Compliance Team through the third-party order analysis system, and chargeback data similarly was not available for Endo's generic products, Endocet and Buprenorphine HCl Injection. This data has since been loaded into Endo's order analysis system, and an additional check has been put into place to ensure that the data continues to be available there. During her interview, the Senior Manager of DEA Compliance explained that all of the orders that were cleared during the time period in which this information was unavailable were

cleared because other information available to the team justified clearance independently of this downstream data. While the Monitor continues to analyze the implementation and verification of this data integration, the Monitor appreciates Endo's voluntary disclosure and remediation of this issue before the Monitor could formally detect and recommend steps on it.

10.16 ***Oversight***. Each member of the 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, each member of the DEA Compliance Team also indicated that there is 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, although Endo has added its SOM program to its annual enterprise risk assessment review. At this time, the Monitor has no recommendations on this particular issue, particularly given that Endo is already in the process of making relevant changes that will be discussed further in the next Report.

10.17 ***Training***. The 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. The Monitor recognizes each of these forms of training as beneficial but notes a desire to understand how and when a relevant employee will receive such training. As noted, Endo is updating its policies, procedures, and training materials and adding additional personnel support for the DEA Compliance Team. While

the Monitor does not have a recommendation at this time, the Monitor will request a list of all training provided to the DEA Compliance Team.

10.18 Members of the DEA Compliance Team consistently reported that they feel well-supported in their roles; do not have difficulty balancing their responsibilities; frequently communicate with one another; feel that they have all the necessary hardware and software resources available to them to perform their jobs (with the exception of the recommendation made in Section 10.13(a), above); have all the training they need; feel the Team is highly valued within the organization; and have no concerns about how the DEA Compliance Team is run.

10.19 ***Assistance to law enforcement.*** The Senior Director of DEA Compliance indicated that he is involved in receiving and responding to inquiries from law enforcement related to ongoing investigations. He explained that the requests often pertain to technical aspects of Endo's products, such as confirming a product's dosage or weight, or confirming whether the product is counterfeit or not.

10.20 ***Other Provisions of the VOI.***

(a) Because Endo has not identified an Opioid Product order as suspicious since at least 2018, the Monitor is satisfied that Endo has not provided to any direct customer an Opioid Product identified as a Suspicious Order.

(b) The Senior Director of DEA Compliance confirmed that no Attorney General or controlled substances regulatory agency of a Participating State has requested a report regarding any direct customer or downstream customer in such State identified as a party to the VOI, or any customer relationship in such State terminated by Endo relating to diversion or potential for diversion.

(c) Multiple Endo employees confirmed that they are not aware of any orders from retail pharmacies or Health Care Providers since the date of the VOI.

10.21 The Monitor has requested continuing production of sales figures, pended orders, investigations, and release justifications related to Opioid Products. The Monitor is also continuing to investigate other aspects of Endo's SOM program, including the customizability of the third-party order analysis system, information regarding the budget for the DEA Compliance Team, and any planned future updates to the standard operating procedures or training procedures and materials for new and existing employees.

11. CLINICAL DATA TRANSPARENCY (VOI § IV)

11.1 This section requires Endo to share summaries of the results of all prior Endo-Sponsored Studies through its publicly available website (see http://www.endo.com/endopharma/r-d/clinical-research) and, with respect to any new Opioid Product, make the certain clinical data available through a third-party data archive, including data sets, study reports, protocols, and statistical analysis plans.

11.2 Endo certified to the Monitor that Endo withdrew one of its branded Opioid Products, OPANA® ER, from the market in 2017 and discontinued research and development of new Opioid Products.

11.3 The Monitor has reviewed the information available on Endo's website at http://www.endo.com/endopharma/r-d/clinical-research. Of all the active, ongoing, non-Phase 1 studies sponsored by Endo, none on Endo's website are related to Opioid Products. Endo has also published completed Endo-sponsored studies, including thirty Opioid-related studies, on its website.

11.4 The Monitor continues to review this area and will consider seeking a relevant certification from Endo regarding any details that cannot be independently and publicly confirmed.

11.5 The Monitor preliminarily 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.

11.6 The Monitor is continuing to evaluate compliance with this Section IV.

12. THE ETHICS HOTLINE

12.1 Endo maintains an ethics hotline through which employees, customers, and members of the public can submit comments or complaints about Endo and its products.

12.2 The Monitor reviewed a chart with high-level information regarding all of the reports received through the ethics hotline in 2022. The chart provided the following information regarding the complaints received: company, location, date of report, "primary issue," and the platform through which the complaint was raised. The "primary issue" ranged from "Good Operating Practices," to "Improper Drug and Alcohol Use," "Promoting Our Products," "Ask a Question," and "Other." Based on both document review and employee interviews, virtually all of the hotline complaints have nothing to do with Opioids.

12.3 The Senior Director of Compliance Investigations at Endo, who is responsible for the ethics hotline, represented that there was only one complaint that only vaguely and tangentially mentioned Opioids or Opioid Products and provided that complaint. The Monitor directly reviewed that complaint and confirmed this characterization. The record related to the complaint showed that a representative from Endo reached out to the complainant two days after receipt of the complaint and then closed the complaint the next month. The Senior Director of Compliance Investigations credibly explained that a representative from Endo inadvertently failed to inform the complainant that the investigation had been closed. When this issue was noted, 10 months later, she promptly sought additional information from the complainant, if any, and notified the complainant through the Ethics hotline system that the case was being closed. Notably, the

complainant did not follow up in the interim or respond to Endo's request for additional information.

12.4 The Monitor also audited complete, anonymized information related to nine complaints that had "primary issues" listed that could potentially fall within the parameters of the VOI (*e.g.*, a category of "Other"). None of those complaints regarded Opioids, Opioid Products, or any of the issues within the VOI.

12.5 The Monitor notes that the type of complaints coming through the hotline are consistent with other industry uses of complaint programs and did not expect specific complaints regarding the VOI. However, the Senior Director explained that the hotline does now have a specific category in its "primary issue" dropdown list for VOI-related concerns.

12.6 Notably, the Monitor informed all Endo employees interviewed that concerns could be raised through the hotline anonymously or outside the presence of any other Endo employee or agent by directly contacting the Monitor's counsel. To date, no Endo employee (or member of the public) has contacted the Monitor or the Monitor's counsel to raise any concerns beyond what was freely discussed above in interviews.

12.7 Endo will continue to provide complaints related to Opioid Products or VOI compliance within two business days of receipt.

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. The Monitor looks forward to continuing on this path in the next reporting period and beyond.

* * *

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

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