

**UNITED STATES BANKRUPTCY COURT  
SOUTHERN DISTRICT OF NEW YORK**

*In re*

**ENDO INTERNATIONAL plc, et al.,**

**Debtors.<sup>1</sup>**

**ENDO INTERNATIONAL plc, et al.,**

**Plaintiffs,**

**-against-**

**COMMONWEALTH OF KENTUCKY, et al.,<sup>2</sup>**

**Defendants.**

**Chapter 11**

**Case No. 22-22549 (JLG)**

**(Jointly Administered)**

**Adv. Proc. No. 22-07039 (JLG)**

**Related Docket Nos. 2, 61**

**ORDER GRANTING DEBTORS' MOTION FOR A PRELIMINARY INJUNCTION  
PURSUANT TO SECTION 105(a) OF THE BANKRUPTCY CODE**

This matter having come before the Court on the above-captioned debtors' (the "Debtors") Complaint and *Motion For a Preliminary Injunction Pursuant to Section 105(a) of the Bankruptcy Code* (the "Motion"),<sup>3</sup> and the Court having reviewed the Complaint and the Motion, as well as (a) *the Debtors' Memorandum of Law in Support Of Motion for a Preliminary Injunction Pursuant to Section 105(a) of the Bankruptcy Code* [D.I. 3], (b) *the Declaration of*

<sup>1</sup> 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.

<sup>2</sup> The complete list of the Defendants is set forth in the caption of the Debtors' Complaint for Injunctive Relief [D.I. 1] ("Complaint") and in Exhibit A attached thereto.

<sup>3</sup> Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Motion.

*Ray Dombrowski in Support of Debtors' Motion for a Preliminary Injunction Pursuant to Section 105(a) of the Bankruptcy Code [D.I. 4]; (c) the Declaration of Mark Bradley in Support of Debtors' Motion for a Preliminary Injunction Pursuant to Section 105(a) of the Bankruptcy Code [D.I. 5]; and (iv) the Declaration of Mark Bradley in Support of Chapter 11 Petitions and First Day Papers [Main Case D.I. 38], together with any responses to the Motion, and, having considered the evidence and arguments submitted at the hearing on November 10, 2022, the Court FINDS AND CONCLUDES as follows:*

A. The plaintiffs in this adversary proceeding are the Debtors. The defendants in this adversary proceeding are the Governmental Defendants listed in the caption to the Complaint (also identified on Exhibit A to the Complaint). Exhibit A to the Complaint will be made an exhibit hereto upon the signing of this Order.

B. The Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 157(a)-(b) and 1334(b) and the Amended Standing Order of Reference M-431, dated January 31, 2012 (Preska, C.J.). This is a core proceeding pursuant to 28 U.S.C. § 157(b). The venue is proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409. Due and proper notice of the Motion was sufficient under the circumstances.

C. The Debtors seek an order pursuant to section 105 of the Bankruptcy Code enjoining and prohibiting the Governmental Defendants from continuing or commencing against the Debtors any Covered Action.

D. The Debtors further seek an order entering the Voluntary Operating Injunction set forth in Appendix 1 against the Debtors.

E. The Debtors have demonstrated that a preliminary injunction is warranted in order to enjoin the continuation or commencement of the Covered Actions for 270 days (the “Injunction Period”).

F. The Debtors have demonstrated that in the absence of the requested injunction (assuming, without deciding, that the automatic stay does not apply of its own force to any such actions), the Debtors, their estates, their reorganization efforts, and their bankruptcy cases will suffer irreparable harm, and the Court's jurisdiction will be impaired with respect to the above-captioned cases, including because the commencement or continuation of any Covered Action will substantially erode or divert estate resources, will substantially distract or divert the Debtors and their management and key employees, and will impede the bankruptcy cases, the Debtors' estates, and their reorganization efforts, including the Debtors' ability to conduct a value-maximizing sale process. The Debtors have further demonstrated that the harm to the Governmental Defendants, if any, due to imposition of the requested injunction is minimal and is outweighed or substantially outweighed by the harms that would result to the Debtors, their estates, their reorganization efforts, and their bankruptcy cases in the absence of the requested injunction. The Debtors have further demonstrated that, with the benefit of the requested injunction, there is a reasonable likelihood that they will successfully conduct a value-maximizing sale process and reorganization. The Debtors have further demonstrated that an injunction is in the public interest because, among other reasons, it is necessary and/or will substantially increase the likelihood for the Debtors to successfully conduct a value-maximizing sale process and reorganization.

G. Accordingly, this Court finds it appropriate to enter a preliminary injunction as provided herein pursuant to section 105(a) of the Bankruptcy Code and/or Rule 7065 of the Bankruptcy Rules.

H. The legal and factual bases set forth in the Complaint, the Motion, the Opening Brief, the declarations and other supporting papers, and at the hearing establish just cause for the relief granted herein.

I. The Governmental Defendants identified at Appendix 2 of this Order have each consented and agreed to abide by the terms of this Order, without the need to have any order or injunction entered against them (each, a “Voluntarily Bound Party” and, collectively, the “Voluntarily Bound Parties”); *provided*, for the avoidance of doubt, that the Voluntarily Bound Parties, by virtue of such consent and agreement, shall not be bound or otherwise prejudiced by the conclusions and findings set forth in paragraphs E, F, G, and H of this Order so long as they continue to abide by the terms of this Order. The Official Committee of Opioid Claimants has agreed to support the relief requested, but will not be bound or otherwise prejudiced by the conclusions and findings in the last two sentences of paragraph F.

J. If a Voluntarily Bound Party ceases to abide by the terms of this Order, then such party (i) shall no longer be considered a Voluntarily Bound Party as described in Paragraph I of this Order and (ii) shall immediately become subject to, and bound by, this Order and all of its provisions. If a Voluntarily Bound Party ceases to abide by the terms of this Order, all of the Debtors’ rights are reserved with respect to seeking further relief from the Court.

Based on these findings and conclusions, the Court ORDERS that:

1. The Motion is granted.

2. The Debtors' request to enjoin the Covered Actions for a period of 270 days from the date of this Order pursuant to section 105 of the Bankruptcy Code is granted.

3. For clarity, the Covered Actions include every lawsuit and administrative proceeding identified on Exhibit A to the Complaint, as well as any future actions by governmental units alleging substantially similar facts or causes of action that could have been commenced before the Petition Date that are civil (as opposed to criminal) in nature, but excludes discovery that may be taken from Debtors in connection with actions or proceedings in which no Debtor is named a party. The Debtors' rights are reserved with respect to moving to stay any judicial, administrative, investigatory or other action or proceeding not included in this Motion at any time in the future. For the avoidance of doubt, this Order only applies to pending and prospective actions and proceedings that are civil (as opposed to criminal) in nature.

4. The Governmental Defendants, other than the Voluntarily Bound Parties, are prohibited and enjoined from commencing or continuing to prosecute any Covered Actions against the Debtors for a period of 270 days from the date of this Order, pursuant to section 105 of the Bankruptcy Code. This injunction includes, without limitation: (i) the pursuit of discovery, including depositions, from the Debtors or their officers, directors, employees, or agents (but, for the avoidance of doubt, does not include seeking discovery or depositions from other parties) in connection with the Covered Actions; (ii) the enforcement of any discovery order against the Debtors in connection with the Covered Actions; and (iii) further motion practice, except, in each case, in connection with actions or proceedings in which no Debtor is a named party. It does not include, and no person is enjoined, from (i) continuing to prosecute, pursue discovery, enforce discovery orders, or engage in further motion practice, against non-Debtor defendants in any of the Covered Actions, or (ii) seeking discovery from the Debtors' officers, directors, employees,

agents, advisors, and consultants who were named defendants in the Covered Actions as of the Petition Date.<sup>4</sup>

5. If a Voluntarily Bound Party ceases to abide by the terms of this Order, then such party (i) shall no longer be considered a Voluntarily Bound Party as described in Paragraph I of this Order and (ii) shall immediately become subject to, and bound by, this Order and all of its provisions.

6. The Debtors are authorized to take all steps necessary or appropriate to carry out this Order.

7. Nothing in this Order shall prevent the Debtors from seeking a further extension of the injunction provided for herein.

8. Except as expressly set forth in this Order, this Order shall not affect the exceptions contained in sections 362(b), 365(b)(4), and 365(e)(2) of the Bankruptcy Code or the right of any party-in-interest to seek relief from the automatic stay in accordance with section 362(d) of the Bankruptcy Code or with respect to an unexpired lease or executory contract under section 365 of the Bankruptcy Code.

9. If during the pendency of the injunction provided for herein, either (i) any inactive action currently pending against the Debtors becomes active, or (ii) any new action is commenced against the Debtors that is civil (as opposed to criminal) in nature (in either case, an “Additional Action”), then the Debtors may promptly serve the plaintiff or plaintiffs therein (the “Applicable Plaintiff”) with a copy of the Complaint, the Motion, the Opening Brief, and this Order (collectively the “Service Documents”). The Debtors shall file a notice of such service on the docket promptly after service. If the Applicable Plaintiff in such Additional Action does not

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<sup>4</sup> It is understood that no directors or officers were named defendants in any Covered Action as of the Petition Date.

file and serve an objection within seven (7) days of service of the Service Documents, then the Court shall determine without further proceedings whether such Additional Action shall be enjoined pursuant to this Order. If the Applicable Plaintiff files and serves an objection, then the Debtors shall have the right to file and serve a response to the objection within seven (7) days of service of such objection, after which the Court shall determine without further proceedings whether such Additional Action shall also be enjoined pursuant to this Order.

10. All applicable statutes of limitations and similar time limits on the commencement of Additional Actions, and all deadlines (including deadlines for appeals) in any currently pending Covered Action, shall be tolled or otherwise inoperative for the duration of this preliminary injunction plus an additional 30 days after the preliminary injunction is terminated.

11. The time for all defendants to answer the Complaint is extended to the day that is 284 days from the date of this Order, subject to further extension by agreement of the parties and/or order of the Court. All claims and defenses of the parties, including those under Rule 12 of the Federal Rules of Civil Procedure made applicable to this proceeding by Rule 7012 of the Bankruptcy Rules, are expressly preserved.

12. Any party subject to this Order, and the Voluntarily Bound Parties by virtue of their consent and agreement as set forth herein, may seek relief from any of the provisions of this Order, including from the stay of further proceedings in this adversary proceeding, for cause shown. This Order is without prejudice to the Debtors' right to argue that the Covered Actions are subject to the automatic stay imposed by section 362(a) of the Bankruptcy Code.

13. The Debtors shall be subject to the Voluntary Operating Injunction annexed hereto as Appendix 1.

14. Pursuant to Rule 7065 of the Federal Rules of Bankruptcy Procedure, the Debtors are relieved from posting any security pursuant to Rule 65(c) of the Federal Rules of Civil Procedure.

15. The Debtors shall serve a copy of this Order on counsel for the Governmental Defendants within ten (10) business days from the entry of this Order.

16. The Court shall retain jurisdiction to hear and determine all matters arising from or related to the implementation, interpretation, or enforcement of this Order.

Dated: November 15, 2022  
New York, New York

/s/ James L. Garrity, Jr.

THE HONORABLE JAMES L. GARRITY, JR.  
UNITED STATES BANKRUPTCY JUDGE



**Appendix 1**

**Voluntary Operating Injunction**

## ENDO INJUNCTIVE RELIEF TERM SHEET

### I. DEFINITIONS

- A. “Bankruptcy Code” shall mean title 11 of the United States Code, 11 U.S.C. §§ 101–1532, as may be amended from time to time.
- B. “Bankruptcy Court” shall mean the United States Bankruptcy Court for the Southern District of New York.
- C. “Cancer-Related Pain Care” shall mean care that provides relief from pain resulting from a patient’s active cancer or cancer treatment as distinguished from treatment provided during remission.
- D. “Chapter 11 Cases” shall mean the cases to be commenced by Endo International plc and certain of its direct and indirect subsidiaries in the Bankruptcy Court under chapter 11 of the Bankruptcy Code.
- E. “Debtors” shall mean Endo International plc and certain of its direct and indirect subsidiaries, as debtors and debtors-in-possession in the Chapter 11 Cases.
- F. “Downstream Customer Data” shall mean transaction information that Endo collects relating to its direct customers’ sales to downstream customers, including chargeback data tied to Endo providing certain discounts, “867 data” and IQVIA data.
- G. “Effective Date” shall mean the earlier of (1) the consummation of the sale of substantially all of the assets of the Debtors in the Chapter 11 Cases or (2) the effective date of a plan of reorganization for all or substantially all of the Debtors.
- H. “End-of-Life Care” shall mean care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home.
- I. “Endo” shall mean Endo Pharmaceuticals Inc. (“EPI”), Par Pharmaceutical, Inc. (“PPI”) and all of their parents, subsidiaries, predecessors, successors, joint ventures, divisions, assigns, officers, directors, agents, partners, principals, current employees, and affiliates acting on behalf of EPI or PPI in the United States.
- J. “Endo’s Opioid Business” shall mean Endo’s business operations relating to the manufacture and sale of Opioid Product(s) in the United States and its territories.
- K. “Health Care Provider” shall mean any U.S. based physician or other health care practitioner who is licensed to provide health care services and/or prescribes pharmaceutical products and any medical facility, practice, hospital, clinic, or pharmacy.
- L. “Including but not limited to”, when followed by a list or examples, shall mean that list or examples are illustrative instances only and shall not be read to be restrictive.

- M. “In-Kind Support” shall mean payment or assistance in the form of goods, commodities, services, or anything else of value.
- N. “Lobby” and “Lobbying” shall have the same meaning as “lobbying activities” and “lobbying contacts” under the federal lobbying disclosure act, 2 U.S.C. § 1602 *et seq.*, and any analogous state or local provisions governing the person or entity being lobbied in that particular state or locality. As used in this document, “Lobby” and “Lobbying” include Lobbying directly or indirectly, through grantees or Third Parties.
- O. “OCC” shall mean the Official Committee of Opioid Claimants, appointed in the Chapter 11 Cases.
- P. “Opioid(s)” shall mean all natural, semi-synthetic, or synthetic chemicals that interact with opioid receptors and act like opium. The term Opioid shall not include such chemicals used in products with an FDA-approved label that lists the treatment of opioid or other substance use disorder, abuse, addiction, dependence, or overdose as their “indications or usage.” For the avoidance of doubt, the term Opioid shall not include the opioid antagonists naloxone or naltrexone.
- Q. “Opioid Product(s)” shall mean all current and future medications containing Opioids approved by the U.S. Food & Drug Administration (“FDA”) and listed by the Drug Enforcement Administration (“DEA”) as Schedule II, III, or IV pursuant to the federal Controlled Substances Act (including but not limited to buprenorphine, codeine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, oxycodone, oxymorphone, tapentadol, and tramadol). The term “Opioid Products(s)” shall not include (i) methadone, buprenorphine, or other products with an FDA-approved label that lists the treatment of opioid or other substance use disorder, abuse, addiction, dependence or overdose as their “indications or usage”, insofar as the product is being used to treat opioid abuse, addiction, dependence or overdose, or (ii) raw materials, immediate precursors, and/or active pharmaceutical ingredients (“APIs”) used in the manufacture or study of Opioids or Opioid Products, but only when such materials, immediate precursors, and/or APIs are sold or marketed exclusively to DEA-licensed manufacturers or DEA-licensed researchers.
- R. “OUD” shall mean opioid use disorder defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5)*, as updated or amended.
- S. “Participating State(s)” shall mean Alaska, Arizona, Colorado, Connecticut, Delaware, District of Columbia, Georgia, Guam, Hawai’i, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, North Carolina, North Dakota, Ohio, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, the U.S. Virgin Islands, Utah, Vermont, Virginia, Washington, Wisconsin, and Wyoming, and any other state or territory of the United States that timely elects and satisfies the requirements to participate.

- T. “Petition Date” shall mean the date on which the Chapter 11 Cases are commenced.
- U. “Promote,” “Promoting,” “Promotion,” and “Promotional” shall mean dissemination of information or other practices intended or reasonably anticipated to increase sales or prescriptions, or that attempts to influence prescribing practices of Health Care Providers in the United States.
- V. “Qualified Researcher” shall mean any researcher holding a faculty appointment or research position at an institution of higher education, a research organization, a nonprofit organization, or a government agency.
- W. “Suspicious Order” shall have the same meaning as provided by the Controlled Substances Act, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder and analogous state laws and regulations.
- X. “Third Party” shall mean any person or entity other than Endo or a government entity.
- Y. “Treatment of Pain” shall mean the provision of therapeutic modalities to alleviate or reduce pain.
- Z. “Unbranded Information” shall mean any information that does not identify a specific branded or generic product(s).

## II. SCOPE

- A. The provisions of this Agreement shall apply immediately upon the Petition Date, but for Sections IV and VI, which shall apply immediately upon the Effective Date. The provisions of this Agreement shall apply both while Endo is in bankruptcy and after Endo emerges from bankruptcy, and they shall apply to the operation of Endo's Opioid Business by any subsequent purchaser (regardless of whether Endo is sold through the bankruptcy process or after bankruptcy, and regardless whether the purchaser buys all or just a portion of Endo's Opioid Business; as such, no reference to the term "Endo" in this Agreement shall be construed as a basis, by itself, to excuse compliance with an obligation by a subsequent purchaser). For the avoidance of doubt, nothing in this Agreement applies to the operation of a subsequent purchaser's pre-existing opioid business.
- B. In connection with its Chapter 11 Cases, Endo consents to the entry of a final judgment or consent order, effective upon the Effective Date, imposing all of the provisions of this Agreement in state court in each of the Participating States. During the pendency of the Chapter 11 Cases, this Agreement is enforceable in the Bankruptcy Court. After the Effective Date, this Agreement is enforceable in state court in each of the Participating States. Endo agrees that seeking entry or enforcement of such a final judgment or consent order will not violate any other injunctions or stays that it will seek, or that may otherwise apply, in connection with its Chapter 11 Cases.
- C. Any rights granted to the OCC in this Agreement shall be limited to the time period in which the OCC is in existence, and in no event shall such rights continue in existence beyond the Effective Date, and such rights shall not be enforceable against any subsequent purchaser of Endo's Opioid Business.

## III. INJUNCTIVE RELIEF

### A. General Provisions

1. Endo shall not make any written or oral statement about Opioids or Opioid Products that is false, misleading, deceptive, unfair or unconscionable.
2. Subject to subsections III.C.2, 4, 6 and 7, III.E.9 and III.F.4 below, Endo shall not make any written or oral 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.
3. Endo shall not represent that Opioids or Opioid Products have approvals, characteristics, uses, benefits, or qualities that they do not have.

**B. Ban on Certain High Dose Opioids**

1. Endo shall not commence manufacturing, Promoting, or distributing any Opioid Product that exceeds 30 milligrams of oxycodone per pill. For the avoidance of doubt, this restriction shall not apply to the manufacture or distribution of injectable Opioid products used primarily in hospice, hospital, or other inpatient settings.

**C. Ban on Promotion**

1. Endo shall not engage in Promotion of Opioids or Opioid Products, including but not limited to, by:
  - a. Employing or contracting with sales representatives or other persons to Promote Opioids or Opioid Products to Health Care Providers, patients, or members of pharmacy and therapeutics committees or other persons involved in determining the Opioid Products included in formularies;
  - b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of Opioids or Opioid Products;
  - c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to Opioids or Opioid Products;
  - d. Creating, sponsoring, operating, controlling, or otherwise providing financial support or In-Kind Support to any website, network, and/or social or other media account for the Promotion of Opioids or Opioid Products;
  - e. Creating, sponsoring, distributing, or otherwise providing financial support or In-Kind Support for materials Promoting Opioids or Opioid Products, including but not limited to brochures, newsletters, pamphlets, journals, books, and guides;
  - f. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote Opioids or Opioid Products, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements; or
  - g. Engaging in Internet search engine optimization or other techniques designed to Promote Opioids or Opioid Products by improving rankings or making content appear among the top results in an Internet search or otherwise be more visible or more accessible to the public on the Internet.

2. Notwithstanding subsection III.C.1 directly above, Endo may:
  - a. Maintain a corporate website;
  - b. Maintain a website that contains principally the following content for any Opioid Product: the FDA-approved package insert, medication guide, and labeling, and a statement directing patients or caregivers to speak with a licensed Health Care Provider, and Risk Evaluation and Mitigation Strategy (REMS) materials;
  - c. Provide information or support the provision of information as expressly required by law or any state or federal government agency with jurisdiction in the state where the information is provided, including but not limited to information necessary for Endo to comply with its regulatory obligations pursuant to the Federal Food, Drug and Cosmetic Act or the Controlled Substances Act;
  - d. Provide the following by mail, electronic mail, on or through Endo's corporate or product websites or through other electronic or digital methods: FDA-approved package insert, medication guide, approved labeling for Opioid Products or other prescribing information for Opioid Products that are published by a state or federal government agency with jurisdiction in the state where the information is provided;
  - e. Provide scientific and/or medical information in response to an unsolicited request by a Health Care Provider consistent with the recommendations set forth in the FDA's Draft Guidance for Industry, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011), as updated or amended by the FDA, and Guidance for Industry, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), as updated or amended by the FDA;
  - f. Provide a response to any unsolicited question or request from a patient or caregiver, directing the patient or caregiver to the FDA-approved labeling or to speak with a licensed Health Care Provider without describing the safety or effectiveness of Opioids or any Opioid Product or naming any specific provider or healthcare institution; or directing the patient or caregiver to speak with their insurance carrier regarding coverage of an Opioid Product;
  - g. Provide Health Care Economic Information, as defined at 21 U.S.C. § 352(a), to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis

consistent with standards set forth in the FDA's Draft Questions and Answers Guidance for Industry and Review Staff, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities* (Jan. 2018), as updated or amended by the FDA;

- h. Provide information relating solely to the pricing of any Opioid Product;
  - i. Provide information, through a product catalog or similar means, related to an Opioid or Opioid Product, including, without limitation, pricing information, weight, color, shape, packaging size, type, reference listed drug, National Drug Code ("NDC") label, and such other descriptive information (including information set forth in a standard Healthcare Distribution Alliance Form or technical data sheet and the FDA approval letter) sufficient to identify the products available, to place an order for a product, and to allow the product to be loaded into a customer's inventory and ordering system or Third Party pricing compendia;
  - j. Provide information in connection with patient support information on co-pay assistance and managing pain in End-of-Life Care and/or Cancer-Related Pain Care relating to the use of Opioids for managing such pain, as long as the information identifies Endo as the source of the information; and
  - k. Provide rebates, discounts, and other customary pricing adjustments to DEA-registered customers and contracting intermediaries, such as Buying Groups, Group Purchasing Organizations, and Pharmacy Benefit Managers, except as prohibited by section III.G.
3. Except as permitted in subsection III.C.4 below, Endo shall not engage in the Promotion of products for the treatment of Opioid-induced side effects (for the avoidance of doubt, "Opioid-induced side effects" does not include OUD, addiction, abuse, dependence, or overdose), including but not limited to:
- a. Employing or contracting with sales representatives or other persons to Promote products for the treatment of Opioid-induced side effects to Health Care Providers or patients;
  - b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events to Promote products for the treatment of Opioid-induced side effects;
  - c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs that Promote products for the treatment of Opioid-induced side effects; or



- d. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote products for the treatment of Opioid-induced side effects, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements.
4. Notwithstanding subsection III.C.3 directly above, Endo may Promote products for the treatment of Opioid-induced side effects (i) so long as such Promotion does not associate the product with Opioids or Opioid Products, or (ii) where such Promotion concerns a product's indication to reverse overdoses and/or treat Opioid addiction. Nothing herein shall prevent Endo from linking to the FDA label associated with a product.
5. Treatment of Pain
  - a. Endo shall not, either through Endo or through Third Parties, engage in Promotion of the Treatment of Pain in a manner that encourages the utilization of Opioids or Opioid Products.
  - b. Endo shall not, either through Endo or through Third Parties, Promote the concept that pain is undertreated in a manner that encourages the utilization of Opioids or Opioid Products.
  - c. Endo shall not disseminate Unbranded Information, including Unbranded Information about a medical condition or disease state, that contains links to branded information about Opioid Products or otherwise Promotes Opioids or Opioid Products.
6. Notwithstanding subsection III.C.5 directly above, Endo may Promote or provide educational information about the Treatment of Pain with non-Opioid products or therapies, including Promoting or providing educational information about such non-Opioid products or therapies as alternatives to Opioid use so long as such non-Opioid Promotional or educational information does not Promote Opioids or Opioid Products.
7. Nothing herein shall prevent Endo from sponsoring or providing financial support or In-Kind Support for an accredited or approved continuing medical education program required by either an FDA-approved REMS program or other federal or state law or regulation applicable in the state where the program is provided through an independent Third Party, which shall be responsible for the continuing medical education program's content without the participation of Endo.

**D. No Financial Reward or Discipline Based on Volume of Opioid Sales**

1. Endo shall not provide financial incentives to its sales and marketing employees or discipline its sales and marketing employees based upon sales volume or sales

quotas for Opioid Products. For the avoidance of doubt, this provision shall not prohibit financial incentives (*e.g.*, customary raises or bonuses) based on the performance of the overall company or branded, generics, or sterile injectable business segments, as measured by EBITDA, revenue, cash flow, or other similar financial metrics.

2. Endo shall not offer or pay 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. For the avoidance of doubt, this provision shall not prohibit rebates or chargebacks to the extent permitted by other provisions of this Agreement.
3. Endo's compensation policies and procedures shall ensure compliance with this Agreement.

**E. Ban on Funding/Grants to Third Parties**

1. Subject to subsections III.C.2, 4, 6 and 7, Endo shall not, directly or indirectly, provide 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. For the avoidance of doubt, this provision does not prohibit support expressly allowed by this Agreement or required by a federal or state agency. This provision does not prohibit an accredited independent continuing medical education grant related to TLC599 or Lidoderm (or any other non-Opioid products or therapies that Endo and the Participating States may subsequently agree shall not be subject to this provision) given in accordance with the Standards for Integrity and Independence in Accredited Continuing Education of the ACCME.
2. Endo shall not create, sponsor, provide financial support or In-Kind Support to, or otherwise operate or control any medical society or patient advocacy group that primarily engages in conduct that Promotes Opioids, Opioid Products, or the Treatment of Pain. This provision does not prohibit an accredited independent continuing medical education grant related to TLC599 or Lidoderm (or any other non-Opioid products or therapies that Endo and the Participating States may subsequently agree shall not be subject to this provision) given in accordance with the Standards for Integrity and Independence in Accredited Continuing Education of the ACCME.
3. Subject to subsections III.C.2, 4, 6 and 7, Endo shall not provide links to any Third Party website or materials or otherwise distribute 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.

4. Endo shall not use, assist, or employ any Third Party to engage in any activity that Endo itself would be prohibited from engaging in pursuant to this Agreement.
5. Endo shall not enter into any contract or agreement with any person or entity or otherwise attempt 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.
6. Endo shall not compensate or provide 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, *i.e.*, any entity, other than an individual, that pays or reimburses for the dispensing of prescription medicines, including but not limited to managed care organizations and pharmacy benefit managers. Nothing in this provision, however, prohibits Endo from using independent contractors who operate under the direction of Endo to provide information to a payor, formulary committee, or other similar entity as permitted in subsection III.C.2, provided that any such persons are bound by the terms of this Agreement. Nor does this provision prohibit the payment of customary rebates or other pricing concessions to third-party payers, including state Medicaid programs, as part of an overall pricing agreement.
7. No officer or management-level employee (vice president-level or above) of Endo may concurrently serve as a director, board member, employee, agent, or officer of any entity (other than Endo International plc or a direct or indirect wholly-owned subsidiary thereof) that primarily engages in conduct that Promotes Opioids, Opioid Products, products indicated for the treatment of Opioid-related side effects, or the Treatment of Pain. For the avoidance of doubt, nothing in this provision shall preclude an officer or management-level employee of Endo from concurrently serving on the board of a hospital.
8. Endo shall play no role in appointing persons to the board, or hiring persons to the staff, of any entity (other than Endo International plc or a direct or indirect wholly-owned subsidiary thereof) that primarily engages in conduct that Promotes Opioids, Opioid Products, products indicated for the treatment of Opioid-induced side effects, or products indicated for the Treatment of Pain. For the avoidance of doubt, nothing in this paragraph shall prohibit Endo from fully and accurately responding to unsolicited requests or inquiries about a person's fitness to serve as an employee or board member at any such entity.
9. For the avoidance of doubt:
  - a. Nothing in this section III.E shall be construed or used to prohibit Endo from providing financial or In-Kind Support to:

- i medical societies and patient advocate groups who are principally involved in issues relating to (I) the treatment of OUD; (II) the prevention, education and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (III) rescue medications for opioid overdose; or
  - ii universities, medical institutions, or hospitals, for the purpose of addressing, or providing education on, issues relating to (I) the treatment of OUD; (II) the prevention, education and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (III) rescue medications for opioid overdose.
- b. The prohibitions in this section III.E shall not apply to engagement with Third Parties based on activities related to (i) medications with an FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their “indications and usage,” to the extent they are sold to addiction treatment facilities; (ii) raw materials, APIs and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials, APIs and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories; or (iii) education warning about drug abuse or promoting prevention or treatment of drug misuse.
- c. Endo will be in compliance with subsections III.E.2 and III.E.3 with respect to support of an individual Third Party to the extent that a Participating State determines that such support does not increase the risk of the inappropriate use of Opioids and that Endo has not acted for the purpose of increasing the use of Opioids.

## **F. Lobbying Restrictions**

- 1. Endo shall not Lobby for the enactment of any federal, state, or local legislative or regulatory provision that:
  - a. 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
  - b. pertains to the classification of any Opioid or Opioid Product as a scheduled drug under the Controlled Substances Act.
- 2. Endo shall not Lobby against the enactment of any federal, state or local legislative or regulatory provision that supports:

- a. The use of non-pharmacologic therapy and/or non-Opioid pharmacologic therapy to treat chronic pain over or instead of Opioid use, including but not limited to third party payment or reimbursement for such therapies;
  - b. The use and/or prescription of immediate release Opioids instead of extended release Opioids when Opioid use is initiated, including but not limited to third party reimbursement or payment for such prescriptions;
  - c. The prescribing of the lowest effective dose of an Opioid, including but not limited to third party reimbursement or payment for such prescription;
  - 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, including but not limited to third party reimbursement or payment for naloxone;
  - f. The use of urine testing before starting Opioid use and annual urine testing when Opioids are prescribed, including but not limited to third party reimbursement or payment for such testing;
  - g. Evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for OUD, including but not limited to third party reimbursement or payment for such treatment; or
  - h. The implementation or use of Opioid drug disposal systems.
3. Endo shall not Lobby against the enactment of any federal, state or local legislative or regulatory provision expanding the operation or use of prescription drug monitoring programs (“PDMPs”), including but not limited to provisions requiring Health Care Providers to review PDMPs when Opioid use is initiated and with every prescription thereafter.
  4. Notwithstanding the foregoing restrictions in subsections III.F.1-3, the following conduct is not restricted:
    - a. Lobbying against the enactment of any provision of any state, federal, municipal, or county taxes, fees, assessments, or other payments;
    - b. Challenging the enforcement of, or suing for declaratory or injunctive relief with respect to legislation, rules or regulations referred to in subsection III.F.1;
    - c. Communications made by Endo in response to a statute, rule, regulation, or order requiring such communication;

- d. Communications by an Endo representative appearing before a federal or state legislative or administrative body, committee, or subcommittee as a result of a mandatory order or subpoena commanding that person to testify;
  - e. Responding, in a manner consistent with this Agreement, to an unsolicited request for the input on the passage of legislation or the promulgation of any rule or regulation when such request is submitted in writing specifically to Endo from a government entity directly involved in the passage of that legislation or promulgation of that rule or regulation;
  - f. Lobbying for or against provisions of legislation or regulation that address other subjects in addition to those identified in subsections III.F.1-3, so long as Endo does not support specific portions of such legislation or regulation covered by subsection III.F.1 or oppose specific portions of such legislation or regulation covered by subsections III.F.2-3;
  - g. Making a public comment to a federal or state agency in response to a Federal Register or similar notice or an unsolicited federal or state legislative committee request for public comment on proposed legislation;
  - h. Responding to requests from the DEA, the FDA, or any other federal or state agency or legislative or administrative body, and/or participating in FDA or other agency panels at the request of the agency; and
  - i. Participating in meetings and other proceedings before the FDA, FDA advisory committee or other FDA committee in connection with the approval, modification of approval, or oversight of Endo's own products.
5. Endo shall provide notice of the prohibitions in section III.F to all employees engaged in Lobbying; incorporate the prohibitions in section III.F 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.

**G. Ban on Prescription Savings Programs**

1. Endo shall not directly or indirectly offer any discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.
2. Endo shall not directly or indirectly provide financial support to any Third Party for discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.

3. Endo shall not directly or through Third Parties assist patients, Health Care Providers, or pharmacies regarding the claims and/or prior authorization process required for third party payers to approve claims involving any Opioid Product.

#### **H. Monitoring and Reporting of Direct and Downstream Customers**

1. Endo shall 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. Utilize all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer;
  - b. Utilize all reasonably available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product;
  - c. Utilize all information 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; and
  - d. Upon request of the Attorney General or controlled substances regulatory agency of a Participating State (unless otherwise required by law), report to such requesting State Attorney General or agency any direct customer or downstream customer in such State identified as part of the monitoring required by (a)-(c), above, and any customer relationship in such State terminated by Endo relating to diversion or potential for diversion. These reports shall include the following information, to the extent known to Endo:
    - i The identity of the downstream registrant and the direct customer(s) identified by Endo engaged in the controlled substance transaction(s), to include each registrant's name, address, business type, and DEA registration number;
    - ii The dates of reported distribution of controlled substances by direct customers to the downstream registrant during the relevant time period;
    - iii The drug name, drug family or NDC and dosage amounts reportedly distributed;

- iv The transaction or order number of the reported distribution; and
  - v A brief narrative providing a description of the circumstances leading to Endo's conclusion that there is a risk of diversion.
2. Endo shall 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.
  3. Upon request, Endo shall promptly provide reasonable assistance to law enforcement investigations of potential diversion and/or suspicious circumstances involving Opioid Products in the United States.
  4. Endo agrees that it will refrain from providing an Opioid Product directly to a retail pharmacy or Health Care Provider. For avoidance of doubt, "retail pharmacy" does not include pharmacies directly affiliated with medical insurance companies that principally fill prescriptions by mail delivery or private delivery services such as UPS or FedEx.

#### **I. Miscellaneous Terms**

1. To the extent that any provision in this Agreement conflicts with federal or relevant state law or regulation, the requirements of the law or regulation will prevail. To the extent that any provision in this Agreement 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 this Agreement, Endo may comply with such law or regulation. In the event Endo identifies such a conflict, it shall provide written notice to the Attorney General of the relevant State(s) pursuant to section V.D below.
2. The Participating States and Endo enter into this Agreement solely for the purpose of settlement, and nothing contained therein may be taken as or construed to be an admission or concession concerning the strength or weakness of any claim or defense, or concerning any other matter of fact or law. Endo expressly denies any violation of law, rule, or regulation or any liability or wrongdoing. No part of this Agreement, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Endo. Nor shall any part of this Agreement be construed as approval by any Participating State of any prior business act or practice. This Agreement is not intended for use by any Third Party for any purpose, including submission to any court for any purpose; provided, however, that the OCC or the Future Claims Representative ("FCR") may enforce those provisions of this Agreement that establish specific information rights in the Bankruptcy Court only during the OCC's and FCR's existence (respectively), and in no event after the Effective Date.



3. For the avoidance of doubt, this Agreement shall not be construed or used as a waiver or limitation of any defense otherwise available to Endo in any action, and nothing in this Agreement shall be construed or used to prohibit Endo in any way whatsoever from taking legal or factual positions with regard to any Opioid Product(s) in litigation or other legal or administrative proceedings.
4. Nothing in this Agreement shall be construed to limit or impair Endo's ability (a) to communicate its positions and respond to media inquiries concerning litigation, investigations, reports, or other documents or proceedings relating to Endo or its Opioid Products, or (b) to maintain a website explaining its litigation positions and responding to allegations concerning its Opioid Products.
5. Upon the request of the Attorney General of any Participating State (or the OCC or FCR), Endo shall provide the Attorney General of such Participating State (or the OCC or FCR for informational purposes only, not to be shared with any other person, and subject to the confidentiality provisions of the Protective Order in the Chapter 11 Cases) with copies of the following, within 30 days of the request:
  - a. Any litigation or civil or criminal law enforcement subpoenas or Civil Investigative Demands relating to Endo's Opioid Product(s); and
  - b. Warning or untitled letters issued by the FDA regarding Endo's Opioid Product(s) and all correspondence between Endo and the FDA related to such letters.
6. The parties by stipulation may agree to a modification of this Agreement, which modified agreement shall be presented to the court specified in section II.B for approval; provided that the parties may jointly agree to a modification only by a written instrument signed by or on behalf of both Endo and the Attorney(s) General of the Participating State(s).
7. During the time period in which the OCC is in existence, no modification may be made to any provision granting rights to the OCC without the OCC's consent. Similarly, during the time period in which the FCR is in existence, no modification may be made to any provision granting rights to the FCR without the FCR's consent.
8. Endo shall provide regular training, at least once per year, to relevant employees on their obligations imposed by this injunction. Endo shall provide such training to any new relevant employees in the course of their onboarding.

**J. Compliance with Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid or Any Opioid Product**

1. Subject to subsection III.I.1 above, Endo shall comply with all applicable laws and regulations that relate to the sale, Promotion, distribution, and disposal of any Opioid or any Opioid Product, including but not limited to:
  - a. [State] Controlled Substances Act, including all guidance issued by the applicable state regulator(s) and related regulations;
  - b. The Federal Controlled Substances Act, including all guidance issued by the DEA;
  - c. The Federal Food, Drug and Cosmetic Act, or any regulation promulgated thereunder;
  - d. FDA Guidances;
  - e. [State] Consumer Protection Laws; and
  - f. [State] laws and regulations related to opioid prescribing, distribution, and disposal.
2. For avoidance of doubt, this section J shall not apply to products that Endo stopped selling prior to the Petition Date.

**IV. CLINICAL DATA TRANSPARENCY**

**A. Data to Be Shared**

1. Endo shall continue 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>):
  - a. “Endo-Sponsored Studies” means pre-marketing clinical research and post-marketing clinical research that Endo “takes responsibility for and initiates” as “sponsor,” as “sponsor” is defined in 21 C.F.R. § 312.3(b) and that involves an intervention with human subjects with an Opioid Product.
  - b. The summaries shall be truthful and balanced and may include redactions to protect personal identifying information, trade secret and confidential commercial information, and information that may provide a road map for defeating a product’s abuse-deterrent properties.
2. With respect to any Endo-Sponsored Studies relating to any new Endo Opioid Product, whether acquired or developed, or any new indication for an Endo Opioid Product sold by Endo as of the Petition Date, Endo shall, within 30 days

after regulatory approval or 18 months after study completion, whichever occurs later, make the following clinical data available through a third-party data archive that makes clinical data available to Qualified Researchers with a bona fide scientific research proposal:

- a. Fully analyzable data set(s) (including individual de-identified participant-level data);
  - b. The clinical study report(s) redacted for commercial or personal identifying information;
  - c. The full protocol(s) (including the initial version, final version, and all amendments); and
  - d. Full statistical analysis plan(s) (including all amendments and documentation for additional work processes) and analytic code.
3. With respect to any Endo-Sponsored Studies relating to Opana or Opana ER conducted prior to the Petition Date, information required in subsection IV.A.2 above shall be made available as described in that subsection within 60 days after the Effective Date.

**B. Third-Party Data Archive**

- a. The third-party data archive referenced above shall have a panel of reviewers with independent review authority to determine whether the researchers are qualified, whether a research application seeks data for bona fide scientific research, and whether a research proposal is complete.
- b. The panel may exclude research proposals with a commercial interest.
- c. Endo shall not interfere with decisions made by the staff or reviewers associated with the third-party data archive.
- d. Any data sharing agreement with a Qualified Researcher who receives shared data via the third-party data archive shall contain contact information for Endo's pharmacovigilance staff. Every agreement shall require the lead Qualified Researcher to inform Endo's pharmacovigilance staff within 24 hours of any determination that research findings could bear on the risk-benefit assessment regarding the product. The lead Qualified Researcher may also share findings bearing on the risk-benefit assessment regarding the product with regulatory authorities. Endo's pharmacovigilance staff shall take all necessary and appropriate steps upon receipt of such safety information, including but not limited to notifying the appropriate regulatory authorities or the public.

- e. Endo shall bear all costs for making data and/or information available to the third-party data archive.

## **V. ENFORCEMENT**

- A. For the purpose of resolving disputes with respect to Endo's compliance with this Agreement, should any Participating State have a reasonable basis to believe that Endo has engaged in a practice that violates a provision of this Agreement, such Participating State shall notify Endo in writing of the specific objection, identify with particularity the provision of the Agreement that the practice allegedly violates, and give Endo thirty (30) days to respond in writing to the notification; provided, however, that any Participating State may take any action authorized by law if such Participating State believes that, because of the specific practice, a threat to health or safety of the public requires immediate action. Promptly after Endo's receipt of a written notice from a Participating State under this section, Endo shall provide such written notice to the OCC and FCR for informational purposes only, not to be shared with any other person, and subject to the confidentiality provisions of the Protective Order in the Chapter 11 Cases.
- B. Upon receipt of written notice, Endo shall provide a good-faith written response to the applicable Participating State's notification, with a copy to the OCC and FCR for informational purposes only, not to be shared with any other person, and subject to the confidentiality provisions of the Protective Order in the Chapter 11 Cases, containing either a statement explaining why Endo believes it is in compliance with the relevant provision of the Agreement, or a detailed explanation of how the alleged violation occurred and a statement explaining how and when Endo intends to remedy or has remedied the alleged breach. Nothing in this section shall be interpreted to limit a Participating State's investigative authority with respect to conduct occurring after the Effective Date, to the extent such authority exists under applicable law, after providing Endo an opportunity to respond to the notification described in section V.A above, and Endo reserves all of its rights in responding to a Civil Investigative Demand (CID) or investigative subpoena issued pursuant to such authority.
- C. The applicable Participating State may agree, in writing (with a copy to be promptly provided by Endo to the OCC and FCR for informational purposes only, not to be shared with any other person, and subject to the confidentiality provisions of the Protective Order in the Chapter 11 Cases), to provide Endo with additional time beyond thirty (30) days to respond to a notice provided under section V.A above.
- D. In the event of a conflict between the requirements of the Agreement and any other law, regulation, or requirement such that Endo cannot comply with the law without violating the terms of the Agreement or being subject to adverse action, including fines or penalties, Endo shall document such conflicts and notify the applicable Participating State of the extent to which Endo will comply with the Agreement in order to eliminate the conflict within thirty (30) business days of Endo's discovery of the conflict. Endo

shall comply with the terms of the Agreement to the fullest extent possible without violating the law.

- E. Endo or a Participating State may request that Endo and such Participating State meet and confer regarding the resolution of an actual or potential conflict between the Agreement and any other law, or between interpretations of the Agreement by different courts. In the event such Participating State disagrees with Endo's interpretation of the conflict, such Participating State reserves the right to pursue any remedy or sanction that may be available regarding compliance with this Agreement. Nothing herein is intended to modify or extend the jurisdiction of any judicial authority as provided by law.
- F. During the pendency of the Chapter 11 Cases, any (i) assertion of claims that Endo has violated the Agreement, (ii) commencement of any separate civil action to enforce compliance with this Agreement or (iii) assertion of other rights relating to or arising out of this Agreement, in each case, by a Participating State or any interested party shall be asserted in or brought before the Bankruptcy Court, and the Bankruptcy Court shall have exclusive jurisdiction over such action.
- G. After the Effective Date, and subject to the notice provision and exception thereto described in section V.A above, the applicable Participating State shall be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of Endo that relate to Endo's compliance with the relevant provision of the Agreement pursuant to such Participating State's CID or investigative subpoena authority and may assert any claim that Endo has violated the Agreement in a separate civil action to enforce compliance with this Agreement.

## **VI. PUBLIC DISCLOSURE**

### **A. Definitions**

As used in this section:

“Document(s)” means original or duplicate writings, recordings, or photographs as defined in Federal Rule of Evidence 1001.

“Endo Witness” means a witness who testified, whether at deposition or trial, in his or her capacity as a current or former Endo employee.

“Opioid-Related Action” means any of the following: the Opioid Multi-District Litigation (*In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804 (N.D. Ohio)); any of the constituent cases pending in the Opioid Multi-District Litigation; and any action pending in any other forum in the United States or its territories that asserts claims substantially similar to the foregoing in a forum other than the Opioid Multi-District Litigation. For avoidance of doubt, a case that asserts antitrust- or patent-based claims is not an Opioid-Related Action for purposes of this section.

“Testimony” means any writing or recording of sworn testimony taken of an Endo Witness during a court proceeding or deposition in an Opioid Related Action.

## **B. Documents Subject to Public Disclosure**

1. Endo shall provide the following Documents to the Participating States to be placed in a public document repository for public disclosure in perpetuity, except for the redactions authorized by section C:
  - a. All Documents and privilege logs Endo produced to any of the parties (including the Participating States) in Opioid-Related Actions, in response to opioid-related investigative demands, or in response to other formal or informal opioid-related production requests, prior to the Petition Date.
  - b. All Documents and privilege logs Endo produced in the Opioid Multi-District Litigation (*In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804 (N.D. Ohio)) prior to the Petition Date.
  - c. All Testimony from the matters identified in paragraphs B.1.a and B.1.b.
  - d. Notwithstanding the foregoing, Endo need not provide a Document that is a duplicate of another Document that it provides to the Participating States. The parties shall work cooperatively to identify an efficient, timely, and cost-effective means of identifying duplicate Documents that need not be provided.
2. All documents produced under this provision shall be provided in electronic format with all related metadata to the extent that such metadata are not exempt from public disclosure under section VI.C. Endo and the Participating States will work cooperatively to develop technical specifications for the productions. Certain details related to requirements set forth in this subsection and in subsections C and D below shall be delineated by letter agreement between Endo and a Participating State at a later date as authorized by the Bankruptcy Court.

## **C. Information That May Be Redacted**

The following categories of information are exempt from public disclosure:

1. Information subject to trade secret protection. A “trade secret” is information, including a formula, pattern, compilation, program, device, method, technique or process, that (a) derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure and use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Even if the information falls within the definition, “trade secret” does not include information

or communications concerning the sale, marketing, or promotion of Opioid Products.

2. Confidential personal information. “Confidential personal information” means individual Social Security or tax identification numbers, personal financial account numbers, passport numbers, driver license numbers, home addresses, personal telephone numbers, personal email addresses, and other personally identifiable information protected by law from disclosure. “Confidential personal information” does not include the names of prescribers or of officers, directors, employees, agents, attorneys, or consultants of Endo or of a government agency.
3. Information that is inappropriate for public disclosure because it is subject to personal privacy interests recognized by law (e.g., HIPAA), or the confidentiality interests of third parties that Endo may not abrogate.
4. Information regarding Endo employees’ personal matters unrelated to Endo (including emails produced by Endo custodians discussing vacation or sick leave, family, or other personal matters), or such other matters on which Endo and the Participating States may agree. For avoidance of doubt, no Endo employee shall be construed to be a third-party beneficiary of this Agreement based on this exemption.
5. Information subject to the attorney-client privilege, work product protection, or other legally valid privilege.

**D. Redaction of Documents Containing Protected Information**

1. Whenever a Document contains information subject to an exemption under section C, Endo must provide the Document in redacted form and indicate the basis for each such redaction in the Document’s metadata. Endo shall narrowly tailor its redactions so as to protect only the information that is exempt from disclosure under section C. The redacted documents produced by Endo may be publicly disclosed in accordance with Section F below.
2. Endo must provide to the Participating States a redaction log identifying the basis for each redaction, with sufficient detail to allow assessment of the redaction’s merits. The log is subject to public disclosure in perpetuity. The log shall be produced simultaneously with the production of documents required by Section G.
3. In addition to the redacted documents, Endo shall, upon the Participating States’ request, also produce to the Participating States all documents identified in section B above in unredacted form (except for redactions pursuant to section C.5 above). Such unredacted documents shall be available only to the Participating States unless Endo’s claim of exemption under section C is successfully

challenged in accordance with this section, or the trade secret designation expires in accordance with section E.

4. Anyone, including members of the public and the press, may challenge the appropriateness of redactions by providing written notice to Endo and a Participating State, which Participating State shall review the challenge and inform Endo of whether the challenge has sufficient merit to warrant triggering the remaining provisions of this paragraph. If the challenge is not resolved by agreement, it must be resolved in the first instance by a third party to be jointly appointed by the Participating States and Endo to resolve such challenges. The decision of the third party may be appealed to a court with enforcement authority over this Agreement. If not so appealed, the third party's decision is final. In connection with such challenge, a Participating State may provide copies of relevant unredacted documents to the parties or the decisionmaker, subject to appropriate confidentiality and/or in camera review protections, as determined by the decisionmaker. Each party shall bear its own costs in any such redaction challenge process.

#### **E. Review of Trade Secret Redactions**

Seven years after the Effective Date, Endo (or any purchaser of substantially all of Endo's assets) shall review all assertions of trade secret protection made in accordance with section C.1 and provide the Participating States with a correspondingly updated redaction log in the same format as the initial redaction log required by section D. Any newly unredacted documents may then be publicly disclosed by the Participating States in accordance with section F.

#### **F. Public Disclosure through a Document Repository**

The Participating States shall coordinate to publicly disclose all Documents subject to public disclosure pursuant to this section through a public repository maintained by a governmental, non-profit, or academic institution or entity. The Participating States shall coordinate to specify the terms of any such repository's use, protection, and preservation of those Documents, including allowing the repository to index, screen, and make searchable all Documents subject to public disclosure.

#### **G. Timeline for Production**

Endo must produce all required Documents within nine months from the Effective Date. This timeline may be extended by written agreement between Endo and the Participating State(s) taking delivery of Endo's Documents pursuant to section F.

#### **H. Costs**

Endo shall pay the reasonable costs and expenses associated with the review of Endo's Documents subject to public disclosure. In addition, Endo shall pay \$2.75 million on the plan's



Effective Date, but in any event no later than immediately prior to the conversion or dismissal of the Chapter 11, to help defray the costs and expenses of the establishment and maintenance of the public document repository. All costs and expenses in excess of this amount shall be paid by the Gross Public Settlement. For the avoidance of doubt, this amount is in addition to the Company's obligation to pay the reasonable costs and expenses associated with the review of the Company's documents to be disclosed through the public document repository.

## **VII. INDEPENDENT MONITOR**

### **A. Appointment of Monitor**

1. Endo agrees that it will retain Gil Kerlikowske as an independent monitor (the "Monitor") to evaluate and monitor Endo's compliance with this Agreement from the Petition Date through the Effective Date (the "Monitor Term"). The Monitor Term shall not extend beyond the Effective Date but may be reduced by written consent of both the Endo Multi-State Executive Committee (the "Endo EC") and the Official Committee of Opioid Claimants (the "OCC"); prior to deciding whether to give its consent, the OCC shall consult with and consider (but is not bound by) the views of the FCR.
2. Unless justifiable cause exists for the removal of the Monitor, the Monitor shall serve the entire Monitor Term. For purposes of this paragraph, justifiable cause exists if, and only if, (x) the Monitor resigns or becomes unable to fulfill his duties due to disability or death; (y) Endo and the Endo EC and the OCC agree, in writing, to both the removal of the Monitor and to the effective date of such removal (prior to deciding whether to agree to any removal, the OCC shall consult with and consider, but is not bound by, the views of the FCR); or (z) a court finds that the Monitor: (a) has a conflict of interest that would undermine public confidence in the objectivity of his work; (b) has unreasonably failed to fulfill his material obligations under this Agreement or pursuant to the Work Plan (as defined in subsection VII.B.3); (c) has engaged in any act of dishonesty, misappropriation, embezzlement, intentional fraud, or similar conduct; or (d) has engaged in an intentional act of bias or prejudice in relation to his material obligations under this Agreement or pursuant to the Work Plan (as defined in subsection VII.B.3). Justifiable cause shall not include Endo's or the Participating States' or the OCC's disagreements with the decisions of the Monitor pursuant to this Agreement, except that such decisions may be proffered as evidence that one of the foregoing bases for removal applies.
3. If the Monitor is removed pursuant to subsection VII.A.2 before the Bankruptcy Court enters a sale order (in the case of a sale of the Debtors' assets) or a confirmation order (in the case of a plan of reorganization), then Endo, the Endo EC, the Ad Hoc First Lien Group, and the OCC shall, within 30 days of the date of the Monitor's removal, identify and agree

upon an appropriate replacement to be appointed within 30 days of the date the previously appointed Monitor's duties are terminated, with such agreement not to be unreasonably withheld. Prior to identifying or agreeing on any appropriate replacement monitor, the OCC shall consult with and consider (but is not bound by) the views of the FCR. A replacement monitor shall be subject to removal only if justifiable cause exists for such removal, as described in subsection VII.A.2.

## **B. Monitor's Responsibilities**

1. The Monitor's duties shall be as follows:
  - a. The Monitor shall perform his duties according to the terms of this Agreement and shall be vested all rights and powers reasonably necessary to carry out such powers, duties, and responsibilities enumerated herein.
  - b. The Monitor shall review and provide reports as outlined below.
  - c. Subject to any legally recognized privilege and as reasonably necessary to perform his duties hereunder, the Monitor shall have full and complete access to Endo's personnel, books, records, and facilities, and to any other relevant information, as the Monitor may reasonably request. Endo shall develop such information as the Monitor may reasonably request and shall fully, completely and promptly cooperate with the Monitor. The Monitor may raise with the Bankruptcy Court any issues relating to any failure of or delay in such cooperation for an expedited resolution by the Bankruptcy Court.
  - d. The Monitor shall serve, without bond or other security, at the cost and expense of Endo, with the Monitor's fees subject to final approval by the Bankruptcy Court. The Monitor shall have the authority to employ, upon written consent from Endo (such consent not to be unreasonably withheld, delayed or conditioned), and upon Court approval, at the cost and expense of the Debtors' estates, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's responsibilities. Requests to employ such individuals should be directed to Endo's Chief Legal Officer (with a copy to the Endo EC) and Endo shall provide a written response to such requests no later than ten (10) business days after their receipt. The Monitor will work in good faith with Endo to ensure that the Monitor and any approved consultants will follow Endo's policies and procedures with respect to any payments remitted directly by Endo. In no event shall fees for the Monitor's work, inclusive of all employees, attorneys, or any consultants on which

the Monitor may rely, exceed \$25,000 per month over the course of the Monitor Term.

- e. The Monitor shall have no obligation, responsibility, or liability for the operations of Endo.
- f. The Monitor shall sign onto any protective order entered by the Bankruptcy Court (“Protective Order”), and any confidentiality agreement consistent with any Protective Order as deemed necessary by the parties, and each of the Monitor’s consultants, accountants, attorneys and other representatives and assistants shall also sign onto any Protective Order entered by the Bankruptcy Court, and any confidentiality agreement consistent with any Protective Order as deemed necessary by the parties; provided, however, that nothing shall restrict the Monitor from providing any information to the Court and the parties consistent with the terms of any Protective Order.
- g. Should Endo or the Monitor not comply with this Agreement, the Monitor shall notify Endo’s Chief Legal Officer (or Endo shall notify the Monitor) of such non-compliance in writing (email is sufficient). Should Endo or the Monitor not cure, remedy, or otherwise satisfy the other party in respect to any such non-compliance within thirty (30) calendar days, Endo or the Monitor shall promptly seek an order from the Bankruptcy Court requiring compliance or such other remedies as may be appropriate under the circumstances.
- h. The Monitor shall make a good faith effort to leverage Endo’s existing compliance mechanisms when reviewing Endo’s compliance with this Agreement.
- i. The Monitor shall make a good faith effort to perform his duties and oversee compliance with this Agreement in a manner that does not unreasonably disrupt Endo’s business operations. In this regard, Endo shall designate senior officials within the office of the Chief Legal Officer to serve as the primary points of contact for the Monitor in order to facilitate the Monitor’s access to documents, materials, or staff necessary to review Endo’s compliance with this Agreement. The Monitor shall communicate any request for documents, materials, or access to staff to the designated contacts, unless otherwise instructed. Where reasonably possible, the Monitor (in his sole discretion) may accept certifications of compliance with the terms of this Agreement. For the avoidance of doubt, nothing in this paragraph shall be interpreted to prohibit the Monitor from speaking with an employee of Endo.

2. Reporting:
  - a. The Monitor must file an initial report with the Bankruptcy Court regarding compliance by Endo with the terms of this Agreement (as of and after the Petition Date) no later than 90 days after the Work Plan (as defined in subsection VII.B.3) is finalized, and then one additional report at least 180 days after the initial report or, if the Monitor Term concludes prior to that time, upon the conclusion of the Monitor Term (the “Monitor Reports”). The Court may, in response to such reports, provide further direction to the Monitor as it deems appropriate. To the extent permissible by law, these reports (in whole or in part) may be filed under seal or subject to such other confidentiality restrictions contained in a Protective Order. The content of Monitor Reports shall be set forth in the Work Plan.
  - b. Prior to issuing any Monitor Report, the Monitor shall confer with Endo, the Endo EC, and the OCC, either jointly or separately (in the discretion of the Monitor), regarding its preliminary findings and the reasons for those findings. The OCC shall consult with the FCR upon learning of the Monitor’s preliminary findings but is not bound by the FCR’s views of such preliminary findings. Endo shall have the right to submit written comments to the Monitor, which shall be appended to the final version of the Monitor Report.
  - c. The Monitor’s duties shall exclude any oversight or review of Endo’s compliance with the Public Disclosure part of this Agreement (Part VI).
3. Work Plan: The manner in which the Monitor will carry out his compliance responsibilities under this Agreement, the general scope of information that the Monitor will seek to review in fulfilling his duties and, where applicable, the methodologies to be utilized shall be set forth in a work plan (the “Work Plan”). Within 30 days after the Monitor’s appointment, the Endo EC, the OCC, and Endo shall agree with the Monitor on the Work Plan with such agreement not to be unreasonably withheld. Prior to agreeing on the Work Plan, the OCC shall consult with and consider (but is not bound by) the views of the FCR. For the avoidance of doubt, the Work Plan shall be accompanied by a budget, and that budget shall demonstrate that the total cost to Endo of the proposed Work Plan shall not exceed \$25,000 per month over the course of the Monitor Term. If the Monitor, the Endo EC, the OCC, and Endo fail to reach agreement on the Work Plan within the designated time frame, the Monitor, the Endo EC, the OCC, and Endo will submit any disputed issues to the Bankruptcy Court for resolution.

### VIII. COMPLIANCE TERM

- A. Unless addressed in section VIII.B or VIII.C, each provision of this Agreement shall apply for 8 years from the Petition Date.
- B. The provisions of section III.A (“General Provisions”), section III.C (“Ban on Promotion”), section III.D (“No Financial Reward or Discipline Based on Volume of Opioid Sales”), section III.G (“Ban on Prescription Savings Programs”), section III.H (“Monitoring and Reporting of Direct and Downstream Customers”), section III.I (“Miscellaneous Terms”), section III.J (“Compliance with Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid or Any Opioid Product”), and section VI (“Public Disclosure”) shall not be subject to any term.
- C. The provisions of Part VII (“Independent Monitor”) shall apply for the term described therein.

**Appendix 2**

**Voluntarily Bound Parties**

1. Multi-State Endo Executive Committee.
2. States of Alaska, Arizona, Colorado, Connecticut, Delaware, Georgia, Guam, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, Nevada, North Carolina, North Dakota, Ohio, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, the U.S. Virgin Islands, Utah, Vermont, Virginia, Washington, Wisconsin, and Wyoming. *See Verified Statement of the Multi-State Endo Executive Committee Pursuant to Bankruptcy Rule 2019 ¶ 6, Ex. A [Main Case D.I. 125]; Amendment to Verified Statement of the Multi-State Endo Executive Committee Pursuant to Bankruptcy Rule 2019 [Main Case D.I. 141].*
3. District of Columbia
4. Opioid Plaintiffs Executive Committee formed in connection with the nationwide opioid multi-district litigation proceedings.