U.S. Department of Justice

Consumer Protection Branch

450 5th St NW
Washington, DC 20001

February 28, 2024

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Re: Plea Agreement with Endo Health Solutions Inc.

Dear Counsel:

This letter sets forth the plea agreement ("Agreement") between the United States Department of Justice, Civil Division, Consumer Protection Branch ("United States") and your client, Endo Health Solutions Inc. ("EHSI").

Charge

Conditioned on the understandings specified below, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the United States will accept a guilty plea from EHSI to a one-count Information (the "Information"), to be filed in the U.S. District Court for the Eastern District of Michigan (the "Court"), which charges EHSI with a misdemeanor violation of the Food, Drug, and Cosmetic Act ("FDCA"), contrary to Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in that EHSI caused the introduction and delivery for introduction into interstate commerce of Opana ER, a drug that was misbranded in that the drug's labeling lacked adequate directions for use.

Agreement Not to Prosecute

If EHSI enters a guilty plea and a judgment of conviction is entered that is consistent with the terms of the agreed disposition included in this Agreement, and if EHSI otherwise fully complies with all of the terms of this Agreement, the United States agrees that, other than the charge in the Information in this case, it will not bring any other criminal charges or criminal forfeiture actions against EHSI, Endo International plc, or their present or former companies, affiliates, divisions, or subsidiaries, or their predecessors, successors, or assigns (including, for the avoidance of doubt, any purchaser of the assets of the foregoing entities in the jointly administered bankruptcy cases of *In re Endo International plc*, Bankr. S.D.N.Y. Case No. 22-22549 (the "Endo Bankruptcy")) (collectively, the "Released Parties") for conduct which (1) is covered by the Information; (2) falls within the scope of the investigations conducted by the United States Attorney's Office for the Southern District of Florida and the Consumer Protection Branch of the Department of Justice, or (3) was known to the United States Attorney's Office for the Southern District of Florida or the Consumer Protection Branch of the Department of Justice as of the date of the execution of this Agreement and which relates to the Released Parties' production, sale, marketing, promotion or distribution of Opana ER between 2006 and the present.

The non-prosecution provisions of this sub-section are binding on the Consumer Protection Branch, Civil Division, of the Department of Justice, the United States Attorney's Offices for each of the 94 judicial districts of the United States, and the Criminal Division of the United States Department of Justice, with the exception that it does not prohibit any component of the United States Department of Justice from bringing charges against any culpable individual as a result of such investigation. An investigation and prosecution of any culpable individual, if any, is specifically excluded from the release in this paragraph. EHSI understands that this Agreement does not bind any other government agency, or any component of the Department of Justice, except as specified in this Agreement.

Sentencing Guidelines

The violation of 21 U.S.C. §331(a) and 333(a)(1) to which EHSI is agreeing to plead guilty carries a statutory maximum fine equal to the greatest of: (1) $200,000; (2) twice the gross amount of any pecuniary gain that any persons derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. *See* 18 U.S.C. § 3571(c)(5), 3571(d). Fines imposed by the sentencing judge may be subject to the payment of interest.

While the fine provisions of the United States Sentencing Guidelines do not apply to organizational defendants for misdemeanor violations of the FDCA, *see* U.S.S.G. § 8C2.1, the parties stipulate that the Guidelines have been used as a reference to determine the appropriate multiplier for criminal actions brought against organizations under that provision consistent with previous corporate FDCA misdemeanor cases.

Using these fine provisions, EHSI's culpability score of 5 is calculated as follows:

1. 5 points base, *see* U.S.S.G. § 8C2.5(a);

2. 2 points added because EHSI had more than 50 employees and an individual

within substantial authority personnel participated in, condoned, or was willfully ignorant of the offense, *see id*. § 8C2.5(b)(4);

3. with 2 points subtracted because EHSI accepts responsibility for its criminal conduct, *see id*. § 8C2.5(g).

4. Under U.S.S.G. § 8C2.6, a culpability score of 5 results in a 1.0-2.0 multiplier for any criminal fine.

The pecuniary gain earned by EHSI as a result of the sales of misbranded Reformulated Opana ER was approximately $543,000,000. Therefore, the advisory Guidelines Fine Range would be $543,000,000 to $1,086,000,000.

The statutory maximum fine is $1,086,000,000.

In addition to imposing a fine on EHSI, the sentencing judge will order EHSI to pay an assessment of $125, pursuant to Title 18, United States Code, Section 3013, which assessment must be paid by the date of sentencing.

Agreed Disposition

The United States and EHSI agree to recommend and advocate to the Court that, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the appropriate disposition of this case is as follows (the "Agreed Disposition"):

1. FINE: The sentence imposed shall include a criminal fine in the amount of $1,086,000,000;

2. FORFEITURE: Subject to the terms of this Agreement, the sentence shall include criminal forfeiture in the amount of $450,000,000 to be satisfied as discussed below;

3. RESTITUTION: No restitution shall be entered because restitution to other persons is not administratively feasible in this case, and attempting to fashion an order to provide restitution to any such possible persons would result in complication and prolongation of the sentencing process that would outweigh the need to provide restitution to any such possible persons under 18 U.S.C. § 3663(a)(1)(B)(ii); and

4. PROBATION: EHSI shall not be subject to a term of probation.

The Agreed Disposition takes into account, among other things, EHSI's status as a debtor in the Endo Bankruptcy, and EHSI's agreement to an allowed, general unsecured claim not subject to reconsideration or subordination in the amount of $475,600,000, which shall be deemed satisfied as a result of the consummation of the U.S. Government Settlement Agreement (as defined below), to resolve its civil liability arising from the Department of Justice's civil investigation relating to similar conduct (attached as **Exhibit B**) (the "Civil Settlement Agreement").

Criminal Fine

The parties agree that the criminal fine imposed by the Court as part of the Agreed Disposition shall be treated as an allowed, general unsecured claim not subject to reconsideration or subordination in the Endo Bankruptcy, to be paid in accordance with the terms of a separate agreement (the "U.S. Government Settlement Agreement") by and among EHSI, the United States and other relevant parties, providing for the terms of resolving such claim and other federal government claims in the Endo Bankruptcy.

Procedural Matters

The parties agree that, within 3 business days after the expiration of the stay under Fed. R. Bankr. P. 3020(e) following the United States Bankruptcy Court for the Southern District of New York's (the "Bankruptcy Court") confirmation under 11 U.S.C. § 1129 of the chapter 11 plan of reorganization first filed by EHSI and its debtor affiliates in the Endo Bankruptcy on December 19, 2023 at docket number 3355 (as may be amended, modified, or supplemented from time to time, the "Plan of Reorganization"), the parties will jointly request a plea hearing before the Court pursuant to Rule 11 of the Federal Rules of Criminal Procedure. The parties will further request that the plea hearing occur on the earliest possible date available to the Court.

Pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the United States and EHSI agree to make a joint recommendation and advocate to the Court that the Agreed Disposition is the appropriate disposition of this case. The parties agree to request that the Court's acceptance of EHSI's plea and the Plea Agreement, pursuant to Rule 11(c)(3)(A), be deferred until the date of the sentencing hearing (the "Sentencing Hearing Date").

The parties further agree to request that the Sentencing Hearing Date take place no earlier than the date on which the order entered by the Bankruptcy Court confirming the Plan of Reorganization becomes final and non-appealable, but in any event prior to the Plan of Reorganization becoming effective. The parties may jointly agree to request a Sentencing Hearing Date prior to the order confirming the plan becoming final and non-appealable. The Plan of Reorganization shall be amended to provide (or the order confirming the Plan of Reorganization shall provide) that the Court's acceptance of this Agreement and imposition of a sentence consistent with the Agreed Disposition is a condition precedent to the effectiveness of the Plan of Reorganization.

In the event the Endo Bankruptcy is converted from a chapter 11 case to a chapter 7 case, or the Endo Bankruptcy is dismissed, subject to EHSI's right to withdraw from its plea of guilty and from this Agreement upon the occurrence of a Plea Withdrawal Triggering Event, as defined below, the parties agree to jointly request that a plea hearing before the Court pursuant to Rule 11 of the Federal Rules of Criminal Procedure and the Sentencing Hearing Date take place within fourteen days of such event, to the extent a plea hearing and/or sentencing hearing has not yet occurred.

Pursuant to Rule 11(c)(1)(C), if the Court accepts this Agreement on the Sentencing Hearing Date, the Court will be bound to impose a sentence consistent with the Agreed Disposition. If, however, the sentencing judge rejects this Agreement and the Agreed Disposition, pursuant to

Rule 11(c)(5), EHSI will have the opportunity to withdraw its plea of guilty and withdraw from the Plea Agreement, and the United States may also withdraw from the Plea Agreement.

Additionally, prior to the Sentencing Hearing Date, EHSI may withdraw its plea of guilty and from this Agreement if the following "Condition Precedent to Agreement Effectiveness" is not satisfied or any of the following "Plea Withdrawal Triggering Events" occurs:

Condition Precedent to Agreement Effectiveness

(1) the Bankruptcy Court shall have approved EHSI's entry into and performance under this Agreement.

Plea Withdrawal Triggering Events

(1) The Bankruptcy Court rejects, or otherwise declines to approve, EHSI's and its debtor affiliates' entry into and performance under the Civil Settlement Agreement;

(2) the Bankruptcy Court rejects, or otherwise declines to approve, EHSI's and its debtor affiliates' entry into and performance under the U.S. Government Settlement Agreement;

(3) the Bankruptcy Court converts the Endo Bankruptcy from a chapter 11 case to a chapter 7 case, or the Bankruptcy Court dismisses the Endo Bankruptcy;

(4) the Bankruptcy Court denies confirmation of, or otherwise declines to confirm, the Plan of Reorganization which contemplates this Plea Agreement;

(5) if, upon the exercise of its fiduciary duties, EHSI concludes that one or more of the conditions precedent to emergence from bankruptcy as contemplated in the Plan of Reorganization cannot reasonably be satisfied and therefore provides notice on the public docket of the Endo Bankruptcy that it is withdrawing or abandoning the Plan of Reorganization; or

(5) the Department of Health and Human Services Office of Inspector General ("HHS-OIG") exercises, or confirms its intent to exercise such authority in writing, any available authority to exclude any of EHSI's parent companies or any of their respective affiliates, divisions, or subsidiaries (other than EHSI), or its or their successors or assigns (including, for the avoidance of doubt, any purchaser of the assets of the foregoing entities in the Endo Bankruptcy), from participation in Federal health care programs based, in any part, on the production, sale, marketing, promotion or distribution of Opana ER between 2006 and the present, including the conduct described in **Schedule A**, the Information filed at the time of the plea hearing, or the Civil Settlement Agreement.

If a Plea Withdrawal Triggering Event occurs, EHSI shall determine whether to withdraw its plea of guilty, and shall notify the United States of its decision, within 14 days. If EHSI elects to withdraw its plea of guilty, EHSI may also elect to withdraw from the Agreement. If a Plea Withdrawal Triggering Event has occurred and EHSI elects to withdraw its plea of guilty after the

Court has accepted EHSI's plea, the United States agrees that EHSI will have met the conditions set forth in Rule 11(d)(2)(B). If EHSI elects not to withdraw its plea of guilty within 14 days of a Plea Withdrawal Triggering Event, EHSI will have waived its right to withdraw its plea based on that Plea Withdrawal Triggering Event, except under the circumstances set forth in Rule 11(c)(5). EHSI's decision not to withdraw its plea based on a Plea Withdrawal Triggering Event does not waive its right to withdraw its plea based on another Plea Withdrawal Triggering Event. If a Plea Withdrawal Triggering Event does not occur, EHSI shall not be permitted to withdraw its plea of guilty, except under the circumstances set forth in Rule 11(c)(5). EHSI and the United States may jointly to agree the extend the 14-day period referenced herein.

In the event that EHSI withdraws its guilty plea, the Information filed at the time of the plea hearing shall remain pending and EHSI will waive defenses based on the Speedy Trial Act and the relevant statute of limitations with respect to the offense conduct set forth in the Information for a period of 180 days from the date of withdrawal. Nothing in this Agreement shall be deemed a waiver by EHSI of the provisions of Federal Rule of Evidence 410.

Rights Regarding Sentencing

Except as otherwise provided in this Agreement, the parties reserve their rights to correct any misstatements relating to the sentencing proceedings and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, the parties may inform the sentencing judge and the United States Probation Office of: (1) this Agreement; and (2) the full nature and extent of EHSI's activities and relevant conduct with respect to this case.

Stipulations

The United States and EHSI stipulate and agree to the statements set forth in the attached **Schedule A**, which hereby are made a part of this Agreement. To the extent that the parties do not stipulate to a particular fact or legal conclusion, each reserves the right to argue the existence of and the effect of any such fact or conclusion upon the sentence. Moreover, this agreement to stipulate on the part of the United States is based on the information and evidence that the United States possesses as of the date of this agreement. Thus, if the United States obtains or receives additional evidence or information prior to sentencing that it determines to be credible and to be materially in conflict with any stipulation in the attached **Schedule A**, the United States shall not be bound by any such stipulation. These stipulations do not restrict the parties' right to respond to questions from the Court and to correct misinformation that may be provided to the Court. Accordingly, the parties agree that they will not challenge at any time, using any means, the District Court's acceptance of those stipulated facts.

Waiver of Appeal and Post-Sentencing Rights

The United States and EHSI agree that, provided that the District Court imposes a sentence in accordance with this Rule 11(c)(1)(C) Agreement, neither party will appeal that sentence. EHSI further agrees that, in exchange for the concessions the United States made in entering into this Rule 11(c)(1)(C) Agreement, and provided that this Agreement remains in full force and effect it will not challenge its conviction for any reason by any means, other than ineffective assistance of

counsel, and it will not challenge or seek to modify any component of its sentence for any reason by any means, other than ineffective assistance of counsel. The term "any means" includes, but is not limited to, a direct appeal under 18 U.S.C. § 3742 or 28 U.S.C. § 1291, a motion to vacate the sentence under 28 U.S.C. § 2255, or any other motion, however captioned, that seeks to attack or modify any component of the judgment of conviction or sentence.

Forfeiture

Subject to the proviso at the end of this paragraph, as part of its acceptance of responsibility for its violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), and pursuant to 18 U.S.C. §982(a)(7) and 18 U.S.C. § 24(a)(2), EHSI agrees to forfeit to the United States all of its right, title, and interest in all property EHSI obtained that constituted and was derived, directly and indirectly, from gross proceeds traceable to misbranded Opana ER that was introduced or delivered for the introduction into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). EHSI further agrees that the aggregate value of such property was $450,000,000; that one or more of the conditions set forth in 21 U.S.C. § 853(p) exists; and that the United States is therefore entitled to forfeit substitute assets in an amount not to exceed $450,000,000 (the "Forfeiture Judgment"); *provided* that if EHSI withdraws, for any reason, from the Agreement or its plea of guilty, the United States shall not be entitled to the Forfeiture Judgment and any statements contained herein relating thereto shall be deemed null and void.

In order to avoid the unnecessary imposition of duplicative fines, penalties, and/or forfeiture for the same or similar misconduct, the United States agrees to credit against the Forfeiture Judgment the aggregate nominal amount allocated in settlement of claims asserted by state, tribal, or local government entities (the "Public and Tribal Opioid Claims") under the Plan of Reorganization up to the total amount of the Forfeiture Judgment (the "Public and Tribal Opioid Credit"). The Plan of Reorganization contemplates that the Public and Tribal Opioid Claims may be satisfied either by (i) a series of installment payments in an aggregate nominal amount in excess of $450,000,000, or (ii) a lump-sum discounted prepayment intended to equal the present value of the aforementioned installment payments. Irrespective of which payment option is utilized, the United States agrees that the effectiveness of the Plan of Reorganization will result in a Public and Tribal Opioid Credit in excess of $450,000,000 and will fully, finally, and permanently satisfy the Forfeiture Judgment no later than one business day after the effective date of the Plan of Reorganization.

The parties agree that no earlier than the Sentencing Hearing Date, upon the Court's acceptance of this Plea Agreement, the Court will enter an agreed order of forfeiture (the "Forfeiture Order") implementing the Forfeiture Judgment and providing that the Forfeiture Judgment shall not become final or effective until one business day after the effective date of the Plan of Reorganization and that until such time the Forfeiture Judgment shall not be incorporated into the criminal judgment. The parties further agree that the Forfeiture Order shall provide that the Forfeiture Judgment will be fully, finally, and permanently satisfied by the Public and Tribal Opioid Credit no later than one business day after the effective date of the Plan of Reorganization.

If, however, by the Sentencing Hearing Date, the Endo Bankruptcy is converted from a chapter 11 case to a chapter 7 case, the Endo Bankruptcy is dismissed, or EHSI provides notice on the public docket of the Endo Bankruptcy that it is withdrawing or abandoning the Plan of

Reorganization, subject to EHSI's right to withdraw from its plea of guilty and from this Agreement upon the occurrence of a Plea Withdrawal Triggering Event, then the Forfeiture Order by the Court shall become effective as of the Sentencing Hearing Date and be incorporated into the criminal judgment.

In the event that the Public and Tribal Opioid Credit does not occur, and subject in all respects to EHSI's right to withdraw its plea of guilty and withdraw from this Agreement upon the occurrence of a Plea Withdrawal Triggering event, EHSI agrees to the following:

(a) EHSI will tender to the United States Marshals a payment in satisfaction of the Forfeiture Judgment within 60 business days following entry of the judgment of conviction. If this payment is not paid by close of business of the 60th day following the entry of the judgment of conviction: (1) interest shall accrue on any unpaid portion thereof at the judgment rate of interest from that date; and (2) the United States shall be authorized to conduct any discovery needed to identify, locate, or dispose of property sufficient to pay the Forfeiture Judgment in full or in connection with any petitions filed with regard to proceeds or substitute assets, including depositions, interrogatories, and requests for production of documents, and the issuance of subpoenas.

(b) EHSI will not file, or cause any other person or entity to file, or assist any other person or entity in filing, any claim to the Forfeiture Judgment, or in any other way interfere with or delay the forfeiture of the Forfeiture Judgment.

(c) EHSI will not file a claim or a petition for remission or mitigation in any proceeding involving the Forfeiture Judgment and will not cause or assist anyone else in doing so.

(d) Upon reasonable request from the United States, EHSI will agree to reasonably cooperate with the United States in connection with responding to any claims asserted against the Forfeiture Judgment.

(e) EHSI will waive the requirements of Rules 32.2 and 43(a) of the Federal Rules of Criminal Procedure regarding notice of the forfeiture in the charging instrument, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. EHSI understands that criminal forfeiture is part of the sentence that may be imposed in this case and waives any failure by the court to advise it of this pursuant to Rule 11(b)(1)(J) of the Federal Rules of Criminal Procedure when the plea is entered. EHSI will waive any and all constitutional, statutory, and other challenges to the forfeiture on any and all grounds, including that the forfeiture constitutes an excessive fine or punishment under the Eighth Amendment.

Cooperation

EHSI shall continue to cooperate with the United States' ongoing investigation, if any, and any resulting prosecutions, if any, pertaining to investigations by the Consumer Protection Branch and United States Attorney's Office for the Southern District of Florida in connection with matters

relating to the production, sale, marketing, promotion or distribution of Opana ER until 180 days after the effective date of the Plan of Reorganization. As reflected by Sections 9.28.700 through 9.28.750 in the Justice Manual, EHSI's cooperation will include: (1) upon request, making disclosures of all relevant facts about any individuals who were involved in the misconduct that falls within the scope of the investigation conducted by the Consumer Protection Branch of the Department of Justice and the United States Attorney's Office for the Southern District of Florida (including, but not limited to, the conduct that forms the basis for this Agreement, including conduct described in **Schedule A** and the Information); (2) to the extent possible, making witnesses available for interview and providing the United States relevant documentary evidence; and (3) voluntary disclosure of other wrongdoing identified by EHSI.

Notwithstanding any provision of this Agreement, EHSI is not required to: (1) request of its current or former directors, officers, agents, or employees that they forgo seeking the advice of an attorney or that they act contrary to that advice; (2) take any action against its directors, officers, agents, or employees for following their attorney's advice; and (3) waive any privilege or claim of work product protection.

Other Provisions

No provision of this Agreement shall preclude EHSI from pursuing in an appropriate forum, when permitted by law, an appeal, collateral attack, writ, or motion claiming that EHSI received constitutionally ineffective assistance of counsel.

Corporate Authorization

EHSI agrees that, subject to obtaining approval from the Bankruptcy Court, it is authorized to enter into this Agreement, that it has authorized the undersigned corporate representative, to take this action, and that all corporate formalities for such authorization have been observed.

EHSI has provided to the United States a certified copy of a resolution of the governing body of EHSI, affirming that it has authority to enter into this Agreement and has (1) reviewed this Plea Agreement in this case; (2) consulted with outside legal counsel in this matter; (3) authorized execution of this Agreement; (4) authorized EHSI to enter a conditional plea of guilty if authorized in the Endo Bankruptcy; and (5) authorized the undersigned corporate representative to execute this Agreement and all other documents necessary to carry out the provisions of this Agreement. A copy of this resolution attached hereto as **Exhibit A**.

No Other Promises

This Agreement and the Exhibits hereto constitute the plea agreement between EHSI and the United States and together their terms supersede any previous agreements between them. No additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties.

Sincerely,

AMANDA LISKAMM
DIRECTOR

Gabriel H. Scannapieco
Assistant Director

Tara M. Shinnick
Ben Cornfeld
Trial Attorneys
Consumer Protection Branch
Civil Division
Department of Justice

COMPANY REPRESENTATIVE'S CERTIFICATE

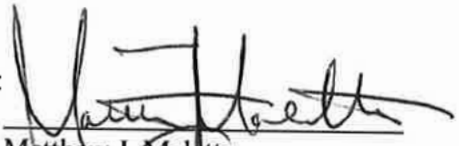
I have read this Agreement and carefully reviewed every part of it with outside counsel for Endo Health Solutions Inc. (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Outside counsel and I discussed all of the Agreement's provisions, including those addressing the charges, sentencing, stipulations, and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this Agreement. Counsel fully advised me of the rights of the Company, of possible defenses, of the provisions of the U.S. Sentencing Guidelines, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Executive Vice President, Chief Legal Officer and Secretary of the Company and that I have been duly authorized by the Board of Directors of the Company to execute this Agreement on behalf of the Company. My ability to bind the Company remains subject to approval by the United States Bankruptcy Court for the Southern District of New York.

Date: February 28, 2024

Endo Health Solutions Inc.

By: 

Matthew J. Maletta
Executive Vice President,
Chief Legal Officer & Secretary

CERTIFICATE OF COUNSEL

I am counsel for Endo Health Solutions Inc. (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined the relevant Company documents and have discussed the terms of this Agreement, including those addressing the charges, sentencing, stipulations, and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this Agreement, with the Company's Board of Directors. Based on our review of the foregoing materials and discussion, I am of the opinion that, subject to approval of the United States Bankruptcy Court for the Southern District of New York, the representative of the Company has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of the Agreement with the Board of Directors, the Chief Executive Officer, and the Chief Legal Officer & Secretary of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the provisions of the U.S. Sentencing Guidelines, and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: February 28, 2024

Endo Health Solutions Inc.

By: 

Carole S. Rendon
Baker & Hostetler LLP
Counsel for Endo Health Solutions Inc.

Schedule A

Endo Health Solutions Inc. admits that it is responsible for the acts of its employees and agents, described below, and admits the following facts:

1. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. At all times relevant to the Information, defendant Endo Health Solutions Inc. (hereinafter "ENDO"), was either a direct or indirect parent company of Endo Pharmaceuticals Inc. and was a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

2. ENDO was engaged in the pharmaceutical business throughout the United States, including in the Eastern District of Michigan. ENDO's business included the marketing, promotion, and sales of extended-release opioid drugs containing oxymorphone under the brand names Opana ER and reformulated Opana ER with INTAC (hereinafter "reformulated Opana ER").

3. Between 2006 and December 2016, ENDO marketed Opana ER, and then reformulated Opana ER, to prescribers and healthcare providers throughout the United States. Between 2006 and July 2017, ENDO sold Opana ER and then reformulated Opana ER throughout the United States.

4. Opana ER and reformulated Opana ER were Schedule II drugs under the Controlled Substances Act. The DEA defines Schedule II drugs as those drugs "with a high potential for abuse, with use potentially leading to severe psychological or physical dependence." The labels for Opana ER and reformulated Opana ER contained "black box" warnings of serious risks from taking the opioid medication, such as addiction and respiratory depression, which can lead to death.

5. The U.S. Food and Drug Administration (FDA) first approved Opana ER in 2006 for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. In July 2010, ENDO submitted a new drug application (NDA) to FDA for a reformulated version of Opana ER. In that NDA, ENDO asked FDA to approve a product label that stated: "[reformulated Opana ER] is formulated as a hard tablet to withstand crushing forces in excess of 800 Newtons. In standardized . . . studies, [reformulated Opana ER] demonstrated resistance to crushing, breaking, pulverization or powdering; however, the clinical significance of these properties and the impact on abuse liability has not been established."

6. In January 2011, FDA, after receiving the clinical data submitted by ENDO, recommended that reformulated Opana ER's "product label should not include language asserting that [it] provides resistance to crushing, because it may provide a false sense of security since the product may be chewed and ground for subsequent abuse."

7. In December 2011, FDA approved reformulated Opana ER, which ENDO called Opana ER with INTAC, which was bioequivalent to Opana ER. FDA did not, however, approve labeling for reformulated Opana ER describing crush resistance, tamper resistance, or abuse-

deterrent properties, because FDA concluded that the available data was inadequate to support such labeling.

8. In February 2012, ENDO submitted proposed promotion materials for reformulated Opana ER to FDA for advisory review. In April 2012, FDA sent ENDO a marketing claims review letter stating that claims and representations in the proposed promotion materials suggesting that reformulated Opana ER offered any therapeutic advantage over the original formulation—including claims of "mechanical stability," "mechanical strength," and "obstacle[s]" or "resistance to crushing by tools"—"ha[ve] not been demonstrated by substantial evidence or clinical experience" and "misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation . . . confers some form of abuse deterrence properties when this has not been demonstrated by substantial evidence." The FDA concluded:

> We are especially concerned from a public health perspective because the presence of this information in the detail aid could result in health care practitioners or patients thinking that the new formulation is safer than the old formulation, when this is not the case.

Following FDA's recommendation, ENDO removed the proposed claims identified in FDA's claims review letter and did not include them in ENDO's marketing and promotional materials for reformulated Opana ER.

9. In February 2013, ENDO submitted an NDA supplement to FDA, proposing new labeling regarding abuse deterrence for reformulated Opana ER. In May 2013, FDA denied ENDO's request for the addition of abuse deterrent language on reformulated Opana ER's label, noting that the drug could still be abused by being ground into powder or cut into small pieces, the data submitted was insufficient, and that the "ease with which the product can be manipulated . . . [is] not consistent with a formulation that would provide a reduction in oral, intranasal or intravenous abuse of OPANA ER."

10. ENDO hired hundreds of sales representatives to conduct in-person marketing of Opana ER and reformulated Opana ER (known in the industry as "detailing") of healthcare providers. ENDO's analyses showed that its detailing of healthcare providers was effective at increasing the drug's sales, which is a finding generally consistent with the effect of detailing efforts for branded pharmaceuticals in the industry.

11. Despite FDA's guidance to ENDO, from April 2012 through May 2013, certain ENDO sales representatives marketed reformulated Opana ER to prescribers by touting Opana ER's purported abuse deterrence, crush resistance and/or tamper resistance. Moreover, certain ENDO sales managers were aware that certain sales representatives were making claims regarding reformulated Opana ER's purported abuse deterrence, crush resistance, and/or tamper resistance during sales calls.

12. In January 2013, ENDO supplied its sales representatives with demonstration cards that contained sample rods of the INTAC technology used in reformulated Opana ER. Some ENDO sales representatives improperly hit the demonstration rods with hammers and conducted

other demonstrations with sample rods to attempt to convey the message that reformulated Opana ER was, in fact, crush proof, tamper resistant, and/or abuse deterrent until May 2013.

13. In December 2016, ENDO voluntarily stopped the detailing of reformulated Opana ER by sales representatives to healthcare providers.

14. ENDO continued to sell reformulated Opana ER until July 2017. ENDO voluntarily withdrew the product from the market after FDA requested that ENDO do so due to concerns related to intravenous abuse of the product.

15. The FDA-approved labeling for reformulated Opana ER did not provide adequate information for healthcare providers to safely prescribe reformulated Opana ER for use as an opioid that is abuse deterrent. For example, the FDA approved labeling for reformulated Opana ER did not reflect reformulated Opana ER's purported abuse-deterrent, crush resistant, and/or tamper resistant properties that certain sales representatives conveyed to healthcare providers when marketing reformulated Opana ER (as described in paragraphs 11 and 12 above).

16. As a result of the conduct described above, ENDO is responsible for the misbranding of reformulated Opana ER by marketing the drug in a manner designed to convey abuse deterrence, but with a label that failed to include adequate directions for use for its claimed abuse deterrence, in violation of the Federal Food, Drug, and Cosmetic Act.

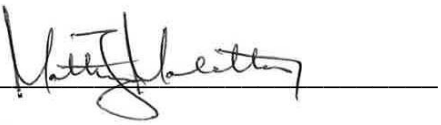
Exhibit A

SECRETARY'S CERTIFICATE

ENDO HEALTH SOLUTIONS INC.

February 27, 2024

I, Matthew J. Maletta, the Executive Vice President, Chief Legal Officer & Secretary of Endo Health Solutions Inc. ("EHSI") hereby certify, in my capacity as the Secretary of EHSI, and not individually, that the resolution attached hereto as Exhibit A were duly approved by the Board of Directors of EHSI on February 13, 2024, have not been amended, modified, revoked or rescinded as of the date hereof, and are in full force and effect.

By: 

Name: Matthew J. Maletta

Title: Executive Vice President, Chief Legal Officer & Secretary

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EXHIBIT A

RESOLUTIONS

OF THE

BOARD OF DIRECTORS

(the "Board")

OF

ENDO HEALTH SOLUTIONS INC.

(the "Company")

February 13, 2024

WHEREAS, the Company is a wholly-owned subsidiary of Endo International plc, a public limited company incorporated in Ireland (the "Parent"); and

Purpose

WHEREAS, the purpose of these resolutions is to consider and approve a proposal whereby the Company will approve entry into a (i) plea agreement (the "Plea Agreement"), in resolution of a criminal claim filed in the Chapter 11 Cases by the United States Department of Justice (the "DOJ"), and (ii) civil settlement agreement (the "Civil Settlement Agreement"), in resolution of a civil claim filed by the DOJ.

Chapter 11 Background

WHEREAS, on August 16, 2022 (the "Petition Date"), the Parent, the Company, and certain other Parent subsidiaries (together with the Parent and the Company, the "Group") commenced bankruptcy cases (the "Chapter 11 Cases") pursuant to chapter 11 of title 11 of the United States Code, 11 U.S.C. §§ 101-1532 (the "Bankruptcy Code") by filing voluntary petitions for relief in the U.S. Bankruptcy Court for the Southern District of New York (the "U.S. Bankruptcy Court").

Plan of Reorganization

WHEREAS, the Company and other members of the Group filed a chapter 11 plan of reorganization (the "Plan") and related disclosure statement (the "Disclosure Statement") with the Bankruptcy Court. The Plan proposes to, among other things, implement the terms of the

Resolutions negotiated with key parties-in-interest, and to provide for the treatment of other classes of claims and interests, in each case in accordance with the terms of the Plan;

WHEREAS, drafts of the Plan and the Disclosure Statement, which contains information and exhibits regarding the assets, liabilities, and business affairs of the Group to provide creditors and other interest holders with adequate information to make an informed judgment and vote on the proposed Plan, have been presented to the Board;

WHEREAS, if the Plan is approved by the Bankruptcy Court, the Plan will be implemented and result in the reorganization of the Company and other members of the Group;

WHEREAS, it is a condition precedent to the confirmation of the Plan that a resolution be reached with the DOJ with respect to its criminal and civil claims;

WHEREAS, a resolution of the criminal claim is contingent on a Group entity entering a criminal plea, which entity may be the Company;

Plea Agreement

WHEREAS, the Company, through its legal counsel, has been engaged in discussions with the United States Attorney's Office for the Southern District of Florida and the United States Department of Justice, Civil Division, Consumer Protection Branch (collectively, the "United States") in connection with their investigation into potential criminal violations related to the Company's or its affiliates' production, sale, marketing, promotion or distribution of Opana ER. **WHEREAS**, the board of directors of the Parent (together with any committees thereof, the "Parent Board") has met and considered presentations by outside legal counsel and advisors with relevant expertise regarding the possible ramifications of a potential criminal misdemeanor plea by the Company (a "Company Plea");

WHEREAS, the Board met on December 1, 2023 (the "December 1 Board Meeting"), to consider a potential DOJ Resolution, including a potential Company Plea, and considered the input of the Parent Board and outside counsel and advisors with relevant expertise, who advised the Board fully of the consequences of entering into the Plea Agreement and also reviewed its fiduciary duties with respect to key stakeholders, including the Parent;

WHEREAS, the Board having reviewed the near-final forms of the Plea Agreement and Civil Settlement Agreement with outside counsel, approve (x) entry into the Plea Agreement and Civil Settlement Agreement and (y) performance of any actions necessary to implement the Plea Agreement and Civil Settlement Agreement and any actions contemplated thereby.

NOW THEREFORE BE IT:

RESOLVED, that in the judgment of the Board it is desirable and in the best interests of the Company's creditors, stakeholders, and other parties-in-interest that the Company approve (x) entry into the Plea Agreement and Civil Settlement Agreement and (y) performance of any actions necessary to implement the Plea Agreement and Civil Settlement Agreement and

any actions contemplated thereby; provided, that any material modification to the Plea Agreement or Civil Settlement Agreement will be subject to further approval of the Board;

General Authorizations

RESOLVED, that the Chief Executive Officer of the Company or Parent, Chief Financial Officer of the Company or Parent, the Chief Legal Officer and Secretary of the Company, and any Executive of the Company or Parent (or their designees) (the "Authorized Officers" and each individually an "Authorized Officer"), with full authority to act without the others, be, and each of them individually hereby is, authorized, empowered and directed, in the name of and on behalf of the Company, to (or to delegate to any other officer of the Company the authority and power to) negotiate, execute and deliver or cause to be negotiated, executed and delivered, now and in the future, all agreements, amendments, certificates, instruments and other documents and to take or cause to be taken any and all such further actions in connection with the foregoing resolutions and the transactions contemplated thereby, in each case, as each Authorized Officer deems necessary, desirable or appropriate to effect the Plea Agreement and Civil Settlement and any actions that may be contemplated thereby and thereunder, and to carry out fully the purpose and intent of the foregoing resolutions; and be it further

RESOLVED, that each of the Authorized Officers is hereby authorized, in the name of and on behalf of the Company to cause such pleadings or other documents to be filed with the United States Bankruptcy Court for the Southern District of New York as may be necessary or appropriate for the Plea Agreement to become effective and to effect the transactions contemplated thereby; and be it further

RESOLVED, that legal counsel for the Company is authorized, empowered and directed, on behalf of the Company (x) to execute and deliver the Certificate of Counsel forming part of the Plea Agreement and all other documentation required to be executed by legal counsel in connection with the Plea Agreement and (y) to take all actions and execute and deliver all other documents as any Authorized Officer shall deem necessary or appropriate in connection with the Plea Agreement and any transactions or actions contemplated thereby, including entering the guilty plea set forth therein subject to the conditions set forth therein; and be it further

RESOLVED, that any person dealing with any Authorized Officer in connection with any of the foregoing matters shall be conclusively entitled to rely upon the authority of such Authorized Officer and by his or her execution of any document, agreements or instrument, the same to be a valid and binding obligation of the Company enforceable in accordance with its terms; and be it further

RESOLVED, that any and all actions, whether previously taken or to be taken at any time into the future, by or at the direction of the Company, or by or at the direction of any of the managers, directors, or officers of each the Company, directly or indirectly in connection with the documents, transactions and actions contemplated by the foregoing resolutions, be and hereby are adopted, ratified, confirmed and approved in all respects as and for the acts and deeds of the Company.

Exhibit B

SETTLEMENT AGREEMENT

This Settlement Agreement (this "Agreement") is entered into among (a) the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the Defense Health Agency (DHA), acting on behalf of the TRICARE Program; the Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits Program (FEHBP); and the United States Department of Veterans Affairs (VA) (collectively, the "United States"); (b) Endo Health Solutions Inc. ("Endo"); and (c) relator Loretta Reed ("Relator"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

RECITALS

A. At all relevant times, Endo, a Delaware corporation, manufactured, marketed, and sold pharmaceutical products in the United States, including long-acting opioid analgesics Opana ER and Opana ER with INTAC (collectively, "Opana ER"). Opana ER is an opioid drug whose label contained "black box" warnings of serious risks from taking the drug, such as addiction and respiratory depression, which can lead to death.

B. On April 29, 2019, Relator filed a *qui tam* action against Endo and others in the United States District Court for the Southern District of Florida captioned *United States ex rel. Reed v. Endo International PLC, et al.*, No. 9:19-cv-80574 (S.D. Fla.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) and the analogous provisions of a number of state and local false claims acts (the "Civil Action").

C. On August 16, 2022 (the "Petition Date"), Endo and seventy-five affiliated entities (collectively, the "Initial Debtors") each filed a voluntary petition under Chapter 11 of Title 11 of

the United States Code (the "Bankruptcy Code") in the United States Bankruptcy Court for the Southern District of New York (the "S.D.N.Y. Bankruptcy Court"). On May 25, 2023 and May 31, 2023, a total of four additional entities (together with the Initial Debtors, the "Debtors") filed voluntary petitions under Chapter 11 of the Bankruptcy Code. The Debtors are operating their businesses and managing their properties as debtors in possession pursuant to Bankruptcy Code §§ 1107(a) and 1108. On August 17, 2022, the S.D.N.Y. Bankruptcy Court entered an order authorizing the joint administration and procedural consolidation of the Debtors' chapter 11 cases pursuant to Federal Rule of Bankruptcy Procedure 1015(b) under the case captioned *In re Endo International PLC, et al.*, No. 22-22549 (Bankr. S.D.N.Y.) (the "Chapter 11 Cases") (Jointly Administered). The Debtors in the Chapter 11 Cases are listed in **Exhibit A** hereto along with the last four digits of each Debtor's registration number in the applicable jurisdiction.

D. On May 30, 2023, the United States Department of Justice, Civil Division, Fraud Section ("Fraud Section") filed Claim No. 3157 on behalf of HHS, DHA, OPM, and VA against Endo in the Chapter 11 Cases, alleging that from 2011 to 2017 Endo knowingly caused the submission of false and fraudulent claims to federal healthcare programs for prescriptions of Opana ER without a medically accepted indication.

E. On such date as may be determined by the Court, Endo will plead guilty pursuant to Fed. R. Crim. P. 1l(c)(l)(C) (the "Plea Agreement") to an Information to be filed in *United States v. Endo Health Solutions Inc.*, Criminal Action No. [to be assigned] (E.D. Mich.) (the "Criminal Action") that will allege a single misdemeanor violation of Title 21, United States Code, Sections 331(a), 333(a)(1) and 352(f)(1), namely, the introduction into interstate commerce of a misbranded drug, Opana ER.

F. The United States contends that Endo caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (Medicaid); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (TRICARE); the FEHBP, 5 U.S.C. §§ 8901-8914; and the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17 (VA) (collectively, the "Federal Healthcare Programs").

G. The United States contends that it has certain civil claims against Endo arising from Endo's marketing, promotion and sale, and manufacturing of Opana ER from 2011 to 2017, as alleged in the Addendum to the Fraud Section's Claim No. 3157 filed in the Chapter 11 Cases, attached hereto in **Exhibit B**. The conduct set forth in this Paragraph G is referred to below as the "Covered Conduct."

H. On December 19, 2023, the Debtors filed an amended chapter 11 plan of reorganization in the S.D.N.Y. Bankruptcy Court, which will incorporate the terms of this Agreement and the transactions contemplated hereunder. Pursuant to the chapter 11 plan, substantially all of the Debtors' assets will be directly or indirectly acquired by an entity (including its ultimate parent, the "Buyer") which will be owned on the effective date of such plan by certain of the Debtors' creditors.

I. This Agreement is neither an admission of wrongdoing or liability by Endo or by the Debtors nor a concession by the United States that its claims are not well founded. Endo and the Debtors deny all allegations in Claim No. 3157 and deny that they engaged in the Covered Conduct.

J. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the United States' claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. The Debtors agree that the United States shall have an allowed, not subject to reconsideration or subordination, general unsecured claim in the Chapter 11 Cases in the amount of Four Hundred Seventy-Five Million Six Hundred Thousand Dollars ($475,600,000) ("Civil Settlement Claim Amount"). The Civil Settlement Claim Amount shall be deemed satisfied as provided for in the U.S. Government Settlement Agreement as defined in Paragraph 2 below.

2. The chapter 11 plan and supporting documents, including the U.S. Government Settlement Agreement (defined below) and this Agreement, shall provide for the allowance and treatment of Claim No. 3157 and any other potential claims associated with the Covered Conduct to the extent set forth in this Agreement. The satisfaction in full of the Civil Settlement Claim Amount shall be provided for in a separate agreement (the "U.S. Government Settlement Agreement") consistent with the DOJ Economic Term Sheet[1] and otherwise in form and substance satisfactory to the Debtors, the United States, and the Buyer, to be docketed in the Chapter 11 Cases, and subject to the approval of the S.D.N.Y. Bankruptcy Court as set forth herein. Only the amount(s) up to Two Hundred Thirty-Two Million Dollars ($232,000,000.00) paid to the United States in satisfaction of the Civil Settlement Claim Amount shall constitute restitution to the United States.

3. Conditioned upon either (a) the United States exercising its Call Right and receiving the Prepayment Amount as specified in the U.S. Government Settlement Agreement,

[1] "DOJ Economic Term Sheet" means that term sheet appended as Exhibit A to the *Notice of Filing of Term Sheet* filed at docket no. 3118 on the docket of the Chapter 11 Cases.

(b) the Purchaser Parent exercising its right to pay the Prepayment Amount as specified in the U.S. Government Settlement Agreement, or (c) the United States receiving an installment payment as specified in the U.S. Government Settlement Agreement, and as soon as feasible after receipt, the United States shall pay to the Relator a fifteen (15) percent share of the actual amount that the United States receives in satisfaction of the Civil Settlement Claim Amount by electronic funds transfer (the "Relator's Share"). If the United States receives payment in installment payments, the Relator shall receive a fifteen (15) percent share of each installment payment in satisfaction of the Civil Settlement Claim Amount. For avoidance of doubt, other than as specified in this Agreement, Relator has no entitlement to a share of any other claim by the United States against Endo, whether civil, criminal, or administrative.

4. Endo agrees to pay Relator's reasonable expenses, attorneys' fees and costs on the effective date of the chapter 11 plan of reorganization, as contemplated by 31 U.S.C. § 3730(d) and comparable provisions of any applicable state statutes, in the amount of $75,000, and will do so in accordance with written instructions to be provided by Relator's counsel, in full and complete satisfaction of Relator's claims for attorneys' fees, expenses, and costs. No additional attorneys' fees, expenses, or costs, whether related to 31 U.S.C. § 3730(d)(1) or otherwise, shall be paid to or claimed by Relator or her counsel.

5. Subject to the exceptions in Paragraph 8 (concerning reserved claims) below, and conditioned on Paragraphs 1 and 2 above and Paragraph 11 (concerning treatment of claims in the Chapter 11 Cases) below and the United States' receipt of any payment as specified in the U.S. Government Settlement Agreement, the United States releases Endo together with its current and former parent corporations; direct or indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them

(collectively, the "Released Entities") from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; or the common law theories of payment by mistake, unjust enrichment, nuisance, and fraud.

6. Endo understands and acknowledges that as a result of the guilty plea described in Paragraph E of the Preamble above, it will be excluded pursuant to 42 U.S.C. § 1320a-7(a)(1) from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). Such exclusion shall have national effect and shall be effective after Endo has been convicted, as defined in 42 U.S.C. § 1320a-7(i), and after notice has been provided in accordance with 42 U.S.C. § 1320a-7(c) and 42 C.F.R. §§ 1001.2001–1001.2002. After Endo is excluded, Federal health care programs shall not pay anyone for items or services, including administrative and management services furnished, ordered, or prescribed by Endo in any capacity.

7. Conditioned upon either (a) the United States' exercising its Call Right and receiving the Prepayment Amount as specified in the U.S. Government Settlement Agreement, (b) the Purchaser Parent exercising its right to pay the Prepayment Amount and the United States receiving the Prepayment Amount as specified in the U.S. Government Settlement Agreement, or (c) the United States receiving an installment payment as specified in the U.S. Government Settlement Agreement, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases the Released Entities together with their current or former owners, officers, directors, employees, agents, shareholders, and attorneys; and the heirs, representatives, family members, successors and assigns of any of them) from claims for relief, actions, rights, causes of action, suits, debts, obligations, liabilities, demands, losses, damages, costs and expenses of any

kind, whether known or unknown as of the Effective Date that Relator has, may have, could have asserted, or may assert in the future against the Released Entities on her behalf, on behalf of the United States, on behalf of any state or local government or sovereign, or on behalf of any other person or entity, including but not limited to any claim relating to in any way the Covered Conduct, the allegations in the *qui tam* complaint, the investigation and prosecution of this matter, or the negotiation of the Agreement, any claims for attorneys' fees, costs, or expenses, including under 31 U.S.C. § 3730(d) or any other state or local law that is similar, comparable, or equivalent to 31 U.S.C. § 3730(d) (including, without limitation, the law governing each claim set forth in the *qui tam* complaint), including all liability, claims, demands, actions or causes of action existing as of the Effective Date, fixed or contingent, in law or in equity, in contract or in tort, or under any federal or state statute, regulation, or common law; ***provided however***, that Relator's release of her state false claims act claims shall not become effective until the earlier of: (a) the adjudication by the United States District Court for the Southern District of Florida of the majority of Relator's claim(s) to a relator's share under any state law that is similar, comparable, or equivalent to 31 U.S.C. § 3730(d); (b) the settlement or resolution of the majority of such claim(s); or (c) two (2) calendar years after the effective date of the plan of reorganization in the chapter 11 cases. Notwithstanding anything to the contrary herein, Relator's state false claims act claim(s) shall not impose any liability or obligation on the Released Entities after the Effective Date of this Agreement. Relator represents and warrants that she has not assigned or transferred any of her claims to any person, entity, or thing.

8. Notwithstanding the releases given in Paragraph 5 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released under this Agreement:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal Healthcare Programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability of corporate entities other than the Released Entities;

h. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

i. Any liability for failure to deliver goods or services due; and

j. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

9. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement, the U.S.

Government Settlement Agreement, the Civil Action, the Criminal Action, and/or any recovery by the United States relating to Endo.

10. Subject to the exceptions in Paragraph 7, Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, releases the Released Entities, and their officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) or any other state or local law that is similar, comparable, or equivalent to 31 U.S.C. § 3730(d) (including, without limitation, the law governing each claim set forth in the qui tam complaint) for expenses or attorneys' fees and costs.

11. In connection with the Chapter 11 Cases, the United States and Endo and the Debtors agree:

a. The Debtors shall file a motion or other appropriate request (an "Approval Motion") seeking approval to enter into and perform this Agreement, which may include seeking such approval as part of the Debtors' seeking confirmation of a chapter 11 plan. Before filing such Approval Motion, the Debtors shall obtain the United States' consent as to form of such Approval Motion or the applicable provisions of a chapter 11 plan related to approval of this Agreement (not to be unreasonably withheld).

b. The proposed order approving the Debtors' performance hereunder shall provide that, upon the Effective Date, the Civil Settlement Claim Amount shall not be subordinated, disallowed, or reconsidered in these Chapter 11 Cases, including based on 11 U.S.C. §§ 510, 726(a)(4) or for any other reason, and shall be fully satisfied through the approval of, and the Buyer's entry into, the U.S. Government Settlement Agreement.

c. The Debtors will not propose a sale, chapter 11 plan of reorganization, or liquidation that is materially inconsistent with this Agreement unless this Agreement is rescinded.

d. Endo and the United States each have the option to rescind this Agreement in all respects in the event of any of the following:

(1) If the S.D.N.Y. Bankruptcy Court does not grant the Approval Motion.

(2) If the S.D.N.Y. Bankruptcy Court does not grant the Debtors' motion or other appropriate request seeking approval to enter into and perform under the Plea Agreement.

(3) If the S.D.N.Y. Bankruptcy Court does not grant the Debtors' motion or other appropriate request seeking approval to enter into and perform under the U.S. Government Settlement Agreement.

(4) If the S.D.N.Y. Bankruptcy Court does not confirm a chapter 11 plan of reorganization submitted by the Debtors that contemplates the Debtors' entry into this Agreement (a "Plan").

(5) If, upon the exercise of their fiduciary duties, the Debtors withdraw or abandon any Plan.

e. Nothing in this Agreement shall affect the United States' right to object to any proposed chapter 11 plan of reorganization or liquidation for any reason not covered by this Agreement.

12. Nothing in this Agreement exempts the United States or Relator from or otherwise grants any relief under the bar date order, to the extent applicable, entered in the Chapter 11 Cases on April 3, 2023, as amended on June 23, 2023 and July 14, 2023 with respect to the Debtors.

13. If Endo defaults on any material obligation under this Agreement; if there is a dismissal or conversion of the Chapter 11 Cases, voluntary or otherwise; or if the Debtors'

obligations under this Agreement are voided for any reason, the United States in its sole discretion may elect to rescind the releases in this Agreement and pursue the Civil Action or bring any civil and/or administrative claims, actions, or proceedings against Endo for the Covered Conduct. In the event of a rescission, the United States fully reserves any and all setoff and recoupment rights, claims, and defenses as to the Debtors that the United States may have, and the United States may pursue its claims in the Chapter 11 Cases as well as in any other case, action, or proceeding, in each case, subject to applicable law. In the event of a rescission, the Debtors fully reserve all rights, claims, privileges, and defenses with respect to the United States or Relator and any claims that the United States or Relator may assert, including any claim, case, action or proceeding in connection with the Covered Conduct.

14. If Endo or the Debtors exercise the option of recission pursuant to Paragraph 11 of this Agreement or if the United States exercises the option of rescission pursuant to any Paragraph of this Agreement, the Agreement will be rescinded except for Paragraphs 11, 13, 14, and 27. If this Agreement is rescinded for any reason, the Debtors will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims, actions or proceedings that are brought by the United States within sixty (60) calendar days of written notification that the releases have been rescinded, except to the extent such defenses were available on the last date that this Agreement is executed by any Party.

15. The satisfaction of the Civil Settlement Claim Amount, as provided for in the U.S. Government Settlement Agreement, represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct and such other claims that are

resolved in connection with the U.S. Government Settlement Agreement due solely to the Debtors' financial condition.

16. Endo waives and shall not assert any defenses Endo may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

17. Endo fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Endo has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct, the United States' investigation or prosecution thereof, or the Civil Action other than any liability based upon obligations created by this Agreement; *provided* that the releases described in this paragraph shall be withdrawn and rescinded without need for further action by Endo if the United States' releases described in Paragraph 5 of this Agreement are rescinded for any reason, including pursuant to Paragraph 13 of this Agreement.

18. Conditioned on the effectiveness of the releases in Paragraphs 5 and 7 of this Agreement and subject to the reservation at the end of this Paragraph, Endo fully and finally releases Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Endo has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct, Relator's investigation or prosecution thereof, or the Civil Action other than any liability based upon obligations created by this Agreement. Endo

specifically reserves and does not release its right to contest on any basis any claim by Relator to an award of expenses, attorneys' fees, and costs.

19. The Civil Settlement Claim Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, or carrier), TRICARE, FEHBP, or any state payer, related to the Covered Conduct; and Endo agrees not to resubmit to any Medicare contractor, TRICARE, FEHBP, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

20. Endo agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Endo, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement and any related plea agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) Endo's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement, the U.S. Government Settlement Agreement, and any related plea agreement; and

(5) the payment the United States receives pursuant to this Agreement and the U.S. Government Settlement Agreement and any payments that Relator might receive, including costs and attorneys' fees;

are unallowable costs for government contracting purposes and under the Medicare, Medicaid, TRICARE, and FEHBP Programs (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Endo, and Endo shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Endo or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Endo further agrees that within ninety (90) days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid fiscal agents and FEHBP carriers and/or contractors, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Endo or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Endo agrees that the United States, at a minimum,

shall be entitled to recoup from Endo any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Endo or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Endo or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Endo's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

21. Endo agrees to reasonably cooperate fully and truthfully with the United States' investigation relating to the Covered Conduct of individuals and entities not released in this Agreement. Upon reasonable notice, Endo shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its reasonable best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Unless already produced or publicly available, Endo further agrees to furnish to the United States, upon reasonable request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf. Notwithstanding any provision of this Agreement, (1) Endo is not required to request

of their current or former officers, agents, or employees that they forgo seeking the advice of an attorney or that they act contrary to that advice; (2) Endo is not required to take any action against their officers, agents, or employees for following their attorney's advice; and (3) Endo is not required to waive or furnish to the United States any materials subject to any privilege or claim of work product protection. Endo's obligations as set forth in this paragraph will terminate one hundred eighty (180) calendar days after the Effective Date.

22. This Agreement is intended to be for the benefit of the Parties, entities and individuals referenced herein only. The Parties do not release any claims against any other person or entity, except to the extent provided for herein and in Paragraph 23 (waiver for beneficiaries paragraph) below.

23. Endo agrees that it waives and shall not seek payment for any of the healthcare billings covered by this Agreement from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

24. Within five (5) business days of the Agreement Effective Date in the U.S. Government Settlement Agreement, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1).

25. Except as provided in Paragraph 4 above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

26. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

27. This Agreement is governed by the laws of the United States. The venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Florida, provided that disputes regarding any provisions of this Agreement related to the Chapter 11 Cases may also be heard by the S.D.N.Y. Bankruptcy Court, including but not limited to Paragraphs 1, 2, 5, 7, 8, 11, 12, 13, 14, 15, 27, 31, and 34. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

28. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

29. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

30. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

31. This Agreement is binding on Endo's and the Debtors' successors, transferees, heirs, and assigns, including any reorganized debtor, in any and all forms, or trustee appointed in these Chapter 11 Cases or under a confirmed plan.

32. This Agreement is binding on Relator's successors, transferees, heirs, assigns, agents, and representatives.

33. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

34. This Agreement is effective on the day that the last of the following events has occurred (the "Effective Date"): (1) the date that the S.D.N.Y. Bankruptcy Court approves Endo's performance hereunder and (2) the effective date of any confirmed Plan. Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[SIGNATURE PAGE(S) FOLLOW]

THE UNITED STATES OF AMERICA

DATED: 2/28/2024 BY: _____

NATALIE A. WAITES
CHRISTOPHER TERRANOVA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 2/28/2024 BY: _____

MATTHEW J. FEELEY
Assistant United States Attorney
United States Attorney's Office
Southern District of Florida

DATED: _____ BY: SUSAN GILLIN Digitally signed by SUSAN GILLIN Date: 2024.02.26 18:53:48 -05'00'

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____ BY: _____

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____ BY: _____

EDWARD M. DEHARDE
Deputy Associate Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____ BY: _____

PAUL ST. HILLAIRE
Assistant Inspector General for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____

NATALIE A. WAITES
CHRISTOPHER TERRANOVA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____

MATTHEW J. FEELEY
Assistant United States Attorney
United States Attorney's Office
Southern District of Florida

DATED: _____ BY: _____

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 02/26/2024 BY: BLEY.PAUL.NICHOLAS.1099873821 Digitally signed by BLEY.PAUL.NICHOLAS.1099873821 Date: 2024.02.26 10:55:45 -05'00'

for

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____ BY: _____

EDWARD M. DEHARDE
Deputy Associate Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____ BY: _____

PAUL ST. HILLAIRE
Assistant Inspector General for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____

NATALIE A. WAITES
CHRISTOPHER TERRANOVA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____

MATTHEW J. FEELEY
Assistant United States Attorney
United States Attorney's Office
Southern District of Florida

DATED: _____ BY: _____

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____ BY: _____

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____ BY: EDWARD DEHARDE Digitally signed by EDWARD DEHARDE Date: 2024.02.28 14:59:24 -05'00'

EDWARD M. DEHARDE
Deputy Associate Director of Federal Employee Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____ BY: _____

PAUL ST. HILLAIRE
Assistant Inspector General for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____

NATALIE A. WAITES
CHRISTOPHER TERRANOVA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____

MATTHEW J. FEELEY
Assistant United States Attorney
United States Attorney's Office
Southern District of Florida

DATED: _____ BY: _____

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____ BY: _____

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____ BY: _____

EDWARD M. DEHARDE
Deputy Associate Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____ BY: PAUL ST HILLAIRE Digitally signed by PAUL ST HILLAIRE Date: 2024.02.27 17:43:59 -05'00'

PAUL ST. HILLAIRE
Assistant Inspector General for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

ENDO

DATED: 2/28/2024 BY: _____

MATTHEW MALETTA
Executive Vice President, Chief Legal Officer and Secretary
Endo Health Solutions Inc.

DATED: 2/28/2024 BY: _____

CAROLE S. RENDON
Baker Hostetler LLP
Counsel for Endo Health Solutions Inc.

RELATOR LORETTA REED

DATED: 2/23/24 BY: _____
LORETTA REED

DATED: _____ BY: _____
ERIC L. YOUNG
Young Law Group
Counsel for Loretta Reed

RELATOR LORETTA REED

DATED: _____ BY: _____
LORETTA REED

DATED: 2-23-2024 BY: _____
ERIC L. YOUNG
Young Law Group
Counsel for Loretta Reed

EXHIBIT A – LIST OF DEBTORS

1. 70 Maple Avenue, LLC (1491);
2. Actient Pharmaceuticals LLC (7232);
3. Actient Therapeutics LLC (2019);
4. Anchen Incorporated (8760);
5. Anchen Pharmaceuticals, Inc. (9179);
6. Astora Women's Health Ireland Limited (5829);
7. Astora Women's Health, LLC (0427);
8. Auxilium International Holdings, LLC (9643);
9. Auxilium Pharmaceuticals, LLC (6883);
10. Auxilium US Holdings, LLC (8967);
11. Bermuda Acquisition Management Limited (N/A);
12. BioSpecifics Technologies LLC (4851);
13. Branded Operations Holdings, Inc. (6945);
14. DAVA International, LLC (9945);
15. DAVA Pharmaceuticals, LLC (7354);
16. Endo Aesthetics LLC (0218);
17. Endo Bermuda Finance Limited (4093);
18. Endo Designated Activity Company (7135);
19. Endo Eurofin Unlimited Company (2009);
20. Endo Finance IV Unlimited Company (2779);
21. Endo Finance LLC (6481);
22. Endo Finance Operations LLC (6355);
23. Endo Finco Inc. (5794);
24. Endo Generics Holdings, Inc. (4834);
25. Endo Global Aesthetics Limited (2898);
26. Endo Global Biologics Limited (2735);
27. Endo Global Development Limited (4785);
28. Endo Global Finance LLC (7754);
29. Endo Global Ventures (4244);
30. Endo Health Solutions Inc. (2871);
31. Endo Innovation Valera, LLC (3622);
32. Endo International plc (3755);
33. Endo Ireland Finance II Limited (0535);
34. Endo LLC (6640);
35. Endo Luxembourg Finance Company I S.à r.l. (3863);
36. Endo Luxembourg Holding Company S.à.r.l. (7168);
37. Endo Luxembourg International Financing S.à.r.l. (2905);
38. Endo Management Limited (4866);
39. Endo Par Innovation Company, LLC (2435);
40. Endo Pharmaceuticals Finance LLC (5768);
41. Endo Pharmaceuticals Inc. (5829);

42. Endo Pharmaceuticals Solutions Inc. (7911);
43. Endo Pharmaceuticals Valera Inc. (9931);
44. Endo Procurement Operations Limited (7840);
45. Endo TopFin Limited (8086);
46. Endo U.S. Inc. (0786);
47. Endo US Holdings Luxembourg I S.à.r.l. (7910);
48. Endo Ventures Aesthetics Limited (9967);
49. Endo Ventures Bermuda Limited (0688);
50. Endo Ventures Cyprus Limited (1544);
51. Endo Ventures Limited (6029);
52. Generics Bidco I, LLC (6905);
53. Generics International (US) 2, Inc. (5075);
54. Generics International (US), Inc. (6489);
55. Generics International Ventures Enterprises LLC (4685);
56. Hawk Acquisition Ireland Limited (4776);
57. Innoteq, Inc. (3381);
58. JHP Acquisition, LLC (7861);
59. JHP Group Holdings, LLC (7688);
60. Kali Laboratories 2, Inc. (6751);
61. Kali Laboratories, LLC (4898);
62. Luxembourg Endo Specialty Pharmaceuticals Holding I S.à r.l. (0601);
63. Moores Mill Properties L.L.C. (9523);
64. Operand Pharmaceuticals Holdco II Limited (0648);
65. Operand Pharmaceuticals Holdco III Limited (0649);
66. Operand Pharmaceuticals II Limited (1365);
67. Operand Pharmaceuticals III Limited (1366);
68. Paladin Labs Canadian Holding Inc. (N/A);
69. Paladin Labs Inc. (1410);
70. Par Laboratories Europe, Ltd. (9597);
71. Par Pharmaceutical 2, Inc. (4895);
72. Par Pharmaceutical Companies, Inc. (8301);
73. Par Pharmaceutical Holdings, Inc. (3135);
74. Par Pharmaceutical, Inc. (8342);
75. Par Sterile Products, LLC (0105);
76. Par, LLC (1286);
77. Quartz Specialty Pharmaceuticals, LLC (5368);
78. Slate Pharmaceuticals, LLC (6201);
79. Timm Medical Holdings, LLC (8744); and
80. Vintage Pharmaceuticals, LLC (7882).

EXHIBIT B

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re: ENDO INTERNATIONAL PLC, *et al.*, Debtors.	Chapter 11 Case No. 22-22549 (JLG) (Jointly Administered)

ADDENDUM TO PROOF OF CLAIM OF THE UNITED STATES OF AMERICA

1. The United States of America submits this proof of claim on behalf of the Department of Health and Human Services (HHS) and its component agency, the Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program (Medicare) and is responsible for overseeing the Medicaid program (Medicaid); the Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits program (FEHBP); the Defense Health Agency, which administers the TRICARE program (TRICARE); and the Department of Veterans Affairs (VA) (collectively, the United States) against the following debtors in this matter (collectively, the Debtors or Endo):

   a. Endo International PLC (No. 22-22549);

   b. Endo Health Solutions Inc. (No. 22-22573); and

   c. Endo Pharmaceuticals Inc. (No. 22-22590).

2. Debtors all filed voluntary petitions under Chapter 11 of the Bankruptcy Code on August 16, 2022, thereby initiating these proceedings. The Court entered an order establishing May 31, 2023, as the deadline by which each governmental entity must file a proof of claim against any of the Debtors.

3. The United States reserves the right to amend or supplement this Proof of Claim in any respect, to fix or liquidate any claims stated herein, or to specify the quantity of expenses, damages, attorney's fees and costs incurred by the United States, including seeking post-petition interest in the event the Debtors are determined to be solvent and such claim would become due.

4. With respect to Proof of Claim Form Section 7, How much is the claim?, and subject to the reservations of rights herein, the United States estimates that it has a civil claim for single damages in the amount of $232 million, or in excess thereof, plus treble damages and penalties. This amount is estimated based upon the findings to date of the United States' civil investigation of Endo, which remains ongoing.

5. With respect to Proof of Claim Form Section 9, What is the basis of the claim?, and subject to the reservations of rights herein, the United States alleges upon information and belief as set forth below. The United States' civil investigation of Endo remains ongoing, and the United States expressly reserves its right to amend or supplement the allegations below.

PRELIMINARY STATEMENT

6. This Proof of Claim is based on the United States' non-dischargeable civil claims under the False Claims Act (FCA), 31 U.S.C. §§ 3729–33, and the equitable principle of Unjust Enrichment, arising from Endo's marketing and sale from 2011 through 2017 of its long-acting opioid analgesics Opana ER and Opana ER with INTAC (collectively, "Opana ER") that caused false or fraudulent claims to be submitted to federal healthcare programs, including Medicare, Medicaid, TRICARE, FEHBP, and VA.

7. Endo set national sales targets of between $500 million and $1 billion for Opana ER and maintained an extensive sales force to market and/or sell Opana ER to healthcare providers (HCPs) and pharmacies.

8. In its marketing campaign for Opana ER, Endo targeted HCPs whom Endo knew were writing and/or facilitating prescriptions of Opana ER that were not for a medically accepted indication.

9. As set forth below, Endo knowingly caused the submission of false and fraudulent claims to federal healthcare programs for prescriptions of Opana ER without a medically accepted indication.

FACTUAL ALLEGATIONS

10. Opana ER is an opioid drug whose label contained "black box" warnings of serious risks from taking the drug, such as addiction and respiratory depression, which can lead to death.

11. Endo knew, at the time that it was marketing Opana ER, that abuse of the drug was contributing to the opioid epidemic. Endo reviewed reports of misuse, abuse, dependence, overdose, and death related to Opana ER. Endo also reviewed Drug Enforcement Administration (DEA) alerts, law enforcement reporting, and other public reports identifying Opana ER as an opioid drug that increasingly was being abused.

12. During the relevant period, Endo used an aggressive marketing scheme to generate revenue from Opana ER prescriptions. Endo used its large sales force to directly market Opana ER to high volume prescribers of opioids, including many prescribers that Endo knew were prescribing Opana ER or other opioids for non-medically accepted indications.

13. Endo's sales tactics for Opana ER included "hypertargeting" the highest volume prescribers of opioids generally and Opana ER in particular, and focusing on pain clinics, physicians' assistants, and nurse practitioners, because Endo believed those HCPs were more receptive to Endo's marketing efforts.

14. For example, when Endo launched the reformulated Opana ER in late 2011, Endo's Vice President of Sales directed Endo's regional business directors to "prioritize biggest [opioid] writers first" and "call on these targets weekly." The regional business directors then told their district managers, who in turn told Endo's sales representatives, that "it's critical to our re-launch that we are hyper-targeting our top targets." Endo's top Opana ER targets were outlier opioid prescribers; namely, those HCPs who prescribed the highest levels of opioids in general and/or Opana ER in particular.

15. Endo specified the tactics and required actions for its sales representatives to follow in hyper-targeting high-volume opioids prescribers. Endo used sales goals, incentive compensation plans, and performance reviews to ensure that its sales force aggressively marketed Opana ER to high-volume opioids prescribers.

16. When Endo employees raised concerns about prescribers believed to be engaged in abuse, diversion, or pill mill prescribing, Endo often ignored or minimized such concerns and continued to directly market Opana ER to such prescribers. On numerous occasions, Endo stopped marketing Opana ER to such prescribers only once the prescriber had lost their license or law enforcement had taken action against the prescriber. Endo placed such prescribers on a "do not call" list that indicated that sales representatives should not make marketing calls to those prescribers. Endo's "do not call" list relied on ad hoc reports from sales representatives; Endo did not seek to proactively identify and add problem prescribers to its "do not call" list.

17. In 2015, after marketing Opana ER for years, Endo sought to further increase prescriptions with a "sales force blitz." To ensure that it was "pulling all the levers" it could "to drive incremental growth" of Opana ER prescriptions, Endo partnered with a consulting company to add about 3,000 priority HCP targets to the call lists for Endo's sales representatives. Nearly all

of these priority targets were chosen because they prescribed a high volume of opioids in general or Opana ER in particular. Endo used sales goals and sales contests to ensure that sales representatives directly marketed to these high-volume opioids prescribers, including those whom Endo had previously identified as posing risks of abuse and diversion.

18. As a result of Endo hypertargeting high-volume opioids prescribers to begin writing Opana ER prescriptions, or to write more Opana ER prescriptions, Endo knew that by November 2016 fewer than ten percent of all Opana ER prescribers wrote more than half of all Opana ER prescriptions.

Advance Pain Therapeutics

19. Advance Pain Therapeutics (APT) was a Knoxville, Tennessee area pain clinic run by Dr. Allen Foster. Endo aggressively marketed Opana ER to Dr. Foster and APT, and its sales representatives visited APT hundreds of times.

20. At least as early as September 2007, Endo knew APT was a pill mill engaged in diversion of opioids, including Opana ER. That month, an Endo sales representative reported to Endo management that "[t]he office has patients waiting in the parking lot in lounge chairs. I feel that it is just a matter of time before the DEA closes him down." The sales representative told Endo that Dr. Foster was the "#3 rxer [prescriber]" of Opana ER, but "he could prescribe soooo much more."

21. Aware of the large volume of prescriptions at issue, Endo chose to continue targeting APT and Dr. Foster to write Opana ER prescriptions.

22. Endo sales representatives also observed numerous other signs of diversion at APT, including that most patients paid for prescriptions in cash, many patients traveled long distances

to attend the clinic, the clinic employed a security guard, and individuals exhibiting suspect behavior congregated in the parking lot.

23. Endo nonetheless continued to target Dr. Foster to write Opana ER prescriptions until February 2011, when he pled guilty to healthcare fraud for billing for face-to-face visits with patients that never occurred.

24. Further, even after it stopped marketing to Dr. Foster, Endo continued to target APT and its prescribers to write Opana ER prescriptions. Endo received warnings of pill mill conduct at APT, including that the "[t]he patients at this location are not the type of patients Endo wants," "[t]he practice lacks qualified staff," "patients are milling around the parking areas," and "the selling environment is unsafe and uncomfortable." Nevertheless, Endo chose to continue marketing Opana ER to APT's prescribers "[b]ecause so much volume of product was involved." Endo did not stop marketing Opana ER to APT until October 2013.

25. After Endo knew that Dr. Foster and APT were engaged in abuse, diversion, and/or pill mill prescribing of Opana ER, Dr. Foster wrote thousands of Opana ER prescriptions before Endo stopped marketing the opioid drug to him, and APT's other prescribers who worked at the clinic wrote thousands more Opana ER prescriptions before Endo stopped marketing the opioid drug to APT and its prescribers.

Bearden Healthcare

26. Bearden Healthcare (Bearden) was a Knoxville, Tennessee area pain clinic run by Drs. Frank and Janet McNiel. Endo knew prescribers at Bearden were engaged in abuse, diversion, and/or pill mill prescribing of Opana ER as early as 2006, when an Endo employee reported to Endo that Bearden had "a number of characteristics typical of a 'pill mill.'"

27. Additionally, in February 2008, an Endo sales representative warned Endo that the representative had witnessed suspected diversion at Bearden, including that "a large proportion of prescriptions [are] being paid for in cash," "a high frequency of prescriptions [are] to replace lost prescriptions," and "drugs and doses being prescribed are not individualized." Further, in August 2008, another Endo sales representative confirmed to Endo that "McNiel runs a pill mill."

28. While Endo ceased in-person marketing to Dr. Frank McNiel in 2008 due to diversion concerns, it continued to permit him to use Endo's pharmacy locator service for Opana ER, and Dr. Frank McNiel's patients were able to use Endo's prescription savings cards to obtain discounted Opana ER. Additionally, Endo sales representatives marketed Opana ER to his wife Dr. Janet McNiel in 2015 and 2016.

29. The McNiels and other prescribers who worked for Bearden collectively wrote thousands of Opana ER prescriptions after Endo knew the prescribers at Bearden were engaged in abuse, diversion, and/or pill mill prescribing of Opana ER, but before it stopped targeting them to write Opana ER prescriptions.

30. Dr. Frank McNiel was convicted in 2019 of unlawfully distributing opioids, and Dr. Janet McNiel surrendered her medical license in November 2020 for improper prescribing of opioids.

Drs. Xiulu Ruan and John Patrick Couch

31. Drs. Xiulu Ruan and John Patrick Couch ran a pain clinic in Mobile, Alabama. Their clinic exhibited extensive red flags of diversion, including crowded waiting rooms, physicians' assistants and nurse practitioners abusing controlled substances on-site, Dr. Couch's frequent absence from the clinic during work hours, use of pre-printed, pre-signed prescriptions, armed security guards in the waiting room, and intoxicated patients in the waiting room.

32. Despite these red flags, Endo sales representatives aggressively marketed Opana ER to Drs. Ruan and Couch and their pain clinic, and Endo's sales representatives visited the clinic over 1,200 times. Moreover, certain sales representatives had personal relationships with Dr. Ruan. For example, several Endo sales representatives worked with Dr. Ruan to form an exotic car club.

33. Endo management also had a close relationship with Dr. Ruan. Endo hired a sales representative after Dr. Ruan told the company that "he would double his business overnight if Endo were to bring him onboard." In addition, Endo engaged Dr. Ruan for Endo's "speaker program," paying him fees to tout the benefits of Opana ER to other HCPs.

34. Despite these close relationships, and the red flags that Drs. Ruan and Couch were engaged in diversion, Endo continued to market Opana ER to the clinic until Drs. Ruan and Couch were arrested in April 2015. Drs. Ruan and Couch together wrote thousands of Opana ER prescriptions after Endo knew the clinic to be engaged in abuse, diversion, and/or pill mill prescribing of Opana ER but before Endo stopped marketing Opana ER to them.

35. Drs. Ruan and Couch were convicted at trial for, among other charges, prescribing opioids outside the usual course of professional practice in violation of the Controlled Substances Act, conspiracy to commit those Controlled Substances Act (CSA) violations, healthcare fraud, mail and wire fraud, conspiracy to violate the Racketeer Influenced and Corrupt Organizations Act (RICO) Act, and, in Dr. Ruan's case, money laundering. *See United States v. Ruan*, 56 F.4th 1291 (11th Cir. 2023) (affirming all convictions except vacating and remanding for new trial on CSA charges).

* * *

36. In sum, Endo had actual knowledge and/or deliberately ignored that many HCPs were prescribing Opana ER without a medically accepted indication, including for diversion and

abuse of Opana ER, but nonetheless continued to aggressively market Opana ER to those HCPs, including by use of Endo's prescription savings cards and pharmacy locator. In addition, Endo recklessly ignored the risks that the high-volume opioid prescribers that Endo chose to hyper-target included a disproportionate share of prescribers engaged in abuse and diversion of opioids. Together, those HCPs wrote tens of thousands of Opana ER prescriptions after Endo became aware of or had a basis to believe the HCPs were improperly prescribing Opana ER.

CAUSES OF ACTION AGAINST ENDO

37. Based on the foregoing conduct, the United States asserts that it has certain legal claims against Endo, as set forth below. The United States reserves its right to supplement these legal claims and the allegations set forth above based on additional information obtained during its investigation.

False Claims Act

38. The United States incorporates the preceding paragraphs here.

39. Through its marketing and related conduct, from 2011 to 2017, Endo knowingly caused the submission of false and fraudulent claims to federal healthcare programs for Opana ER that was prescribed without a medically accepted indication, including for diversion and abuse.

40. More specifically, claims for opioids that were prescribed without a medically accepted indication are not covered by federal healthcare programs.

41. It was reasonably foreseeable that many of those Opana ER prescriptions would be for federal healthcare program beneficiaries and that claims for those prescriptions would be submitted to federal healthcare programs. Many such prescriptions or claims based on such prescriptions were, in fact, submitted to and paid for by federal healthcare programs.

EXHIBIT B

Unjust Enrichment

42. The United States incorporates the preceding paragraphs here.

43. Endo was enriched at the expense of federal healthcare programs.

44. Equity and good conscience militate against permitting Endo to retain revenues and profits resulting from its misconduct.

AMOUNT OF CLAIM

45. Based on the above allegations, and subject to amendments which may occur as a result of the United States' ongoing civil investigation, the United States estimates that Endo has caused single damages for false and fraudulent claims in the amount of $232 million or in excess thereof. The FCA allows the United States to recover treble damages plus penalties.

GENERAL RESERVATION OF RIGHTS

46. The filing of this Proof of Claim is not intended to: (a) waive the right to seek withdrawal of the reference with respect to the subject matter of the Proof of Claim, any objection or other proceedings commenced with respect thereto, or any other proceedings commenced in this proceeding against or otherwise involving the United States; or (b) constitute an election of remedies that waives or otherwise affects any other remedy.

47. The United States expressly reserves all rights of setoff and recoupment that the United States may have, including any right under 11 U.S.C. § 553 to setoff, against the claims herein, debts owed (if any) to Debtors by the United States, or any federal agency.

48. Additional documentation in support of this Proof of Claim is too voluminous to attach, but is available upon request.

49. The United States reserves the right to amend any of the foregoing information, including the amount of its claim, based on its ongoing review and investigation of the matters alleged herein, or for any other reason.

Dated: May 30, 2023

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

MARKENZY LAPOINTE
United States Attorney
Southern District Of Florida