

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Attorney's Office for the Eastern District of Michigan and the United States Attorney's Office for the Northern District of New York and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the ("United States")), and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (collectively referred to herein as "Mallinckrodt").

II. RECITALS

A. Mallinckrodt plc is a publicly traded company incorporated in Ireland with its United States headquarters located in Hazelwood, Missouri.

B. Mallinckrodt is a manufacturer of pharmaceuticals, including controlled substances and non-controlled prescription medications, and is registered with the DEA as both a manufacturer and distributor, as reflected in the Registrations listed on Exhibit A. Mallinckrodt manufactures pharmaceuticals at various locations in the United States, including at a facility located in Hobart, New York, and distributes the controlled substances it manufactures.

C. At all times relevant to this Agreement, Mallinckrodt was required to operate in accordance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the "CSA"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The CSA places a duty on registrants to maintain effective controls against

diversion of controlled substances and is designed to ensure that controlled substances are not diverted outside this system.

E. Mallinckrodt is a manufacturer and distributor of oxycodone and hydrocodone products. As controlled substances under the CSA, the DEA regulates the manufacture, distribution, sale, and possession of oxycodone and hydrocodone.

F. In order to meet its obligation to safeguard these controlled substances, Mallinckrodt is required to have in place certain processes, including to design and operate a system to detect "suspicious orders" for controlled substances, and to inform DEA of "suspicious orders." *See* 21 C.F.R. § 1301.74(b).

G. The regulations promulgated under the CSA also include requirements for manufacturers to maintain certain specified records. *See* 21 C.F.R. § 1304.22.

H. The CSA authorizes the imposition of a civil penalty of up to \$10,000 for each violation of § 842(a)(5). 21 U.S.C. § 842 (c)(1)(B).

I. The CSA also makes it "unlawful for any person who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration." 21 U.S.C. § 842(a)(2). Those registered by the Attorney General to manufacture and distribute controlled substances are authorized to do so "to the extent authorized by their registration *and in conformity with other provisions of this subchapter* [emphasis added]." 21 U.S.C. § 822(b). The United States contends that a registrant distributing while violating provisions of the CSA and its implementing regulations is acting outside of 21 U.S.C. § 822(b) authorized conduct and is therefore in violation of 21 U.S.C. § 842(a)(2), and penalties for any such violation shall not exceed

\$25,000. 21 U.S.C. § 842(c)(1)(A).

J. The DEA is the Department of Justice (“DOJ”) component agency responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

K. The Attorney General, through the United States Attorneys, has authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

L. The United States contends that it has certain civil claims against Mallinckrodt under 21 U.S.C. §§ 842(a)(1), 842(a)(2), and 842(a)(5) for engaging in the Covered Conduct as defined in Section L below, from January 1, 2008, through the Effective Date of this Agreement (the “Covered Time Period”).

M. For purposes of this Agreement, “Covered Conduct” shall mean the following conduct, for the Covered Time Period:

1. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt’s alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt’s alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt’s alleged failure to:

- a) conduct adequate due diligence of its customers;
- b) detect and report to the DEA orders of unusual size and frequency;
- c) detect and report to the DEA orders deviating substantially from

normal patterns including but not limited to those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006, and December 27, 2007:

- (1) orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 - (2) orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
 - (3) orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware.
- d) use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
- e) take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.
2. With respect to the manufacture of controlled substances at Mallinckrodt's Hobart, NY facility, Mallinckrodt's alleged:
- a) failure to take actual weights of controlled substances at all stages

of the manufacturing process;

b) use of a "target" tablet weight for purposes of reconciling batch records and determining the number of units of finished form manufactured even though the actual average weight of the tablets in any specific batch sometimes deviated from the target weight, resulting in discrepancies between the actual number of units of finished form manufactured and the extrapolated weight of the controlled substances in a batch and what Mallinckrodt's records showed as the number of units of finished form manufactured and the extrapolated weight;

c) commingling of dust collector waste and assignment of dust losses to particular batches without confirming how much dust was actually attributable to any specific batch;

d) failure to check-weigh controlled substances received into the facility;

e) failure to maintain accurate records of substances transferred from the manufacturing process to Mallinckrodt's analytical laboratories, maintaining such information only in individual technician logbooks that were not readily available for the DEA to review; and

f) failure to include substances held in certain vaults/storage as part of the biennial inventory, and records provided for vaults containing discrepancies with respect to weight, missing substances, incorrect lot/batch numbers, and incorrect or incomplete drug names.

N. This Settlement Agreement is not an admission of liability for civil penalties for the Covered Conduct under the CSA. However, Mallinckrodt agrees that at certain times during the Covered Time Period prior to January 1, 2012, certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006, and December 27, 2007. Mallinckrodt further agrees that at certain times during the Covered Time Period, at Mallinckrodt's Hobart, New York facility, certain of Mallinckrodt's recordkeeping and physical security practices at that facility were, in some respects, not consistent with DEA regulations.

O. Mallinckrodt contends that over the past several years, Mallinckrodt has implemented additional compliance safeguards to ensure that it meets its obligations as a DEA registrant and has taken significant steps to combat the diversion and abuse of opioids.

P. To avoid the delay, expense, inconvenience, and uncertainty of litigation of these claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Mallinckrodt shall pay the United States the sum of Thirty-Five Million Dollars (\$35,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

2. In consideration of the fulfillment of the obligations of Mallinckrodt under this Agreement, the United States agrees to:

- a. Fully and finally release Mallinckrodt and its current and former subsidiaries, affiliates, facilities, predecessors, successors and registrants (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842, which the United States has asserted, could have asserted, or may assert in the future against the Released Parties related to the Covered Conduct during the Covered Time Period; and
- b. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct during the Covered Time Period.

3. Contemporaneously with the execution of this Settlement Agreement, Mallinckrodt will enter into an Administrative Memorandum of Agreement ("MOA"), which will resolve administrative claims that DEA has or may have against Mallinckrodt related to the Covered Conduct. See MOA attached hereto in Appendix A. Mallinckrodt acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the

CSA. Mallinckrodt represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion.

4. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any component of DOJ, based on the Covered Conduct.

5. Mallinckrodt fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which Mallinckrodt has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

6. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including Mallinckrodt) are the following:

- 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, including the suspension and debarment rights of any federal agency;
- 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; and
- f. Any liability of individuals.

7. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against Mallinckrodt for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

8. Mallinckrodt agrees that any and all costs it has, will, or may incur in connection with this matter - including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

9. Mallinckrodt warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain

solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Mallinckrodt, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to defraud any entity to which Mallinckrodt was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

10. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, Mallinckrodt commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of Mallinckrodt's debts, or seeking to adjudicate Mallinckrodt as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for Mallinckrodt or for all or any substantial part of Mallinckrodt's assets, Mallinckrodt agrees as follows:

- a. Mallinckrodt's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and Mallinckrodt will not argue or otherwise take the position in any such case, proceeding, or action that: (i) Mallinckrodt's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) Mallinckrodt was

insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to Mallinckrodt;

b. If Mallinckrodt's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. Mallinckrodt agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that Mallinckrodt will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that Mallinckrodt will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States within 90 calendar days of written notification to Mallinckrodt that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such

defenses were available on the Effective Date of the Settlement Agreement;
and (iii) the United States may pursue any and all claims it had as of July 1,
2014, in the case, action, or proceeding referenced in the first clause of this
Paragraph, as well as in any other case, action, or proceeding; and

c) Mallinckrodt acknowledges that its agreements in this Paragraph are
provided in exchange for valuable consideration provided by and through
this Settlement Agreement.

11. Each Party to this Settlement Agreement will bear its own legal expenses and other
costs incurred in connection with this matter, including those for the preparation and performance
of this Settlement Agreement.

12. Except as provided in Paragraph 2, this Settlement Agreement is intended to be for
the benefit of the Parties only.

13. Mallinckrodt represents that this Settlement Agreement is freely and voluntarily
entered into, without any degree of duress or compulsion whatsoever. Mallinckrodt also
acknowledges that it was represented by legal counsel of its choosing throughout the negotiation
and execution of this Settlement Agreement.

14. Mallinckrodt consents to the disclosure of this Settlement Agreement, information
about this Settlement Agreement, the settlement terms memorialized herein, and the MOA by the
United States to the public.

15. Nothing in this Settlement Agreement constitutes an agreement by the United States
concerning characterization of the Settlement Amount for purposes of Title 26 of the United States
Code (Internal Revenue Code).

16. This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdictions and venues for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Eastern District of Michigan or the United States District Court for the Northern District of New York.

17. This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and Mallinckrodt with respect to the settlement of claims against Mallinckrodt for the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of Mallinckrodt and an authorized representative of the United States.

18. This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

19. This Settlement Agreement is binding on Mallinckrodt and its successors, transferees, and assigns.

20. This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.

21. For purposes of construing this Settlement 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.


22. Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and Mallinckrodt have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

UNITED STATES OF AMERICA


DANIEL L. LEMISCH
Acting United States Attorney
Eastern District of Michigan

Dated: 7/11/17


LESLIE WIZNER
Assistant U.S. Attorney
U.S. Attorney's Office
Eastern District of Michigan
211 W. Fort St., Suite 2001
Detroit, MI 48226

GRANT C. JAQUITH
Acting United States Attorney
Northern District of New York

Dated: 7/9/17


MICHAEL D. GADARMAN
Assistant U.S. Attorney
U.S. Attorney's Office
Northern District of New York
100 S. Clinton Street
Syracuse, New York 13261

Dated: _____

DEMETRA ASHLEY
Acting Assistant Administrator
Diversion Control Division
U.S. Drug Enforcement Administration

IN WITNESS WHEREOF, the United States and Mallinckrodt have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

UNITED STATES OF AMERICA

DANIEL L. LEMISCH
Acting United States Attorney
Eastern District of Michigan

Dated: _____

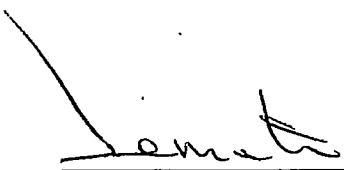
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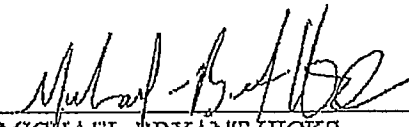
Dated: 7-7-17



DEMETRA ASHLEY
Acting Assistant Administrator
Diversion Control Division
U.S. Drug Enforcement Administration

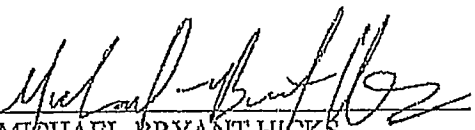
Mallinckrodt, LLC

Dated: _____



MICHAEL BRYANT HICKS
Senior Vice President and General Counsel
Mallinckrodt, LLC

Mallinckrodt, plc

Dated: _____


MICHAEL BRYANT HICKS
Senior Vice President and General Counsel
Mallinckrodt, plc

Dated: 7/7/17


BRIEN T. O'CONNOR
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D. LINDEN BARBER
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Dated: _____

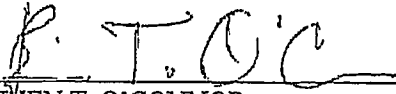
MICHAEL-BRYANT HICKS
Senior Vice President and General Counsel
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Mallinckrodt, plc

Dated: _____

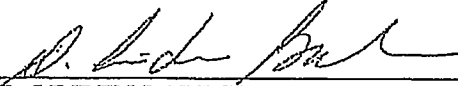
MICHAEL-BRYANT HICKS
Senior Vice President and General Counsel
Mallinckrodt, plc

Dated: 7/7/17



BRIAN T. O'CONNOR
Ropes & Gray LLP
Counsel for Mallinckrodt

Dated: July 7, 2017



D. LINDEN BARBER
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