
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): March 7, 2022

Mallinckrodt plc
(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction
of incorporation)

001-35803
(Commission
File Number)

98-1088325
(IRS Employer
Identification No.)

College Business & Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland
(Address of principal executive offices)

+353 1 6960000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act: None

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01. Entry Into a Material Definitive Agreement.

As previously disclosed, Mallinckrodt plc, an Irish public limited company in examination under Part 10 of the Companies Act 2014 of Ireland (“Mallinckrodt”), and Mallinckrodt ARD LLC, a California limited liability company (“ARD” and, together with Mallinckrodt, the “Mallinckrodt Parties”) had agreed to a settlement in principle with the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services (collectively, the “United States”), certain other governmental parties and certain relators to settle a range of litigation matters and disputes relating to Acthar Gel, which settlement would be effective concurrently with the plan of reorganization to be confirmed in the proceedings voluntarily initiated by Mallinckrodt and certain of its subsidiaries (including ARD) under chapter 11 of title 11 of the United States Code (the “Bankruptcy Code”) in the U.S. Bankruptcy Court for the District of Delaware (the “Bankruptcy Court”). On March 7, 2022, the Mallinckrodt Parties executed two settlement agreements (the “Settlement Agreements”) with the United States and the relators to implement the proposed settlement.

Under the Settlement Agreements, the Mallinckrodt Parties have agreed to pay a total of \$260 million plus interest (accruing at an annual rate of 0.6255%) to the Department of Justice and other parties over seven years and to maintain Acthar Gel’s base date average manufacturer price as that of the third quarter of 1990 in CMS’s drug data reporting system. Additionally, the Mallinckrodt Parties have agreed to dismiss their appeal of the CMS Medicaid rebate dispute, currently pending in the Court of Appeals for the D.C. Circuit. In return, the United States will drop its demand for nearly \$640 million in retroactive Medicaid rebates for Acthar Gel, will dismiss a False Claims Act (“FCA”) lawsuit in the District of Massachusetts relating to the Medicaid rebate dispute, and will dismiss an FCA suit in the Eastern District of Pennsylvania relating to legacy Questcor interactions with an independent charitable foundation.

The obligations under the Settlement Agreements described above are effectively conditioned upon consummation of the plan of reorganization of Mallinckrodt and its subsidiaries. As previously disclosed, on March 2, 2022, the Bankruptcy Court entered an order (the “Confirmation Order”) confirming the Fourth Amended Joint Plan of Reorganization (with Technical Modifications) of Mallinckrodt Plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code (as amended, supplemented or otherwise modified, the “Plan”). Notwithstanding the entry of the Confirmation Order, consummation of the Plan remains subject to the satisfaction or waiver of various conditions precedent set forth in the Plan, including that the High Court of Ireland shall, in the examinership proceedings initiated therein by Mallinckrodt’s directors, make an order pursuant to Section 541 of the Companies Act of Ireland confirming a scheme of arrangement with respect to Mallinckrodt which is based on and consistent in all respects with the Plan (a “Scheme of Arrangement”), and that such Scheme of Arrangement shall become effective in accordance with its terms (or shall become effective concurrently with the effectiveness of the Plan).

The foregoing summary of the Settlement Agreements is not complete and is qualified in its entirety by reference to the Settlement Agreements, which are filed as Exhibits 10.1 and 10.2 to this Current Report on Form 8-K and incorporated into this Item 1.01 by reference.

Item 8.01. Other Events.

In connection with the Settlement Agreements, (a) the Mallinckrodt Parties have entered into separate settlement agreements with certain states, the Commonwealth of Puerto Rico, the District of Columbia and the above-noted relators, which further implement the settlement established by the Settlement Agreements, and (b) Mallinckrodt also entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services, which requires Mallinckrodt to maintain its corporate healthcare compliance program and to undertake a set of defined compliance obligations for a period of five years from the date the agreement was signed.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.1	<u>Settlement Agreement, dated as of March 7, 2022, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, Mallinckrodt plc, Mallinckrodt ARD LLC and James Landolt.</u>
10.2	<u>Settlement Agreement, dated as of March 7, 2022, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, Mallinckrodt plc, Mallinckrodt ARD LLC, Charles Strunck, Lisa Pratta and Scott Clark.</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MALLINCKRODT PLC
(registrant)

By: /s/ Bryan M. Reasons
Bryan M. Reasons
Executive Vice President & Chief Financial Officer
(principal financial and accounting officer)

Date: March 11, 2022

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among 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”) (collectively, the “United States”), Mallinckrodt plc and Mallinckrodt ARD LLC (f/k/a Questcor Pharmaceuticals, Inc.), debtors and debtors-in-possession acting on behalf of themselves and their estates (collectively, “Mallinckrodt”)¹, and James Landolt (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. In order to obtain federal reimbursement for its covered outpatient drugs under any state Medicaid programs, *see* 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”), all of which the federal government jointly finances with the states, a pharmaceutical manufacturer must opt into the Medicaid Drug Rebate Program (“MDRP”). The MDRP’s implementing statute, 42 U.S.C. § 1396r-8 (the “Rebate Statute”), requires such manufacturers to enter into a Rebate Agreement. The Rebate Statute sets the terms of the Rebate Agreement. The Rebate Statute and Rebate Agreement require the manufacturer to pay each state Medicaid program a quarterly amount that potentially includes an inflation-based “additional rebate” for each “dosage form and strength” of a single source drug or an innovator multiple source drug. *See* 42 U.S.C. § 1396r-8(c)(2)(A). If the drug was approved by the Food and Drug Administration (“FDA”) on or prior to October 1, 1990, any additional rebate equals the difference, if any, between the drug’s current quarter

¹ References to Mallinckrodt shall include and encompass any reorganized Mallinckrodt created by the Approved Plan (defined herein) confirmed by the Bankruptcy Court. For the avoidance of doubt: (a) reorganized Mallinckrodt plc and reorganized Mallinckrodt ARD LLC shall be considered successors to Mallinckrodt plc and Mallinckrodt ARD LLC, respectively, and be fully responsible for any liabilities, obligations, or conditions included in this Settlement Agreement; (b) the Approved Plan shall provide for (i) the reorganization and continued corporate existence of Mallinckrodt plc and Mallinckrodt ARD LLC and (ii) the vesting of the assets of Mallinckrodt plc and Mallinckrodt ARD LLC in reorganized Mallinckrodt plc and Mallinckrodt ARD LLC upon the effective date of the confirmed Approved Plan.

“average manufacturer price” (“AMP”) and the drug’s AMP for the third quarter of 1990 increased by the rate of inflation. For a “subsequently approved” drug (*i.e.*, a “covered outpatient drug approved by the Food and Drug Administration after October 1, 1990”), any additional rebate equals the difference, if any, between the drug’s current quarter AMP and its AMP for the first full calendar quarter after the date on which “the drug was first marketed,” increased by the rate of inflation. *See* 42 U.S.C. § 1396r-8(c)(2)(B). The AMP that serves as the starting point for the “additional rebate” calculation is commonly called the “Base Date AMP.”

B. Mallinckrodt plc is an Irish public limited company. Its subsidiary, Mallinckrodt ARD, LLC (*f/k/a* Questcor Pharmaceuticals, Inc.), is a California limited liability company with its principal place of business in New Jersey. Mallinckrodt does business as a pharmaceutical manufacturer in the United States and markets H.P. Acthar Gel (“Acthar”) in the United States.

C. On September 20, 2018, James Landolt filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States ex rel. John Doe v. Mallinckrodt ARD, LLC*, No. 1:18-cv-11931-PBS, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). The Civil Action alleges that Mallinckrodt knowingly and improperly avoided paying rebates to the Medicaid program for Mallinckrodt’s drug Acthar. The United States intervened in the Civil Action on March 2, 2020, and filed a Complaint-in-Intervention on March 3, 2020.

D. The United States contends that it has certain civil claims against Mallinckrodt arising from conduct alleged in the United States’ Complaint-in-Intervention in the Civil Action for the time period of January 1, 2013 through and including June 30, 2020. That conduct is referred to below as the “Covered Conduct.”

E. Mallinckrodt admits and agrees that there is only one Acthar, that FDA approved Acthar pursuant to a New Drug Application in 1952, and that Acthar was first produced, distributed, and marketed prior to 1990. Mallinckrodt has reinstated in CMS's drug data reporting system (DDR) the Base Date AMP for Acthar as Acthar's AMP from the third quarter of 1990, and agrees that it will not change that Base Date AMP in the DDR.

F. Relator claims entitlement under 31 U.S.C. § 3730(d) and comparable provisions of any applicable state statutes to a share of the proceeds of this Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

G. Mallinckrodt will enter into separate settlement agreements (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states, which for the purposes of this agreement include the Commonwealth of Puerto Rico and the District of Columbia, in settlement of the conduct released in those separate Medicaid State Settlement Agreements. States with which Mallinckrodt executes a Medicaid State Settlement Agreement in the form to which Mallinckrodt and the States have agreed through a State Negotiating Team, or in a form otherwise agreed to by Mallinckrodt and an individual State, shall be defined as "Medicaid Participating States."

H. The Parties have negotiated this Agreement in good faith and at arm's length and intend the Agreement to be consummated through (a) the voluntary cases under chapter 11 of the Bankruptcy Code (as defined below) (the "Chapter 11 Cases") filed in the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") Case No. 20-12522 (JTD), by Mallinckrodt ARD LLC and certain of its affiliates and subsidiaries on October 12, 2020, (b) the examinership proceeding to be commenced by Mallinckrodt plc under the laws of Ireland (the "Examinership Proceeding"), and (c) the proceedings commenced under Part IV of the Canadian Companies Arrangement Act to recognize in Canada the Chapter 11 Cases and to recognize in Canada certain orders of the Bankruptcy Court (the "Canadian Recognition Proceeding") and, collectively with the Chapter 11 Cases and the Examinership Proceeding, the "Bankruptcy Proceedings").²

² Capitalized terms not otherwise defined herein shall have the meaning ascribed to them in Exhibit A.

In consideration of the mutual promises and obligations of this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Mallinckrodt shall pay to the United States and the Medicaid Participating States collectively, \$233,707,865.18, plus interest accruing at an annual rate of 0.6255%, running from September 21, 2020, in eight installments, pursuant to the installment payment schedule described in Exhibit B (the "Settlement Amount"). The interest described in the foregoing sentence shall accrue on the outstanding balance of the remaining installment payments and all then-accrued interest shall be payable in cash to the United States and the Medicaid Participating States contemporaneously with each installment payment as set forth on Exhibit B. Of the Settlement Amount, Mallinckrodt shall pay \$123,642,146.73 (plus accrued interest) to the United States ("Federal Settlement Amount") by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of Massachusetts, and \$110,065,718.45 (plus accrued interest) ("State Settlement Amount") to the Medicaid Participating States pursuant to the terms of Medicaid State Settlement Agreements that Mallinckrodt has or will enter into with the Medicaid Participating States. The entire Settlement Amount shall be considered restitution. The entire balance of the Settlement Amount, or any portion thereof, may be prepaid without premium or penalty. If Mallinckrodt elects to prepay the Settlement Amount, or any portion thereof, interest shall accrue through the

date on which Mallinckrodt makes said prepayment. If Mallinckrodt is sold, merged, or transferred, or all or substantially all of the assets of Mallinckrodt (on a consolidated basis) are sold, merged, or transferred into another non-affiliated entity, Mallinckrodt shall promptly notify the United States, and all remaining payments owed pursuant to the Settlement Agreement shall be accelerated and become immediately due and payable upon consummation of such transaction.

2. Conditioned upon the United States receiving the Settlement Amount installment payments from Mallinckrodt, the United States agrees that it shall pay by electronic funds transfer to Relator twenty (20) % of each such payment received under the Agreement (“Relator’s Share”) as soon as feasible after receipt of the payment.

3. Mallinckrodt has agreed to pay Relator’s reasonable expenses, attorneys’ fees and costs, as contemplated by 31 U.S.C. § 3730(d) and comparable provisions of any applicable state statutes and will do so subject to terms set forth in a separate agreement that Mallinckrodt and Relator will enter into contemporaneously with this agreement.

4. Subject to the exceptions in Paragraph 7 (concerning reserved claims) below, and subject to Paragraph 10 (concerning disclosure of assets), and subject to Paragraphs 19 and 20, below (concerning bankruptcy), and upon the United States’ receipt of the Settlement Amount, the United States releases Mallinckrodt, together with its current or former parent corporations; subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (the “Mallinckrodt Releasees”), from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 CFR Part 0; Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 7 (concerning reserved claims) below, and subject to Paragraph 10 (concerning disclosure of assets), and subject to Paragraphs 19 and 20, below (concerning bankruptcy), and upon the United States' receipt of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases the Mallinckrodt Releasees from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33.

6. In consideration of the obligations of Mallinckrodt in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Mallinckrodt plc and upon the United States' receipt of full payment of the Settlement Amount, plus interest due under Paragraph 1, the OIG-HHS shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Mallinckrodt under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 7 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Mallinckrodt from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in paragraphs 4 and 6 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- 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 exclusion from Federal health care 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; and
- f. Any liability of individuals.

8. Relator and his 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 his 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 and/or the Civil Action.

9. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, fully and finally releases the Mallinckrodt Releasees, and their officers, agents, and employees, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated, outside of those contemplated in a separate agreement that Mallinckrodt and Relator will enter into contemporaneously with this agreement) that Relator has asserted, could have asserted, or may assert in the future against Mallinckrodt related to the Civil Action or the Covered Conduct and Relator's investigation or prosecution thereof, or any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

10. Mallinckrodt has provided sworn financial disclosures and supporting documents (“Financial Disclosures”) to the United States, and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Mallinckrodt warrants that the Financial Disclosures are complete, accurate, and current as of the date provided. If the United States learns of asset(s) in which Mallinckrodt had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Mallinckrodt’s obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Mallinckrodt on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by \$12.5 million or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct in the United States District Court for the District of Massachusetts, or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Mallinckrodt’s previously undisclosed assets. In the event that the United States recovers additional amounts under this Paragraph, those funds constitute payments under this Agreement for purposes of Paragraph 2, which entitles Relator to 20% of those proceeds. Mallinckrodt agrees not to contest any collection action undertaken by the United States pursuant to this provision, and agrees that it will immediately pay the United States (i) a ten-percent (10%) surcharge of the amount collected in the collection action, or (ii) the United States reasonable attorneys’ fees and expenses incurred in such an action, in each case, to the extent allowed by 28 U.S.C. § 3011.

In the event that the United States, pursuant to this paragraph, rescinds this Agreement, Mallinckrodt waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, including theories related to the Bankruptcy Proceedings such as discharge, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to Mallinckrodt that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on September 20, 2018.

11. Mallinckrodt waives and shall not assert any defenses Mallinckrodt 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.

12. Mallinckrodt fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that Mallinckrodt 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 or the United States' investigation or prosecution thereof.

13. Mallinckrodt fully and finally releases the Relator and his heirs, successors, attorneys, agents, and assigns from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Mallinckrodt has asserted, could have asserted, or may assert in the future against Relator related to the Civil Action or the Covered Conduct and Relator's investigation or prosecution thereof.

14. The Settlement 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, carrier or any state payer) related to the Covered Conduct; and Mallinckrodt agrees not to resubmit to any Medicare contractor 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.

15. Mallinckrodt 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-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Mallinckrodt, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audits and investigations of the matters covered by this Agreement;
- (3) Mallinckrodt's investigation, defense, and corrective actions undertaken in response to the United States' audits and investigations in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement;

- (5) the payment Mallinckrodt makes to the United States pursuant to this Agreement and any payments that Mallinckrodt may make to Relator, including for costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to OIG-HHS,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 15.a.6 that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Mallinckrodt.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Mallinckrodt, and Mallinckrodt 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 Mallinckrodt or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Mallinckrodt further agrees that within 120 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, 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 Mallinckrodt 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. Mallinckrodt agrees that the United States, at a minimum, shall be entitled to recoup from Mallinckrodt 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 Mallinckrodt or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Mallinckrodt 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 Mallinckrodt's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. Mallinckrodt agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Mallinckrodt shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its 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. Mallinckrodt further agrees to furnish to the United States, upon 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.

17. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 18 (waiver for beneficiaries paragraph), below.

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

19. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Mallinckrodt's financial condition as reflected in the Financial Statements referenced in Paragraph 10.

a. In the event that Mallinckrodt fails to pay any portion of the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above, Mallinckrodt shall be in default of Mallinckrodt's payment obligations ("Payment Default"). The United States will provide a written Notice of Payment Default, and Mallinckrodt shall have an opportunity to cure such Payment Default within seven (7) business days from the date of receipt of the Notice of Payment Default by making the payment due under the payment schedule and paying any additional interest accruing under the Agreement up to the date of payment. Notice of Payment Default will be delivered to Mallinckrodt, or to such other representative as Mallinckrodt shall designate in advance in writing. If Mallinckrodt fails to cure the Payment Default within seven (7) business days of receiving the Notice of Payment Default and in the absence of an agreement

with the United States to a modified payment schedule (“Uncured Payment Default”), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Payment Default, on the remaining unpaid total (principal and interest balance).

b. In the event of an Uncured Payment Default, Mallinckrodt agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action, reinstate the Complaint-in-Intervention or bring any civil and/or administrative claim, action, or proceeding against Mallinckrodt in the United States District Court for the District of Massachusetts for the claims that would otherwise be covered by the releases provided in Paragraphs 4 and 6 above, with any recovery reduced by the amount of any payments previously made by Mallinckrodt to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to Mallinckrodt and/or affiliated companies by any department, agency, or agent of the United States at the time of Payment Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Payment Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Mallinckrodt agrees immediately to pay the United States (i) a ten-percent (10%) surcharge of the amount collected in the collection action, or (ii) the United States reasonable attorneys’ fees and expenses incurred in such an action, in each case, to the extent allowed by 28 U.S.C. § 3011. In the event that the United States opts to rescind this Agreement pursuant to this Paragraph, Mallinckrodt waives and agrees not to plead, argue, or otherwise

raise any defenses of statute of limitations, laches, estoppel or similar theories, including theories related to the Bankruptcy Proceedings such as discharge, to any civil or administrative claims that are (i) filed by the United States against Mallinckrodt within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on September 20, 2018. Mallinckrodt agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

c. In the event of an Uncured Payment Default and rescission of this Agreement by the United States, Relator shall be entitled to recover his award and to expenses, attorneys' fees and costs under 31 U.S.C. § 3730(d) on any False Claims Act claims brought by or on behalf of the United States based on the Covered Conduct. Relator's entitlement to his share of proceeds under 31 U.S.C. § 3730(d) would be reduced by the amount of any payments previously paid to Relator under Paragraph 2 of this Agreement. Relator's entitlement to expenses, attorneys' fees and costs under 31 U.S.C. § 3730(d) would be reduced by the amount any payments that Mallinckrodt previously paid to Relator as acknowledged in the separate agreement that Mallinckrodt and Relator entered into on will enter into contemporaneously with this agreement, referenced in paragraph 3 of this Agreement.

d. In the event of an Uncured Payment Default, OIG-HHS may exclude Mallinckrodt from participating in all Federal health care programs until Mallinckrodt pays the Settlement Amount, with interest, and reasonable costs as set forth above ("Exclusion for Default"). OIG-HHS will provide written notice of any such exclusion to Mallinckrodt. Mallinckrodt waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court.

Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Mallinckrodt wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-3005. Mallinckrodt will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Payment Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

20. In exchange for valuable consideration provided in this Agreement, Mallinckrodt agrees to the following:

a. The Definitive Documents related to the Bankruptcy Proceedings shall be consistent in all material respects with this Agreement and shall not in any manner, by their terms, contain any provisions that amend, modify, supplement, supersede or conflict with, any of the provisions of this Agreement in any manner that is materially adverse to, or materially prejudicial to the United States or the Relator, in each case, with respect to their rights under this Settlement Agreement. The Definitive Documents shall be in form and substance reasonably acceptable to the United States. In addition, Mallinckrodt shall take such actions as may be reasonably necessary or appropriate in the Bankruptcy Proceedings (including, without limitation, assuming its obligations under this Agreement pursuant to the Approved Plan, the Canadian Recognition Proceeding, and the Scheme of Arrangement) to ensure Mallinckrodt will be able to comply with its obligations under this Agreement.

b. Where the provisions of this Agreement refer or apply to the Chapter 11 Cases, the Bankruptcy Court, and/or the Plan (including the Definitive Documents and any other documentation relating or relevant thereto) or events, circumstances, or procedures in the United States (the "US Process") but do not equally reference or apply to the Examinership Proceeding, the Irish court, the Canadian Recognition Proceeding, the Canadian court, and/or the Scheme of

Arrangement (including the Definitive Documents or any other documentation relating or relevant thereto) or equivalent events, circumstances, or procedures in Ireland or Canada (the "Foreign Processes"), those provisions relating to the US Process shall be deemed to apply or refer equally to the Foreign Processes (and, if necessary, this Agreement will be deemed to include provisions relating to the Foreign Processes which correspond to provisions relating to the US Process) to ensure that the rights and obligations of the United States and the Relator under this Agreement apply equally to the Foreign Processes in the same way as the US Process, to the fullest extent necessary in order to implement the terms, spirit, and intent of this Agreement. Mallinckrodt shall (i) provide the United States with a copy of the Approved Plan or any other plan or reorganization or liquidation for which it intends seek approval from the Bankruptcy Court no later than ten days prior to filing such plan with the Bankruptcy Court, and (ii) obtain approval of the Approved Plan from the United States. The United States shall not withhold approval without a reasonable, good faith basis and will inform Mallinckrodt of the reasons for withholding approval, if any. Mallinckrodt shall have seven (7) days to revise the plan and seek approval of the revised plan from the United States.

c. If the Chapter 11 Cases or the Irish Examinership of Mallinckrodt of Mallinckrodt are converted or dismissed, the United States and the Medicaid Participating States shall have the right to rescind this agreement with the same protections, contemplated in paragraph 19.b., as though Mallinckrodt has committed a Payment Default.

d. The United States may, in its sole discretion, declare that the occurrence of any of the following events is a default of Mallinckrodt's obligations under this Agreement (each "an Event of Default"):

-
- i. the Plan Effective Date does not occur on or before June 30, 2022, or such later date to which the United States may consent (such consent not to be unreasonably withheld);
 - ii. the Bankruptcy Court (or other court of competent jurisdiction) enters an order, (A) directing the appointment of an examiner with expanded powers or a trustee in any of the Chapter 11 Cases, or (B) converting any of the Chapter 11 Cases to cases under chapter 7 of the Bankruptcy Code;
 - iii. the Bankruptcy Court (or other court of competent jurisdiction, including the Irish Court) enters an order, the effect of which would render the Approved Plan incapable of consummation on the terms set forth in this Agreement.
 - iv. the Bankruptcy Court (or other court of competent jurisdiction, including the Irish court) grants relief that is inconsistent with this Agreement;
 - v. issuance by the Bankruptcy Court or any other court of competent jurisdiction, including the Irish court, of any ruling, judgment or order enjoining the consummation of this Agreement or the Approved Plan, or denying approval of this Agreement;
 - vi. (a) the filing of a pleading by Mallinckrodt seeking to withdraw, amend or modify the Approved Plan, any of the Definitive Documents, or any motion to assume or approve this Agreement, which withdrawal, amendment, modification or filing is not consistent with this Agreement in any material respect, or (b) if

Mallinckrodt, files any motion or pleading that is not consistent with this Agreement in any material respect and such motion or pleading has not been withdrawn prior to the earlier of (i) three (3) business days after Mallinckrodt receives written notice from the United States that such motion or pleading is inconsistent with this Agreement, and (ii) the entry of an order of a court approving such motion;

- vii. the Bankruptcy Court enters an order denying confirmation of the Approved Plan; and
- viii. any court of competent jurisdiction has entered a judgment or order declaring this Agreement to be unenforceable.

An Event of Default may be waived by the written consent of the United States.

e. (1) If an Event of Default occurs and has not been waived by written consent of the United States; or (2) if, before the Settlement Amount is paid in full, Mallinckrodt or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Mallinckrodt's debts, or to adjudicate Mallinckrodt as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Mallinckrodt or for all or any substantial part of Mallinckrodt's assets (in each case, other than the Bankruptcy Proceedings contemplated by this Agreement) (collectively a "Future Insolvency Proceeding") or if Mallinckrodt's obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) in a Future Insolvency Proceeding or in any other case, proceeding or action:

- i. the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Mallinckrodt for the claims that would otherwise be covered by the releases provided in Paragraphs 4 and 6 above, including but not limited to, by re-filing the Complaint-in- Intervention in the United States District Court for the District of Massachusetts; *provided*, that any such claims shall be reduced by the amount of any payments received pursuant to this Agreement;
- ii. In the event that the United States rescinds the releases in this Agreement and brings a claim, action, or proceeding against Mallinckrodt for claims that would otherwise be covered by the releases provided in Paragraphs 4 and 6 above, Relator, at his sole option, may rescind his releases in Paragraphs 5 and 9 and shall be entitled to a share of the proceeds of any False Claims Act claim, action, or proceeding brought by the United States, less any payments received pursuant to this Agreement;
- iii. in any Future Insolvency Proceeding in which this Agreement is not assumed and the Settlement Amount is not otherwise paid in full, the United States shall be entitled to, at its option an undisputed, noncontingent, and liquidated claim that is not subject to reconsideration or subordination against Mallinckrodt for either: (A) the then-unpaid balance of the Settlement Amount, or (B) single damages of \$640 million, plus any applicable False Claims Act multiplier and penalties;

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- iv. if any payments are avoided and recovered by Mallinckrodt, a receiver, trustee, custodian, or similar official for Mallinckrodt, Relator shall, within thirty days of written notice from the United States to the undersigned Relator's counsel, return any portions of such payments already paid by the United States to Relator pursuant to Paragraph 2;
 - v. Mallinckrodt shall not argue or otherwise contend in a Future Insolvency Proceeding that the United States' claim, action, or proceeding in respect of the matters covered by this Settlement Agreement is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Mallinckrodt waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, including theories related to the Bankruptcy Proceedings such as discharge, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to Mallinckrodt that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on September 20, 2018; and

- vi. OIG-HHS may exclude Mallinckrodt from participating in all Federal health care programs until Mallinckrodt cures the default and/or pays the unpaid portion of the Settlement Amount, interest due, and collection costs. OIG-HHS will provide written notice of any such exclusion to Mallinckrodt. Mallinckrodt waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion Mallinckrodt wishes to apply for reinstatement, Mallinckrodt must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Mallinckrodt will not be reinstated unless and until the OIG approves such request for reinstatement. The option for exclusion for default as described in this Paragraph is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

f. Mallinckrodt's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547 or 11 U.S.C. § 548(a)(1), and Mallinckrodt shall not argue or otherwise take the position in any Future Insolvency Proceeding or in any other case, proceeding, or action that: (i) Mallinckrodt's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Mallinckrodt; or (iii) the mutual promises, covenants, and obligations set forth herein are not intended to and do not, in fact, represent a reasonably equivalent exchange of value or that such mutual promises, covenants and obligations are intended to hinder, delay, or defraud any entity to which Mallinckrodt was or became indebted to on or after the date of this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

21. In evaluating whether to execute this Agreement, the Parties warrant 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 the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, 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 that is not intended to hinder, delay, or defraud any entity to which Mallinckrodt was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

22. Upon receipt of the First Installment Payment described in Paragraph 1, above, and Exhibit B, attached, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal pursuant to the terms of this Settlement Agreement of all claims against Mallinckrodt pursuant to Rule 41(a)(1). The Joint Stipulation of Dismissal shall be with prejudice as to the United States' and the Relator's claims in the Civil Action against Mallinckrodt as to the Covered Conduct and pursuant to the terms and conditions of this Agreement.

23. Within ten days after the Effective Date of this Agreement, Mallinckrodt will file a motion to hold in abeyance the appeal captioned *Mallinckrodt ARD LLC v. Verma*, No. 20- 5154, in the United States Court of Appeals for the District of Columbia Circuit (the "DC Appeal"). Upon filing of the Joint Stipulation of Dismissal referenced in paragraph 22, Mallinckrodt will file a motion to dismiss the DC Appeal, pursuant to Federal Rule of Appellate Procedure 42(b), with each party to bear its own costs.

24. Except as otherwise provided herein, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

26. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. 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.

27. 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 or Relator from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

28. Nothing herein is intended to, or does, in any manner waive, limit, impair or restrict the ability of the United States to protect and preserve its rights, remedies and interests, including any other claims against Mallinckrodt or other parties, or its full participation in the Bankruptcy Proceedings. Furthermore, nothing in this Agreement shall be construed to prohibit the United States (or Relator with respect to his claim for expenses, attorneys' fees and costs) from appearing as a party-in-interest in any matter to be adjudicated in the Bankruptcy Proceedings so long as any appearance by the United States or Relator and the positions advocated by the United States or Relator in connection therewith are consistent with this Agreement.

29. In the event of any conflict among the terms and provisions in Definitive Documents, on the one hand, and this Agreement, on the other hand, the terms and provisions of this Agreement shall control.

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

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

32. This Agreement is binding on Mallinckrodt's successors, transferees, heirs, and assigns.

33. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

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

35. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 03/07/2022

BY: /s/ Augustine Ripa
AUGUSTINE RIPA
MICHAEL HOFFMAN
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 03/04/2022

BY: /s/ Evan Panich
EVAN PANICH
Assistant United States Attorney
District of Massachusetts

DATED: 02/07/2022

BY: /s/ Lisa M. Re
LISA M. RE
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

MALLINCKRODT ARD, LLC - DEFENDANT

DATED: 03/03/2022

BY: /s/ Mark Casey

Mark Casey
Vice President & General Counsel

DATED: 03/03/2022

BY: /s/ Michele Sartori

WILLIAM KETTLEWELL
MICHELE SARTORI
Hogan Lovells LLP
Counsel for Mallinckrodt ARD, LLC

MALLINCKRODT PLC

DATED: 03/03/2022

BY: /s/ Mark Casey
Mark Casey
EVP, Chief Legal Officer

DATED: 03/03/2022

BY: /s/ Michele Sartori
WILLIAM KETTLEWELL
MICHELE SARTORI
Hogan Lovells LLP
Counsel for Mallinckrodt plc

JAMES LANDOLT – RELATOR

DATED: 2/4/22

BY: /s/ James Landolt

JAMES LANDOLT

DATED: 2/4/2022

BY: /s/ Linda C. Severin

LINDA C. SEVERIN

SUZANNE E. DURRELL

Whistleblower Law Collaborative, LLC

Counsel for James Landolt

EXHIBIT A: CERTAIN DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

- a. “**Approved Plan**” means a plan of reorganization for Mallinckrodt that is consistent in all material respects with this Agreement.
- b. “**Approved Plan Effective Date**” means the date on which the Approved Plan becomes effective in accordance with its terms.
- c. “**Definitive Documents**” means all material agreements, schedules and Bankruptcy Court or other judicial or regulatory orders that are necessary to implement this Settlement Agreement, including the Confirmation Order and the Approved Plan.
- d. “**Scheme of Arrangement**” means the scheme of arrangement based on the Plan to be submitted for approval in the Examinership Proceeding.

Exhibit B – Installment Payment Schedule

Mallinckrodt will pay the Settlement Amount to the United States and the Medicaid Participating States in eight installments as follows:

- a. \$13,483,146.07, plus interest on the full unpaid amount, upon the Approved Plan Effective Date in the Chapter 11 Cases contemplated in recital H of this Agreement, (“First Installment Payment”) with \$7,133,200.78 paid to the United States and \$6,349,945.29 paid to the Medicaid Participating States;
- b. \$13,483,146.07, plus interest on the full unpaid amount, shall be due within one year of the First Installment Payment, with \$7,133,200.78 paid to the United States and \$6,349,945.29 paid to the Medicaid Participating States;
- c. \$17,977,528.09, plus interest on the full unpaid amount, shall be due within two years First Installment Payment, with \$9,510,934.36 paid to the United States and \$8,466,593.73 paid to the Medicaid Participating States;
- d. \$17,977,528.09, plus interest on the full unpaid amount, shall be due within three years of the First Installment Payment, with \$9,510,934.36 paid to the United States and \$8,466,593.73 paid to the Medicaid Participating States;
- e. \$29,213,483.15, plus interest on the full unpaid amount shall be due within four years of the First Installment Payment, with \$15,455,268.34 paid to the United States and \$13,758,214.81 paid to the Medicaid Participating States;
- f. \$29,213,483.15, plus interest on the full unpaid amount shall be due within five years of the First Installment Payment, with \$15,455,268.34 paid to the United States and \$13,758,214.81 paid to the Medicaid Participating States;
- g. \$56,179,775.28, plus interest on the full unpaid amount shall be due within six years of the First Installment Payment, with \$29,721,669.88 paid to the United States and \$26,458,105.40 paid to the Medicaid Participating States;
- h. \$56,179,775.28, plus interest on the full unpaid amount shall be due within seven years of the First Installment Payment, with \$29,721,669.89 paid to the United States and \$26,458,105.39 paid to the Medicaid Participating States.

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among 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”) (collectively, the “United States”), Mallinckrodt plc and Mallinckrodt ARD LLC (f/k/a Questcor Pharmaceuticals, Inc.), debtors and debtors-in-possession acting on behalf of themselves and their estates (collectively, “Mallinckrodt”)¹, and Charles Strunck, Lisa Pratta, and Scott Clark (each a “Relator” and, collectively, the “Relators”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. When a patient obtains a prescription drug covered by Medicare, the patient may be required to make a payment, which may take the form of a “copayment,” “coinsurance,” or “deductible” (collectively “co-pays”). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration – which includes money or any other item of value (such as a co-pay) – to induce Medicare beneficiaries to purchase, or their physicians to prescribe, the companies’ drugs that are reimbursed by Medicare.

B. Mallinckrodt plc is an Irish public limited company. Its subsidiary, Mallinckrodt ARD, LLC (f/k/a Questcor Pharmaceuticals, Inc.), is a California limited liability company with its principal place of business in New Jersey. Mallinckrodt does business as a pharmaceutical manufacturer in the United States and markets H.P. Acthar Gel (“Acthar”) in the United States.

¹ References to Mallinckrodt shall include and encompass any reorganized Mallinckrodt created by the Approved Plan (defined herein) confirmed by the Bankruptcy Court. For the avoidance of doubt: (a) reorganized Mallinckrodt plc and reorganized Mallinckrodt ARD LLC shall be considered successors to Mallinckrodt plc and Mallinckrodt ARD LLC, respectively, and be fully responsible for any liabilities, obligations, or conditions included in this Settlement Agreement; (b) the Approved Plan shall provide for (i) the reorganization and continued corporate existence of Mallinckrodt plc and Mallinckrodt ARD LLC and (ii) the vesting of the assets of Mallinckrodt plc and Mallinckrodt ARD LLC in reorganized Mallinckrodt plc and Mallinckrodt ARD LLC upon the effective date of the confirmed Approved Plan.

C. On January 20, 2012, Charles Strunck and Lisa Pratta filed an action in the United States District Court for the Eastern District of Pennsylvania captioned *United States ex rel. Strunck v. Questcor Pharmaceuticals, Inc.*, Civil Action No. 12-175 (BMS), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Strunck Action”). On June 12, 2017, the Court accepted for filing the Fourth Amended Complaint in the Strunck Action.

D. On April 4, 2013, Scott Clark filed an action in the United States District Court for the Eastern District of Pennsylvania captioned *United States, et al., ex rel. Clark v. Questcor Pharmaceuticals, Inc.*, Civil Action No. 13-cv-01776 (BMS), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Clark Action”).

E. The Strunck and Clark Actions are collectively referred to as the “Civil Actions.” The Civil Actions allege, *inter alia*, that Mallinckrodt provided illegal remuneration to Medicare patients in violation of the Anti-Kickback Statute, in the form of co-pay subsidies for Acthar.

F. The United States intervened in the Civil Actions on March 6, 2019, and filed the United States’ Complaint-in-Intervention on June 4, 2019 (“United States’ Complaint-in-Intervention”). On September 3, 2019, the United States and Mallinckrodt ARD LLC entered into a civil False Claims Act settlement (“2019 FCA Agreement”) to resolve allegations related to twelve Questcor sales representatives for the time period January 1, 2009 to December 31, 2013 (hereinafter, the “Resolved Acthar Claims”). By September 20, 2019, Mallinckrodt made the payment required under the 2019 FCA Agreement concerning the Resolved Acthar Claims and the parties filed a joint stipulation of dismissal and proposed order required by the 2019 FCA Agreement. The court entered the proposed order on September 24, 2019.

G. The United States contends that it has certain civil claims against Mallinckrodt arising from conduct alleged in the United States’ Complaint-in-Intervention in the Civil Actions that were not resolved by the 2019 FCA Agreement. That conduct is referred to below as the “Covered Conduct.”

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

I. The Parties have negotiated this Agreement in good faith and at arm's length and intend the Agreement to be consummated through (a) the voluntary cases under chapter 11 of the Bankruptcy Code (as defined below) (the "Chapter 11 Cases") filed in the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") Case No. 20-12522 (JTD), by Mallinckrodt ARD LLC and certain of its affiliates and subsidiaries on October 12, 2020, (b) the examinership proceeding to be commenced by Mallinckrodt plc under the laws of Ireland (the "Examinership Proceeding"), and (c) the proceedings commenced under Part IV of the Canadian Companies Arrangement Act to recognize in Canada the Chapter 11 Cases and to recognize in Canada certain orders of the Bankruptcy Court (the "Canadian Recognition Proceeding" and, collectively with the Chapter 11 Cases and the Examinership Proceeding, the "Bankruptcy Proceedings").²

J. This Agreement is neither an admission of liability by Mallinckrodt nor a concession by the United States that its claims are not well founded.

In consideration of the mutual promises and obligations of this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree and covenant as follows:

² Capitalized terms not otherwise defined herein shall have the meaning ascribed to them in Exhibit A.

TERMS AND CONDITIONS

1. Mallinckrodt shall pay to the United States \$26,292,134.82, plus interest accruing at an annual rate of 0.6255%, running from September 21, 2020, in eight installments, pursuant to the installment payment schedule described in Exhibit B (the "Settlement Amount"), by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Eastern District of Pennsylvania. The interest described in the foregoing sentence shall accrue on the outstanding balance of the remaining installment payments and all then-accrued interest shall be payable in cash to the United States contemporaneously with each installment payment as set forth on Exhibit B. The entire Settlement Amount shall be considered restitution. The entire balance of the Settlement Amount, or any portion thereof, may be prepaid without premium or penalty. If Mallinckrodt elects to prepay the Settlement Amount, or any portion thereof, interest shall accrue through the date on which Mallinckrodt makes said prepayment. If Mallinckrodt is sold, merged, or transferred, or all or substantially all of the assets of Mallinckrodt (on a consolidated basis) are sold, merged, or transferred into another non-affiliated entity, Mallinckrodt shall promptly notify the United States, and all remaining payments owed pursuant to the Settlement Agreement shall be accelerated and become immediately due and payable upon consummation of such transaction.

2. Conditioned upon the United States receiving the Settlement Amount installment payments from Mallinckrodt, the United States agrees that it shall pay by electronic funds transfer to Relators Strunck and Pratta (collectively) nineteen (19) % of each such payment received under the Agreement ("Relator's Share") as soon as feasible after receipt of the payment.

3. Mallinckrodt has agreed to pay Relators' Strunck and Pratta's reasonable expenses, attorneys' fees and costs, as contemplated by 31 U.S.C. § 3730(d) and comparable provisions of any applicable state statutes and will do so subject to terms set forth in a separate agreement that Mallinckrodt and Relators Strunck and Pratta will enter into contemporaneously with this agreement.

4. Subject to the exceptions in Paragraph 7 (concerning reserved claims) below, and subject to Paragraph 10 (concerning disclosure of assets), and subject to Paragraphs 19 and 20, below (concerning bankruptcy), and upon the United States' receipt of the Settlement Amount, the United States releases Mallinckrodt, together with its current or former parent corporations; subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (the "Mallinckrodt Releasees"), from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 CFR Part 0; Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 7 (concerning reserved claims) below, and subject to Paragraph 10 (concerning disclosure of assets) and subject to Paragraphs 19 and 20, below (concerning bankruptcy), and upon the United States' receipt of the Settlement Amount, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release the Mallinckrodt Releasees from any civil monetary claim the Relators have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33.

6. In consideration of the obligations of Mallinckrodt in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Mallinckrodt plc and upon the United States' receipt of full payment of the Settlement Amount, plus interest due under Paragraph 1, the OIG-HHS shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Mallinckrodt under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 7 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Mallinckrodt from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in paragraphs 4 and 6 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- 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 exclusion from Federal health care 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; and
- f. Any liability of individuals.

8. Relators and their 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 Strunck and Pratta's receipt of Relator's Share, Relators and their 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 Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Actions.

9. Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, fully and finally release the Mallinckrodt Releasees, and their officers, agents, and employees, from any liability (including attorneys' fees, costs, and expenses of every kind and however denominated, outside of those contemplated in a separate agreement that Mallinckrodt and Relators Strunck and Pratta will enter into contemporaneously with this agreement) that Relators have asserted, could have asserted, or may assert in the future against Mallinckrodt related to the Civil Actions or the Covered Conduct and Relators' investigation or prosecution thereof, or any liability to Relators arising from the filing of the Civil Actions, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs. Notwithstanding the foregoing, this release does not include Relator Clark's separate claims against Mallinckrodt for retaliation in violation of 31 U.S.C. § 3730(h) and Oregon law, currently pending in the Chapter 11 Cases.

10. Mallinckrodt has provided sworn financial disclosures and supporting documents ("Financial Disclosures") to the United States, and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Mallinckrodt warrants that the Financial Disclosures are complete, accurate, and current as of the date provided. If the United States learns of asset(s) in which Mallinckrodt had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Mallinckrodt's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Mallinckrodt on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by \$12.5 million or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct in the United States District Court for the Eastern District of Pennsylvania, or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Mallinckrodt's previously undisclosed assets. Mallinckrodt agrees not to contest any collection action undertaken by the United States pursuant to this provision, and agrees that it will immediately pay the United States (i) a ten-percent (10%) surcharge of the amount collected in the collection action, or (ii) the United States reasonable attorneys' fees and expenses incurred in such an action, in each case, to the extent allowed by 28 U.S.C. § 3011.

In the event that the United States, pursuant to this paragraph, rescinds this Agreement, Mallinckrodt waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, including theories related to the Bankruptcy Proceedings such as discharge, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to Mallinckrodt that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on January 20, 2012.

11. Mallinckrodt waives and shall not assert any defenses Mallinckrodt 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.

12. Mallinckrodt fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that Mallinckrodt 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 or the United States' investigation or prosecution thereof.

13. Mallinckrodt fully and finally releases the Relators and their respective heirs, successors, attorneys, agents, and assigns from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Mallinckrodt has asserted, could have asserted, or may assert in the future against Relators related to the Civil Actions or the Covered Conduct and Relators' investigation or prosecution thereof. Notwithstanding the foregoing, this release does not include any claims Mallinckrodt may have against Relator Clark relating to his separate claims against Mallinckrodt for retaliation in violation of 31 U.S.C. § 3730(h) and Oregon law, currently pending in the Chapter 11 Cases.

14. The Settlement 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, carrier or any state payer) related to the Covered Conduct; and Mallinckrodt agrees not to resubmit to any Medicare contractor 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.

15. Mallinckrodt 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-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Mallinckrodt, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audits and investigations of the matters covered by this Agreement;
- (3) Mallinckrodt's investigation, defense, and corrective actions undertaken in response to the United States' audits and investigations in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment Mallinckrodt makes to the United States pursuant to this Agreement and any payments that Mallinckrodt may make to Relators, including for costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to OIG-HHS,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 15.a.6 that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Mallinckrodt.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Mallinckrodt, and Mallinckrodt 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 Mallinckrodt or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Mallinckrodt further agrees that within 120 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, 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 Mallinckrodt 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. Mallinckrodt agrees that the United States, at a minimum, shall be entitled to recoup from Mallinckrodt 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 Mallinckrodt or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Mallinckrodt 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 Mallinckrodt's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. Mallinckrodt agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Mallinckrodt shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its 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. Mallinckrodt further agrees to furnish to the United States, upon 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.

17. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 18 (waiver for beneficiaries paragraph), below.

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

19. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Mallinckrodt's financial condition as reflected in the Financial Statements referenced in Paragraph 10.

a. In the event that Mallinckrodt fails to pay any portion of the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above, Mallinckrodt shall be in default of Mallinckrodt's payment obligations ("Payment Default"). The United States will provide a written Notice of Payment Default, and Mallinckrodt shall have an opportunity to cure such Payment Default within seven (7) business days from the date of receipt of the Notice of Payment Default by making the payment due under the payment schedule and paying any additional interest accruing under the Agreement up to the date of payment. Notice of Payment Default will be delivered to Mallinckrodt, or to such other representative as Mallinckrodt shall designate in advance in writing. If Mallinckrodt fails to cure the Payment Default within seven (7) business days of receiving the Notice of Payment Default and in the absence of an agreement with the United States to a modified payment schedule ("Uncured Payment Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Payment Default, on the remaining unpaid total (principal and interest balance).

b. In the event of an Uncured Payment Default, Mallinckrodt agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Actions, except with respect to the Resolved Acthar Claims, reinstate the Complaint-in-Intervention or bring any civil and/or administrative claim, action, or proceeding against Mallinckrodt in the United States District Court for the Eastern District of Pennsylvania for the claims that would otherwise be covered by the releases provided in Paragraphs 4 and 6 above, with any recovery reduced by the amount of any payments previously made by Mallinckrodt to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Actions, except with respect to the Resolved Acthar Claims; (iii) offset the remaining unpaid balance from any amounts due and owing to Mallinckrodt and/or affiliated companies by any department, agency, or agent of the United States at the time of Payment Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Payment Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Mallinckrodt agrees immediately to pay the United States (i) a ten-percent (10%) surcharge of the amount collected in the collection action, or (ii) the United States reasonable attorneys' fees and expenses incurred in such an action, in each case, to the extent allowed by 28 U.S.C. § 3011. In the event that the United States opts to rescind this Agreement pursuant to this Paragraph, Mallinckrodt waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, including theories related to the Bankruptcy Proceedings such as discharge, to any civil or administrative claims that are (i) filed by the United States against Mallinckrodt within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on January 20, 2012. Mallinckrodt agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

c. In the event of an Uncured Payment Default, OIG-HHS may exclude Mallinckrodt from participating in all Federal health care programs until Mallinckrodt pays the Settlement Amount, with interest, and reasonable costs as set forth above (“Exclusion for Default”). OIG-HHS will provide written notice of any such exclusion to Mallinckrodt. Mallinckrodt waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Mallinckrodt wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Mallinckrodt will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Payment Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

20. In exchange for valuable consideration provided in this Agreement, Mallinckrodt agrees to the following:

a. The Definitive Documents related to the Bankruptcy Proceedings shall be consistent in all material respects with this Agreement and shall not in any manner, by their terms, contain any provisions that amend, modify, supplement, supersede or conflict with, any of the provisions of this Agreement in any manner that is materially adverse to, or materially prejudicial to the United States, in each case, with respect to its rights under this Settlement Agreement. The Definitive Documents shall be in form and substance reasonably acceptable to the United States. In addition, Mallinckrodt shall take such actions as may be reasonably necessary or appropriate in the Bankruptcy Proceedings (including, without limitation, assuming its obligations under this Agreement pursuant to the Approved Plan, the Canadian Recognition Proceeding, and the Scheme of Arrangement) to ensure Mallinckrodt will be able to comply with its obligations under this Agreement.

b. Where the provisions of this Agreement refer or apply to the Chapter 11 Cases, the Bankruptcy Court, and/or the Plan (including the Definitive Documents and any other documentation relating or relevant thereto) or events, circumstances, or procedures in the United States (the "US Process") but do not equally reference or apply to the Examinership Proceeding, the Irish court, the Canadian Recognition Proceeding, the Canadian court, and/or the Scheme of Arrangement (including the Definitive Documents or any other documentation relating or relevant thereto) or equivalent events, circumstances, or procedures in Ireland or Canada (the "Foreign Processes"), those provisions relating to the US Process shall be deemed to apply or refer equally to the Foreign Processes (and, if necessary, this Agreement will be deemed to include provisions relating to the Foreign Processes which correspond to provisions relating to the US Process) to ensure that the rights and obligations of the United States under this Agreement apply equally to the Foreign Processes in the same way as the US Process, to the fullest extent necessary in order to implement the terms, spirit, and intent of this Agreement. Mallinckrodt shall (i) provide the United States with a copy of the Approved Plan or any other plan or reorganization or liquidation for which it intends seek approval from the Bankruptcy Court no later than ten days prior to filing such plan with the Bankruptcy Court, and (ii) obtain approval of the Approved Plan from the United States. The United States shall not withhold approval without a reasonable, good faith basis and will inform Mallinckrodt of the reasons for withholding approval, if any. Mallinckrodt shall have seven (7) days to revise the plan and seek approval of the revised plan from the United States.

c. If the Chapter 11 Cases or the Irish Examinership of Mallinckrodt are converted or dismissed, the United States shall have the right to rescind this agreement with the same protections, contemplated in paragraph 19.b., as though Mallinckrodt has committed a Payment Default.

d. The United States may, in its sole discretion, declare that the occurrence of any of the following events is a default of Mallinckrodt's obligations under this Agreement (each "an Event of Default"):

- i. the Plan Effective Date does not occur on or before June 30, 2022, or such later date to which the United States may consent (such consent not to be unreasonably withheld);
- ii. the Bankruptcy Court (or other court of competent jurisdiction) enters an order, (A) directing the appointment of an examiner with expanded powers or a trustee in any of the Chapter 11 Cases, or (B) converting any of the Chapter 11 Cases to cases under chapter 7 of the Bankruptcy Code;
- iii. the Bankruptcy Court (or other court of competent jurisdiction, including the Irish Court) enters an order, the effect of which would render the Approved Plan incapable of consummation on the terms set forth in this Agreement.
- iv. the Bankruptcy Court (or other court of competent jurisdiction, including the Irish court) grants relief that is inconsistent with this Agreement;

- v. issuance by the Bankruptcy Court or any other court of competent jurisdiction, including the Irish court, of any ruling, judgment or order enjoining the consummation of this Agreement or the Approved Plan, or denying approval of this Agreement;
- vi. (a) the filing of a pleading by Mallinckrodt seeking to withdraw, amend or modify the Approved Plan, any of the Definitive Documents, or any motion to assume or approve this Agreement, which withdrawal, amendment, modification or filing is not consistent with this Agreement in any material respect, or (b) if Mallinckrodt, files any motion or pleading that is not consistent with this Agreement in any material respect and such motion or pleading has not been withdrawn prior to the earlier of (i) three (3) business days after Mallinckrodt receives written notice from the United States that such motion or pleading is inconsistent with this Agreement, and (ii) the entry of an order of a court approving such motion;
- vii. the Bankruptcy Court enters an order denying confirmation of the Approved Plan; and
- viii. any court of competent jurisdiction has entered a judgment or order declaring this Agreement to be unenforceable.

An Event of Default may be waived by the written consent of the United States.

e. (1) If an Event of Default occurs and has not been waived by written consent of the United States; or (2) if, before the Settlement Amount is paid in full, Mallinckrodt or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Mallinckrodt's debts, or to adjudicate Mallinckrodt as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Mallinckrodt or for all or any substantial part of Mallinckrodt's assets (in each case, other than the Bankruptcy Proceedings contemplated by this Agreement) (collectively a "Future Insolvency Proceeding") or if Mallinckrodt's obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) in a Future Insolvency Proceeding or in any other case, proceeding or action:

- i. the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Mallinckrodt for the claims that would otherwise be covered by the releases provided in Paragraphs 4 and 6 above, including but not limited to, by re-filing the Complaint-in-Intervention in the United States District Court for the Eastern District of Pennsylvania; *provided*, that any such claims shall be reduced by the amount of any payments received pursuant to this Agreement;
- ii. in any Future Insolvency Proceeding in which this Agreement is not assumed and the Settlement Amount is not otherwise paid in full, the United States shall be entitled to, at its option an undisputed, noncontingent, and liquidated claim that is not subject to reconsideration or subordination against Mallinckrodt for either: (A) the then-unpaid balance of the Settlement Amount, or (B) single damages of \$72 million, plus any applicable False Claims Act multiplier and penalties;

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- iii. if any payments are avoided and recovered by Mallinckrodt, a receiver, trustee, custodian, or similar official for Mallinckrodt, Relators shall, within thirty days of written notice from the United States to the undersigned Relators' counsel, return any portions of such payments already paid by the United States to Relators pursuant to Paragraph 2;
 - iv. Mallinckrodt shall not argue or otherwise contend in a Future Insolvency Proceeding that the United States' claim, action, or proceeding in respect of the matters covered by this Settlement Agreement is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Mallinckrodt waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, including theories related to the Bankruptcy Proceedings such as discharge, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to Mallinckrodt that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on January 20, 2012; and

- v. OIG-HHS may exclude Mallinckrodt from participating in all Federal health care programs until Mallinckrodt cures the default and/or pays the unpaid portion of the Settlement Amount, interest due, and collection costs. OIG-HHS will provide written notice of any such exclusion to Mallinckrodt. Mallinckrodt waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion Mallinckrodt wishes to apply for reinstatement, Mallinckrodt must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Mallinckrodt will not be reinstated unless and until the OIG approves such request for reinstatement. The option for exclusion for default as described in this Paragraph is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

f. Mallinckrodt's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547 or 11 U.S.C. § 548(a)(1), and Mallinckrodt shall not argue or otherwise take the position in any Future Insolvency Proceeding or in any other case, proceeding, or action that: (i) Mallinckrodt's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Mallinckrodt; or (iii) the mutual promises, covenants, and obligations set forth herein are not intended to and do not, in fact, represent a reasonably equivalent exchange of value or that such mutual promises, covenants and obligations are intended to hinder, delay, or defraud any entity to which Mallinckrodt was or became indebted to on or after the date of this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

21. In evaluating whether to execute this Agreement, the Parties warrant 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 the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, 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 that is not intended to hinder, delay, or defraud any entity to which Mallinckrodt was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

22. Upon receipt of the First Installment Payment described in Paragraph 1, above, and Exhibit B, attached, the Parties shall promptly sign and file in the Civil Actions a Joint Stipulation of Dismissal pursuant to the terms of this Settlement Agreement of all claims against Mallinckrodt pursuant to Rule 41(a)(1). The Joint Stipulation of Dismissal shall be with prejudice as to the United States' and the Relators claims in the Civil Actions against Mallinckrodt as to the Covered Conduct and pursuant to the terms and conditions of this Agreement.

23. Except as otherwise provided herein, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

25. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of Pennsylvania. 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.

26. 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.

27. Nothing herein is intended to, or does, in any manner waive, limit, impair or restrict the ability of the United States to protect and preserve its rights, remedies and interests, including any other claims against Mallinckrodt or other parties, or its full participation in the Bankruptcy Proceedings. Furthermore, nothing in this Agreement shall be construed to prohibit the United States from appearing as a party-in-interest in any matter to be adjudicated in the Bankruptcy Proceedings so long as any appearance by the United States and the positions advocated by the United States in connection therewith are consistent with this Agreement.

28. In the event of any conflict among the terms and provisions in Definitive Documents, on the one hand, and this Agreement, on the other hand, the terms and provisions of this Agreement shall control.

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.

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31. This Agreement is binding on Mallinckrodt's successors, transferees, heirs, and assigns.
 32. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.
 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 date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 3/7/2022

BY: /s/ Jennifer Arbittier Williams
JENNIFER ARBITTIER WILLIAMS
United States Attorney
Eastern District of Pennsylvania

/s/ Gregory B. David
GREGORY B. DAVID
Chief, Civil Division

/s/ Charlene K. Fullmer
CHARLENE K. FULLMER
Deputy Chief, Civil Division

/s/ Colin Cherico
COLIN CHERICO
PAUL KOOB
MATTHEW HOWATT
Assistant United States Attorneys

DATED: 03/07/2022

BY: /s/ Augustine Ripa
AUGUSTINE RIPA
DANIEL SCHIFFER
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
LISA M. RE
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

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

AUGUSTINE RIPA
DANIEL SCHIFFER
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____

WILLIAM M. McSWAIN
United States Attorney
Eastern District of Pennsylvania

GREGORY B. DAVID
Chief, Civil Division

CHARLENE K. FULLMER
Deputy Chief, Civil Division

COLIN CHERICO
PAUL KOOB
MATTHEW HOWATT
Assistant United States Attorneys

DATED: 02/07/2022

BY: /s/ Lisa M. Re _____

LISA M. RE
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

MALLINCKRODT ARD, LLC - DEFENDANT

DATED: 03/03/2022

BY: /s/ Mark Casey

MARK CASEY

Executive Vice President & Chief Legal Officer

DATED: March 3, 2022

BY: /s/ Bradley Klein

BRADLEY KLEIN

AVIA DUNN

Skadden Arps Slate Meagher & Flom LLP

Counsel for Mallinckrodt ARD, LLC

MALLINCKRODT PLC

DATED: 03/03/2022

BY: /s/ Mark Casey

MARK CASEY

Executive Vice President & Chief Legal Officer

DATED: March 3, 2022

BY: /s/ Bradley A. Klein

BRADLEY KLEIN

AVIA DUNN

Skadden Arps Slate Meagher & Flom LLP

Counsel for Mallinckrodt PLC

CHARLES STRUNCK – RELATOR

DATED: 2/7/2022

BY: /s/ Charles Strunck
CHARLES STRUNCK

DATED: 2/7/2022

BY: /s/ Ross Begelman
ROSS BEGELMAN
Begelman & Orlow, P.C.
Counsel for Strunck

LISA PRATTA – RELATOR

DATED: 2/4/2022

BY: /s/ Lisa Pratta

LISA PRATTA

DATED: 2/4/2022

BY: /s/ Ross Begelman

ROSS BEGELMAN

Begelman & Orlow, P.C.

Counsel for Pratta

SCOTT CLARK – RELATOR

DATED: 3-3-22

BY: /s/ Andrew Scott Clark
SCOTT CLARK

DATED: 3/3/22

BY: /s/ Brian J. McCormick, Jr.
BRIAN J. McCORMICK, Jr.
Ross Feller Casey, LLP
Counsel for Clark

DATED: 3/3/2022

BY: /s/ Jennifer J. Middleton
JENNIFER J. MIDDLETON
Johnson Johnson Lucas & Middleton, PC
Counsel for Clark

EXHIBIT A: CERTAIN DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

- a. “**Approved Plan**” means a plan of reorganization for Mallinckrodt that is consistent in all material respects with this Agreement.
- b. “**Approved Plan Effective Date**” means the date on which the Approved Plan becomes effective in accordance with its terms.
- c. “**Definitive Documents**” means all material agreements, schedules and Bankruptcy Court or other judicial or regulatory orders that are necessary to implement this Settlement Agreement, including the Confirmation Order and the Approved Plan.
- d. “**Scheme of Arrangement**” means the scheme of arrangement based on the Plan to be submitted for approval in the Examinership Proceeding.

Exhibit B – Installment Payment Schedule

Mallinckrodt will pay the Settlement Amount to the United States in eight installments as follows:

- a. \$1,516,853.93, plus interest on the full unpaid amount, upon the Approved Plan Effective Date in the Chapter 11 Cases contemplated in recital I of this Agreement (“First Installment Payment”);
- b. \$1,516,853.93, plus interest on the full unpaid amount, shall be due within one year of the First Installment Payment;
- c. \$2,022,471.91, plus interest on the full unpaid amount, shall be due within two years of the First Installment Payment;
- d. \$2,022,471.91, plus interest on the full unpaid amount, shall be due within three years of the First Installment Payment;
- e. \$3,286,516.85, plus interest on the full unpaid amount shall be due within four years of the First Installment Payment;
- f. \$3,286,516.85, plus interest on the full unpaid amount shall be due within five years of the First Installment Payment;
- g. \$6,320,224.72, plus interest on the full unpaid amount shall be due within six years of the First Installment Payment;
- h. \$6,320,224.72, plus interest on the full unpaid amount shall be due within seven years of the First Installment Payment.