UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11256 / November 30, 2023

SECURITIES EXCHANGE ACT OF 1934
Release No. 99058 / November 30, 2023

AAE Release No. 4476 / November 30, 2023

ADMINISTRATIVE PROCEEDING
File No. 3-21806

In the Matter of **MALLINCKRODT PLC** **Respondent.**	**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF THE EXCHANGE ACT 0F 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER**

I.

The Securities and Exchange Commission ("Commission") deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 ("Securities Act") and Section 21C of the Exchange Act of 1934 ("Exchange Act"), against Mallinckrodt plc ("Mallinckrodt" or "Respondent").

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the "Offer") which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-And-Desist Proceedings Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Making Findings, and Imposing a Cease-And-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds[1] that:

Summary

1. This matter concerns failures by Mallinckrodt, a publicly traded pharmaceutical company during the relevant time period, to properly disclose in its periodic filings with the Commission a material loss contingency stemming from a claim by the Centers for Medicare and Medicaid Services ("CMS") that Mallinckrodt had been overcharging Medicaid for the company's flagship drug, Acthar Gel ("Acthar"). By January 2019, Mallinckrodt's potential liability for this claim had grown to more than $500 million. Mallinckrodt failed to disclose in its periodic filings this potential liability and relatedly that the issue could reduce its future net sales of Acthar, Mallinckrodt's most important product during the relevant time period, by approximately $100 million a year.

2. In May 2019, when Mallinckrodt first disclosed its dispute with CMS in conjunction with filing a lawsuit against the agency, the company's stock price dropped approximately 25%. In June 2020, after losing its lawsuit against CMS at the trial court and while its appeal was pending, Mallinckrodt recorded a $640 million liability.

3. Under the federal securities laws and Generally Accepted Accounting Principles ("GAAP"), a public company is required to disclose material loss contingencies that are reasonably possible, and trends or uncertainties that are reasonably likely to affect future net sales. By no later than February 2019, Mallinckrodt had a material loss contingency in connection with CMS's claim that was reasonably possible. This loss contingency and the related potential reduction in future net sales of Acthar should have been, but were not, disclosed in Mallinckrodt's annual report filed on Form 10-K on February 26, 2019 and the company's quarterly report filed on Form 10-Q on May 7, 2019. Additionally, Mallinckrodt did not adequately disclose in these periodic filings a False Claim Act investigation by the United States Attorney's Office for the District of Massachusetts ("USAO for D. Mass") related to this matter.

4. As a result of the conduct described herein, Mallinckrodt violated the antifraud provisions of Securities Act Sections 17(a)(2) and (3); the reporting provisions of Exchange Act Section 13(a) and Rules 12b-20, 13a-1, and 13a-13 thereunder; the books and records provisions of Exchange Act Section 13(b)(2)(A), the internal accounting control provisions of Exchange Act Section 13(b)(2)(B); and the disclosure controls and procedures requirements of Exchange Act Rule 13a-15(a).

Respondent

5. Mallinckrodt is a pharmaceutical company incorporated in Ireland and headquartered in Dublin, Ireland. It has executive offices in Hazelwood, Missouri and Bridgewater, New Jersey. During the relevant time period, Mallinckrodt's securities traded on the New York Stock Exchange and were registered under Section 12(b) of the Exchange Act. The

[1] The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

company filed for Chapter 11 bankruptcy protection on October 12, 2020. On June 16, 2022, the company's Chapter 11 plan became effective and it emerged from bankruptcy protection. *See In re Mallinckrodt plc*, No. 20-12522 (Bankr. D. Del.). On August 28, 2023, Respondent filed again for Chapter 11 bankruptcy protection. *See In re Mallinckrodt plc*, No. 23-11258 (Bankr. D. Del.). Respondent's second Chapter 11 plan was confirmed on October 10, 2023.

FACTS

Background

6. Acthar is a drug used to treat a number of rare autoimmune diseases. It was Mallinckrodt's most important product, generating nearly $6 billion in net sales between 2014 and 2019 and comprising approximately one-third of the company's annual net sales in 2017, 2018, and 2019.

7. Approximately 10% of Acthar's sales were to Medicaid patients through the Medicaid Drug Rebate Program ("MDRP"), which is administered and regulated by the CMS. To ensure that state Medicaid programs generally pay the lowest prices for drugs, the MDRP requires pharmaceutical manufacturers to rebate back to state Medicaid programs a certain percentage of each sale of any drug sold to a Medicaid patient. The rebate rate is calculated according to a formula set by statute.

8. In 2012, Mallinckrodt's predecessor, Questcor, Inc. ("Questcor"), requested CMS to permit a certain change to the calculation of the rebate for Acthar in the MDRP in order to lower the rebates Questcor paid to state Medicaid programs for sales of Acthar. Based on representations by Questcor regarding a recent approval by the Food and Drug Administration ("FDA") in 2010 for a new indication for Acthar, CMS permitted the change by two written letters in 2012, which took effect the following year. This change significantly lowered the Medicaid rebates paid on sales of Acthar in the MDRP, which increased annual net sales of Acthar by approximately $90 to $100 million.

9. Mallinckrodt acquired Questcor in 2014.

CMS Notifies Mallinckrodt that Basis for Lowered Rebate Rate for Acthar is Incorrect

10. In April 2016, CMS notified Mallinckrodt that the basis for the lowered rebate rate for Acthar was incorrect. Under the contract pharmaceutical manufacturers sign with CMS to participate in the MDRP, manufacturers are generally required to correct past rebate underpayments when a rebate calculation is corrected. Accordingly, correcting the rebate calculation in 2016 would have created an approximate $250 million liability for Mallinckrodt for the company's past three years of rebate underpayments. It also would have reduced future net sales of Acthar by approximately $90 to $100 million annually.

11. Mallinckrodt did not correct its rebate calculation as requested by CMS. In four emails exchanged in 2016 and two in 2017, Mallinckrodt disputed the issue with CMS. During this time Mallinckrodt did not disclose to investors that CMS had requested that the company revert to the original rebate rate or that the company was disputing the request on the basis of 2012 approval letters CMS sent to Questcor.

12. In November 2018, CMS sent a letter to Mallinckrodt directing it to correct the MDRP rebate rate for Acthar. It stated that it intended to mark Acthar as "out of compliance" in the MDRP—preventing further sales of Acthar to Medicaid patients—unless the company complied within 30 days. CMS also stated that it may also consider referring the matter to the Department of Justice and the Department of Health and Human Services ("HHS"), Office of the Inspector General. By this time, reverting to the original rebate rate would have created a liability of more than $500 million for past underpayments and reduced the company's future annual net sales for Acthar by approximately $100 million. Mallinckrodt asked CMS for a meeting and to refrain from taking action until after the meeting. CMS agreed and the meeting eventually occurred on March 7, 2019.

13. In the meantime, in January 2019, the USAO for D. Mass issued to Mallinckrodt a civil investigative demand ("CID") under the False Claims Act ("FCA"), requesting, among other things, documents related to the reset of the Acthar rebate rate in 2012, Mallinckrodt's calculation of Acthar rebates in the MDRP, and communications with the government about the rebate rate ("FCA Investigation").

Mallinckrodt's 2018 Form 10-K Contained Material Misstatements

14. Mallinckrodt's 2018 annual report filed on Form 10-K on February 26, 2019, contained material misstatements and omissions. The company did not disclose the material loss contingency stemming from CMS's claim that Mallinckrodt was underpaying Medicaid rebates on sales of Acthar. Under GAAP, Accounting Standards Codification ("ASC") Subtopic 450-20, *Loss Contingencies* ("ASC 450-20") requires disclosure of material loss contingencies that are reasonably possible. A loss contingency is reasonably possible when the chance of an event occurring is more than remote but less than likely. When Mallinckrodt filed its 2018 Form 10-K, it was reasonably possible that the company would incur a material liability for underpaying Medicaid rebates on sales of Acthar.

15. The company also failed to disclose in its Form 10-K the possible material reduction in future Acthar net sales—of approximately $100 million per year—if the company were required to revert to the original rebate rate as instructed by CMS. Reg. S-K Item 303(b)(2)(ii)[2] requires disclosure of "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material … unfavorable impact on net sales … ." Mallinckrodt should have disclosed in its 2018 Form 10-K the Acthar rebate issue and its potential material impact on future net sales of Acthar.

16. The company's 2018 Form 10-K contained other related material misstatements. The Form 10-K included annual net sales for Acthar, but did not state that the sales figures were possibly overstated by approximately $100 million per year. And in a risk disclosure relating to its participation in the MDRP and other government-payer programs, Mallinckrodt stated that the government "may take a position to the contrary" to Mallinckrodt regarding "how to properly calculate and report payments," which could lead the government to impose penalties and other

[2] During the relevant time period, this requirement was codified at Reg. S-K Item 303(a)(3)(iii). Following amendment to the rule in 2021, the requirement was recodified at Reg. S-K Item 303(b)(2)(ii). *See Management's Discussion and Analysis, Selected Financial Data, and Supplementary Financial Information*, SEC Release No. 33-10890, 86 Fed. Reg. 2080–2134, 2021 WL 75951 (Jan. 11, 2021).

financial consequences. This statement was materially misleading because at the time the risk was not merely hypothetical: CMS had in fact already had taken such a position on the Medicaid rebate rate for Acthar.

17. The company's disclosure in the Form 10-K regarding the FCA Investigation was also inadequate. It stated: "In January 2019, the Company received a CID from the U.S. Attorney's Office for the District of Massachusetts for documents related to the Company's participation in the Medicaid Drug Rebate Program. The Company is in the process of responding to this demand for documents, and intends to cooperate with the investigation." This disclosure was materially misleading because it omitted the following material facts about the investigation: that it was a FCA investigation, that it concerned the company's most important product Acthar, and that it related to the potential underpayment of hundreds of millions of dollars in Medicaid rebates on Acthar sales.

Mallinckrodt's First Quarter 2019 Form 10-Q Contained Material Misstatements

18. Mallinckrodt and CMS had a meeting on March 7, 2019, regarding the Acthar rebate rate. CMS informed Mallinckrodt that its position remained the same—that Mallinckrodt had been underpaying Medicaid rebates for Acthar and that it needed to correct the rebate rate for Acthar in the MDRP system. On March 11, 2019, Mallinckrodt requested that CMS refrain from taking enforcement action until Mallinckrodt could present its concerns to the CMS Deputy Administrator and the Office of the General Counsel for HHS. On March 27, 2019, the General Counsel of HHS informed Mallinckrodt that CMS had already made a decision and that a meeting with him would not be productive.

19. By no later than March 2019, Mallinckrodt was preparing to potentially file a lawsuit against CMS in connection with the Acthar rebate issue in the event the dispute was not resolved. In April, Mallinckrodt sent a letter to CMS and the General Counsel of HHS to "seek to engage" on a "potential middle ground" resolution. Mallinckrodt proposed to revert to the original rebate rate prospectively, which would have reduced the company's future net sales of Acthar by approximately $100 million annually, and CMS would acknowledge that Mallinckrodt's past use of the post-2012 rebate calculation was appropriate. This would have resulted in the government foregoing any claims to more than $500 million in past rebate underpayments. On April 29, 2019, the Office of the General Counsel of HHS informed Mallinckrodt that its position remained the same and that it was not considering the company's proposal.

20. As with its 2018 Form 10-K, Mallinckrodt's 2019 first quarter report, filed on Form 10-Q on May 7, 2019, also contained similar material misstatements and omissions relating to its potential underpayment of Medicaid rebates. The company did not disclose the material loss contingency, as required by GAAP, or disclose the potential material impact to the company's future net sales, as required by Reg. S-K Item 303. The Form 10-Q also included the same misleading disclosure regarding the related False Claim Act investigation.

21. On May 10, 2019, CMS sent Mallinckrodt another letter, later determined to be CMS's final decision, directing the company to correct the rebate rate for Acthar in the MDRP. CMS gave Mallinckrodt 14 days to comply with the request. CMS also rejected the proposal in Mallinckrodt's April 2019 letter.

22. On May 21, 2019, the company filed a Form 8-K disclosing the Acthar rebate dispute and that it had filed a lawsuit seeking to prevent CMS from removing Acthar from the MDRP or changing its rebate calculation. Mallinckrodt also announced that its former guidance that it would achieve at least $1 billion in net sales for Acthar in 2019 could no longer be relied upon. This was the first public disclosure that Mallinckrodt had potentially underpaid Medicaid rebates for Acthar by more than $500 million and that there could be a material reduction in its future net sales of Acthar. The company's stock price dropped approximately 25% following this announcement.

Subsequent Events

23. In March 2020, the USAO for D. Mass unsealed a complaint against Mallinckrodt under the FCA, alleging that Mallinckrodt's predecessor Questcor, had violated the FCA by misleading CMS in 2012 to obtain the new and incorrect MDRP rebate rate, and that Mallinckrodt continued to violate the FCA when it knowingly continued to pay that rebate rate even after CMS notified Mallinckrodt in April 2016 that it was incorrect. The company's stock dropped 26% following this disclosure.

24. Later in March 2020, in the company's litigation against CMS, the district court granted the government's motion for summary judgment, ruling that Mallinckrodt was required to revert to the original rebate rate and to pay more than $600 million to correct its past rebate underpayments. *See Mallinckrodt ARD LLC v. Verma*, 444 F. Supp. 3d 150 (D.D.C. 2020). After the court of appeals subsequently denied the company's request for a stay pending its appeal, Mallinckrodt accrued the more than $600 million liability in its books and records on June 15, 2020. In its following quarterly report filed on Form 10-Q on August 4, 2020, Mallinckrodt included a going concern disclosure, stating that the CMS liability, coupled with significant liability related to the opioid crisis and other matters, "raised substantial doubt about the Company's ability to continue as a going concern." Mallinckrodt subsequently filed for Chapter 11 bankruptcy protection in October 2020. As part of its reorganization plan approved on March 2, 2022, *see In re Mallinckrodt plc*, No. 20-12522 (Bankr. D. Del.), Mallinckrodt agreed to pay $234.7 million to settle both the FCA lawsuit and any other claims that states or the federal government may have had related to Mallinckrodt's underpayment of Medicaid rebates for Acthar.

Mallinckrodt Offered Securities During this Time Period

25. During the relevant time period, Mallinckrodt was offering securities to its employees through an employee stock purchase program pursuant to Forms S-8 filed on May 4, 2016 and March 12, 2019, including restricted stock units granted in 2019.

Mallinckrodt Lacked Sufficient Internal Accounting Controls and Failed to Maintain Disclosure Controls and Procedures

26. During the relevant time period, Mallinckrodt did not have sufficient internal accounting controls and failed to maintain disclosure controls and procedures for loss contingencies. The company's loss contingencies policy, which implemented ASC 450, required the company to conduct and document in writing an analysis about the likelihood of any material loss contingency. The policy also required consideration of whether contingencies determined to

be remote (and therefore not required to be disclosed under ASC 450) should nonetheless be disclosed. No such analysis of a loss contingency was ever documented because there were not adequate procedures that prompted such analysis.

27. The company also had a disclosure committee responsible for assisting company executives in determining whether the company's periodic reports contained required disclosures. The disclosure committee's charter specified that its responsibilities included reviewing draft periodic and current reports for compliance with the securities laws and also considering whether other issues not already included in a draft report, including contingencies and legal matters, should be disclosed. The disclosure committee met prior to each quarter close to review the draft Form 10-K or Form 10-Q. But there was no policy or procedure for considering new disclosure issues not already identified and included in draft reports reviewed by the disclosure committee. The Acthar rebate issue and possible disclosure of a loss contingency for the underpayment of Medicaid rebates on Acthar sales were never submitted to or considered by the disclosure committee before the 2018 Form 10-K or the Q-1 2019 Form 10-Q.

Violations

28. As a result of the conduct described above, Mallinckrodt violated Section 17(a)(2) of the Securities Act, which makes it unlawful for "any person in the offer or sale of any securities . . . directly or indirectly . . . to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading."

29. Mallinckrodt violated Section 17(a)(3) of the Securities Act, which makes it unlawful for "any person in the offer or sale of any securities . . . to engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser."

30. Mallinckrodt violated Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, and 13a-13 thereunder, which require every issuer with securities registered pursuant to Section 12 of the Exchange Act, to file with the Commission annual and quarterly reports containing such information as the Commission's rules may require and such further material information as may be necessary to make the required statements, in light of the circumstances under which they were made, not misleading.

31. Mallinckrodt violated Section 13(b)(2)(A) of the Exchange Act, which requires reporting companies to make and keep books, records, and accounts which, in reasonable detail, accurately and fairly reflect their transactions and dispositions of their assets.

32. Mallinckrodt violated Section 13(b)(2)(B) of the Exchange Act, which requires all reporting companies to devise and maintain a system of internal accounting controls sufficient to, among other things, provide reasonable assurances that, among other things, transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles.

33. Mallinckrodt violated Exchange Act Rule 13a-15(a), which requires issuers required to file reports pursuant to Section 13(a) or 15(d) to, among other things, maintain disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e).

Civil Penalty

34. In determining whether to accept the Respondent's Offer and not impose a penalty of $40,000,000, the Commission has considered the Respondent's financial condition and the undertakings below.

Undertakings

Respondent has undertaken to:

35. Identify, within 30 days of the date of entry of the Order, at its own expense, a compliance consultant ("the Consultant"), not unacceptable to the Commission staff, to conduct a comprehensive review and evaluation of the adequacy of Respondent's policies and procedures respecting:

a. the company's disclosure controls and procedures relating to collection and assessment of information concerning potential risks, contingencies, trends, and uncertainties; and

b. the implementation and sufficiency of Mallinckrodt's internal accounting controls related to GAAP ASC 450. The review shall include, but not be limited to, a review of the Respondent's policies, practices, procedures, and controls relating to GAAP ASC 450.

36. Respondent shall provide, within 60 days of the issuance of this Order, a copy of the engagement letter detailing the Consultant's responsibilities to the Commission staff.

37. Respondent shall require the Consultant to complete its review and evaluation, and to make its recommendations in a written report ("Report"), within six (6) months of entry of this Order.

38. Respondent shall require the Consultant to issue the Report simultaneously to Respondent and the Commission staff. The Report shall include a description of the Consultant's review and evaluation, the conclusions reached, and the Consultant's recommendations for changes or improvements to Respondent's internal accounting controls and disclosure controls and procedures.

39. Respondent shall adopt and implement all recommendations in the Consultant's Report as soon as practicable, but in any event no later than within 180 days of the issuance of the Report. As to any recommendation that Respondent considers to be unduly burdensome or impractical, Respondent may, within 30 days of the issuance of the Report, submit in writing to the Consultant and the Commission staff a proposed alternative reasonably designed to accomplish the same objectives. As to any recommendation on which Respondent and the Consultant do not agree within 30 days thereafter, after attempting in good faith to reach an agreement, Respondent will

abide by the determination of the Consultant. As to any such disputed recommendation, the Consultant shall inform Respondent and the Commission staff of the Consultant's final determination within 60 days after issuance of the Report.

40. Respondent shall provide all written material required herein to be provided to the Commission staff to Brian O. Quinn, Assistant Director, Division of Enforcement, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

41. Respondent shall cooperate fully with the Consultant, including providing the Consultant with access to its files, books, records, and personnel as reasonably requested for the above-referenced review, and obtaining the cooperation of respective employees or other persons under Respondent's control, subject to Respondent's right to withhold from disclosure any information or records protected by the attorney client privilege or the attorney work product doctrine.

42. Respondent shall require the Consultant to report to the Commission staff on its activities as the Commission staff may request.

43. Respondent and the Consultant shall agree that the Consultant is an independent third-party and not an employee or agent of the Respondent. In addition, Respondent and the Consultant shall agree that no attorney-client relationship will be formed between them.

44. The reports by the Consultant will likely include confidential financial, proprietary, competitive business or commercial information. Public disclosure of the reports could discourage cooperation, impede pending or potential government investigations or undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except (1) pursuant to court order, (2) as agreed to by the parties in writing, (3) to the extent that the Commission determines in its sole discretion that disclosure would be in furtherance of the Commission's discharge of its duties and responsibilities, or (4) is otherwise required by law.

45. Respondent agrees to require that these undertakings shall be binding upon any acquiror or successor in interest to Respondent.

46. Respondent may apply to the Commission staff for an extension of the deadlines set forth above before their expiration and, upon a showing of good cause by Respondent, the Commission staff may, in its sole discretion, grant such extensions for whatever time period it deems appropriate.

47. Respondent shall certify, in writing, compliance with the undertaking(s) set forth above. The certification shall identify the undertaking(s), provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Commission staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such evidence. The certification and supporting material shall be submitted to Brian O. Quinn, Assistant Director, Division of Enforcement, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549, with a copy to the Office of Chief Counsel of the Enforcement Division, no later than sixty (60) days from the date of the completion of the undertakings.

IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent Mallinckrodt's Offer.

Accordingly, it is hereby ORDERED that**:**

A. Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Respondent Mallinckrodt cease and desist from committing or causing any violations and any future violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act, Sections 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act, and Exchange Act Rules 12b-20, 13a-1, 13a-13, and 13a-15(a).

B. Respondent shall comply with the undertakings enumerated in Paragraphs 35–47 above.

By the Commission.

Vanessa A. Countryman
Secretary