UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. BRIAN J. SUTHOFF, Defendant.	Civil Action No. 26-cv-_____ JURY TRIAL DEMANDED

COMPLAINT

Plaintiff, Securities and Exchange Commission (the "Commission"), alleges the following against defendant Brian J. Suthoff ("Suthoff" or "Defendant"):

SUMMARY

1. This case involves insider trading by Suthoff in the shares of Massachusetts-based Sage Therapeutics Inc. ("Sage" or the "Company") ahead of a Company announcement that its primary drug candidate had been denied approval by the Food and Drug Administration ("FDA") for the treatment of major depressive disorder ("MDD") (the "Announcement").

2. Between on or about June 2, 2023, and on or about June 7, 2023, a Sage insider, to whom Suthoff owed a duty of trust and confidence (the "Insider"), learned material non-public information ("MNPI") regarding the FDA's position on Sage's application for Zuranolone for the treatment of MDD. Suthoff misappropriated this information from the Insider and then liquidated the Sage shares he had held for more than two years based on this MNPI. In doing so, he breached the duty of trust and confidence he owed the Insider.

3. On August 4, 2023, Sage announced for the first time that the FDA had denied approval for MDD—approximately 93% of the target market for Zuranolone. Sage's stock price

fell approximately 53% from the previous day's closing price on the bad news. Suthoff avoided losses of approximately $19,680 by illegally dumping his Sage shares in advance of the Announcement.

NATURE OF THE PROCEEDING AND RELIEF SOUGHT

4. The Commission brings this action pursuant to Sections 21(d), 21(e), and 21A of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. § 78u(d), (e), and 78u-1].

5. The Commission seeks a permanent injunction against Suthoff, enjoining him from engaging in the transactions, acts, practices, and courses of business of the type alleged in this Complaint; disgorgement of ill-gotten gains, including losses avoided, from the unlawful insider trading activity set forth in this Complaint, together with prejudgment interest; a civil penalty pursuant to Section 21A of the Exchange Act [15 U.S.C. §78u-1], and the Insider Trading and Securities Fraud Enforcement Act of 1988; an order barring him from serving as an officer or director of a public company for five years, pursuant to Section 21(d)(2) of the Exchange Act [15 U.S.C. §78u(d)(2)]; and such other relief as the Court may deem appropriate.

JURISDICTION AND VENUE

6. The Court has jurisdiction over this action pursuant to Sections 21(d), 21(e), 21A, and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 78u(e), 78u-1, and 78aa].

7. Venue is proper in this Court pursuant to Sections 21(d), 21A, and 27 of the Exchange Act [15 U.S.C § 78u(d), 78u-1, and 78aa]. Sage was headquartered in Massachusetts, Suthoff resides in Massachusetts, and certain of the acts, practices, transactions, and courses of business alleged in this Complaint occurred within the District of Massachusetts.

8. Suthoff, directly or indirectly, made use of the means or instrumentalities of transportation or communication in interstate commerce, or the mails, including the internet and

the telephone.

DEFENDANT

9. **Brian Suthoff**, age 56, resides in Boston, Massachusetts. Suthoff is president of a private company that purports to provide data services related to merchant trade credit customers and another private company that is a marketing strategy firm. He was previously an officer or senior employee of several private companies, some of which were acquired by public issuers. Suthoff owed a duty of trust and confidence to the Insider, who, during the relevant period, was a senior Sage employee and member of a committee pertaining to Zuranolone (the "Committee").

RELEVANT ENTITY

10. **Sage Therapeutics Inc.** was a Delaware corporation based in Cambridge, Massachusetts and focused on the development of treatments for brain health disorders. During the relevant period, Sage's common stock was registered with the Commission and traded on the Nasdaq Global Market under the ticker symbol SAGE. In 2022, a year before the conduct at issue, Sage reported less than $7.7 million in revenue from product sales for an injectable postpartum depression treatment. In December 2022, Sage and its business partner, Company A, submitted a New Drug Application ("NDA") for Zuranolone as a potential oral treatment for postpartum depression and MDD.

STATEMENT OF FACTS

A. The Insider was Under a Duty to Keep Information Concerning Zuranolone's Approval Prospects Confidential.

11. The Insider worked at Sage during the relevant time period.

12. Throughout the Insider's Sage employment, the Insider was subject to – and acknowledged in writing having read and understood – several internal policies regarding insider

trading and the use of confidential information. These policies included a general "Policy on Insider Trading," applicable all Sage employees, and a "Special Trading Procedures for Insiders," applicable to employees, like the Insider, who were exposed to MNPI in the ordinary course.

13. Sage's Policy on Insider Trading expressly identified "types of information that should be considered very carefully to determine whether they are material," including "information related to decisions by regulatory authorities regarding the Company's product candidates."

B. The Likelihood of Zuranolone Being Approved for the Treatment of MDD Was Critical to Sage's Business Prospects.

14. On December 6, 2022, Sage and its business partner, Company A, announced they had submitted the Zuranolone NDA requesting authorization from the FDA to market and sell Zuranolone as a potential oral treatment for postpartum depression and MDD. Sage also announced publicly on February 6, 2023, that the target date for the FDA to decide whether to approve Zuranolone for either or both those indications was August 5, 2023.

15. Sage projected that of the two proposed indications, MDD would constitute at least 93% of the target market. In its Form 10-K filed with the SEC on February 16, 2023, Sage stated that "approximately 21 million adults in the U.S. reported at least one major depressive episode in 2021," while estimating "that approximately 500,000 women in the U.S. each year may experience symptoms of [postpartum depression.]"

16. Accordingly, Company A agreed to make milestone payments to Sage of $150 million if Zuranolone was approved for the treatment of MDD, and $75 million if it was approved for the treatment of postpartum depression. By comparison, in its Form 10-K filed with the SEC on February 16, 2023, Sage reported just $7.69 million in product revenue for all

of 2022.

C. The Insider Learned MNPI about Zuranolone.

17. In anticipation of its final decision on the Zuranolone NDA, on June 2, 2023, the FDA sent Sage a redlined version of the proposed labeling for the drug that struck all references to MDD. The FDA also communicated to Sage that, "our assessment is that substantial evidence of effectiveness has not been demonstrated for the use of Zuranolone in the treatment of MDD" and identified deficiencies in each of the clinical trials Sage had submitted in support of MDD.

18. The following morning, June 3, 2023, the members of the Committee, including the Insider, received an email titled "CONFIDENTIAL – HIGHLY SENSITIVE AND MATERIAL." The email contained a link to the FDA's comments striking MDD from the proposed Zuranolone label, noted that the "[MDD] indication has been struck," and remarked that "the FDA comments are surprising and disappointing." The email also characterized the information as "extremely restricted" and admonished recipients not to discuss or provide any information about the FDA's comments with other personnel.

19. Also on June 3, 2023, the Insider was invited to a Committee meeting via Zoom to discuss "additional context and detail regarding FDA label comments and the plan to address the comments…"

20. On June 5, 2023, the FDA met with Sage and Company A ahead of its final decision on the Zuranolone NDA. During the meeting, the FDA noted several criticisms with the Zuranolone efficacy data submitted in support of the MDD indication. When Sage and Company A queried whether there was a path forward with respect to MDD, the FDA advised that there did not appear to be other options for securing approval for MDD absent additional data. Neither Sage nor Company A submitted any such additional data for the NDA.

21. On June 6, 2023, the Insider attended a Committee meeting by Zoom regarding the FDA's comments.

22. Also on June 6, 2023, Sage's corporate counsel notified all Sage employees, including the Insider, by email of an earlier-than-usual "Quarterly trading blackout in effect" concerning trading in Sage stock. The email stated: "Given the stage of the FDA's review of Zuranolone NDA, we have decided to close the trading window today instead of next week, when Sage's quarterly trading blackout would usually go into effect." The email reminded all employees to "keep confidential all information relating to the Zuranolone NDA review process," that "you… are not permitted" to trade Sage stock, and that "you cannot…give a trading tip[ ] if at any time, even during an open window, you are aware of material, non-public information of any kind related to Sage's business."

23. Later on June 6, 2023, the Insider received a second email from corporate counsel, sent to approximately 50 Sage employees who were "involved in the ongoing interactions with the FDA regarding the Zuranolone NDA." The email instructed that "you must keep confidential and not disclose anything about these interactions with the FDA, or even give a directional indication of the nature of these discussions (even a thumbs up or thumbs down) to anyone inside Sage or externally who is not in this working group."

24. The Insider was also invited to several Zuranolone-related meetings on June 7, 2023, including a Committee meeting to discuss proposed revisions to the MDD indication.

D. Suthoff Misappropriated MNPI Concerning Zuranolone and Traded on It.

25. Suthoff misappropriated MNPI concerning the FDA's label comments from the Insider between at least June 2, 2023 and June 7, 2023.

26. Then, on the morning of June 8, 2023, Suthoff placed an order to liquidate the Sage shares he had held for more than two years. This was the only securities transaction in his

brokerage account that month.

E. Sage Announced It Had been Denied Approval for MDD, and Its Stock Price Plummeted.

27. After the securities markets closed on August 4, 2023, Sage and Company A announced that the FDA had approved Zuranolone for the treatment of postpartum depression but had denied approval for MDD, consistent with the FDA's June 2, 2023, label comments and statements at the June 5, 2023 meeting.

28. The Announcement resulted in Sage's stock price dropping more than 53%, from a closing price of $36.10 per share on Friday, August 4, 2023, to a closing price of $16.75 per share on Monday, August 7, 2023.

29. Suthoff avoided losses of $19,680 by liquidating his Sage holdings two months before, at an average price of $56.11 per share.

F. Suthoff Breached the Duty of Trust and Confidence Owed to the Insider by Selling his Shares.

30. Suthoff traded on the basis of information about the FDA striking MDD from Zuranolone's proposed label. In doing so, Suthoff knew, or recklessly disregarded, that such information was not publicly known or disseminated prior to the Announcement.

31. The FDA's label comments were also material. For example, approval for an MDD indication was critical to Sage's business prospects because it would have triggered a $150 million milestone payment from Company A to Sage and because MDD constituted at least 93% of the projected market for Zuranolone. Additionally, Sage's stock price declined more than 53% on the news that Zuranolone had not been approved for the treatment of MDD.

32. Suthoff knew, or recklessly disregarded, that the FDA's decision to strike all references to MDD from Zuranolone's proposed label was material because he liquidated his

Sage holdings that he had held for more than two years soon after learning MNPI.

33. Suthoff willfully or recklessly violated a duty of trust and confidence he owed the Insider by selling Sage stock on the basis of MNPI.

FIRST CLAIM FOR RELIEF
Violation of Section 10(b) of the Exchange Act and Rule 10b-5

34. The Commission realleges and incorporates by references the allegations in paragraphs 1 through 33 above.

35. As set forth above, Defendant misappropriated and traded Sage securities on the basis of material nonpublic information about Sage in breach of Defendant's duty of trust and confidence to the Insider. Defendant knew, consciously avoided knowing, or was reckless in not knowing that this information was material and nonpublic.

36. By engaging in the conduct described above, Defendant, directly or indirectly, in connection with the purchase or sale of securities, by use of the means or instrumentalities of interstate commerce, or the mails, or the facilities of a national securities exchange:
(a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, or courses of business which operated or would operate as a fraud or deceit upon any person in connection with the purchase or sale of any security.

37. By engaging in the conduct described above, Defendant violated, and unless restrained and enjoined will continue to violate, Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5.

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that this Court:

A. Permanently restrain Defendant, his agents, servants, employees and attorneys, and those persons in active concert or participation with him who receive actual notice of the injunction by personal services or otherwise, and each of them, from violating Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)], and Rule 10b-5 thereunder [17 C.F.R §240.10b- 5] by (i) buying or selling a security of any issuer, on the basis of material nonpublic information, in breach of a fiduciary duty or other duty of trust or confidence that is owed directly, indirectly, or derivatively, to the issuer of that security or the shareholders of that issuer, or to any other person who is the source of the information; or (ii) by communicating material nonpublic information about a security or issuer, in breach of a fiduciary duty or other duty of trust or confidence, to another person or persons for purposes of buying or selling any security;

B. Order Defendant to disgorge, with prejudgment interest, all ill-gotten gains, including losses avoided, that were obtained by reason of the unlawful conduct alleged in this Complaint;

C. Order Defendant to pay an appropriate civil monetary penalty pursuant to Section 21A of the Exchange Act [15 U.S.C. §78u-1];

D. Enter an order barring Defendant from serving as an officer or director of certain public companies for five years, pursuant to Section 21(d)(2) of the Exchange Act [15 U.S.C. §78u(d)(2)];

E. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and

F. Grant such other further relief as the Court may deem just and proper.

JURY DEMAND

The Commission demands a jury in this matter for all claims so triable.

Dated: January 26, 2026

Respectfully submitted,

/s/ *Martin F. Healey*

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