

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

THE BOOTH FAMILY TRUST, derivatively
on behalf of BIOGEN INC.,

Plaintiff,

vs.

MICHEL VOUNATSOS, STELIOS
PAPADOPOULOS, ALEXANDER J.
DENNER, CAROLINA D. DORSA, JESUS
B. MANTAS, WILLIAM A. HAWKINS,
NANCY L. LEAMING, RICHARD C.
MULLIGAN, BRIAN S. POSNER, ERIC K.
ROWINSKY, and STEPHEN A. SHERWIN,

Defendants,

-and-

BIOGEN INC.,

Nominal Defendant.

NO.

DEMAND FOR JURY TRIAL

VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiff, the Booth Family Trust, by its undersigned attorneys, brings this stockholder derivative action on behalf of nominal defendant Biogen Inc. (“Biogen” or the “Company”) against the members of the Company’s Board of Directors for their breaches of fiduciary duties,

violations of the federal securities laws, and other misconduct that resulted in material damage to the Company and its stockholders. These allegations are made upon personal knowledge with respect to Plaintiff and, as to all other matters, upon information and belief based upon the investigation and analysis by Plaintiff's counsel, including, among other things, a review of the Company's press releases and public filings with the United States Securities and Exchange Commission ("SEC"), corporate governance documents published on the Company's website, transcripts of Biogen investor conference calls, news reports, financial analyst reports, and other publicly available information about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a stockholder derivative action brought by Plaintiff on behalf of Biogen against the current members of its Board of Directors (the "Board" or the "Individual Defendants") for their breaches of fiduciary duties, violations of the federal securities laws, and other misconduct.

2. The Individual Defendants were required as directors of a public company to fulfill the highest fiduciary duties of loyalty, good faith and due care. As part of their fiduciary duties, they were required to ensure that Biogen implemented and maintained an effective system of internal controls to ensure that the Company operated in compliance with the laws, rules and regulations that guide its core operations. Likewise, they were required to act when faced with red flags of misconduct. The Individual Defendants utterly failed to fulfill these fiduciary duties owed to Biogen and its stockholders.

3. The Individual Defendants' failures to fulfill their fiduciary duties has resulted in significant damage to Biogen and its stockholders, leading to a substantial fine and censure by the federal government, a securities fraud class action lawsuit, and a lawsuit for close to two billion dollars in damages brought by an insurance provider.

4. First, the Department of Justice charged Biogen and co-conspirators of running a "seed and sweep" scheme in violation of the Anti-Kickback Statute ("AKS") in connection with its sales and marketing practices for three multiple sclerosis drugs, Tysabri, Avonex, and Tecfidera (collectively the "MS Drugs"). Biogen initially "seeded" the market by dispensing the MS Drugs free of charge to thousands of patients who did not have insurance coverage or whose insurance did not cover the prohibitively priced drugs. Biogen then proceeded to "sweep" the patients from its free-drug program into Medicaid Part D, and illegally covered the patients' substantial co-pays by funneling money through patient assistance programs ("PAPs").

5. In 2016, Biogen disclosed that the United States Department of Justice (the "DOJ") had subpoenaed records regarding the Company's sales and marketing practices. A whistleblower suit was subsequently brought against Biogen under the False Claims Act, 31 U.S.C. § 3730 (b)(2), and related state laws (the "Whistleblower Action") detailing the illegal seed and sweep scheme. After conducting a thorough investigation into Biogen and the PAPs, the DOJ intervened in the Whistleblower Action. Ultimately, Biogen was fined \$22 million and its co-conspirators fined millions more for their parts in the scheme.¹

¹ Department of Justice, Office of Public Affairs, *Biogen Agrees to Pay \$22 Million to Resolve Alleged False Claims Act Liability for Paying Kickbacks*, Dec. 17, 2020, <https://www.justice.gov/opa/pr/biogen-agrees-pay-22-million-resolve-alleged-false-claims-act-liability-paying-kickbacks>; Department of Justice, U.S. Attorney's Office, *Third Foundation Resolves Allegations that it Conspired with Pharmaceutical Companies to Pay Kickbacks to*

6. The damage to Biogen from the Individual Defendants' breaches of fiduciary duty and other misconduct continues, however, as Biogen was recently sued for close to two billion dollars by Humana, a Medicaid insurance provider, to recover the amounts it paid to cover improper Medicaid claims submitted as part of the seed and sweep scheme.

7. Second, Biogen engaged in a scheme to tailor data from clinical studies for its drug to treat Alzheimer's disease, aducanumab, and to pressure the United States Food and Drug Administration (the "FDA") to approve the drug.

8. In March of 2019, the Company terminated its clinical trials of aducanumab because they indicated that the drug was not effective. In light of the importance of the drug to Biogen's business plan, however, Biogen determined to adjust the data and findings from its clinical studies to make it appear that a different conclusion could be reached. Behind the scenes, Biogen's Chief Medical Officer secretly met with the Head of the FDA Office of Neuroscience, an old colleague, to push for approval. Biogen officials and FDA officials subsequently agreed to collaborate on getting FDA approval for aducanumab. The Board appears to have been expressly informed of the improper agreement.

9. Despite this collaboration, and attempts to conceal negative data analyses, an FDA advisory committee ("Advisory Committee") voted almost unanimously against the approval of the Alzheimer drug. Regardless, Biogen pressed forward. Eventually, the head of the FDA's oncology office extended a lifeline to the Company by suggesting accelerated approval of the drug based on its ability to remove plaque, an angle Biogen had never seriously

Medicare Patients, Nov. 20, 2019, <https://www.justice.gov/usao-ma/pr/third-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay-kickbacks>.

pursued. At a meeting convened to determine whether the FDA would approve aducanumab for its ability to remove plaque, Biogen worked with its FDA collaborators to invite, and empower with a vote, the heads of certain FDA offices with no connection to Alzheimer drugs.

10. On June 7, 2021, the FDA approved aducanumab. The decision and a subsequent investigative report revealing the collaboration between Biogen and the FDA were met with shock and dismay by regulators, hospitals and clinics. Three of nine permanent Advisory Committee members resigned, with one calling the approval “probably the worst drug approval decision in recent U.S. history.”²

11. The government launched several investigations into the approval and dozens of hospitals and more than a thousand outpatient clinics refused to prescribe the Alzheimer drug, arguing against its efficacy. The SEC and the Federal Trade Commission (“FTC”) have also launched independent investigations. Insurers called the drug “experimental and investigational” and refused to cover it. The FDA is investigating the recent death of a patient shortly after taking aducanumab.

12. Two securities class actions have since been filed against the Company and certain of its directors and officers for their false and misleading statements and material omissions concerning the clinical trials of aducanumab and its approval by the FDA that artificially inflated the price of Biogen stock. The Company is subject to substantial costs defending itself in the lawsuits and will be subject to substantial further costs in resolving them.

² Jeffrey Toobin, *The Road to Aduhelm: What One Ex-FDA Adviser Called ‘Probably the Worst Drug Approval Decision in Recent US History’ for an Alzheimer’s Treatment*, CNN, Sept. 27, 2021, <https://www.cnn.com/2021/09/26/politics/alzheimers-drug-aduhelm-fda-approval/index.html>.

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