UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

OKLAHOMA FIREFIGHTERS PENSION AND RETIREMENT SYSTEM, Plaintiff, v. BIOGEN INC., MICHEL VOUNATSOS, ALFRED SANDROCK, AND ALISHA ALAIMO, Defendants.	)	CIVIL ACTION NO. 22-10200-WGY

YOUNG, D.J. March 29, 2023

MEMORANDUM AND ORDER

I. INTRODUCTION

Lead Plaintiff Oklahoma Firefighters Pension and Retirement System ("Oklahoma Firefighters") bring[1] this securities fraud putative class action against the Defendants Biogen Inc. ("Biogen"), Michel Vounatsos ("Vounatsos"), Biogen's former Chief Executive Officer, Alisha Alaimo ("Alaimo"), President of Biogen U.S., and Alfred Sandrock ("Sandrock"), Biogen's former Chief Medical Officer.[2] Although the complaint indulges in a lengthy description of the allegedly unlawful nature of Biogen's contacts with the Food and Drug Administration ("FDA"), the core

[1] For stylistic reasons, this Court utilizes the plural to refer to lead Plaintiff Oklahoma Firefighters.

[2] Vounatsos, Alaimo, and Sandrock are collectively referred to as "Individual Defendants."

of Oklahoma Firefighters' case concerns the failed commercial rollout of Aduhelm, an innovative treatment for Alzheimer's disease developed by Biogen. Specifically, Oklahoma Firefighters allege that the Defendants made twenty-five false and misleading statements, which can be regrouped into six categories: (1) statements concerning the Defendants' assertion that over 900 healthcare sites were "ready" to implement treatment with Aduhelm on June 7 and 8, 2021, (2) statements concerning potential obstacles in diagnosing the presence of amyloid plaques in patients with Alzheimer's disease, (3) statements concerning Medicare coverage, (4) statements concerning Aduhelm's price, (5) statements concerning a potential agreement with the Veterans Health Administration ("VA") to provide Aduhelm to veterans, and (6) statements in Dr. Sandrock's open letter to the Alzheimer's disease community allegedly describing Biogen's interactions with the FDA.

The Defendants move to dismiss for failure to state a claim. The grounds alleged are failure to plead facts with particularity establishing (1) that any of the challenged statements are false or misleading and (2) a strong inference of scienter.

After careful evaluation, this Court **GRANTS** the Defendants' motion to dismiss. Ultimately fatal to Oklahoma Firefighters' case is the constant misrepresentation of what the Defendants

said. For example, contrary to what Oklahoma Firefighters alleges or implies, Vounatsos and Alaimo never promised that 900 sites would have implemented treatment with Aduhelm, never claimed that potential bottlenecks to prescribing the drug "were solved," and never asserted that Medicare coverage was "automatic" upon FDA approval. Pl.'s Opp'n at 30, ECF No. 44. Nor did Sandrock ever state that Biogen's interactions with the FDA to resurrect Aduhelm were "appropriate and not out of the ordinary." Compl. ¶ 244, ECF No. 30. Nor did acting FDA Commissioner Janet Woodcock ever "concede" there "have been contact[s] between the FDA and Biogen 'outside the formal correspondence process.'" Compl. ¶ 244. A securities fraud complaint cannot rest on a house of cards made of mischaracterized statements. See Kin-Yup Chun v. Fluor Corp., No. 3:18-CV-01338-X, 2021 WL 1788626, at *7 (N.D. Tex. May 5, 2021) (holding statements not false or misleading where plaintiff mischaracterized statements and/or defendants "never said" what plaintiff alleged). Fairly read, none of the challenged statements are actionable under the Private Securities Litigation Reform Act ("PSLRA"). For this reason alone, the Complaint does not survive the Defendants' motion to dismiss.

Moreover, after careful evaluation, this Court concludes that the scienter allegations are also deficient. As to the 900

sites "ready" statements, Oklahoma Firefighters' case primarily rests on (1) the statements of eight low-ranking former Biogen employees and (2) the occurrence of an internal investigation regarding site readiness. Conspicuously absent from the Complaint, however, are any allegations that said employees directly interacted with the Individual Defendants. Equally missing is any factual allegation regarding the timing, outcome, and knowledge of the internal investigation by the Defendants. Therefore, this Court cannot infer scienter. With respect to the other statements, the scienter allegations are so wanting that they can be readily dismissed. Therefore, even were this Court to rule that some of the statements made by the Defendants were false or misleading, the Complaint must nonetheless be dismissed because the facts alleged do not support a strong inference of scenter.

II. PROCEDURAL HISTORY

Pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), a class action complaint for violation of the Securities Exchange Act of 1934 was initially filed on February 7, 2022, by Oklahoma Firefighters, individually and on behalf of others similarly situated, against Biogen, Vounatsos, Alaimo, and Sandrock. Class Action Complaint ("Orig. Compl."), ECF No. 1. On June 27, 2022, Oklahoma Firefighters filed a consolidated

class action complaint ("complaint") alleging the same two counts. Consolidated Class Action Complaint ("Compl."), ECF No. 30. The putative class is comprised of investors who purchased or otherwise acquired Biogen stock between June 7, 2021, and January 11, 2022, inclusive (the "Class Period"). Compl. ¶ 3. The complaint contains two counts for violation of Section 10(b) of the Exchange Act, 15 U.S.C. §78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5 (count 1), and violations of § 20(A) of the Exchange Act, 15 U.S.C. §78t(a) (count 2). Compl. ¶¶ 306-321.

On July 27, 2022, the Defendants filed a motion to dismiss both counts of the complaint. Defs.' Mot. Dismiss Amended Compl. ("Defs.' Mot."), ECF No. 39. The parties have fully briefed the issue. Consolidated Mem. Law Supp. of Defs.' Mot. Dismiss the Amended Compl. ("Defs.' Mem."), ECF No. 40; Lead Pl. Oklahoma Firefighters Pension and Retirement System's Opp'n Defs.' Mot. Dismiss ("Pl.'s Opp'n"), ECF No. 44; Consolidated Reply Mem. Further Supp. Defs.' Mot. Dismiss the Amended Compl. ("Defs.' Reply"), ECF No. 48.

This Court has jurisdiction over this action. Subject matter jurisdiction is proper pursuant to 28 U.S.C. §1331 and § 27 of the Exchange Act, 15 U.S.C. § 78a and 28 U.S.C. § 1331. The Defendants have not challenged this Court's personal jurisdiction over them. Venue is proper in this judicial

district pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b).

III. FACTS ALLEGED

Biogen is a global biopharmaceutical company focused on the development of treatments for serious neurological diseases. Compl. ¶ 38. By 2019, Biogen faced declining sales and increasing competition. Id. ¶¶ 7, 43-51.

Aduhelm is a monoclonal antibody treatment that is purportedly capable of reducing the presence of amyloid beta in the brain. Id. ¶ 39. Some research suggests that reduction of amyloid beta plaques could help treating and preventing neurological decline from Alzheimer's disease. Id. Many individuals diagnosed with Alzheimer's, however, test negative to the presence of amyloid beta plaques. Id.

A. The FDA's Approval of Aduhelm

Biogen first licensed Aduhelm in 2007 from Neuroimmue AG, a Swiss biopharmaceutical company. Id. ¶ 52. After years of its own research, Biogen began a Phase I trial to evaluate the treatment's efficacy in treating Alzheimer's disease. Id. ¶ 53. The results of the study were so impressive that Biogen immediately decided to begin two separate Phase III trials known as "EMERGE" and "ENGAGE." Id. Patients' enrollment for the study begun in early 2016. Id.

Years later, in 2019, Biogen decided to bring in outside experts to examine the data collected during Phase III. Id. ¶ 54. For longer term Phase III trials, such a futility analysis is common practice. Id. The outside experts concluded, in March of 2019, that neither ENGAGE nor EMGERGE showed sufficient clinical benefit to warrant submitting Aduhelm for FDA approval and advised that the treatment be abandoned. Id. ¶ 55. Biogen agreed with that recommendation, and, on March 21, 2019, it announced its decision to discontinue Aduhelm research. Id. Following the announcement, Biogen's stock took a beating: Biogen's shares price plummeted from $320.59 on March 20, 2019, to $226.88 on March 21, 2019. Id. ¶ 56.

In response, according to news reports, Biogen's Chief Medical Officer Alfred Sandrock decided to reach out to the FDA to determine if there was any path forward for approval. Id. ¶ 9. Allegedly, Billy Dunn, the head of the FDA's Division of Neuroscience and a former colleague of Sandrock, became an internal advocate at the FDA for Aduhelm's approval. Id. These facts are presently the subject of Congressional, FTC, and SEC investigations, as well as an investigation by the Office of the Inspector General of U.S. Health and Human Services. Id. ¶ 10. Also, STAT Case News and the New York Times wrote exposés on Biogen's contacts with the FDA. Id.

In July 2020, Biogen submitted Aduhelm to the FDA for

approval. Id. ¶ 11. Biogen explained that its submission was justified based on a new analysis of the Phase III trials data. Id.

Biogen's submission was not well received by FDA's Peripheral and Central Nervous System Drug Advisory Committee (the "PCNS Advisory Committee"). Id. ¶ 12. On November 6, 2020, the Committee unanimously recommended against approving Aduhelm. Id. The primary reason for this decision was a lack of demonstrable clinical benefit. Id.

This notwithstanding, on June 7, 2021, the FDA approved Aduhelm through its Accelerated Approval process. Id. ¶ 14. Accelerated Approval was justified based on Aduhelm's effects in reducing amyloid beta presence, which was deemed to be an acceptable proxy for the treatment's efficacy. Id. ¶ 84. The FDA approved a broad label for Aduhlem, allowing it to be prescribed to any patient with Alzheimer's, regardless of the stage of the disease. Id. As part of the Accelerated Approval, Biogen was required to complete a Phase IV study within 9 years to determine the efficacy of Aduhelm in-use. Id. On the day Aduhelm was approved by the FDA, Biogen's stock rose by over $100 per share, representing an increase in market capitalization of approximately $14,600,000,000. Id. ¶ 14.

B. Biogen's Site Readiness Analysis

Administering Aduhelm is infrastructure intensive. Id. ¶ 41. Aduhelm is administered as an intravenous infusion over approximately one hour every four weeks. Id. Moreover, patients being treated with Aduhelm must undergo regular MRI monitoring for potentially dangerous side effects, including brain swelling and hemorrhages. Id.

In anticipation of FDA approval of the treatment, Biogen employees designated "Alzheimer's Account Managers" began the process of evaluating treatment sites for their "readiness" to prescribe and administer Aduhelm. Id. ¶ 62. The work was meant to evaluate the "demand for Aduhelm, if it was approved, as well as site capacity and scalability for potential patient treatment." Id. ¶ 63. Site evaluations were tracked first in Excel, and later in systems called Javelin, Veeva, and Qliksense. Id. ¶ 64.

Site "readiness" was evaluated based on five different metrics: "[1] potential patient demand for Aduhelm, [2] the presence of necessary specialists to administer treatment and monitor patients, [3] the ability for the site to confirm amyloid beta in patients, [4] the ability of the site to administer Aduhelm as an infusion, and [5] the ability of the site to use MRIs to monitor patients." Id. ¶ 65. According to the complaint, "[w]hen Biogen would speak about sites being

'ready to treat patients' after FDA approval, they were referring to those sites being deemed ready on these five metrics." Id.

The reports generated through site "readiness" evaluation and shown to supervisors and executives conveyed the data collected in a simplified fashion. Id. ¶ 66. While the underlying tracking system contained data for all the five different metrics, the reports utilized a red (not ready) to green (ready) color system. Id.

C. The June 7 and 8, 2021, Statements

On June 7 and 8, 2021, Vounatsos and Alaimo made several statements which form the bulk of the Oklahoma Firefighters' case.

First, on June 7, 2021, Vounatsos announced that there were 900 sites "ready" to infuse Aduhelm. Id. ¶ 17. The next day, Alaimo similarly stated that there were over 900 sites "ready." Id. ¶ 174. She then went on to explain that "[r]eady means that they have the required capability, infrastructure, education and, most importantly, willingness to treat a patient with a potential new Alzheimer's therapy." Id. Six weeks later, Vounatsos announced that only 325 of the 900 sites had completed, or would not require, an internal "pharmacy and therapeutics committee reviews" ("P&T Review"). Id. ¶ 17. According to the complaint, P&T Review "necessitates a review of

the FDA's approval of the drug, label, cost and whether the treatment would be covered by third-party payers -- none of which could have occurred prior to June 7, 2021." Id. By September 2021, Vounatsos and Alaimo declared that only 50 sites were administering Aduhelm. Id.

Second, on June 7, 2021, the Defendants announced a partnership with Labcorp and Mayo Clinic Laboratories to increase testing capacity of cerebrospinal fluid ("CSF"). Id. ¶ 18. The Defendants stated that most physicians would want to determine the presence of amyloid beta in a patient before prescribing Aduhelm to treat that patient. Id. According to the complaint, the "Defendants omitted to reveal, however, that Biogen's sales force had encountered tremendous resistance, if not downright hostility, from doctors when they suggested CSF analysis as a means to test for amyloid beta." Id.

Third, the Defendants stated that Medicare coverage of Aduhelm was "automatically presumed" following FDA approval. Id. ¶ 19. Oklahoma Firefighters allege that this statement was false and misleading because the U.S. Centers for Medicare and Medicaid Services ("CMS") later engaged in a National Coverage Determination ("NCD") and determined that Medicare coverage for Aduhelm would be "limited to reimbursement for treatments administered to patients enrolled in CMS-approved randomized clinical trials." Id. ¶ 19.

Fourth, Vounatsos stated that Biogen would set the price per patient for Aduhelm at $ 56,000 per year. Id. ¶ 188. The Defendants explained that this price had been the result of "lengthy engagement . . . with scientific leaders, pharmaco-economists, payers, private and public payers." Id. Oklahoma Firefighters claim that the Defendants' statements were false and misleading because "[i]n truth, many third-party payors balked at Aduhelm's price point." Id. On November 18, 2021, Bloomberg News reported that 25 large private insurers would not provide coverage for Aduhelm due to its price. Id. ¶ 21. By late December 2021, Biogen announced that it would halve the annual price of Aduhelm, down to $28,200. Id.

Fifth, the Defendants stated that they were "working to finalize a multiyear agreement with the Veterans Health Administration ("VA") in order to support access for veterans to Aduhelm." Id. ¶ 196. For Oklahoma Firefighters this statement was false and misleading. Prior to the start of the Class Period, Dr. Andrew Budson, a member of the VA, conveyed to Johannah Venturini, Biogen's medical science liaison, that he did not support the VA covering Aduhelm. Id. ¶ 22. On August 11, 2021, the VA announced it would not add Aduhelm to its formulary list. Id. ¶ 248.

D. Aduhelm's Unsuccessful Commercial Rollout

The controversial nature of Aduhelm's approval by the FDA led many healthcare providers to take a skeptical view of the drug. Id. ¶ 16, 258. In fact, safety data published in a peer-reviewed medical journal showed that "41% of patients taking Aduhelm experienced either bleeding or swelling in the brain" and it was reported that a 75-year-old woman who had been participating in a Aduhelm clinical trial had died. Id. ¶ 262, 264. Moreover, the European Union and Japan regulators communicated that they would not, or were unlikely to, approve Aduhelm. Id. ¶¶ 263-264. This led to limited sales of Aduhelm. Id. ¶ 24.

The market reacted accordingly, correcting the price of Biogen's stock. Id. ¶ 25. On November 26, 2021, Bloomberg Business news reported that Biogen's stock price had "given up all its gains from its initial announcement of FDA approval for Aduhelm." Id. By January 12, 2022, Biogen's stock price declined further, capitulating at $225 per share. Id. ¶ 25.

After the Class Period, "Biogen replaced Vounatsos as CEO, terminated its entire Aduhelm sales force, and effectively abandoned Aduhelm as a commercial drug." Id. ¶ 26.

E. Confidential Witnesses

To make its case, Oklahoma Firefighters primarily rely on the statements of eight confidential witnesses who are former

Biogen employees ("FEs"). As shown by the table below, which was offered by the Defendants and not challenged by Oklahoma firefighters, FEs were at least four levels removed from Biogen's senior management:

	Title	**Alleged Responsibilities and Location**	**Employed**	**Reported To**
FE 1	Alzheimer's Account Manager (Compl. ¶¶ 86-102)	Educated and evaluated ADUHELM treatment sites in the "mid-western part of the country" (Compl. ¶ 86)	04/2020 to 05/2022 (Compl. ¶ 86)	No reporting line alleged
FE 2	Alzheimer's Account Manager (Compl. ¶¶ 103-19)	Educated and evaluated ADUHELM treatment sites in the "mid-western party of the country" (Compl. ¶ 103)	Not alleged	No reporting line alleged
FE 3	Access and Reimbursement Manager (Compl. ¶¶ 120-28)	Evaluated infusion site assessments in Central California and Las Vegas, Nevada (Compl. ¶ 120)	10/2020 to 11/2021 (Compl. ¶ 120)	Director of Access and Reimbursement (at least 4 levels removed from "senior Biogen leadership") (Compl. ¶ 121)
FE 4	Director of Account Liaisons (Compl. ¶¶ 129-40)	Oversaw Account Liaisons; reviewed clinical, financial and operational preparedness of health systems in their territory (Compl. ¶¶ 129, 131); location not alleged	03/2020 to 04/2021; not employed during the putative Class Period (Compl. ¶ 129)	Senior Director of Alzheimer's Account Liaisons (at least 4 levels removed from Ms. Alaimo) (Compl. ¶ 130)

	Title	**Alleged Responsibilities and Location**	**Employed**	**Reported To**
FE 5	Senior Territory Business Manager (Compl. ¶¶ 141-50)	Clinical sales of ADUHELM (Compl. ¶ 141); location not alleged	08/2020 to 01/2022 (Compl. ¶ 141)	No reporting line alleged
FE 6	Territory Business Manager (Compl. ¶¶ 151-54)	Clinical sales of ADUHELM in Boston area (Compl. ¶ 151)	08/2020 to 02/2022 (Compl. ¶ 151)	No reporting line alleged
FE 7	Senior Territory Business Manager (Compl. ¶¶ 155-58)	Clinical sales of ADUHELM (Compl. ¶ 155); location not alleged	08/2020 to 03/2022 (Compl. ¶ 155)	Regional Manager (at least 5 levels removed from Ms. Alaimo) (Compl. ¶ 155)
FE 8	Senior Territory Business Manager (Compl. ¶¶ 159-64)	Clinical sales of ADUHELM in the MidAtlantic (Compl. ¶ 159)	08/2020 to 03/2022 (Compl. ¶ 159)	No reporting line alleged

Defs.' Mem. at 19–20.

A more detailed description of each FE's title and responsibility within Biogen follows:

> Former Employee 1 ("FE 1") was an Alzheimer's Account Manager at Biogen from April 2020 until the Aduhelm program was shut down in May 2022. They covered territory in the mid-western part of the country. Their job responsibilities included educating and evaluating treatment sites in order to allow for patients to be treated as quickly as possible after Aduhelm's approval. Any location that was evaluated was referred to as a "treatment site" by Biogen. These were infusion sites, hospital health systems, imaging centers, private neurology practices, and pain

clinics. [Compl. ¶ 86.]

Former Employee 2 ("FE 2") was also an Alzheimer's Account Manager. FE 2 worked with FE 1 in the mid-western part of the country. Like FE 1, their job responsibilities included educating and evaluating treatment sites in order to allow for patients to be treated as quickly as possible after Aduhelm's approval. As with FE 1, the treatment sites FE 2 evaluated included infusion sites, hospital health systems, imaging centers, private neurology practices, and pain clinics. [Id. ¶ 103.]

Former Employee 3 (["]FE 3["]) was an Access and Reimbursement Manager for Biogen from October 2020 to November 2021. Their job responsibilities included evaluating infusion site assessments. As noted above, Aduhelm is a treatment that must be administered via intravenous infusion. FE 3's assigned territory was in Central California and Las Vegas, Nevada. They were one of 130 similar employees across Biogen's U.S. operation. FE 3 was not part of the sales team. FE 3's manager reported to the Director of Access and Reimbursement, Glen Pauly, who in turn reported to Vice President Angie McEvoy. McEvoy reported to Deb Glasser, the head of the Aduhelm Franchise. FE 3's understanding is that Glasser reported directly to senior Biogen leadership and likely Defendant Vounatsos. [Id. ¶ 121-122].

Former Employee 4 ("FE 4") worked as a Director of Account Liaisons from March of 2020 to April 2021. Their responsibilities involved overseeing Account Liaisons in their work assessing site readiness. This involved meetings with employees of various treatment sites to measure that site's "Willingness, Readiness, and Scalability." FE 4 reported to Jennifer Mallek, who was the Senior Director of Alzheimer's Accounts Liaisons, East Division. Mallek reported to Chris Baumgartner, Vice President/Division General Manager for the Alzheimer's Franchise. Baumgartner reported to Deb Glasser, head of the Alzheimer's franchise and Glasser reported to Alaimo. [Id. ¶ 129-130].

Former Employee 6 ("FE 6["]) worked as a Territory Business Manager in the Boston area from August 2020 until February 2022. FE 6's responsibilities included

> the "clinical selling" of Aduhelm to providers, who would then prescribe the treatment to patients. [Id. ¶ 151.]
>
> Former Employee 7 ("FE 7") worked as a Senior Territory Business Manager from August 2020 to March 2022. As with FE 6, FE 7 was responsible for the "clinical selling" of Aduhelm to providers. They reported to Regional Manager Marcy Ross, who in turn reported to Division Manager Kevin Clifton, who report to Vice President Angie McEvoy. McEvoy reported to Deb Glasser. [Id. ¶ 155].
>
> Former Employee 8 ("FE 8") worked as Senior Territory Business Manager for the Alzheimer's Disease business unit from August 2020 to March 2022. FE 8 work was focused on the mid-Atlantic. FE 8 worked directly with potential prescribers of Aduhelm, including neurologists at private medical practices and the outpatient clinics of major hospital [Id. ¶ 159]

Compl. ¶¶ 86, 103, 121-122, 129-130, 151, 155, 155 (emphasis added).

IV. ANALYSIS

Oklahoma Firefighters challenge twenty-five statements made between June 7, 2021, through September 9, 2021, principally concerning Aduhelm's commercialization efforts.[3] These statements can be grouped into the following categories: (1) three statements concerning the Defendants' assertion that over

[3] Oklahoma Firefighters also devote 15 paragraphs, Compl. ¶¶ 60, 69-70, 72-74, 77-83, 96, 113 to statements made before the class period. Pre-class period statements, however, are not actionable. See Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1217 n.31 (1st Cir. 1996); In re Garrett Motion Inc. Sec. Litig., No. 20 Civ. 7992 (JPC), 2022 WL 976269, at *15 (S.D.N.Y. 2022).

900 healthcare sites were ready to implement treatment with Aduhelm following FDA approval, Compl. ¶¶ 170, 172, 174, (2) seven statements concerning potential obstacles in diagnosing the presence of amyloid plaques in patients with Alzheimer's disease, Id. ¶¶ 176, 179, 228, 234, 239, 252, 255, (3) three statements concerning Medicare coverage, Id. ¶¶ 181, 185, 193, 213, (4) eight statements concerning Aduhelm's initial price, Id. ¶¶ 188, 191, 193, 231, 237, (5) three statements concerning a potential agreement with the VA to provide Aduhelm to veterans, Id. ¶¶ 196, 198, and (6) one statement contained in Dr. Sandrock's open letter to the Alzheimer's disease community allegedly describing Biogen's interactions with the FDA, Id. ¶ 243.

The Defendants seek to dismiss the instant case arguing that Oklahoma Firefighters have failed to allege sufficient facts (1) to show that any of the challenged statement was false or misleading, and (2) to establish a strong inference of scienter. See generally Defs.' Mot.

After a careful examination of the record, this Court sides with the Defendants. Drawing all reasonable inferences in favor of Oklahoma Firefighters, none of the alleged statements is actionable under the PSLRA, whether considered separately or taken as a whole. Moreover, the complaint fails to allege

sufficient facts to establish a strong inference of scienter. As a result, dismissal of the action is warranted here.

A. Pleading Standard

To withstand a motion to dismiss, a complaint must "state a claim upon which relief can be granted . . . ." Fed. R. Civ. P. 12(b)(6). The complaint must include sufficient factual allegations that, accepted as true, "state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). Courts "draw every reasonable inference" in favor of the plaintiff, Berezin v. Regency Sav. Bank, 234 F.3d 68, 70 (1st Cir. 2000), but they disregard statements that "merely offer legal conclusions couched as fact or threadbare recitals of the elements of a cause of action," Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 12 (1st Cir. 2011) (brackets, ellipsis, and quotations omitted).

For a viable cause of action under Section 10(b) of the Securities Exchange Act of 1934, Plaintiffs must plead factual allegations that plausibly could give rise to the following two elements: (1) false or misleading statements; (2) a strong inference of scienter (there are also three other required elements which the Defendants do not challenge in their motion to dismiss).

B. The Complaint Does Not Allege any False or Misleading Statement

For their complaint to survive a motion to dismiss, a securities plaintiff must show that "defendants made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading." Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 454 (1st Cir. 2017) (quoting Geffon v. Micrion Corp., 249 F.3d 29, 34 (1st Cir. 2001)). The allegations in the complaint must meet the standard under Fed. R. Civ. P. 9(b) and the "heightened pleading requirements" imposed on private securities litigation. Mississippi Pub. Employees' Ret. Sys. v. Boston Scientific Corp., 523 F.3d 75, 85 (1st Cir. 2008).

To plead falsity under the PSLRA, a plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." Hill v. Gozani, 638 F.3d 40, 55 (1st Cir. 2011) (alteration in original) (quoting 15 U.S.C. § 78u-4(b)(1)). Information is material if a "reasonable investor would have viewed it as having significantly altered the total mix of information made available." Mississippi Pub. Employees', 523 F.3d at 85 (internal quotation marks and citation omitted). "[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor." Omnicare, Inc. v. Laborers Dist. Council

Const. Indus. Pension Fund, 575 U.S. 175, 186 (2015).

Instead, an omission is actionable under Rule 10b-5 only where there is an affirmative duty to disclose. See Basic Inc. v. Levinson, 485 U.S. 224, 239 n.17 (1988) ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). Plaintiffs carry the burden of showing "that defendants . . . omitted to state a material fact necessary to make a statement not misleading." Ganem, 845 F.3d at 454 (quoting Geffon, 249 F.3d at 34). "[T]he mere possession of material, nonpublic information does not create a duty to disclose it." Hill, 638 F.3d at 57 (quoting Cooperman v. Individual, Inc., 171 F.3d 43, 49 (1st Cir. 1999)) (cleaned up). Thus, "in order to get past 'go' on a motion to dismiss, a plaintiff must first identify a statement made by defendants, show how the omission rendered that statement misleading, and finally establish that there was a duty to disclose the omitted information." Ponsa-Rabell v. Santander Sec. LLC, 35 F.4th 26, 34 (1st Cir. 2022).

1. Statements Regarding Site Readiness

Oklahoma Firefighters claim that Vounatsos's and Alaimo's statements that 900 sites were "ready" to administer Aduhelm are false or misleading. Compl. ¶¶ 170, 172, 174. This argument does not pass muster because Oklahoma Firefighters have failed to allege sufficient facts showing that 900 sites were not

capable of infusing Aduhelm at the time the statements were made. Nor have Oklahoma Firefighters properly alleged that Alaimo's statement is inconsistent with the Individual Defendants' later declarations regarding P&T Review.

Oklahoma Firefighters ask this Court to hold that three statements concerning site readiness are false and misleading. The first is Vounatsos's statement reported by Bloomberg Business News on June 7, 2021, claiming that "over 900 infusion sites in the U.S. were prepared and ready to administer the drug." Id. ¶ 170. The second is Vounatsos's statement during the June 8, 2021, Conference Call:

> **Based on our work to date, we estimate there are over 900 sites ready to implement treatment with ADUHELM shortly after approval.** These sites include clinical trial centers with currently confirmed amyloid beta positive patients as well as other sites with the necessary infrastructure to diagnose and treat patients.

Compl. ¶ 172 (Emphasis in original). The third is Alaimo's statement during the June 8, 2021, Conference Call asserting that:

> Now the really great news is that we expect a core group of these sites that they will be ready to move really quickly. **Now we believe, and you heard Michel say, that there are over 900 accounts ready. Let me tell you what ready means. Ready means that they have the required capability, infrastructure, education and, most importantly, willingness to treat a patient with a potential new Alzheimer's therapy.** Now that ADUHELM has been approved, we have local teams throughout the entire country that will prioritize the 900 accounts to support site activation, while our

> expectation is that more sites are going to become ready in parallel. And our teams are laser-focused on getting this product to as many appropriate patients as possible.

Compl. ¶ 174 (Emphasis in original).

Oklahoma Firefighters' challenges to the two statements by Vounatsos, as well as to the first part of Alaimo's statement (until the word "education"), fail for the same reason: Oklahoma Firefighters have not alleged sufficient facts supporting that 900 sites were not "ready" -- meaning that they had the necessary personnel and infrastructure to administer Aduhelm. As Oklahoma Firefighters acknowledge in its complaint, "[w]hen Biogen would speak about sites being 'ready to treat patients' after FDA approval, they were referring to those sites being deemed ready on [] five metrics." Compl. ¶ 65. These five metrics are "potential patient demand for Aduhelm, the presence of necessary specialists to administer treatment and monitor patients, the ability for the site to confirm amyloid beta in patients, the ability of the site to administer Aduhelm as an infusion, and the ability of the site to use MRIs to monitor patients." Id. ¶ 65. Put simply, Oklahoma Firefighters acknowledge that when Biogen spoke of sites being "ready" after FDA approval it sought to signal that said sites had the necessary personnel and infrastructures to administer Aduhelm -- as well as potential for demand for the treatment (which is not

in contention here). That this was what Vounatsos and Alaimo meant when they spoke about site readiness finds confirmation in the plain text of the challenged statements themselves. During the June 8, 2021, Conference Call, Vounatsos explained that the 900 "ready" sites estimate "include[d] clinical trial centers with currently confirmed amyloid beta positive patients as well as other sites with the necessary infrastructure to diagnose and treat patients." Id. ¶ 172 (emphasis added). On the same occasion, Alaimo qualified her statement about 900 sites being ready with the following definition: "[r]eady means that they have the required capability, infrastructure, education . . ." Id. at ¶ 174.

None of Oklahoma Firefighters' factual allegations suffices to show that on June 7 and 8, 2021, 900 sites did not have the necessary infrastructure and personnel to administer Aduhelm. The complaint generally alleges that FE 1 and FE 2 reported that Biogen's site readiness data included "inaccuracies" and that there were "discrepancies" between what that data showed and how it was portrayed in Biogen's public statements. Compl. ¶¶ 91-93, 108-10. Those allegations lack sufficient specificity to establish falsity. First, they do not even begin to quantify the scope of the purported "inaccuracies" or "discrepancies" that would render the Defendants' 900-site estimate misleading. In re Biogen Inc. Secs. Litig., 857 F.3d 34, 42 (1st Cir. 2017)

(affirming dismissal of securities complaint and rejecting former employee statements that "do not even begin to quantify the magnitude of the sales decline at the company level"). Most importantly, the allegations do not specify which sites or how many sites alleged to not be "ready" were included in the 900-site estimate. An unparticularized allegation that "many sites" were not ready is, without more, insufficient to show that Defendants' 900-site estimate was false or misleading and must thus be rejected. Special Situations Fund III QP, L.P. v. Deloitte Touche Tohmatsu CPA, Ltd., 96 F. Supp. 3d 325, 344 (S.D.N.Y. 2015) (Adjectives and "adverbs are not facts").

Equally insufficient are FEs' 1, 2, 4, 6, 7, and 8 allegations concerning the coding of treatment sites administered by the VA. Compl. ¶¶ 95, 97, 99, 112, 115, 134, 140, 158, 162-164. The FEs claim that they were "instructed" to code all VA administered sites ready, even though they did not believe those sites were ready. Compl. ¶¶ 97, 112, 134, 140. Yet, none of the FEs allege that any Defendant did not believe that those sites were ready. As Oklahoma Firefighters acknowledge, Vounatsos and Alaimo were engaged in negotiations with the VA for a multiyear agreement. Compl. ¶¶ 196, 198. Thus, it is reasonable to infer that Biogen personnel at levels higher than any FE were in contact with the VA. Conspicuously absent from the complaint are specific allegations demonstrating

that the VA sites instructed to be coded "ready" were not in fact ready. Moreover, again, the FEs do not allege that the VA sites were included in the 900-site estimate, thereby rendering that estimate incorrect. Therefore, the FEs declarations are insufficient to establish falsity.

Similarly inadequate is Oklahoma Firefighters' allegation that the Individual Defendants subsequent statements that "35% [of the 900 sites identified as ready had] completed a P&T review with a positive outcome or indicated that they [wouldn't] require a P&T review" constitutes an admission that 900 sites were not "ready" on June 7 and 8. Compl. ¶¶ 17, 228. P&T Reviews are separate and apart from whether Biogen deemed a site to be "ready" -- meaning capable to administer treatment with Aduhelm. The complaint describes a "P&T Review" (or a "Pharmacy and Therapeutics" review) as an internal healthcare site review of "the FDA's approval of the drug, label, cost and whether the treatment would be covered by third-party payers." Compl. ¶ 17. Evidently, a P&T Review does not aim at assessing whether a site would have the necessary personal and infrastructural capability to administer Aduhelm. Conversely, P&T Review is a process that infusion sites undertake to determine whether to include a particular treatment in their formulary. Compl. ¶ 258. Thus, the Individual Defendants subsequent statements concerning P&T Review do not in any way advance Oklahoma Firefighter's

contention. In short, the complaint fails to allege the requisite specific facts showing why Defendants' statements that more than 900 sites were "ready" – meaning logistically capable of administering Aduhelm -- were false or misleading when made.

As to the second part of Alaimo's statement, Oklahoma Firefighters allege that on June 8, 2021, Alaimo falsely and misleadingly stated that over 900 accounts had the "willingness to treat a patient with a potential new Alzheimer's therapy." Compl. ¶ 174. This second challenge fails because the complaint does not properly allege that said statement was false or otherwise inconsistent with the Individual Defendants' subsequent declarations concerning P&T Review.

First, FE 6's allegation that one of FE 6's colleagues told FE 6 that key opinion leaders at Tufts Medical Center in Boston communicated to Kyle Terpek, a Biogen medical science liaison, that Tufts would never support Aduhelm is insufficient to establish falsity. Compl. ¶¶ 152, 175. FE 6's allegation is vitiated by the same fundamental flaw characterizing the FEs' statements discussed above. Conspicuously absent is any factual allegation that Alaimo's estimate that more than 900 sites were willing to treat patients with Aduhelm included Tufts Medical Center in Boston and thus rendered that estimate incorrect. Therefore, FE 6's statement is insufficient to establish falsity.

Equally insufficient is Oklahoma Firefighters' contention that the Individual Defendants subsequent statements that only 35% of the 900 sites identified as ready had "completed a P&T Review with a positive outcome or indicated that they [would not] require a P&T review" constitutes an admission that 900 sites were unwilling to treat patients with Aduhelm on June 7 and 8. Id. ¶ 228. This argument fails because it is premised on an unjustifiably broad interpretation of what Alaimo relayed to the investors on June 8. Oklahoma Firefighters interpret Alaimo's statement as an assurance that more than 900 sites would have prescribed Aduhelm. This, however, is not what Alaimo said. Statements of corporate executives are to be read in light of what a reasonable investor would have understood them to mean, Omnicare, Inc., 575 U.S. at 186-87 ("[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor."), not what a wishful, ill-informed investor would have hoped them to mean. Such an expansive interpretation would impose an excessive burden on public disclosures, thereby hindering the vital exchange of information that allows the capital markets to operate. All that Alaimo stated on June 8 is that, at that point in time, more than 900 sites had expressed a willingness to treat patients with an innovative treatment for Alzheimer's disease. Compl. ¶ 174 ("Ready means that they have the . . . willingness to treat a

patient with a potential new Alzheimer's therapy."). It is difficult to conceive how a reasonable investor could have understood her statement to mean something else. As the complaint alleges, a P&T Review is a "time-consuming evaluation of data," Compl. ¶ 91, which requires a "review of the FDA's approval of the drug, label, cost and whether the treatment would be covered by third-party payers." Compl. ¶ 17. Therefore, P&T Reviews "could [not] have occurred prior to June 7, 2021" -- the day before the challenged statements were made. Compl. ¶ 17. This would have left less than 24 hours for 900 sites across the country to conduct a "time-consuming evaluation of data" involving multiple steps, report their conclusion to Biogen, and then for Biogen to gather, process that data, and communicate it to the investors. Compl. ¶ 91. A reasonable investor would not have interpreted Alaimo's statement to be an assurance that this unrealistic scenario is what had happened. A reasonable investor would also have been cognizant of the fact that this was the first and only time a Biogen executive had ever expressed herself in terms of willingness as opposed to logistical readiness. Put simply, what a reasonable investor would have understood Alaimo to mean is that on June 8, 2021, more than 900 sites had expressed a willingness to treat patients with an innovative treatment for Alzheimer's disease -- not that more than 900 sites had successfully conducted a P&T

Review for Aduhelm and would have thus administered the treatment.

If so, Alaimo's statement is not inconsistent with the Individual Defendants' subsequent statements concerning P&T Reviews. It is readily possible to conceive how infusion sites might have been willing to utilize an experimental drug like Aduhelm on or before June 8; but, after having later carefully reviewed supervening data that was not available until June 7 -- including the FDA's approval of the drug, label, cost, and whether the treatment would be covered by third-party payers -- they ultimately refused to prescribe it. In short, the Individual Defendants' statements concerning P&T Review cannot be deemed an admission that on June 8, 2021, 900 sites were unwilling to administer Aduhelm.

Moreover, Oklahoma Firefighters' reliance on Allaire is misplaced. In re Allaire Corp. Sec. Litig., 224 F. Supp. 2d 319 (D. Mass. 2002). In that case, this Court held that the fact that a non-deteriorating product did not work at time "x+1" sufficed to establish that it did not work at time "x" as well. Id. at 330. The analysis of this Court both at times "x" and "x+1" focused on the same question: whether the product at issue functioned. This is not what this Court is called to do here. In this case, the relevant questions at times "x" and "x+1" are different. At time x (June 8, 2021) the question is whether 900

sites had the required willingness to test an innovative treatment for Alzheimer's disease, while at time x+1 (July and September 2021) the focus of the inquiry is whether these sites ultimately agreed to prescribe Aduhelm. As explained above, it is certainly possible to conceive that a site would have answered in a certain fashion at time "x" and later modified its resolve at time "x+1" based on the site's analysis of essential supervening data. Therefore, Allaire is to be distinguished from the present case.[4]

In sum, FE 6 allegations lack the requisite specificity to establish falsity and the Individual Defendants later statements concerning P&T Review are not contradictory to Alaimo's statement that on June 8, 2021, 900 sites were willing to treat

[4] For the same reason, the present case is to be distinguished from In re Boston Scientific Corp. Sec. Litig., No. CV 20-12225-DPW, 2022 WL 17823837 (D. Mass. Dec. 20, 2022) (Woodlock, J.). On January 5, 2023, Oklahoma Firefighters filed an Unopposed Motion for Leave to File Notice of Supplemental Authority and Subsequent Development ("Motion for Supplemental Authority") arguing that Judge Woodlock's opinion in Boston Scientific supports their case. ECF No. 53. Not so. In Boston Scientific, Judge Woodlock ruled that the defendants' statement on August 19, 2020, that 138 accounts were open, was false and misleading because the Defendants later stated, on November 18, 2020, that in reality only 100 accounts had been opened. Boston Scientific No. 20-12225-DPW, 2022 WL 17823837, at * 16. Therefore, similarly to Allaire, Judge Woodlock's inquiry at times "x" (August 19) and "x+1" (November 18) focused on the same question: how many accounts had been opened. As explained above, the relevant questions before this Court at times "x" and "x+1" are different. Therefore, the present case is to be distinguished from Boston Scientific.

patients with an innovative treatment for Alzheimer's disease. Therefore, Oklahoma Firefighters' challenge to the 900 "ready" sites statements fails.

2. Statements Regarding Diagnosing Amyloid Plaques

Oklahoma Firefighters contend that the Defendants omitted material facts when disclosing to the market potential bottlenecks in commercialization. Compl. ¶¶ 176-180, 234, 239, 255. Oklahoma Firefighters focus their challenge on two principal statements: First, a statement by Vounatsos during the June 8, 2021, Conference Call:

> **[T]he desire to confirm amyloid beta pathology by physicians could be a major bottleneck. With this in mind, we have established a program with Labcorp and Mayo Clinic Laboratories to help physicians and patients access CSF diagnostic laboratory testing to aid the diagnosis of Alzheimer's disease.** And we continue to advocate for PET reimbursement from CMS, joining a coalition of health care organization who supports a revised coverage policy.

Compl. ¶ 176 (emphasis in original). Second, a statement by Alaimo during the June 8, 2021, Conference Call:

> The necessity of testing, as Michel has said, has been left to the judgment of the prescribing physicians. And as the label states, ADUHELM is an amyloid beta-directed antibody. Since there hasn't been an approved therapy that is amyloid beta-directed, amyloid confirmation isn't a routine clinical practice of today, and there is currently no reimbursed test for amyloid. Therefore, the majority of patients have not yet been amyloid confirmed.
>
> But Biogen believes access to this testing should be easily available and affordable. **Therefore, we've established a program, as you heard Michel say in his**

> **opening remarks, with Mayo Clinic Labs and Labcorp to help physicians and patients access cerebrospinal fluid diagnostic laboratory testing.** Also, as Michel had referred to, we are continuing to work with a coalition of health care and advocacy organizations to support a pathway to PET reimbursement from CMS, and we believe we will need both the CSF test and the PET reimbursement.

Compl. ¶ 179 (emphasis in original). For Oklahoma Firefighters these statements "misleadingly suggest[] that the bottleneck would be meaningfully addressed by arranging for [Labcorp] and Mayo Clinic[]labs to analyze the spinal fluid, but the real roadblock to Aduhelm prescription was getting the samples in the first place." Compl. ¶ 178. This argument is twofold.

First, Oklahoma Firefighters claim that Vounatsos's and Alaimo's statements are misleading because they suggest that the potential bottleneck stemming from the need to confirm amyloid beta pathology would be "meaningfully addressed" by arranging for Labcorp and Mayo Clinic labs to analyze the spinal fluid. Not so. Absent in the complaint is any allegation that the necessity to analyze spinal fluid was not a potential major bottleneck by itself; and that establishing a program to enhance testing capacity of cerebrospinal fluid would have meaningfully contributed to redressing that bottleneck. All that Oklahoma Firefighters bring before this Court is the conclusory allegation that the real bottleneck concerned the collection of spinal fluid. This is not sufficient "meat on the bone" to

survive a motion to dismiss.

Second, Oklahoma Firefighters claim that Vounatsos's and Alaimo's statements are misleading because they "omitted" to reveal that the real bottleneck was the collection of spinal fluid and not its analysis. Compl. ¶ 178. This argument is predicated on the assumption that a statement omitting facts becomes misleading where there is a "reasonable likelihood that a reasonable investor would consider [the information omitted] important." Pl.'s Opp'n at 14 (citing Glassman v. Computervision Corp., 90 F.3d 617, 632 (1st Cir. 1996). This is not the law. Contrary to Oklahoma Firefighters' argument, it is not sufficient that the omitted information be relevant for a statement to be misleading. In re Praecis Pharms., Inc. Sec. Litig., No. 04-12581-GAO, 2007 WL 951695, at *7 (D. Mass. Mar. 28, 2007) (O'Toole, J.) (dismissing complaint and rejecting argument that "the omitted facts would have been of material interest to a prospective investor who would like to know as much as possible about the [c]ompany and its business. Under [First Circuit] precedents, however, that is not the applicable standard of liability."). Instead, a securities plaintiff must "show how the omission rendered [the challenged] statement misleading." Ponsa-Rabell v. Santander Sec. LLC, 35 F.4th 26, 34 (1st Cir. 2022).

Here, Oklahoma Firefighters failed to allege sufficient

facts to show that the suspected omission rendered the challenged statements misleading. The gist of Oklahoma Firefighters' argument is that by informing the public about their efforts to redress a problem (increasing testing capacity) the Defendants assumed a duty to disclose another problem (the potential challenges associated with the collection of spinal fluid). Pl.'s Opp'n at 13-14. In this sense, the present case is similar to Backman. Polaroid Corp., 910 F.2d 10 (1st Cir. 1990). There, the securities plaintiff argued that the defendants' statement about one issue (that a certain product was being sold below cost) was misleading because the defendants had omitted to reveal another issue (that the number of sales were below expectations). Id. at 16. The court flatly rejected this argument because that "voluntary disclosure of information that a reasonable investor would consider material must be 'complete and accurate.' This, however, does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise." Id. Here, like in Backman, the collection and analysis of spinal fluid are two separate and distinct aspects of the process of diagnosing amyloid plaques. The logistical challenges associated with each phase are similarly distinct. Applying Backman's logic, therefore, disclosure of a bottleneck associated with one of the two phases does not create an obligation to disclose every

possible logistical challenge associated with the other. Absent such a disclosure obligation on the Defendants' part, Oklahoma Firefighters' argument fails.

Of course, a different conclusion would have been warranted had the Defendants elected to comment on logistical challenges related to collecting spinal fluid. Yet this is not what happened here. For this reason, the present case can be distinguished from Allaire and Brumbaugh, upon which Oklahoma Firefighters incorrectly rely. In Allaire, the defendants had issued press releases stating that one of their products "worked wonderfully [and] sales would be excellent." In re Allaire, 224 F. Supp. at 327. This Court held that this statement was misleading because the company knew that said product "was doomed and hence that sales of [that product] would be doomed." Id. at 327. Similarly, in Brumbaugh, the defendants had made representations that a newly signed supply contract would have led to "significant revenue growth." Brumbaugh v. Wave Sys. Corp., 416 F. Supp. 2d 239, 247 (D. Mass. 2006) (Ponsor, J.). The court ruled this statement misleading because the defendants had not disclosed that this was merely a non-exclusive agreement. Id. at 247-48. The Defendants here never made assurances comparable to those made by the Allaire and Brumbaugh defendants. Vounatsos and Alaimo never represented that there would not have been any issue with respect to the collection of

spinal fluid. In fact, the Defendants are not alleged publicly to have discussed the logistical challenges associated with the collection of spinal fluid at all. In short, none of the Defendants' statements concerning logistical challenges associated with diagnosing amyloid plaques were false and misleading when made.

3. Statements Regarding Medicare Coverage

Oklahoma Firefighters charge that Vounatsos's and Alaimo's assertions that "Medicare fee-for-service coverage is automatically presumed with FDA approval" to be false and misleading. Compl. ¶¶ 181, 185, 193, 213. According to Oklahoma Firefighters these statements "falsely denied the possibility of CMS limiting reimbursement for the treatment." Compl. ¶ 184. Oklahoma Firefighters' argument misconstrues Vounatsos's and Alaimo's statements and, therefore, shall be rejected. Vounatsos's and Alaimo's statements never guaranteed that Medicare coverage would have been extended to Aduhelm upon FDA approval. Instead, Vounatsos's and Alaimo's statements are best read as merely indicating that coverage was presumed. The adverb "automatically" qualifies the presumption of coverage, not the coverage itself. Moreover, the Defendants themselves admit that Medicare coverage "typically follow[s] FDA approval." Pl.'s Opp'n at 15. This further confirms that the most sensible construction of Vounatsos's and Alaimo's

statements is that Medicare coverage "typically follow[s]" FDA approval.

Nor have Oklahoma Firefighters shown that market analysts have interpreted these statements any differently. Oklahoma Firefighters rely on two analyst reports in an attempt to demonstrate that "analysts understood from Biogen that Medicare would pay for coverage." Id. at 16. These reports, however, either merely repeat the "automatic presumption" language used in the statements, Block Decl., ECF No. 45, Ex. 2, or note that "Medicare [was] expected to cover vast majority of ADUHELM patients" -- meaning that Medicare coverage was merely presumed, Block Decl., ECF No. 45, Ex. 1. Contrary to Oklahoma Firefighters' argument, the market did not consider Medicare coverage as guaranteed upon FDA approval. Therefore, the Defendants' statements regarding Medicare coverage are not false and misleading.

4. Statements Regarding Aduhelm's Price

Oklahoma Firefighters allege that several statements the Defendants made in relation to the process that Biogen followed to determine the initial price of Aduhelm are misleading. Compl. ¶¶ 187-195, 231, 237. The critical statements are the following:

- The price is set at $56,000 a year, during the normal year after lengthy engagement obviously this is important with scientific leaders, pharmaco-

economists, payers, private and public payers; Compl. ¶ 188

- You know Meg, and we're engaging with Medicare and we're engaging with the private payers since quite a long time; Compl. ¶ 188

- [W]e've been at this for months, as Michel suggested. We've consulted extensively with experts, health economists, clinicians, policy and payer leaders. . . . So we consider this to be a really responsible price; Compl. ¶ 191

- In determining the price, we engaged with stakeholders, including clinical experts, health economics, policymakers and payors on ADUHELM; Compl. ¶ 193

For Oklahoma Firefighters these statements "misleadingly suggested that third-party payors had expressed support, approval, or, at a minimum, a willingness to accept Aduhelm's initial annual price point of $56,000 per patient." Compl. ¶¶ 187-195.

Oklahoma Firefighters misconstrue the statements listed above. All that these statements provide is that Biogen engaged with and received input from payors and other relevant stakeholders, ultimately reaching a price that it considered fair. Defs.' Mem. at 13. It is nowhere present in Biogen's statements that the payors and stakeholders supported, "approv[ed]," or expressed "willingness" to pay a price of $56,000 a year per patient for Aduhelm. Compl. ¶ 189. Moreover, Oklahoma Firefighters nowhere allege that Biogen had failed to engage with relevant stakeholders as it claimed to

have done. Therefore, the statements made by the Defendants in relation to the process through which Biogen determined Aduhelm's initial price are not false or misleading.

5. Statements Regarding an Agreement with the VA

Oklahoma Firefighters fault the Defendants for having claimed that they were "finaliz[ing]" a multiyear coverage agreement with the Veterans Health Administration. Compl. ¶¶ 196-203. For Oklahoma Firefighters this assertion was false and misleading primarily for two reasons. Compl. ¶¶ 197, 199. First, a "leading VA advisor," Dr. Andrew Budson, "conveyed to Biogen's Medical Science Liaison, Johannah Venturini, prior to the start of the Class Period, that he did not support including Aduhelm in the VA's formulary." Compl. ¶ 197. Second, on August 11, 2021, two months after Vounatsos's and Alaimo's statements, the VA announced it would not provide coverage for Aduhelm in its formulary. Id.

This Court rejects Oklahoma Firefighters' contention. First, the fact that a single VA advisor opposed extending coverage for Aduhelm is insufficient to establish that no agreement was being "finalized." Absent from Oklahoma Firefighter's complaint is any allegation that Dr. Andrew Budson could unilaterally have dictated the outcome of the Biogen-VA negotiations. Moreover, it is unclear how the opposition of a single doctor would otherwise have rendered it impossible for

Biogen to reach an agreement with the VA. The complaint provides no answer to this question.

Second, the later announcement of the VA that it would not provide coverage for Aduhelm in its formulary is insufficient to establish earlier falsity. In truth, Oklahoma Firefighters' contention to the contrary amounts to an impermissible pleading of "fraud by hindsight." Allaire, 224 F. Supp. 2d at 329 ("Fraud by hindsight claims are insufficient if a changeable condition exists and there is no evidence or facts pled which demonstrate that the changeable condition did not in fact change post-statement."). A "changeable condition" existed here. Id. Contractual negotiations are well-known to be a complex and multifaceted process, filled with uncertainty and ups and downs. The simple fact that the negotiations ultimately fell apart does not readily lead to an inference that the negotiations had never reached a stage that properly could have been characterized as "final." Nor does the fact that the negotiations broke down demonstrate that it was caused by "a lack of evidence of a robust and meaningful clinical benefit and the known safety signal." Compl. ¶ 248. Absent in the complaint is any allegation of fact explaining why this obstacle could have not been addressed during the negotiations. In fact, the complaint is utterly devoid of factual allegations addressing whether Biogen was in fact working to finalize an agreement with the VA

when those statements were made, or the status of such negotiations at the time. Therefore, Oklahoma Firefighters has not shown that the Defendants' statements regarding an agreement with the VA were false and misleading when made.

6. Statements in Dr. Sandrock's Letter

Finally, Oklahoma Firefighters assert that the open letter of Dr. Sandrock to the Alzheimer's Disease Community contained false and misleading statements. Compl. ¶¶ 243-245. Particularly, Oklahoma Firefighters claim that "Sandrock's statement that Biogen's interactions with the FDA to resurrect Aduhelm was appropriate and not out of the ordinary was materially false and misleading." Id. ¶ 244. This is because, according to Oklahoma Firefighters, Acting FDA Commissioner Woodcock "conceded there have been contact between the FDA and Biogen 'outside the formal correspondence process.'" Id. ¶ 244.

Oklahoma Firefighters overstate their case by mischaracterizing the statements of both Dr. Sandrock and Commissioner Woodcock. First, Dr. Sandrock never stated that "Biogen's interactions with the FDA to resurrect Aduhelm was appropriate and not out of the ordinary." Id. Oklahoma Firefighters appear to reach this conclusion primarily based on three statements. First, Sandrock's statement that "Aduhelm's approval has been the subject of extensive misinformation and understanding." Pl.'s Opp'n at 19. Second, that recently,

"there has been a turn outside the boundaries of legitimate scientific deliberation" concerning Aduhelm's approval. Id. Third, that "it is factually incorrect" to suggest that "Aduhelm's results are 'post-hoc.'" Id. Taken together and in the proper context, these statements cannot be read to mean that "Biogen's interactions with the FDA to resurrect Aduhelm was appropriate and not out of the ordinary."

Given the controversy surrounding the exact nature of Dr. Sandrock's statements, citing extensively from the Open Letter of Dr. Sandrock to the Alzheimer's Disease Community is warranted:

> Unfortunately, ADUHELM's approval has been the subject of extensive misinformation and misunderstanding. It is normal for scientists and clinicians to discuss data from experiments and clinical trials, to debate, and to disagree, on the interpretation of data. That is how science advances and we welcome these discussions. Recently, however, there has been a turn outside the boundaries of legitimate scientific deliberation.
>
> We welcome a formal review into the interactions between the FDA and Biogen on the path to the approval of aducanumab. A better understanding of the facts is good for everyone involved to assure confidence in both the therapy and the process by which it was approved as we prioritize the issues that affect patients.
>
> A step toward such transparency is to correct some of the misinformation we have seen:
>
> **More than 250 drugs have been granted Accelerated Approval by the FDA. . . .**
>
> Several people have stated that all previously

> studied anti-amyloid antibodies clear amyloid from the brain but have failed as a class to demonstrate benefit. This is factually incorrect. First generation anti-amyloid antibodies were not specific for aggregated forms of amyloid beta, or targeted soluble monomeric amyloid beta, or were deficient in effector function. As a result, these antibodies do not clear amyloid from the brain. As such, there is no basis for using the failure of these antibodies as a reason to question the approval of ADUHELM. . . .
>
> Separately, we have seen statements that all of ADUHELM's results are "post hoc" – in other words, that a filter was applied after the fact to interpret the data in a certain way. That is also factually incorrect. The primary and secondary endpoints had been pre-specified in the Phase 3 trial protocols, before the first patient was enrolled into the trials. The ADUHELM label shows the results on these pre-specified endpoints, based on data that had already been collected at the sites by the time the trials were prematurely terminated on March 21, 2019.

Open Letter of Dr. Sandrock to the Alzheimer's Disease Community, ECF. 40, Tab 8, 1, 2 (emphasis added). From the passage above it is apparent that the "misinformation and misunderstanding" to which Dr. Sandrock is referring is primarily twofold. First, that "[s]everal people have stated that all previously studied anti-amyloid antibodies clear amyloid from the brain but have failed as a class to demonstrate benefit." Id. Second, that "all of ADUHELM's results are 'post hoc'." Id. Taken together, these statements in no way can be interpreted -- as Oklahoma Firefighters suggest -- to mean that "Biogen's interactions with the FDA to resurrect Aduhelm was appropriate and not out of the ordinary."

Second, Oklahoma Firefighters mischaracterize Acting Commissioner Woodcock's statement. Acting Commissioner Woodcock did not, contrary to what Oklahoma Firefighters state, "concede[] there have been contact between the FDA and Biogen 'outside the formal correspondence process.'" Compl. ¶ 244. Rather, Acting Commissioner Woodcock only stated that the OIG should conduct an investigation about whether there were any interactions that were inconsistent with FDA policies and procedures:

> There continue to be concerns raised, however, regarding contacts between representatives from Biogen and FDA during the review process, including some that may have occurred outside of the formal correspondence process. . . . I believe that it is critical that the events at issue be reviewed by an independent body such as the Office of the Inspector General in order to determine whether any interactions that occurred between Biogen and FDA review staff were inconsistent with FDA policies and procedures.

Letter of FDA Acting Commissioner Woodcock to FDA Acting Inspector General Grimm, ECF. 40, Tab 7, 1 (emphasis added). It is apparent from this passage that Acting Commissioner Woodcock did not reach any conclusions as to the existence of improper contacts between Biogen and FDA officials. Instead, she requested that further investigation be conducted to assess if such improper contacts had occurred at all. Therefore, reviewing the statements in the proper context reveals that Dr. Sandrock made no false or misleading statements.

In summary, drawing all reasonable inferences on behalf of Oklahoma Firefighters, none of the alleged statements is actionable under the PSLRA, whether considered separately or taken as a whole. Therefore, this action must be dismissed. For the sake of completeness, this Court proceeds below to evaluate whether the scienter allegations are made out.

C. The Scienter Allegations Are Not Made Out

To be actionable under the PSLRA, a statement must be more than merely material and misleading; it also must have been made with the requisite scienter. See ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46 (1st Cir. 2008). Congress has heightened pleading standard for scienter allegations in private enforcement actions. Securities & Exch. Comm'n v. Sharp, 2022 WL 4085676 (D. Mass. 2022) (citing Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit, 547 U.S. 71, 81 (2006). The reasons underlying this important legislative intervention have been aptly described by my colleague Judge Lindsay:

> In particular, Congress sought to reform private securities litigation to discourage unmeritorious class actions, including actions brought because of a decline in stock prices. The aims of the PSLRA are three-fold: '(1) to encourage the voluntary disclosure of information by corporate issuers; (2) to empower investors so that they -- not their lawyers -- exercise primary control over private securities litigation; and (3) to encourage plaintiffs' lawyers to pursue valid claims and Defendants to fight abusive claims.' The PSLRA seeks to curtail the filing of abusive lawsuits at the pleading stage of litigation by establishing uniform and stringent pleading

requirements.

In re Galileo Corp. S'holders Litig., 127 F. Supp. 2d 251, 260 (D. Mass. 2001) (Lindsay, J.) (quoting S. Rep No. 104-98 at 4, 15).

Specifically, the pleaded facts must give rise to a "strong inference" of scienter. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007). This means that the complaint must "with respect to each act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A); see also Boston Scientific Corp., 686 F.3d at30. "It does not suffice that a reasonable factfinder plausibly could infer from the complaint's allegations the requisite state of mind." Tellabs, 551 U.S. at 314. Instead, the inference of scienter must be "cogent and at least as compelling as any other opposing inference of nonfraudulent intent." Id.

1. Statements Regarding Site Readiness

To establish scienter, Oklahoma Firefighters rely on a variety of allegations, which are primarily derived from the statements of eight former Biogen employees. Compl. ¶¶ 85-164; Pl.'s Opp'n at 24-25. As seen earlier in Section III.E. of this opinion, however, none of them are alleged to have been a member of Biogen's "senior management," and none are alleged to have directly reported to any of the Individual Defendants. See

supra Section III.E; See also In re Biogen Inc. Sec. Litig., 857 F.3d 34, 43 (1st Cir. 2017) (holding that the statements attributed to former employees "are 'not described with sufficient particularity' . . . to give rise to a strong inference of scienter as to senior management if none of the witnesses were senior managers and they had little contact with such managers."). In fact, none of the FEs are alleged to have had any contact with any individual Defendant. See In re iRobot Corp. Secs. Litig., No. 19-cv-12536-DJC, 2021 WL 950675, at *10 (D. Mass. 2021) (Casper, J.) (stating the fact that confidential witnesses had little or no ongoing contact with defendant's senior management "undercut[] the Plaintiffs' reliance upon them in the pleadings, particularly when the PSLRA requires that confidential witnesses allege 'with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind'") (quoting 15 U.S.C. § 78u-4(b)(2)(A)). This fact alone puts a serious dent in Oklahoma Firefighters' scienter allegations.

Oklahoma Firefighters push back asserting that "three key facts" demonstrate that the confidential witnesses' concerns regarding the actual number of ready sites "not only reached Defendants, but Defendants knew them to be the true." Pl.'s Opp'n at 25. First, Biogen conducted a formal investigation into the accuracy of site readiness. Id. Based on this,

Oklahoma Firefighters state "it is fair to infer that" Vounatsos and Alaimo were aware of it because they "were publicly discussing the number of ready sites." Id. Second, "Glasser (who reported directly to Alaimo and Vounatsos) began to refer to sites as 'potentially' commercially ready," allegedly "in response" to the "concerns raised" in relation to the investigation. Id. Third, "the results" of the investigation communicated to FE1 and FE2 were that "while it was 'no big deal,' Biogen would do a 'better job with word choices.'" Id.

Oklahoma Firefighters' pushback does not go far. First, Oklahoma Firefighters' allegations fall short of showing that Vounatsos and Alaimo were aware of the occurrence of the internal investigation. The mere fact that Vounatsos and Alaimo were publicly discussing the number of ready sites is insufficient as matter of law to infer such knowledge. Doing otherwise would be equivalent to establishing scienter based solely on the Defendants' status as company executives, which has long been deemed impermissible. Maldonado v. Dominguez, 137 F.3d 1, 10 (1st Cir. 1998) (rejecting argument that defendants "must have known" of facts due to their positions). Nor do the references to Vounatsos and Alaimo attending meetings involving site readiness do much to advance Oklahoma Firefighters' position. Pl.'s Opp'n at 24-25. Vague and generic references to internal reviews and meetings are insufficient as matter of

law to support an inference of scienter absent specific allegations of what Defendants learned during such reviews and meetings. In re iRobot, 2021 WL 950675, at *9.

Second, Oklahoma Firefighters failed to alleged facts establishing that Alaimo and Vounatsos were aware of the results of the investigation at the time the statements were made on June 7 and 8. The investigation was commenced on April 28, 2021. Compl. ¶ 100. Yet, there is no factual allegation before this Court suggesting that the investigation ended or that the results thereof were communicated to Alaimo and Vounatsos on or before June 7 and 8. In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016) (no strong inference of scienter where complaint failed to plead "any specific facts about when the defendants learned of the [ ] adverse events or even when the adverse events occurred"). To the contrary, the complaint indicates that FE 1 and FE 2 were informed that the investigation had been closed only in July 2021 -- a month after the challenge statements were made. Compl. ¶ 100.

Third, Oklahoma Firefighters have not alleged sufficient facts to show that the result of the internal investigation was inconsistent with Alaimo's and Vounatsos's statements that 900 sites were "ready" to administer Aduheilm. Metzler Asset Management GmbH v. Kingsley, 928 F.3d 151 (1st Cir. 2019) (noting that to find scienter "one would need to know ...

whether what [the defendant] learned was at odds with any of his . . . statements."). In fact, Oklahoma Firefighters are unable to identify the outcome of the investigation at all. As FE 1 and FE 2 admit, they were "never informed about the outcome of the [internal] investigation." Compl. ¶¶ 100, 116. To bridge this gap, Oklahoma Firefighters unpersuasively argue that Glasser referred in an email to sites as "potentially" commercially ready "in response" to the investigation. Pl.'s Opp'n at 24. This is mere speculation. Oklahoma Firefighters allege no fact supporting the conclusion that Glasser's email was sent "in response" to the investigation. Nor do Oklahoma Firefighters explain why Glasser wrote the email, why she used the word "potentially," or even what she meant by "potentially commercially ready."

Oklahoma Firefighters further maintain that the results of the investigation communicated by an unnamed person in Employee Relations to FE 1 and FE 2 were that "while it was 'no big deal,' Biogen would do a 'better job with word choices.'" Compl. ¶¶ 100, 116. While this statement lends itself to a possible inference that the results of the investigation partly endorsed FE 1's and FE 2's concerns regarding site readiness, it falls short of supporting a strong inference that the investigation concluded that the 900 sites were not "ready." A finding that 900 sites were not "ready" as communicated to the

investor community would certainly have been "a big deal" for Biogen. Indeed, the fact that the investigation was not seen as a matter of importance within Biogen only strengthens the inference that senior management was not informed of the results of the investigation.

Overall, the scienter allegations before this Court resemble those before the Southern District of New York in Sanofi. In re Sanofi Sec. Litig., 155 F. Supp. 3d 386 (S.D.N.Y. 2016). In that case, the plaintiffs alleged that the defendant company and its former CEO knowingly omitted that the company was engaged in an illegal marketing scheme. Id. at 392. Plaintiffs alleged that an internal investigation was commenced following a whistleblower report, and that the CEO was aware of it due to the operation of certain internal corporate policies. Id. at 406. The court ruled those allegations insufficient because plaintiffs had failed to "reference any specific report or statement" that the CEO reviewed or of which he was aware because there were no "reports of the alleged internal investigation's findings" which would have demonstrated the existence of the illegal scheme. Id. Similarly, Oklahoma Firefighters fail to allege facts showing if, when, and how Alaimo and Vounatsos became aware of the investigation's findings and whether the results of the investigation were inconsistent with the Individual Defendants' statements

concerning site readiness.

Nor does Oklahoma Firefighters' "fraud by hindsight" claim generate any momentum. According to Oklahoma Firefighters "Vounatsos's admission, on July 22, 2021, that only 325 sites were then ready to treat as they had completed, or would forgo, a P&T Review, demonstrates the 900 number was falsely or recklessly made on June 7 and 8." Pl.'s Opp'n at 24. In other words, Oklahoma Firefighters ask this Court to infer scienter retroactively based on facts occurring after the false or misleading statements were made. Courts have uniformly rejected this type of "fraud by hindsight" claims. Ezra Charitable Tr. v. Tyco Int'l, Ltd., 466 F.3d 1, 6 (1st Cir. 2006) ("Pleading 'fraud by hindsight,' essentially making general allegations that 'defendants knew earlier what later turned out badly,' is not sufficient."); Advest, Inc., 512 F.3d at 62 (cleaned up) ("A plaintiff may not plead 'fraud by hindsight'; i.e., a complaint 'may not simply contrast a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud."); Ganem, 845 F.3d at 457 ("'[F]raud by hindsight' does not satisfy the pleading requirements in a securities fraud case."). In sum, this Court holds that Oklahoma Firefighters have failed to plead sufficient facts to support a strong inference of scienter as to the 900 "ready" sites statement.

2. Statements Regarding Diagnosing Amyloid Plaques

Oklahoma Firefighters argue that Vounatsos and Alaimo were aware of the bottlenecks associated with the performance of lumbar punctures. For Oklahoma Firefighters it was "widely acknowledged" within Biogen that the facilities performing the lumbar punctures were a major bottleneck, and that this issue was discussed "all the time." Compl. ¶ 125. These allegations are, of course, too general to support scienter. In re Cabletron Sys., Inc., 311 F.3d 11, 29–30 (1st Cir. 2002) (whether facts provide an adequate basis for inferring scienter depends upon "an evaluation, inter alia, of the level of detail provided by the confidential sources.").

Moreover, FE 3's statements do not establish that Vounatsos and Alaimo were aware of the bottlenecks concerning the collection of spinal fluid. Compl. ¶ 125. FE 3 had conversations regarding the bottleneck with McEvoy, who was two levels removed from senior management. Id. McEvoy, in turn, "intimated" to FE 3 that this issue was "conveyed to more senior individuals" at Biogen. Id. Missing from those allegations, however, are specific facts about whether this intimation was later followed up, who spoke to any Defendant, what was said, and when. In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d 278, 286 (D. Mass. 2013) (Stearns, J.) (a "statement that an unnamed person in no specified position of authority 'made

suggestions' . . . that [managers] may or may not have heard (or paid attention to) is a meager fount for even a whiff of a fraudulent scheme, much less a particularization of its details."); In re Praecis Pharms., Inc. Sec. Litig., 2007 WL 951695, n. 14 at *12 (D. Mass. 2007) (O'Toole, J.) (allegation that a confidential witness informed management that a pricing structure was flawed did not adequately plead scienter because "more than that would be needed to support an allegation that 'management' itself knew the structure to be flawed, as opposed to knowing simply that someone else (of unclear qualifications) thought that to be the case."). Absent those requisite facts, the FE's allegations cannot give rise to a strong inference of scienter as matter of law. Kingsley, 928 F.3d at 161 (The "relevance [of confidential witness statements] is further diminished by the fact that the complaint does not allege that any of the CWs ever spoke with any of the individual defendants or otherwise shared with them their observations."). Therefore, no scienter can be inferred as to the statements regarding diagnosing amyloid plaques.

3. Statements Regarding Medicare Coverage

Oklahoma Firefighters argue that Vounatsos and Alaimo knew or recklessly disregarded that it was misleading to state that Medicare coverage was "automatically presumed" upon FDA

approval. Compl. ¶¶ 182-84. For Oklahoma Firefighters, Vounatsos and Alaimo "no doubt understood the regulatory framework surrounding CMS coverage and knew that NCDs are not uncommon where (1) a treatment is approved under the accelerated approval process, (2) a treatment is expensive, or (3) there is controversy surrounding a treatment's efficacy or safety." Pl.'s Opp'n at 27; Compl. ¶¶ 182-84 (emphasis added).

This Court flatly rejects Oklahoma Firefighters' contention. It is well-established that claims that defendants knew or should have known that their statements were false or misleading based solely on their professional backgrounds are insufficient to support a strong inference of scienter. Leavitt v. Alnylam Pharm., Inc., 525 F. Supp. 3d 259, 266 (D. Mass. 2021) (Gorton, J.) (no inference of scienter "[j]ust because the [i]ndividual [d]efendants are highly educated pharmaceutical executives."). Therefore, no scienter can be inferred as to the statements regarding Medicare coverage.

4. Statements Regarding Aduhelm's Price

Oklahoma Firefighters argue that the Defendants knowingly or recklessly made false or misleading statements in relation to the process that Biogen followed to determine the initial price of Aduhelm.

First, Oklahoma Firefighters contend that scienter can be inferred because the statements of FEs 1, 2, 3, 5, and 6 show

that "Biogen knew that many providers and public payors had expressly refused to make any commitments on Aduhelm until after FDA approval." Pl.'s Opp'n at 28. Not so. FEs 1, 2, 3, 5, and 6's statements indicate what they knew about the process followed by Biogen to determine the initial price of Aduhelm, not what the Defendants knew. In fact, the complaint is utterly devoid of any non-conclusory allegation that what the confidential witnesses knew was communicated to the Defendants. Nor it is alleged that the confidential witnesses ever spoke with the Defendants. Kingsley, 928 F.3d at 161 (The "relevance [of confidential witness statements] is further diminished by the fact that the complaint does not allege that any of the CWs ever spoke with any of the individual defendants or otherwise shared with them their observations."); In re iRobot, 2021 WL 950675, at *10 (The fact that confidential witnesses had little or no ongoing contact with defendant's senior management "undercut[] the Plaintiffs' reliance upon them in the pleadings, particularly when the PSLRA requires that confidential witnesses allege 'with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind'") (quoting 15 U.S.C. § 78u-4(b)(2)(A)). In short, the allegations attributed to the FEs say little about what Defendants "knew."

Second, Oklahoma Firefighters ask this Court to infer

scienter because several third-party payors criticized the price of Aduhelm for being too high subsequent to the price announcement. Pl.'s Opp'n at 18. Of course, this is a textbook "fraud by hindsight" argument, which must be rejected. Ezra, 466 F.3d at 6 ("Pleading 'fraud by hindsight,' essentially making general allegations 'that defendants knew earlier what later turned out badly,' is not sufficient."). Therefore, no scienter can be inferred as to the statements regarding Aduhelm's price.

5. Statements Regarding an Agreement with the VA

Oklahoma Firefighters argue that Vounatsos's and Alaimo's statements that Biogen was working to "finalize" a multiyear agreement with the VA were knowingly false or misleading. Compl. ¶¶ 196, 198. First, for Oklahoma Firefighters, scienter may be inferred because a "leading VA advisor opposed Aduhelm." Pl.'s Opp'n at 29. As previously stated, however, Oklahoma Firefighters' complaint is devoid of a factual allegation that advisor, Dr. Budson, could unilaterally have dictated the outcome of the Biogen-VA negotiations. See supra p.44. In other words, Dr. Budson's contrariety to prescribing Aduhelm was not an insurmountable barrier to reaching an agreement with the VA. See id. Even assuming that the Defendants knew of it, they could not possibly have known on that basis alone that an agreement with the VA could not have been reached. Therefore,

Dr. Budson's opposition is insufficient to establish scienter.

Second, Oklahoma Firefighters maintain that the VA's announcement that it would not support Aduhelm treatment establishes scienter. Pl.'s Opp'n at 29. Not so. Once again, a "general allegations that 'defendants knew earlier what later turned out badly,' is not sufficient." Ezra, 466 F.3d at 6. Therefore, no scienter can be inferred as to the statements regarding an agreement with the VA.

6. Statements in Dr. Sandrock's Letter

Finally, Oklahoma Firefighters allege that Sandrock knew that his statement that "Biogen's interactions with the FDA to resurrect Aduhelm was appropriate and not out of the ordinary" was knowingly false and misleading. Compl. ¶ 244; Pl.'s Opp'n at 29. According to Oklahoma Firefighters, "[Sandrock] personally led Biogen's effort to resuscitate Aduhelm and find an internal FDA champion to shepherd it through an uphill approval process -- he was the one who had been making inappropriate contact outside the formal process with the FDA." Pl.'s Opp'n 29, Compl. ¶¶ 216, 225.

Oklahoma Firefighters' scienter allegation must be rejected because it is premised on a fundamental misunderstanding of Dr. Sandrock's statements. As discussed previously, Dr. Sandrock never said that "Biogen's interactions with the FDA to resurrect Aduhelm was appropriate and not out of the ordinary." See supra

Section IV.B.6. Therefore, no scienter can be inferred as to that statement, which indeed was never spoken.

In sum, this Court holds that the scienter allegations are not made out. What is missing in the complaint are sufficient factual allegations that the Defendants -- not several low-ranking employees -- knew or recklessly disregarded that 900 infusion sites were not "ready" on June 7-8. Generic allegations that Biogen conducted an internal investigation concerning site readiness do not bridge that gap. Nor do the numerous mischaracterizations of the Defendants' statements. Oklahoma Firefighters' inability to plead a "strong" inference of scienter further confirms that the Defendants' motion to dismiss for failure to state a claim ought be granted.

V. CONCLUSION

Oklahoma Firefighters failed to allege sufficient facts to show that any of the challenged statements were false or misleading. This Court thus **GRANTS** the Defendants' motion to dismiss.

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
JUDGE
of the
UNITED STATES[5]

[5] This is how my predecessor, Peleg Sprague (D. Mass. 1841-1865), would sign official documents. Now that I'm a Senior District Judge I adopt this format in honor of all the judicial colleagues, state and federal, with whom I have had the privilege to serve over the past 45 years.