UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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IN RE DENTSPLY SIRONA, INC. SECURITIES LITIGATION

MEMORANDUM AND ORDER

24 Civ. 9083 (NRB)

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NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

These consolidated actions were brought pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rules 10b-5(a), (b), and (c) promulgated thereunder, 17 C.F.R. § 240.10b-5, against Dentsply Sirona, Inc. ("Dentsply" or the "Company") and certain of Dentsply's current and former executives (the "Individual Defendants" and, together with Dentsply, "defendants"), on behalf of a putative class of investors who purchased Dentsply common stock between January 4, 2021 and February 26, 2025[1], inclusive (the "Class Period"). Defendants have moved to dismiss the Amended Complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6).[2]

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[1] HANSAINVEST Hanseatische Investment-Gesellschaft mit beschränkter Haftung and City of Miami General Employees' & Sanitation Employees' Retirement Trust (together, the "Lead Plaintiffs") allege that Dentsply's stock was inflated by defendants' alleged misrepresentations to investors between the date of the first alleged misrepresentation on January 4, 2021, ECF No. 51 ("Amended Complaint" or "AC") ¶ 252, and February 26, 2025, the day before the last corrective disclosure, id. ¶¶ 198, 202.

[2] On July 8, 2025, Dentsply and individual defendants Simon D. Campion ("Campion"), Glenn Coleman ("Coleman"), Andreas G. Frank ("Frank"), Neeraj

This case arises from the collapse of "Byte," a business that manufactured and sold direct-to-consumer "clear aligners" designed to straighten patients' teeth. Dentsply, a global firm specializing in the manufacture of various dental products, purchased Straight Smile, LLC ("Byte") for $1.04 billion in December 2020. AC ¶ 55. On January 4, 2021, the day the purchase was announced, Byte constituted 9.4% of Dentsply's market capitalization and represented a major effort by Dentsply to break into a growing, multi-billion-dollar market for clear aligners. Id. ¶¶ 55-56. Only four years later, on February 27, 2025, in the wake of revelations that Dentsply had systematically sold Byte products to unqualified, "contraindicated" patients and failed to report nearly all of thousands of serious injuries to the FDA over the previous four years, the Company announced that it was writing off and shutting down Byte permanently. Id. ¶¶ 21, 198.

THE AMENDED COMPLAINT

Before addressing the legal arguments raised by the parties, we will briefly summarize the allegations in plaintiffs' 154-page Amended Complaint, which must be accepted as true at this stage of

Gunsagar ("Gunsagar"), and Erania Brackett ("Brackett" and, together with Campion, Coleman, Frank, and Gunsagar the "Joint Defendants") moved to dismiss. See ECF Nos. 69, 70 ("Cooper Decl."), 71 ("Mot."); see also ECF No. 84 ("Reply"). Two other defendants, former Chief Executive Officer ("CEO") Donald M. Casey, Jr. ("Casey") and former Chief Financial Officer ("CFO") Jorge M. Gomez ("Gomez"), are individually represented, and have also moved to dismiss. See ECF Nos. 73, 74 ("Gomez Mot."), 76, 77 ("Casey Mot."), 78 ("Karp Decl."); see also ECF Nos. 85 ("Gomez Reply"), 86 ("Casey Reply").

the litigation. ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007).

I. Byte's Business Model

Throughout the Class Period, Byte was marketed as a direct-to-consumer clear aligner product that would fill a gap between existing direct-to-consumer products such as SmileDirectClub and "in-office" clear aligner products such as Invisalign and SureSmile, Dentsply's own in-office product. AC ¶¶ 47-52, 58, 167. Dentsply distinguished Byte to investors in two primary ways. First, Dentsply executives represented that Byte was intended for use only by patients with "Class I" malocclusion or, in layman's terms, with "mild to moderate [teeth] spacing and crowding." Id. ¶ 110. Prospective patients with "Class II" or "Class III" malocclusion, "complex" cases, or various other "contraindications"[3] were to be screened out and directed towards traditional dentistry or Dentsply's in-office SureSmile product line. See id. ¶ 60 ("Suresmile 'can handle Class I, Class II, Class III'" and "complex cases[.]"). Second, Dentsply represented that Byte was "doctor-directed" and "oversee[n]" "every step of the way" by "licensed dentists and orthodontists." See, e.g., id. ¶¶ 253, 254, 269, 272.

[3] Relevant "contraindications" could include "gum disease, open bite, overjet, severe cases requiring surgery, mixed dentition, prosthetics and implants, and skeletally narrow jaws," among others. AC ¶ 111.

Both of these factors were used to distance Byte from the well-publicized problems faced by SmileDirectClub, a competitor besieged by numerous litigations and driven into bankruptcy in late 2023, in large part because of quality and safety issues. Id. ¶¶ 60-65, 88, 156; see also Franchi v. SmileDirectClub, Inc., 633 F. Supp. 3d 1046, 1074 (M.D. Tenn. 2022) (finding that "SDC's statements regarding their standard of care were false or misleading" under Section 10(b) because "SDC's dentists had no meaningful contact with customers, their only involvement being a superficial review of a photo or impression of a customer's teeth" and "sales assistants . . . handled customer consultations and complet[ed] highly specialized tasks without meaningful oversight from a licensed dentist") (internal quotation marks omitted).

Dentsply executives invited and engaged in comparisons with SmileDirectClub at investor conferences and elsewhere, citing Dentsply's "QA [Quality Assurance] [and] RA [Regulatory Affairs]" expertise as a means to "avoid" the "traps" experienced by its competitor. AC ¶¶ 61, 326. Dentsply also hosted a page on its website titled "How Byte Compares to Smile Direct Club," which claimed patients would have access to a "network" of "dentists and orthodontists" and that patients would be able to "access [a] team at any time," which would "assess every step" of the treatment process. Id. ¶ 63. These comparisons were seized upon by industry

analysts, who positively contrasted Byte's "guarantee[] that your treatment plan will be developed by an orthodontist in your state [and] th[at] you will continue[] to work with a care team of dental professionals that includes dentists" with the "shady" practices of SmileDirectClub, which "doesn't clarify if it will be an orthodontist or a dentist prescribing and overseeing . . . treatment plan[s]." Id. ¶ 65. Dentsply and its executives also highlighted Byte's "good job" at onboarding patients with only "mild-to-moderate occlusion," i.e. "slight[] misalign[ment]," expressing a commitment to divert contraindicated patients away from their product. Id. ¶¶ 60, 258.

II. Byte's Screening Practices and Dentist Involvement

Plaintiffs allege that despite Dentsply's representations that (i) treatment was "doctor-directed" and "overseen" "every step of the way" and (ii) patients with more complex treatment requirements would be screened out, Byte systematically excluded dentists from meaningful oversight and set policies which led to contraindicated patients being approved for treatment. As relevant to these alleged misrepresentations, Byte's onboarding processes and treatment practices are summarized below.

Plaintiffs allege that rather than "doctor-directed" and "overseen" care "every step of the way," Byte patients received

minimal engagement from licensed physicians in the initial prescription phase of treatment. Prospective Byte patients who responded to online or television advertisements were onboarded to the Byte platform in a two-step process, referred to as the "S1" and "S2" stages. AC ¶ 93. In the "S1" stage, Byte would ship a prospective patient an "impression kit" for a refundable $100 deposit, which the prospect would use to make a mold of their teeth. Id. If the S1 mold indicated that a candidate was eligible for treatment, sales representatives would direct patients to the S2 stage. Id. In the "S2" stage, non-dentist treatment planners based in Costa Rica would design a "treatment plan." Id. ¶¶ 94, 96.

Treatment plans prepared by non-dentist employees in Costa Rica would be sent to a remote, U.S.-based dentist for review and approval. Id. ¶ 98. However, the assigned dentist or orthodontist would approve the plan with "only four clicks," where the fourth click merely affixed an e-signature. Id. (describing in detail the information displayed on each "click"). The "four click" review took as little as "two minutes," and the reviewing software did not require a dentist to "scroll through the materials before approving."[4] Id. Moreover, dentists in the network were

[4] The allegations in the Amended Complaint are based, in part, on interviews conducted with former employees at Byte and/or Dentsply. These confidential sources are referred to by number, e.g., "FE-1", and by their position at the

compensated on a "per case" basis, incentivizing the emergence of "super approvers" who signed off on "approximately 30 cases per day" and approved plans at rates as high as "95%." Id. ¶ 99. According to multiple former employees, "beginning in early- to mid-2021 after the acquisition," if one or two dentists rejected a treatment plan, the same treatment plan would simply be "auto-reassign[ed]" to another dentist, such that "a patient could be approved for treatment even if two out of three dentists rejected them."[5] Id. ¶ 100 (emphasis in original).

Plaintiffs further allege that after approving an initial treatment plan, Byte's "network" of "dentists and orthodontists" had no further involvement. Byte "support staff" and "customer service employees" would "provide [ongoing] treatment advice," including recommending "backtracking" and other medical remedies that could result in patient injury. Id. ¶¶ 101-04. According to

Company, rather than by name. FE-2, who worked as a Senior Software Engineer at Byte from February 2019 to January 2022, and who helped design the software used for treatment planning and customer service, based his "two minute" claim on personal experience. Id. ¶¶ 97-101. "FE-2 explained that he could review the rates at which dentists would approve treatment plans and look at metadata which logged, among other times, when [a] case was sent to the dentist for review and when the dentist approved" the treatment plan. Id. ¶ 99 n.4. "FE-2 reported to Byte's Chief Technology Officer, Mark McCrimmon, who in turn reported to Defendant Gunsagar," Byte's CEO. Id. ¶ 97 n.3.

[5] FE-2 and FE-3 independently confirmed the "auto-reassigning" practice. Id. ¶ 100. FE-2 claims that he was personally "told to create this feature by McCrimmon, Byte's CTO, and that McCrimmon "who reported to Gunsagar, . . . was implementing a business decision made by management." Id. FE-2 also alleged that reassignment was done in the S1 stage as well, such that if a treatment planner refused to make a treatment plan due to contraindications or insufficient documentation, the case would be reassigned to another treatment planner. Id. ¶ 97.

one former customer support representative, "[i]f someone had a problem, like their teeth weren't moving the way they should or the aligners didn't fit, we were the ones to give them advice like backtracking to last month's set of aligners[.]" Id. ¶ 103. If patients asked to speak with a licensed dentist, customer service representatives were "unequivocally not permitted to allow [them] to speak to any dentist." Id. ¶ 104. On occasions where a patient repeatedly and persistently demanded to speak to a doctor, they would instead be directed to a remote "dental assistant," who was also not a licensed dentist, and would also give medical advice like "backtracking." Id. ¶¶ 105-07.

Dental assistants were likewise not allowed to refer patients to a dentist and were expected, per company policy, to respond to an unrealistic 50 patient complaints a day. Id. ¶ 106. This high volume of tasks, which included complex medical questions, "result[ed] in a constant backlog of patient complaints awaiting responses." Id. Two former employees, who worked in customer service and as a dental assistant, reported that "customer service managers overseeing [their] work instructed them to prepare instructions to patients to have them alter their aligners at home—including, for example, by asking patients to use a scissors or a nail file to smooth out rough spots in their aligners." Id. ¶ 107. The former employees' claims are corroborated by patient

complaints belatedly reported by Byte to the FDA. Id. ¶ 108. For example, one complaint reported internally in September 2023, but reported to the FDA in October 2024, stated that "Customer service provided molar alignment education and requested the customer file down the sharp edges" of a patient's aligner. Id.

Plaintiffs allege that the practices described above persisted throughout the Class Period, but that they worsened after a change in executive leadership at Dentsply. Defendant Casey was terminated from his position as CEO on April 19, 2022, amidst an investigation by Dentsply's Audit and Finance Committee of Dentsply Board of Directors into "channel-stuffing" in non-Byte business segments.[6] Id. ¶¶ 31-33, 72. Defendant Gomez also resigned as CFO shortly after, on May 6, 2022.[7] Id. ¶ 32. At its May 10, 2022 Earnings Call, "Dentsply disclosed that its audit

[6] Casey and Gomez were named in another securities class action filed in this district arising from alleged "channel-stuffing," whereby defendants, including Casey and Gomez, "artificially inflat[ed] sales by forcing distributors to take on more inventory." San Antonio Fire & Police Pension Fund v. Dentsply Sirona Inc., 732 F. Supp. 3d 300, 310 (S.D.N.Y. 2024). In denying Dentsply's motion to dismiss the complaint, Judge Subramanian of this Court wrote that Casey and Gomez allegedly set an "improper tone at the top," supporting allegations of scienter against them. Id. While the "channel-stuffing" revelations are not directly relevant to the allegations about Byte, plaintiffs point to this "tone," as well as the Company's desire to recover from the "channel-stuffing" "scandal," as supporting a scienter finding in this case. See AC ¶ 227.

[7] When Gomez resigned from Dentsply on May 6, 2025, he immediately assumed a new role as CFO of Moderna, a large pharmaceutical company. AC ¶ 229. However, he departed from Moderna only days later, on May 10, 2025, the same day as Dentsply announced its investigation into "channel-stuffing" during his tenure. Id. ¶ 229 n.11. Plaintiffs allege that his swift exit from Moderna is connected to the investigation. Id. ¶ 73.

committee had previously begun an investigation . . . concerning 'certain financial reporting matters,'" including the Company's "'use of incentives to sell products to distributors.'" Id. ¶ 73. The Audit Committee subsequently released a report on November 1, 2022, "conclud[ing] that . . . Casey and Gomez violated provisions of the Company's Code of Ethics and Business Conduct, did not follow appropriate compliance controls, and created a culture in which employees did not feel comfortable raising concerns without a fear of retaliation." Id. ¶ 78.

Following Casey and Gomez's departure from Byte, Dentsply's board appointed Campion as CEO on August 22, 2022 and Coleman as CFO on September 22, 2022. Id. ¶ 77. The new leadership team reaffirmed the Company's commitment to Byte, which they viewed as a key driver of growth, and as an opportunity to reframe the Company's narrative following the COVID-19 pandemic and the "channel stuffing" revelations. Id. ¶¶ 80-84. Dentsply set an Earnings Per Share ("EPS") target of $3.00, with Campion touting Byte's 20% growth rate as a "key" contributor to that target. Id. ¶¶ 9, 84-86.

In August 2022, Tyler Stoker, Dentsply's Head of Sales and Business for Byte, held a meeting with sales representatives. Id. ¶ 113. At the meeting, Stoker reviewed statistics with staff and "told the sales representatives that those figures would be

improved once they ceased mentioning to customers that they were contraindicated." Id. Stoker's instruction was confirmed by FE-5 and FE-6, who worked as a Manager of Customer Success and an Account Manager respectively, and both of whom attended the meeting. Id. Following the August 2022 meeting, "Byte's sales representatives stopped taking prospective patients' dental histories into account during the sales process." Id. FE-5 reported that "after the August 2022 meeting, rejections went down, and patients who were contraindicated or were otherwise not suitable candidates for at-home aligner treatment were nonetheless approved." Id. ¶ 115. According to FE-6, this policy represented a departure from prior practice, where sales representatives would consider obvious contraindications like "fake teeth" before directing the preparation of a treatment plan. Id. ¶ 114. In short, sale representatives -- at the behest of management -- began directing the preparation of treatment plans regardless of any initial screening. While treatment plans still had to be "approved" by remote dentists using the "four click" process, any initial screening at the S1 stage was eliminated.[8] According to

[8] FE-3, a Byte Professional Care Specialist, raised concerns that "customers with underlying contraindications were being inappropriately approved," but was told by his boss, Clinical Operations Manager Zainab Kleit, that "he needed to go along with whatever the Dentsply dentists and orthodontists said." AC ¶ 117. While defendants point to this deference as indicative of doctor oversight, Mot. at 30-31, the dentist input into the process was the "four click" approval, which could be completed in as little as "two minutes" by remote dentists paid on a "per case" basis. Id. ¶¶ 97-101.

FE-6, "Stoker made it clear [at the August 2022 meeting] that it was not his decision whether to sell to those customers," but rather a decision by unspecified members of senior management. Id. ¶ 113.

FE-5 and FE-6 also reported that Stoker held a second meeting in fall 2022, during which he "highlighted how Byte's rejection rate declined, praised the sales team, [and] reported that sales were increasing." Id. ¶ 116. FE-5 believed that the change in policy previously announced by Stoker in August regarding sales to contraindicated patients was "formulated and approved by Dentsply's senior leadership[,] . . . directly tied to Byte's need to improve its numbers, to ensure bonuses would be paid, and [intended] to keep the new CEO happy." Id.

Following the alleged decision to sell to contraindicated patients in August 2022, Campion and Coleman touted Byte's improved "conversion rate." Id. ¶ 11. The "conversion rate" was defined as the percentage of S1 prospective patients that were approved for aligners in the S2 stage of onboarding. Id. ¶ 94; see also id. ¶ 11 (describing the "conversion rate" as "the rate at which a proposed Byte customer who received an impression kit [in S1] then purchased a Byte aligner [in S2]"). Campion and Coleman attributed the improved "conversion rate" to the "quality of the [patient intake] funnel" and a "much better job of targeting

customers" with mild or moderate malocclusion. Id. ¶¶ 301-15. Plaintiffs allege that these statements were materially false because the higher "conversion rate" was, in fact, driven by the relaxation of Byte's already deficient screening processes for contraindications. Id. ¶ 315.

III. FDA Reporting

Throughout the Class Period, Dentsply was subject to the FDA's Medical Device Reporting rule, 21 C.F.R. Part 803, which requires that any "serious injury" caused by a medical device or any malfunction likely to cause a serious injury be reported to the FDA. See AC ¶ 318 (citing 21 C.F.R. § 803.1). A "reportable event" is defined by the statute as "[a]n event that manufacturers . . . become aware of that reasonably suggests that one of their marketed devices: (i) May have caused or contributed to a . . . serious injury, or (ii) Has malfunctioned and that the device . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 C.F.R. § 803.3(o)(2). Defendants were likewise required to abide by 21 C.F.R. Part 820, which mandated reporting of serious injuries to the FDA within 30 days of discovery of the injury. AC ¶ 134; see also id. ¶ 321 ("21 C.F.R. Part 820, requires 'management with executive responsibility' to assume personal responsibility for compliance with the Medical Device Reporting rule."); 21 C.F.R. § 820.20(a)

("Quality policy. . . . Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.") and (c) ("Management review. Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency[.]"). Any "permanent damage to a body structure," e.g., loss of a tooth, was also required to be reported to the FDA under Dentsply's internal "decision tree" for reporting injuries. Id. ¶ 133. Throughout the Class Period, Dentsply represented in public filings and other communications that it complied with these and other relevant "post-market surveillance" or "PMS" regulations.[9]

Pursuant to the regulations governing Byte aligners, any serious injuries reported to the FDA would be subsequently published on the FDA's publicly-accessible Manufacturer and User

[9] See, e.g., AC ¶ 344 (Dentsply stated in its 2021 and 2022 Sustainability Reports that "'[W]e comply with FDA QSR 820'—the FDA post-market surveillance rule requiring Dentsply to report adverse events associated Byte within 30 days" and also in its 2023 Sustainability Report that "'complying with FDA QSR 820' [is] one of the actions the Company takes."). Dentsply's spokespeople continued to claim as late as June 28, 2024, that "all medical device reports are thoroughly investigated in accordance with 21 CFR 820 and there have been no changes in the quality, safety, or effectiveness of our Byte products." Id. ¶ 174. Throughout the Class Period, the Company represented in its annual Form 10-K filings that it was "in substantial compliance with the laws and regulations that regulate [our] business," including regulations governing "medical devices" "classified by the FDA into a category that renders them subject to the same controls that apply to all medical devices, including regulations regarding alteration, misbranding, notification, record-keeping and good manufacturing practices." Id. ¶ 349; see also id. ¶ 350 (10-Q filings for 2021).

Facility Device Experience ("MAUDE") database. AC ¶ 319. Injury reports on MAUDE would include information on the type of injury and its likely cause, based on internal materials released by the company.[10] Id. ¶¶ 318-20; see also, e.g., id. ¶ 141 (A patient stated that "as I was removing my upper aligner using the provided extraction tool, my front left tooth chipped. This is confusing because I've . . . always followed the instructions carefully. The chipped piece of my tooth is stuck inside the aligner and won't come out," leading the patient to need a "molar removed" and a surgical "bone graft.").

Plaintiffs allege that far from complying with either the law or their own internal guidelines, "Byte was secretly responsible for at least 6,894 serious patient injuries that Dentsply tracked during the Class Period but unlawfully failed to disclose to the FDA." AC ¶ 4. Throughout the Class Period, Dentsply maintained the "Trackwise" database, an internal "quality management system created and licensed by Honeywell that is purpose-built for FDA reporting." Id. ¶ 132. Trackwise "accurately reflected the serious patient injuries from Byte" on an ongoing basis. Id. ¶ 214. Senior executives, including the Individual Defendants, "had access to all patient complaints—including both 'serious'

[10] MAUDE filings were followed closely by regulators and commentators, including "state legislatures, patient advocates," and journalists. AC ¶¶ 18-20.

complaints (those involving injury) and 'non-serious' complaints" through Trackwise. Id.

In addition to having personal access to the Trackwise system, "Dentsply's quality executives met with senior management, including Dentsply's CEO -- i.e., Defendant[s] Casey and Campion -- on patient injuries every quarter." Id. ¶ 215. Plaintiffs' source for this allegation is FE-7, a senior employee who served as Dentsply's Director, Corporate Compliance and Regulatory Affairs, and who designed the "decision tree" for injury reporting. Id. ¶ 132 n.7, 133. FE-7 reported directly to Charles Pigott, Dentsply's Corporate Vice President, Quality and Regulatory, and met personally with Pigott "3-4 times per quarter . . . to discuss injuries." Id. ¶ 132. According to FE-7, Pigott, along with Emily Miner, Dentsply's Chief Quality Officer, met every quarter with Dentsply's CEOs -- Casey and then Campion -- to discuss "patient injuries and injury trends." Id.

Despite this infrastructure for tracking and reporting injuries, Dentsply and its executives failed to report "at least 6,894 serious patient injuries during the Class Period." Id. ¶ 135. The failure to report was not only large in absolute terms, but also relative terms. "97% of the injuries that occurred from the start of the Class Period through December 2023 and at least 83% of the injuries that occurred from the start of the Class

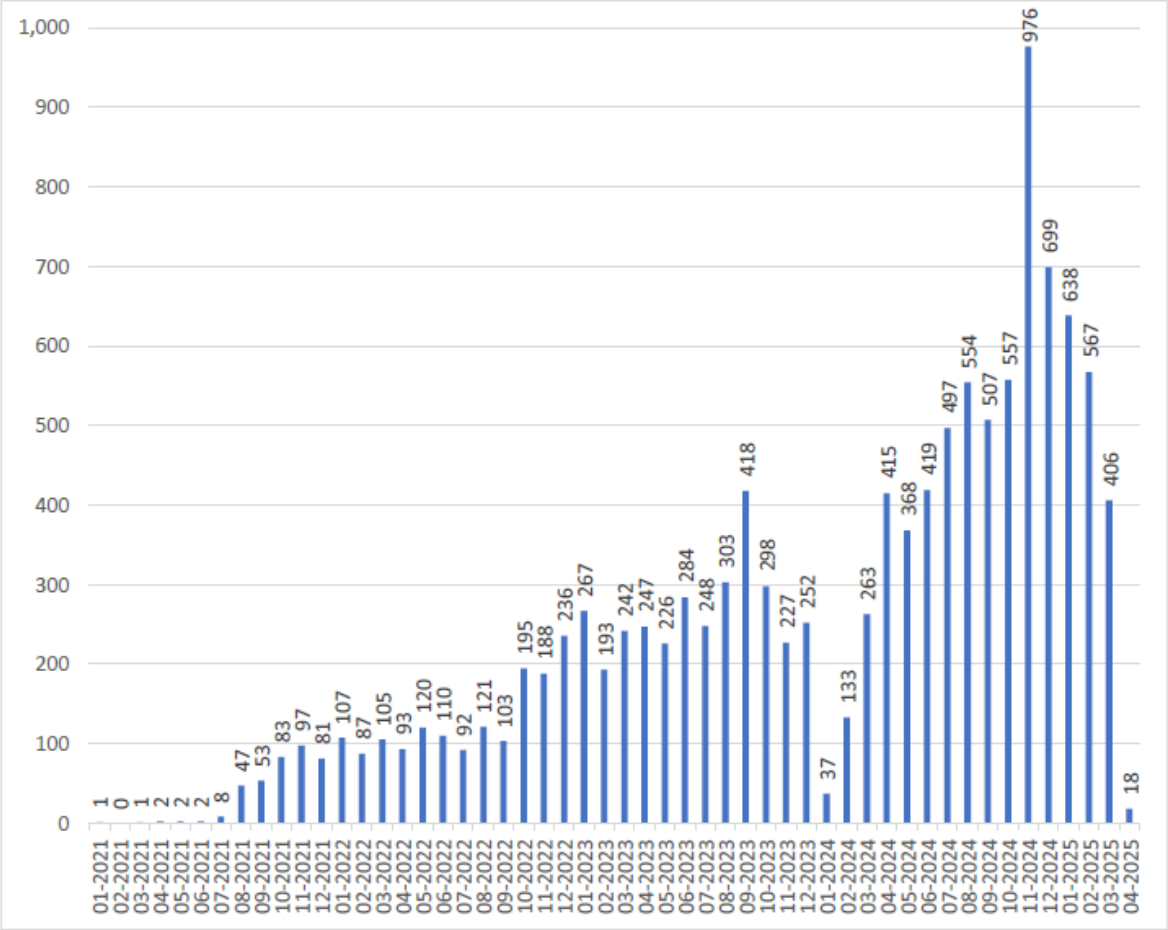
Period through August 2024" were not reported to the FDA. Id. (emphasis in original). The underreporting was so severe that "prior to February 2024, the most injuries Dentsply reported in one month was 19." Id. ¶ 143. Consequently, the FDA, patients, and investors alike were left in the dark about the health and safety risks posed by Byte's clear aligners. The unreported injuries included lacerations, id. ¶ 138, as well as loss of teeth, tooth fractures, and necrosis, id. ¶ 140, sometimes requiring expensive and painful follow-up treatment by licensed, non-Byte dentists and surgeons, id. ¶ 141.

IV. Byte Unravels

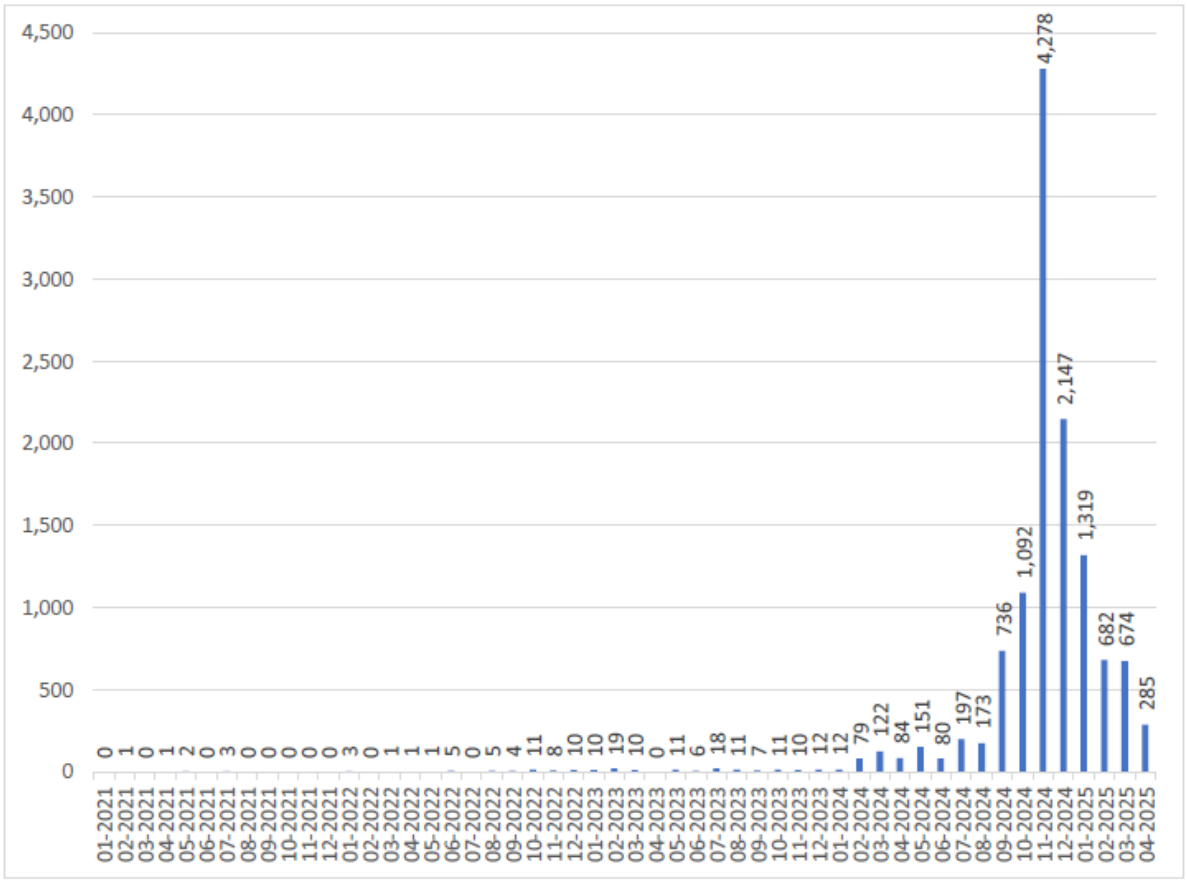
Beginning in February 2024, Dentsply started to retroactively report the backlog of serious patient injuries to the FDA. AC ¶ 173. Although the numbers were low at first, the reports began to attract press coverage, including a June 28, 2024 article from The Capitol Forum, which noted how Dentsply had reported approximately 10 injuries per month for the past three years but now "that number [had] beg[u]n to drastically increase, with 146 injuries submitted in May." Id. In retrospect, Dentsply has admitted that the uptick was caused by the retroactive disclosure of thousands of backlogged injuries, most of which had gone unreported for years. Id. ¶¶ 118-120, 138 n.8, 183-84. Plaintiffs have submitted a graph showing the dates on which Byte injuries occurred, and another

graph showing when these same injuries were actually reported to the FDA:

Adverse event reports by Dentsply for Byte, sorted by month in which Dentsply admits it became aware of the serious patient injury or malfunction



Adverse event reports by Dentsply for Byte, sorted by month in which Dentsply reported them to the FDA



Id. ¶¶ 144-145. These graphs illustrate the near-complete absence of any reporting to the FDA of thousands of injuries from the beginning of the Class Period through February 2024, at the earliest.

Rather than come clean about the cause of the increase in injuries, a Dentsply spokesperson told The Capitol Forum in June 2024 that the surge in reports was "strictly related to our efforts to continuously improve our processes in alignment with current,

global regulatory requirements" and "to strengthen our post market surveillance and medical device reporting," and that "all medical device reports are thoroughly investigated in accordance with 21 CFR 820, and there have been no changes in the quality, safety, or effectiveness of our Byte products." Id. ¶¶ 174, 328; see also ¶¶ 332-33, 337, 342-44. In a subsequent article, published in July 2024, The Capitol Forum quoted a "Company insider" as saying "management likely had known that there was a risk of some kind of FDA action over the failure to submit reports" because "we had a big meeting in July [2024], where they said 'Hey guys, we know our complaints aren't being filed correctly[.]'" Id. ¶ 177. According to the insider, "When people saw those injuries, they were like 'Oh my God, this is bad.' People started looking for new jobs." Id.

The scale of the underreporting problem became clear to investors in a series of alleged corrective disclosures from October 2024 to February 2025. On October 24, 2024, Dentsply announced the "voluntary suspension of sales and marketing" of all Byte aligners, and stated the decision had been reached "in consultation with" the FDA. Id. ¶ 181. The Company further announced "an impairment of goodwill [between] $450-$550 million." Id. ¶ 181. In a "Message for Patients" posted on October 25, 2024, Byte disclosed that "our patient onboarding workflow may not

provide adequate assurance that certain contraindicated patients do not enter treatment with Byte Aligners," and recommended that patients "visit a dentist to review your overall oral health." Id. ¶ 186 (emphasis added). Finally, on a conference call held that same day with investors, defendant Campion admitted that Byte's newly-filed reports were "retrospective," i.e. not timely. Id. ¶ 183.

Dentsply initially characterized the suspension of Byte as the consequence of general regulatory trends, with Campion telling investors that "we continue to believe that the potential risk to patients remains low." Id. ¶ 185. However, on November 7, 2024, Campion revealed that Byte employees' jobs would "cease to exist."[11] On January 14, 2025, Dentsply reported that it would "refocus the Byte business model [on] expanded in-person dentist oversight," and on February 27, 2025 that Byte's goodwill would be "written down to zero" and its trademark "will not be used in the future." Id. ¶¶ 195, 198. Dentsply suffered price declines on each of these days, including a precipitous, 28% decline on

[11] An analyst at the November 7, 2024 call, told Campion, "[I]t sounds like you're telling us you're just shutting down the [Byte] business without just saying you're shutting down the business." AC ¶ 192. Campion replied, "That's not what I'm saying. . . . I'm saying we have a lot of work to do," including "regulatory work, consultation with FDA, trying to figure out a path for this project to get back to the market." Id.

November 7, 2024. Id. ¶¶ 189 (October 25, 2024), 194 (November 7, 2024), 197 (January 14, 2025), 202 (February 27, 2025).

LEGAL STANDARDS

To recover damages for violations of Section 10(b) and Rule 10b-5, a plaintiff must prove "'(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.'" Halliburton Co. v. Erica P. John Fund, Inc., 573 U.S. 258, 267 (2014) (quoting Amgen Inc. v. Conn. Ret. Plans and Trust Funds, 568 U.S. 455, 461 (2013)). On a Rule 12(b)(6) motion to dismiss, the Court must "accept[] all factual allegations in the complaint [as true] and draw[] all reasonable inferences in the plaintiff's favor." ATSI Commc'ns, Inc., 493 F.3d at 98. However, to survive dismissal, plaintiffs must "raise a right to relief above the speculative level," by pleading "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

Securities fraud claims brought under Section 10(b) and Rule 10b-5 are subject to heightened pleading requirements. First, "the circumstances constituting fraud . . . shall be stated with particularity" under Federal Rule of Civil Procedure 9(b). Novak

v. Kasaks, 216 F.3d 300, 306 (2d Cir. 2000) (citation omitted). Rule 9(b) requires that a complaint "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Id. (citation omitted). Second, the Private Securities Litigation Reform Act ("PSLRA") requires that a complaint (i) "'specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts on which that belief is formed,'" ATSI Commc'ns, Inc., 493 F.3d at 99 (quoting 15 U.S.C. § 78u 4(b)(1)), and (ii) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," id. (quoting 15 U.S.C. § 78u-4(b)(2)). Scienter may be established by facts "(1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." Id. A "strong" inference of scienter exists where that inference is "at least as compelling as any opposing inference one could draw from the facts alleged." Id. (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007)) (emphasis in original).

DISCUSSION

Plaintiffs allege that defendants made numerous material misrepresentations and omissions regarding Byte's operations and compliance from January 2021 through March 2024.[12] In the interests of clarity and efficiency, the Court has grouped these statements into four categories: (i) statements regarding "doctor-directed" and "overseen" treatment[13]; (ii) statements regarding Byte's screening process and "conversion rate" for prospective patients[14]; (iii) statements regarding FDA reporting and compliance with relevant regulations[15]; and (iv) 2024 statements regarding continuing investments in Byte, particularly in treatment planners.[16]

In response, defendants raise two primary arguments: (i) that plaintiffs have failed to plead the alleged misrepresentations were materially false or misleading and (ii) that plaintiffs have failed to plead scienter. We will first address defendants'

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[12] AC ¶¶ 253, 254, 255, 258, 259, 261, 263, 265, 266, 267, 269, 270, 272, 274, 276, 277, 279, 280, 281, 282, 283, 284, 287, 289, 291, 293, 294, 295, 296, 297, 298, 299, 301, 302, 304, 305, 306, 307, 308, 309, 310, 311, 312, 314, 326, 328, 332, 333, 337, 342, 343, 344, 349, 353, 355, 356, 357.

[13] AC ¶¶ 253, 254, 255, 258, 259, 261, 263, 265, 266, 267, 269, 270, 272, 274, 276, 277, 279, 280, 281, 282, 283, 284, 287, 289, 326.

[14] AC ¶¶ 291, 293, 294, 295, 296, 297, 298, 299, 301, 302, 304, 305, 306, 307, 308, 309, 310, 311, 312, 314, 326.

[15] AC ¶¶ 326, 328, 332, 333, 337, 342, 343, 344, 349.

[16] AC ¶¶ 353, 355, 356, 357.

arguments as to falsity, then turn to defendants' arguments regarding corporate and individual scienter.

I. Falsity

To establish liability under Rule 10(b), plaintiffs must allege that each alleged misstatement was materially false or misleading. "The test for whether a statement is materially misleading under Section 10(b) . . . is whether the defendants' representations, taken together and in context, would have misled a reasonable investor." City of Hialeah Employees' Ret. Sys. v. Peloton Interactive, Inc., 153 F.4th 288, 295 (2d Cir. 2025) (quoting Rombach v. Chang, 355 F.3d 164, 172 (2d Cir. 2004)) (internal quotation marks omitted).

The Joint Defendants' argument of actual truth is limited to the first category of misstatements regarding the involvement of dentists and orthodontists in patient care. Mot. at 29-31. The Joint Defendants challenge various other statements on different grounds, insisting that they constitute inactionable opinion, corporate "puffery," are forward-looking, or cannot be attributed to the Company. Id. at 31-36; see also ECF No. 70-19 ("Joint Defendants' Chart"); ECF No. 79-1 ("Plaintiffs' Chart"). Defendants Casey and Gomez argue that some of their statements were true because they were made early in the Class Period and that other statements were inactionable opinion, puffery, or

forward-looking. See ECF No. 77-1 ("Casey Chart"); Casey Mot. at 25-29; Gomez Mot. at 16-17. We will limit our discussion to the statements raised in the parties' briefing. See Dentsply Sirona Inc., 732 F. Supp. 3d at 315 ("Rather than combing through the . . . complaint to apply Defendants' arguments to each statement, the Court will consider only those paragraphs cited in their brief[s].").

a. Doctor-Directed and "Overseen" Care Statements

Defendants argue that statements claiming Byte treatment was "doctor-directed" were true in that dentists did, in fact, prescribe patient treatment plans.[17] Mot. at 29-30; Reply at 13-14; see also Casey Mot. at 26. As an initial matter, defendants offer no support for the assumption that the phrase "doctor-directed" is meant to be limited to only an initial prescription, as opposed to ongoing oversight and access. Indeed, the evidence is to the contrary. For example, Byte advertised "Doctor Directed

[17] Defendant Casey argues that his statements that Byte "does a good job" at "targeting people with mild to moderate occlusion," rather than more complex or contraindicated cases, were true because the August 2022 meeting where Tyler Stoker allegedly told sales staff to ignore contraindications occurred after Casey left the Company. Casey Mot. at 26 (citing AC ¶ 258). However, the Amended Complaint lays out numerous facts about longstanding practices that existed before August 2022. See AC ¶¶ 90-129. These practices, taken together, indicate Dentsply did not seriously screen for only "mild to moderate occlusion" at any point during the Class Period, but rather created a process designed to maximize patient approval. Casey's arguments regarding Dentsply's Form 10-K statements on FDA compliance, Casey Mot. at 27, are similarly unavailing given that almost all the serious injuries reported to Dentsply during Casey's tenure were not reported to the FDA. AC ¶¶ 131-33, 137 (showing numbers and percentages of unreported injuries during Casey's tenure).

Care. Licensed doctors and orthodontists with you every step of the way." AC ¶¶ 269-70 (emphasis added). Dentsply also claimed treatment was "doctor-directed" because "dentists and orthodontists prescribe and oversee"[18] care, indicating that "prescrib[ing]" a static plan was only one part of the doctors' purported role. Id. ¶ 253 (January 1, 2021 Press Release).

Even if "doctor-directed" meant "doctor-prescribed," the challenged statements were still false or misleading because the initial approval process included no meaningful oversight by dentists. Treatment plans were not designed by dentists, but rather by non-dentist "treatment planners in Costa Rica." AC ¶¶ 95-97. After the patient had provided payment information, the treatment plan drafted in Costa Rica would be "presented" to a remote, U.S.-based dentist, who would approve the plan with "four clicks," with the fourth click merely affixing an e-signature. Id. at 98. The "four click" review could be completed in "less than two minutes," and Byte's software did not require a dentist to "'scroll through' the materials before approving." Id. Moreover, dentists in the network were compensated on a "per case"

[18] Oversee, Mirriam-Webster, https://www.merriam-webster.com/dictionary/oversee ("SURVEY, WATCH" or "INSPECT, EXAMINE" so as to "to watch over and direct (an undertaking, a group of workers, etc.) in order to ensure a satisfactory outcome; [to] SUPERVISE") (last accessed December 12, 2025); see also Direct, Mirriam-Webster, https://www.merriam-webster.com/dictionary/directed ("Subject to supervision or regulation") (last accessed December 12, 2025).

basis, incentivizing the emergence of "super approvers" who signed off on "approximately 30 cases per day" and approved plans at rates as high as "95%." Id. ¶ 99. Even if a dentist rejected a treatment plan, the same treatment plan would be "auto-reassign[ed]" to another dentist such that "a patient could be approved for treatment even if two out of three dentists rejected them." Id. ¶ 100 (emphasis in original). Plaintiffs have adequately pled that this system was not "doctor-directed" in any substantive sense, but rather designed to maximize the number of prescriptions approved without any meaningful input by dentists or orthodontists.

Aside from the phrase "doctor-directed," defendants utterly ignore Dentsply's full statements that "dentists and orthodontists prescribe and oversee every customer's treatment plan," AC ¶ 253 (emphasis added), that "dentists and orthodontists [would] provi[de]clinical services, including the oversight and control of each customer's clinical treatment," id. ¶ 280 (emphasis added), and that patients received "Doctor Directed Care. Licensed doctors and orthodontists with you every step of the way," id. ¶¶ 269-70 (emphasis added). The language of these statements, and others like them, clearly indicated that dentists would remain engaged with patients after the initial prescription. Id. ¶ 101. Yet, according to the Amended Complaint's well-pled allegations, this

was not the case at any time during the Class Period. According to FE-3, a Professional Care Specialist at Byte from July 2020 to May 2022, Byte "support staff" and "customer service employees" without any type of professional license would "provide treatment advice," including recommending "backtracking" and other medical remedies that could result in patient injury. Id. ¶¶ 101-04. These customer service representatives were "unequivocally not permitted to allow patients to speak to any dentist, including their prescribing dentist." Id. ¶ 104. If a patient insisted on speaking to a dentist, they would instead be directed to a remote, non-dentist "dental assistant," who would also recommend "backtracking" or at-home adjustments to the aligners. Id. ¶¶ 106-07. Dental assistants were also prohibited from referring patients to a licensed dentist or orthodontist and were expected to respond to 50 complaints a day, "resulting in a constant backlog."[19] Id.

[19] Defendants challenge the reliability of FE-3 and FE-4's statements on the grounds that they were at the Company for "fewer than two years" as to FE-3 and "just four months" as to FE-4, and that both were "low-level" employees. Mot. at 30-31; see also id. at 22, 26-28 (making similar arguments about other former employees). However, all that is required at this stage is that former employees "are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." Novak, 216 F.3d at 314. Two years, or even four months, is enough time to understand the workflows, culture, and policies relevant a confidential source's day-to-day tasks. Moreover, FE-3, as a Professional Care Specialist, and FE-4, as a dental assistant, are both qualified to testify regarding Byte's practices for onboarding and servicing patients.

Moreover, it is worth noting that identical statements have been found to be misleading in a securities fraud class action against SmileDirectClub, Byte's direct competitor. In SmileDirectClub, the court found a statement that the company "provided 'excellent clinical care'" was false because "SDC customers were virtually always instantaneously approved for aligners" and "there was not sufficient interaction with a licensed dentist to ensure the safe and effective orthodontic treatment." 633 F. Supp. 3d at 1073. Other statements, that SDC gave patients "seamless communication" with "treating doctor[s]" were likewise misleading where "SDC's dentists had no meaningful contact with customers, their only involvement being a superficial review of a photo or impression of a customer's teeth" and "[i]f customers had issues, they were directed to speak with hygienists rather than a licensed dentist." Id. at 1073-74. Defendants attempt to distinguish SmileDirectClub because Byte "dental assistants" were sometimes involved, Mot. at 31, fails because "[d]ental hygienists" also provided treatment in SmileDirectClub. 633 F. Supp. 3d at 1074. Furthermore, it is clear that, as in SmileDirectClub, "customer support" personnel, who were not even dental assistants, were the first point of contact and routinely gave medical advice. AC ¶¶ 101-04.

Consequently, all of the alleged misrepresentations of "doctor-directed" or "overseen" care were plausibly false or misleading when made and will remain in the case.

b. Opinion and Puffery

Defendants argue that various statements made by Dentsply were inactionable opinions or generic "puffing" statements expressing corporate optimism. See Mot. at 31-34; Joint Defendants' Chart (citing AC ¶¶ 254, 255, 258, 259, 267, 274, 291, 301, 302, 304, 305, 307, 308, 310, 314, 326, 349, 353, 355, 356, 357); Casey Chart (citing AC ¶¶ 255, 258, 259, 326, 349); Gomez Mot. at 16 (citing ¶¶ 348, 349, 350); see also Plaintiffs' Chart. "To be actionable, a misrepresentation must be one of existing fact, and not merely an expression of opinion, expectation, or declaration of intention." In re Moody's Corp. Sec. Litig., 599 F. Supp. 2d 493, 507 (S.D.N.Y. 2009) (internal citation and quotation marks omitted). However, an opinion may still be actionable if (i) "the speaker did not hold the belief she professed" or (ii) "the supporting fact she supplied were untrue." Tongue v. Sanofi, 816 F.3d 199, 209-10 (2d Cir. 2016) (quoting Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund, 575 U.S. 175, 185-86 (2015)). Moreover, "opinions, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose

omission makes the statement misleading to a reasonable investor." Tongue, 816 F.3d at 210 (citing Omnicare, 575 U.S. at 195–96). From the perspective of a "reasonable" investor, an opinion must not only be genuinely held, but must also "fairly align[] with the information in the [speaker]'s possession at the time." Omnicare, 575 U.S. at 188–89.

Relatedly, "[p]uffery is an optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it, thereby rendering it immaterial as a matter of law." In re Gen. Elec. Co. Sec. Litig., 857 F. Supp. 2d 367, 384 (S.D.N.Y. 2012). Companies are generally allowed "to operate with a hopeful outlook," because corporate officers "are not required to take a gloomy, fearful or defeatist view of the future." Oklahoma Police Pension Fund & Ret. Sys. v. Teligent, Inc., No. 19 Civ. 3354 (VM), 2020 WL 3268531, at *10 (S.D.N.Y. June 17, 2020) (quoting Rombach, 355 F.3d at 174). However, even a "puffing" statement is actionable if the speaker "knew that the contrary was true." Novak, 216 F.3d at 312, 315 (finding representation that inventory was "in good shape" misleading where "the complaint provides specific facts concerning the Company's significant write-off of inventory directly following the Class Period").

Defendant Casey makes specific arguments regarding the two alleged misstatements he made on January 4, 2021 and January 13,

2025. Casey Mot. at 26-29. First, Casey argues that his January 4, 2021 statement that Dentsply exclusively treated "mild to moderate occlusion" was true because it was made before the "purported plan to target contraindicated patients was hatched at an internal August 2022 meeting at the Company" led by Tyler Stoker. Casey Mot. at 26 (citing AC ¶ 258). However, although Stoker's instruction exacerbated the problem, many of Byte's deficient screening procedures existed before Dentsply acquired Byte, and thus it is plausible the information presented to Casey during the diligence process did not align with his rosy statements.

Second, Casey argues that his January 13, 2025 statement that Dentsply could "avoid [certain] traps for rapid growth," experienced by SmileDirectClub by leveraging "expertise" in "QA [Quality Assurance], RA [Regulatory Affairs]" is inactionable opinion or puffery. Casey Mot. at 27 (citing AC ¶ 326); see also id. ¶ 255 (similar); Casey Chart at 2. Generally, statements "regarding [defendant's] 'highly disciplined' risk management" are "too general to cause a reasonable investor to rely upon them." ECA & Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co., 553 F.3d 187, 205 (2d Cir. 2009). However, in this context, Casey was asked about (i) a specific competitor -- SmileDirectClub -- and (ii) specific "traps" SmileDirectClub had experienced,

including "quality" concerns. AC ¶ 61. Even in January 2021, Byte already had policies in place that were substantively identical to SmileDirectClub's. See supra Discussion Section I.a.; SmileDirectClub, 633 F. Supp. 3d at 1073-74 (finding that "SDC's dentists had no meaningful contact with customers, their only involvement being a superficial review of a photo or impression of a customer's teeth" and "sales assistants . . . handled customer consultations and complet[ed] highly specialized tasks without meaningful oversight from a licensed dentist") (internal quotation marks omitted). As such, Casey's confident comparison to SmileDirectClub could be viewed by a reasonable investor as materially false or misleading.

The Joint Defendants also contend that certain statements were inactionable "opinion" or "puffery." See Mot. at 31-33; see also Casey Mot. at 28-33. To begin, the identified statements regarding "doctor-directed" or "overseen" treatment, see, e.g., AC ¶¶ 254, 255, 267, 274, are neither opinion nor puffery, because they were not vague or aspirational but rather implied substantive and ongoing engagement by dentists. See supra Discussion Section I.a. Similarly, statements that Dentsply did a "good job" or was "very focused" on Class I "mild to moderate occlusion" were either not genuinely held opinions or did not "align[] with information available" to defendants at the time. AC ¶¶ 258, 259, 291, 305.

Byte maintained longstanding and systemic practices of preparing treatment plans without sufficient documentation[20], approving patients with "four clicks," id. ¶ 98, including "super approver" dentists in their "network," id. ¶ 99, and "auto-reassign[ing]" previously rejected patients to other dentists until one dentist approved, id. ¶ 100, and "backtracking" or otherwise modifying patient treatment plans without doctor oversight and even where more severe malocclusion or other contraindications were indicated, id. ¶¶ 103-08. Although defendants argue that some of the challenged statements were made within a week of the Byte acquisition, Casey Mot. at 26 (citing AC ¶¶ 326, 255, 258); see also Mot. at 33 (citing AC ¶ 326), most or all of these practices were already in place as of January 2021, id. ¶¶ 90-129. Thus, the statements were materially false at the time they were made.

Defendants' statements regarding conversion rates were likewise materially false or misleading because those statements either omitted the cause of increased conversion rates or falsely attributed the rise in rates to a higher quality "funnel." Mot. at 32-33 (citing AC ¶¶ 301, 305, 310, 314); see also id. ¶¶ 302,

[20] Non-dentist treatment planners in Costa Rica were asked to generate treatment plans "with incomplete questionnaire responses and without photos." AC ¶ 97. According to FE-1, who worked as a treatment planner in Costa Rica from 2020 through November 2024, this not an aberration, but rather, the norm. Id. ¶ 96 ("[M]ost of the time key pieces of information would either be missing (left blank) or incomplete, and patients' medical history or photos of the patient's teeth were rarely submitted.") (emphasis added).

304, 307, 308. As we have explained, the conversion rate was "the rate at which a proposed Byte customer who received an impression kit [in the S1 stage of onboarding] then purchased a Byte aligner [at the end of S2]," after purportedly screening out contraindicated or unqualified patients. AC ¶ 11. The Joint Defendants argue that their boasts about a better "funnel" "reflected" defendants' "subjective beliefs regarding [the] conversion rate[]" increase after August 2022. Mot. at 33 (citing Omnicare, 575 U.S. at 184-85) (explaining that opinion statements often include "I believe" or "I think"). However, a speaker's use of "I think," id. ¶¶ 305, 310, or a similar phrase, does not transform the statements into opinions here because each "opinion" "contain[ed] [an] embedded statement[] of fact," namely, that the cause of the increase in conversion rates was better "targeting" of patients or an improved "funnel." Omnicare, 575 U.S. at 185-86 ("Suppose the CEO in our running hypothetical said: 'I believe our TVs have the highest resolution available because we use a patented technology to which our competitors do not have access.' That statement may be read to affirm not only the speaker's state of mind, as described above, but also an underlying fact: that the company uses a patented technology. . . . Accordingly, liability . . . would follow . . . not only if the speaker did not hold the belief she professed but also if the supporting fact she supplied

were untrue."). The statements were made after Stoker's August 2022 instruction that sales staff should overlook patient contraindications, which plaintiffs have plausibly alleged was the true cause of the rate increase. AC ¶¶ 113-14. As such, they were materially false or misleading at the time they were made.

Next, statements that the company "believe[d]" it was in compliance with legal and regulatory requirements, including FDA reporting requirements, are not inactionable opinions. See Mot. at 34 (citing AC ¶¶ 349-50); see also Casey Mot. at 28; Gomez Mot. at 16. The Amended Complaint pleads that the vast majority of thousands of serious injuries were not reported to the FDA, despite defendants' having access to Trackwise logs showing those injuries and attending meetings on patient injuries. See supra Background Section III. In that context, it is plausible that the statements did not "fairly align[] with the information in the [defendants'] possession at the time." Omnicare, 575 U.S. at 188-89.

Finally, statements regarding revenues, growth, and investments in a specific number of treatment planners are not "opinion" or immaterial "puffery," but rather specific factual representations regarding the operations of the company. See Joint Defendants' Chart at 4-5 (citing AC ¶¶ 353, 355, 356, 357).

c. Forward-Looking Statements

Defendants also argue that certain of the alleged misstatements were "forward-looking" and protected by the "safe harbor" provision of the PSLRA. See Joint Defendants' Chart at 1-5 (citing AC ¶¶ 255, 259, 308, 314, 353, 355, 356); Casey Chart at (citing AC ¶¶ 255, 259); see 15 U.S.C. § 78u-5(c). "Forward-looking statements are defined as those that contain, among other things, 'a projection of revenues, income, [or] earnings,' 'plans and objectives of management for future operations,' or 'a statement of future economic performance.'" In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 529 (S.D.N.Y. 2015), aff'd sub nom. Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016) (quoting 15 U.S.C. § 78u-5(i)). A "forward-looking" statement, and only a forward-looking statement, is protected if it is either (1) "identified and accompanied by meaningful cautionary language or"; (2) "is immaterial or"; (3) "plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." Id. (quoting Slayton v. Am. Exp. Co., 604 F.3d 758, 766 (2d Cir.2010)) (emphasis in original).

Almost all the statements identified by defendants as "forward looking" are not, in fact, forward looking, but rather statements of then-present fact. See, e.g., AC ¶¶ 255 ("Byte was built . . . with a full network" and "we're extremely

competitive"), 259 ("we're very focused on mild to moderate occlusion"), 308 ("we have a more focused funnel" and "[we] validate customers"), 314 ("We have focused" and "we're seeing" positive developments), 355 ("We are putting more investments into Byte" and "already started in the fourth quarter"); 356 ("We have invested"), 357 ("We invested").[21] As such, they are ineligible for safe harbor protection.

Dentsply's July 31, 2024 Form 10-Q statement that "reduced sales" of approximately "$6 million" per quarter "will be more than offset by organic growth" is the only unambiguously "forward-looking" statement. AC ¶ 353; see also id. ¶ 354 (excerpting the "organic growth" statement as the portion that was false). However, Lead Plaintiffs argue that this statement was made with "actual knowledge" of falsity, and is thus ineligible for safe harbor protection, because it was "made after Dentsply already knew that the FDA was focused on Byte injuries and Dentsply's failure to report them." ECF No. 79 ("Opp.") at 38-39 (citing AC ¶¶ 144, 176-77, 354). The Court agrees. The statement was made after a July 2024 meeting where management informed employees (i) of the scale of patient injuries and (ii) that patient injuries

[21] Certain portions of three statements include "forward-looking" projections of growth. AC ¶¶ 355, 356, 357. However, because these "mixed" statements include some statements present fact regarding treatment planners, we discuss them, and their eligibility for safe harbor protection, in our section on corporate scienter. See infra Discussion Section II.a.

had not been reported to the FDA. AC ¶ 177. According to one employee, "When people saw those injuries, they were like 'Oh my God, this is bad.' People started looking for new jobs." Id. The fact that rank-and-file Byte employees were capable of perceiving that these problems would result in mass layoffs and/or the end of the Byte's business supports a "strong inference" that management had "actual knowledge," as of July 31, 2024, that future "organic growth" projections were unrealistic.[22] Therefore, this statement is not protected by the PSLRA's "safe harbor."

d. Statements Not Attributable to the Company

The Joint Defendants next argue that several alleged misstatements made by Dr. Angela McMullin, a dentist "affiliated" with Byte, AC ¶¶ 286-87, and William Blair, an investment analytics

[22] Defendants have also failed to identify any "meaningful cautionary language" conveying "substantive information" regarding the impending threat to Byte's bottom line. See Mot. at 34-35 (citing various 10-K and 10-Q statements disclosing "risk factors"). Generic disclaimers that future results may differ are insufficient where there is a specific, known, and existential threat to the business. See, e.g., ECF No. 70-1 (2021 Form 10-K) at 13. More targeted disclaimers that "there can be no assurance that [the direct-to-consumer] business model will not be challenged . . . by state governmental authorities, trade associations, or others" through "legislative or regulatory changes" or that "Failure to comply with applicable laws, rules, [or] regulations . . . could result in a range of governmental enforcement actions" are also insufficient. Id. at 27. The first piece of supposedly cautionary language refers to changes in the law rather than compliance with existing laws. And while the second portion may protect forward-looking statements regarding government enforcement actions, it cannot insulate statements of present fact that Dentsply was complying with FDA regulations. See In re: EZCorp, Inc. Sec. Litigations, 181 F. Supp. 3d 197, 207-08 (S.D.N.Y. 2016) ("The shareholders allege that [defendant's] operating practices violated the OFT's 2012 guidelines. The statements on regulatory compliance are thus not forward-looking relative to [then-existing] regulations, but rather ones of present fact. They are therefore not protected by the PSLRA's safe harbor.").

firm, id. ¶ 337, are not attributable to the Company. Mot. at 35-36. We will address each of these points in turn.

"For purposes of Rule 10b-5, the maker of a statement is the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it." Janus Cap. Grp., Inc. v. First Derivative Traders, 564 U.S. 135, 142-43 (2011). Plaintiffs allege that Dr. McMullin made the misstatements at a January 16, 2024 hearing before the Florida Senate Committee on Health Policy, where she testified in opposition to proposed legislation that would further regulate the clear aligner industry.[23] The Court agrees with defendants that although Dr. McMullin worked as an "affiliated" dentist in Byte's network, AC ¶¶ 165-66, 286-87, she was not an employee with authority to make a statement attributable to the Company. Mot. at 35-36. Affiliated dentists were not direct employees of Byte, id. ¶¶ 99, and there is no indication in the Amended Complaint that the Company had the ability to direct "whether and how" Dr. McMullin made her statements, even if those statements were supportive of Dentsply. Janus, 564 U.S. at 142 ("Without control,

[23] Dr. McMullin testified that individual treatment plans were "reviewed, prescribed, and overseen by a Florida licensed dentist or orthodontist" and that "the patient stays with that same Florida licensed dentist" such that "if there are any issues they run into, the dentist is the one consulted on how to proceed." AC ¶ 287.

a person or entity can merely suggest what to say, not 'make' a statement in its own right.").

However, the Court rejects defendants' position that the statement contained in a September 27, 2024 report published by William Blair is not attributable to Dentsply. Mot. at 35 (citing AC ¶ 337). William Blair's report paraphrased a discussion with management:

> On the company's traditional DTC Byte product, we discussed the recent uptick in MAUDE filings that management attributed to an increase in its own reporting standards to help ensure DTC products are being safely used. The rate of MAUDE filings is expected to normalize into year-end as the company catches up on some filings from ongoing cases today.

AC ¶ 337. "Defendants may be liable for statements made to outside analysts," even if they are not "exact quotations," so long as the content of the "analysts' reports clearly originated from the defendants." In re Apple Inc. Sec. Litig., 2020 WL 2857397, at *18 (N.D. Cal. June 2, 2020) (citing Nursing Home Pension Fund, Local 144 v. Oracle Corp., 380 F.3d 1226, 1235 (9th Cir. 2004)); see also Zagami v. Cellceutix Corp., No. 15 Civ. 7194 (KPF), 2016 WL 3199531, at *6 (S.D.N.Y. June 8, 2016) (distinguishing "narrative" newspaper articles with multiple sources from analyst reports "sufficiently entangled" with Company statements). Here, the content and context of William Blair's report support the

contention that the statement "originated from" and is attributable to Dentsply.

II. Scienter

Defendants next argue that plaintiffs have failed to plead both corporate scienter as to Dentsply and individual scienter as to each of the Individual Defendants. Mot. at 11-28; Casey Mot. at 12-24; Gomez Mot. at 9-16. We will first discuss whether the allegations in the Amended Complaint support corporate scienter as to Dentsply and then discuss the scienter of each individual defendant.

a. Corporate Scienter

Corporate scienter may be established "by pleading facts sufficient to create a strong inference either (1) that 'someone whose intent could be imputed to the corporation acted with the requisite scienter' or (2) that the statements 'would have been approved by corporate officials sufficiently knowledgeable about the company to know' that those statements were misleading." Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, 797 F.3d 160, 177 (2d Cir. 2015). Generally, "[c]ourts in this District have held that 'management level' employees can serve as proxies for the corporation in suits filed under the Exchange Act." Thomas v. Shiloh Indus., Inc., No. 15 Civ. 7449 (KMW), 2017 WL 2937620, at *3 (S.D.N.Y. July 7, 2017). However, "no court has

defined what constitutes a 'management-level' employee, and judges have imputed scienter to corporate defendants from employees who hold many different positions with varying degrees of seniority." Id. For example, in In re BISYS Sec. Litig., the knowledge of a "regional vice president" was imputed to the corporate defendant.[24] 397 F. Supp. 2d 430, 443 (S.D.N.Y. 2005).

i. Motive

The Joint Defendants first argue that plaintiffs have failed to allege that the Individual Defendants had sufficient "motive or opportunity" to commit fraud simply because their compensation was tied to Byte's success. Mot. at 11-12; see also Casey Mot. at 12-15. As a general matter, the Court agrees that the opportunity to profit does not itself suffice. Id. at 12 (quoting ECA, 553 F.3d at 198) ("Motives that are common to most corporate officers, such as . . . the desire to keep stock prices high to increase officer compensation[]" do not establish scienter); see also Casey Mot. at 12-13. Nevertheless, the fact that the Individual Defendants' bonuses were tied to Dentsply's EPS and other, similar metrics,

[24] Numerous non-defendant senior employees at the Company allegedly had knowledge of the falsity of various alleged misstatements but were comparatively more junior than the named Individual Defendants. For example, Tyler Stoker, Head of Sales and Business Development for Byte, gave an instruction to sales staff asking them to ignore patient contraindications, seemingly in an effort to increase the Company's "conversion rate." AC ¶¶ 15, 113. Similarly, several high-ranking compliance executives with responsibility for reporting patient injuries had access to the Trackwise system, actually monitored patient injuries, and provided reports, including to some of the named defendants, regarding injuries at Byte. Id. ¶¶ 132-33, 215

and that those numbers were driven by revenues from Byte is a relevant, though not dispositive, factor, when considered together with other allegations. See AC ¶¶ 236-47; see also Dentsply Sirona Inc., 732 F. Supp. 3d at 318 (finding that Casey and Gomez "just barely hit the thresholds necessary for bonuses," thus supporting scienter as to the "channel stuffing" allegations against them).

Separately, the Court disagrees with the Joint Defendants' assertion that Dentsply's executives had insufficient motive to conceal patient injuries from the FDA. Mot. at 13. At a company meeting in July 2024, employees were told that "we know our complaints aren't being filed correctly[.]" Id. ¶ 177. As noted previously, an employee recalled that "When people saw those injuries, they were like 'Oh my God, this is bad.' People started looking for new jobs." Id. It is reasonable to infer that this insight -- which was self-evident even to rank-and-file Dentsply employees -- was also evident to management, thus providing an incentive to conceal the injuries and thereby delay the day of reckoning. Indeed, Byte employees were laid off en masse only a few months later. Id. ¶ 191.

ii. Circumstantial Evidence

Next, Joint Defendants argue that plaintiffs have failed to allege strong circumstantial evidence that Dentsply acted with scienter with respect to (i) "doctor-directed" and "overseen"

care, (ii) sales to contraindicated patients, (iii) FDA reporting, and (iv) continued investment in Byte, including in treatment planners. Mot. at 13-28.

First, the Joint Defendants insist that defendants did not have "access to particular, identified internal reports that would have alerted them" that the Company's statements regarding "doctor-direct[ed]" and "overseen" treatment were false. Mot. at 15; see also Casey Mot. at 19-20. While this argument could be availing with respect to operational minutiae, it is implausible where, as here, Dentsply's central sales pitch was that Byte was "doctor-directed" and "overseen." See AC ¶ 274 (Defendant Gunsagar: "Who is Byte, right? So we were acquired by Dentsply Sirona at the beginning of the year. [W]e are consumer-focused today, right? Doctor directed, every treatment plan is overseen by a doctor in our network [and] . . . [the] doctor direction piece is important[.]"). It is exceedingly unlikely that defendants would boast of doctor "oversight" on such a consistent and repeated basis, while having no idea what oversight, if any, actually existed. Likewise, court decisions early in the Class Period against SmileDirectClub, Byte's direct competitor, should have placed defendants on notice that their public statements were misleading. See SmileDirectClub, 633 F. Supp. 3d at 1073-74 (finding that "SDC's statements regarding their standard of care

were false or misleading" under Section 10(b) because "SDC's dentists had no meaningful contact with customers" and "sales assistants . . . handled customer consultations and complet[ed] highly specialized tasks without meaningful oversight from a licensed dentist"). Defendants were doubtless aware of SmileDirectClub's struggles because they responded to specific questions about those challenges during the Class Period. See, e.g., AC ¶ 326; see also supra Background Section I. As such, defendants who boasted about doctor oversight, and who contrasted these practices with an identified competitor's, were reckless, at a minimum, in not investigating whether Byte's practices were, in fact, materially different.

Moreover, plaintiffs do allege that defendants "had access to particular, identified internal reports" alerting them to the absence of doctor oversight. FE-2, a software manager who designed the system to "'auto-reassign' cases rejected by one or two dentists to another dentist," was instructed to create this feature by Byte's CTO, Mark McCrimmon, who reported directly to defendant Gunsagar. AC ¶¶ 97, 97 n.3, 100. "FE-2 [also] personally participated in meetings with Gunsagar in which the role of doctors in Byte's patient onboarding and treatment process was discussed," and stated that Gunsagar "directed and enforced the policy mandating [doctors'] limited involvement." Id. ¶ 220. Gunsagar

told investors that he personally looked at Byte's "customer feedback channel" "every day."[25] Id. ¶ 219. Dentsply executives, including the Individual Defendants, also had access to Trackwise, which displayed customer complaints and how those complaints were resolved. Id. ¶¶ 17, 131-133. This database, and the retroactive reports provided to the FDA, clearly showed sales and customer service employees providing medical advice to patients.[26] It is not plausible that executives who knew that the "S1" stage involves "send[ing] molds" to patients, who viewed customer feedback on a daily basis, who had access to the Trackwise database, and who monitored data on conversion rates, would be unaware of basic policies and practices related to doctor oversight.

The Joint Defendants' arguments regarding screening for contraindications and FDA reporting similarly fail.[27] Mot. at 16-

[25] Defendant Casey similarly stated that "literally at the end of every day, I see what they did" and "week by week, day by day, how many aligner trials do we sell, how many—what we call S1s, how [many] people who we send molds to, how many actually converted into Byte." AC ¶ 219.

[26] AC ¶ 108 ("Customer service advised the patient to backtrack"), ("It was reported by the customer service team after reviewing the patient photos that the patient was asked to backtrack in the lower arch. They found that the lower 10 fit the best."), ("Customer service provided molar alignment education and requested the customer file down the sharp edges and soak the aligners in warm water."), ("The customer support team provided tips to scallop the aligners and advised her to wear them for 14 days. The patient reached back out and mentioned that the area was still bleeding, and the tips did not really help," eventually leading to a "root canal," presumably by an in-person, non-Byte dentist).

[27] The first three categories of misstatements are related. See supra pp. 24-25. It is undisputed that selling aligners to contraindicated patients could, and did, result in patient injuries. See AC ¶ 186 (disclosing a surge in unreported serious injuries while simultaneously announcing to patients that "our patient onboarding workflow may not provide adequate assurance that certain

22. The Joint Defendants argue that plaintiffs impermissibly assume defendants "must have known" certain facts by virtue of their positions at the Company, without pleading specific facts demonstrating defendants knew their statements to be false. Mot. at 16-17, 19-21. However, plaintiffs need not show that defendants actually viewed a specific document, but rather that they had "access to contrary facts." See Mot. at 19 (citing Novak, 216 F.3d at 309); see also Setzer v. Omega Healthcare Invs., Inc., 968 F.3d 204, 215 (2d Cir. 2020) ("[S]ecurities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements.") (quoting Novak, 216 F.3d at 309). Here, plaintiffs allege that Dentsply executives, including the Individual Defendants, could log into Trackwise or a similar software called "Snowflake," which accurately reflected patients' injuries throughout the Class Period. AC ¶¶ 17, 131-133. Plaintiffs also allege that FE-7[28], a

contraindicated patients do not enter treatment with Byte Aligners"). If a defendant knew about sales to contraindicated patients, insufficient screening processes, or a lack of doctor-oversight, that supports an inference they knew or should have known about patient injuries. Conversely, if a defendant had access to or viewed patient injury reports, that supports an inference they knew or were reckless in not knowing that treatment plans were being approved for contraindicated patients without sufficient oversight.

[28] Although FE-7, as defendants observe, Mot. at 27, retired from Dentsply before the Class Period, his seniority and knowledge of ongoing reporting procedures renders his testimony still probative, as there is no reason to believe those procedures abruptly ended after his departure.

senior employee who designed Dentsply's "decision tree" for patient injuries, met with Pigott, Dentsply's Corporate Vice President, Quality and Regulatory, "3-4 times a quarter" to discuss patient injuries. Id. ¶ 132. Pigott in turn met with Casey, and then Campion, every quarter "to discuss injuries."[29] Id. ¶ 132. Defendants Gunsagar and Brackett also met with Dentsply's quality executives, "including executives who had direct responsibility for Dentsply's FDA reporting," id. ¶ 131 (listing these reporting executives by name, position, and tenure), and "personally reviewed examples of customer complaints alleging injury and participated in Dentsply's response to FDA concerns regarding the same," id. ¶ 138. These allegations provide "connective tissue" linking employees with knowledge to the makers of the alleged misstatements. See Jackson v. Abernathy, 960 F.3d 94, 99 (2d Cir. 2020).

The Joint Defendants brush off the alleged meetings and quarterly reports because plaintiffs do not allege the "specific" content of those reports beyond "injuries and [injury-related]

[29] FE-8, a Sales Specialist and subsequently a Records Specialist at Byte from March 2021 to January 2025, alleged that "management" "raised awareness of Byte's underreporting at an internal meeting in 2023, [and at another meeting in June 2024,] [and] informed Byte employees that the Company was not sufficiently reporting injuries to the FDA." AC ¶ 144. Defendants protest that plaintiffs do not specify "who specifically 'management' refers to." Mot. at 21. However, even if the members of "management" at the meeting did not include the Individual Defendants, it would be odd for mid- or senior-level managers to provide such transparency to the rank-and-file, while withholding the same information from the Individual Defendants.

trends." See Mot. at 19-20 ("Plaintiffs merely allege that certain Dentsply quality executives provided quarterly reports about patient injuries and trends to Defendants Casey and Campion, . . . and that Defendants Gunsagar and Brackett discussed patient injury complaints with Dentsply's quality executives, . . . without specific detail about what was allegedly discussed during these meetings."). However, such arguments are patently inadequate given the sheer number of patient injuries and the scale of the underreporting problem. See Lewin v. Lipper Convertibles, No. 03 Civ. 1117 (RO), 2004 WL 1077930, at *2 (S.D.N.Y. 2004) (finding scienter as to regulatory reporting violations because "the . . . violations alleged are on such a repeated and pervasive scale that, if proven, they could provide strong circumstantial evidence of recklessness"). Plaintiffs allege that Dentsply "failed to timely report . . . at least 97% of the injuries that occurred from the start of the Class Period through December 2023 and at least 83% of the injuries that occurred from the start of the Class Period through August 2024." AC ¶ 135. Separate and apart from any reporting failure, these injuries numbered in the thousands and were high enough in absolute terms to force the business to shut down.[30] If a meeting held with the CEO "to discuss injuries," id.

[30] Retroactive reports belatedly disclosed to the FDA, and publicly-accessible through MAUDE, show "at least 6,894 serious patient injuries . . . include[ing], among other serious patient injuries, at least 2,466 incidents of deformity/disfigurement, 1,777 incidents of laceration, 1,160 incidents of

¶ 132, did not discuss these injuries, one can rightly wonder what was discussed.

Scienter as to the FDA reporting and contraindication misstatements is also supported by specific allegations that Tyler Stoker, Dentsply's Head of Sales and Business for Byte, held a meeting in August 2022 where he "told the sales representatives that [Byte's conversion rate] would be improved once [sales team members] ceased mentioning to customers that they were contraindicated." AC ¶ 113. Stoker's instruction was independently confirmed by two former sales employees, FE-5 and FE-6, who reported that after the meeting "Byte's sales representatives stopped taking prospective patients' dental histories into account during the sales process." Id. ¶ 114. After the meeting, Campion and Coleman began touting Byte's 20% higher "conversion rate" and attributing the improvement to better "targeting" of eligible patients. See, e.g., AC ¶¶ 15, 307 ("[Campion:] [O]ur funnel is better. So our funnel is smaller, but it's a higher quality funnel as a result of the ton of the work that the team . . . has done."). The Joint Defendants argue that there is no specific allegation that any of the Individual Defendants directed Stoker to take this action. Mot. at 16.

tooth fracture, 345 incidents of tissue breakdown, 189 incidents of hemorrhage/bleeding, and 110 incidents of necrosis." AC ¶ 149.

However, Stoker's scienter can be imputed to the Company, given his senior position and direct involvement in providing the instruction. See In re BHP Billiton Ltd. Sec. Litig., 276 F. Supp. 3d 65, 90 (S.D.N.Y. 2017) (Buchwald, J.) ("Scienter by management-level employees is generally sufficient to attribute scienter to corporate defendants" and the "individual making an alleged misstatement and the one with scienter do not have to be one and the same.") (citation omitted); Shiloh Indus., Inc., 2017 WL 2937620, at *3 (even employees at the "Vice President" level can be "management-level employees" for "purposes of corporate scienter"); In re BISYS Sec. Litig., 397 F. Supp. 2d at 443 (same). Moreover, while FE-5 and FE-6 could not confirm exactly who gave Stoker his orders, "Stoker made it clear [at the August 2022 meeting] that it was not his decision whether to sell to those customers." AC ¶ 113. This fact, combined with the willingness of Campion and Coleman to explain not only that the conversion rate had increased, but why it had increased, supports an inference of scienter. Allegheny Cnty. Employees' Ret. Sys. v. Energy Transfer LP, 532 F. Supp. 3d 189, 228 (E.D. Pa. 2021) (finding scienter where the "[CEO] held himself out to investors as knowledgeable" on the specific problems underlying the misstatements and "spoke in detail about . . . projects" that were delayed).

Plaintiffs have failed, however, to allege scienter as to statements that Byte was "increasing the number of treatment planners" or was making continued investments in Byte. See AC ¶¶ 355-57. Plaintiffs' allegations are based on a single former treatment planner's testimony that Byte "terminated approximately 50 of the 320 treatment planning employees" "at the beginning of 2024." Id. ¶ 158. While these allegations may be sufficient[31] to allege falsity, the Amended Complaint alleges "no connective tissue" that could establish a strong inference of scienter. Jackson, 960 F.3d at 99; Silvercreek Mgmt., Inc. v. Citigroup, Inc., 248 F. Supp. 3d 428, 440–41 (S.D.N.Y. 2017) (holding that it is insufficient to "separately allege misstatements by some individuals and knowledge belonging to some others where there is no strong inference that, in fact, there was a connection between the two") (emphasis in original). Unlike the statements regarding FDA reporting or Byte's standard of care, plaintiffs do not allege any reporting mechanism, meetings, or other germane facts supporting a "strong inference" that defendants knew the statements to be false.

[31] While Dentsply may have "terminated" certain employees, it may also have hired others, thus rendering Dentsply's statements that it was "increasing" the number of treatment planners true. See AC ¶ 358. The Court does not reach its decision on this basis, however, because the heightened pleading standard requiring a "strong inference" of scienter has not been met. ECA, 553 F.3d at 196.

Finally, to the extent the statements of present fact regarding treatment planners also included forward-looking projections of "20%" growth in 2024, they are inactionable. AC ¶¶ 355-57. "[S]tatement[s] may contain some elements that look forward and others that do not, and forward-looking elements may be severable from non-forward-looking elements" when applying the PSLRA "safe harbor." In re Philip Morris Int'l Inc. Sec. Litig., 2020 WL 5632901, at *6 (S.D.N.Y. Sept. 21, 2020). Revenue projections are classic "forward-looking" statements, and thus the requirements to plead scienter are "stricter than for statements of current fact." Slayton, 604 F.3d at 773 (plaintiffs must plead that defendants possessed "actual knowledge" that their forward-looking statements were false at the time they were made, not merely recklessness); see also 15 U.S.C. § 78u-5(c)(1)(B)(ii). Byte did, in fact, grow by 18% in the first quarter of 2024, and while injury rates had begun to increase, it is unclear if defendants knew this would depress growth as of May 15, 2024.[32] Id. ¶ 357. Consequently, these alleged misrepresentations are dismissed from the case.

[32] These statements, made from February to May 2024, are markedly different than the alleged misrepresentation made on July 31, 2024, which projected "organic growth" of at least "$6 million." AC ¶ 353. That statement was made after a July 2024 meeting at which management disclosed the scale of the underreporting problem to employees, see supra p. 20, and after the departure of defendants Frank, Coleman, and Brackett from the Company, see infra pp. 58-59.

b. Individual Scienter

We now turn to defendants' argument that plaintiffs have not adequately alleged that each of the Individual Defendants acted with the required state of mind. Mot. at 11-28; Casey Mot. at 12-24; Gomez Mot. at 8-16. We will address this argument as to each defendant, beginning with defendant Gomez.

Gomez, Dentsply's CFO from the beginning of the Class Period through May 2022, signed Dentsply's 2020 10-K, Dentsply's 2021 10-K, a January 4, 2021 8-K press release, and three 10-Q reports filed in 2021, all of which were co-signed with defendant Casey, and which made representations about "doctor-directed" treatment at Byte and/or "substantial" compliance with reporting obligations. AC ¶¶ 252, 276, 277, 281. Gomez argues that, unlike many of the other defendants, he never made an alleged misrepresentation on an earnings call. Gomez Mot. at 5-6. He also insists that plaintiffs have impermissibly "group-ple[d]" his scienter, instead of making particularized allegations against him. Id. at 8; see also Gomez Reply at 2 (same).

The Court agrees that the allegations of scienter against Gomez are too attenuated to retain him as an individual defendant. First, Gomez departed Dentsply on May 6, 2022, before many of the events alleged in the Amended Complaint occurred, and before many of the alleged misstatements were made. AC ¶ 32. Second, most of

plaintiffs' allegations against Gomez arise from the unrelated "channel stuffing" scandal wherein Casey and Gomez were found to have created an "improper tone at the top." See Dentsply Sirona Inc., 732 F. Supp. 3d at 310. Although the "channel stuffing" violations do not reflect well on Gomez, they cannot be transposed into this case, which concerns an unrelated operational segment (Byte). Third, the fact that Gomez stood to profit from Byte's success if Dentsply hit EPS targets is, standing alone, insufficient to establish scienter. See AC ¶¶ 237-241; ECA, 553 F.3d at 198.

The allegations against Gomez are notably different than the allegations against Casey, Dentsply's former CEO, who served contemporaneously with him. Most importantly, the Amended Complaint alleges that Casey, as well as his successor, Campion, met on a quarterly basis "to discuss [patient] injuries" with Charles Pigott and other quality executives. AC ¶¶ 131-33. By contrast, there is no allegation that Gomez received reports or attended meetings in which information contrary to his public statements was discussed. See Novak, 216 F.3d at 309. Moreover, Casey made specific statements on earnings calls -- in addition to signing general 10-K or 10-Q filings -- in which he held himself out as knowledgeable about the Byte's onboarding procedures and made operational comparisons to Byte's competitors. See AC ¶¶ 71,

("literally at the end of every day, I see what they did . . . week-by-week, day-by-day, how many aligner trials do we sell, how many what we call S1s, how many people who we send molds to, how many actually converted into Byte"), 255 ("whether it's . . . Smile Direct, we feel we're extremely competitive" on "product" and "customer experience"), 299 ("Byte is basically Class I" and "if you have a cavity . . . you need to get to a[n in-person] dentist to get that fixed to come back to fight," i.e. before getting Byte.); see also In re First Const. S'holders Litig., 1991 WL 218083, at *3 (D. Conn. Sept. 13, 1991) (finding scienter, in part because "defendants . . . held themselves out . . . as knowledgeable about" the subject matter of the alleged misstatements); Energy Transfer LP, 532 F. Supp. 3d at 228 (same). Gomez made no similar statements, and thus liability is based entirely on his signing of lengthy 10-K and 10-Q reports containing hundreds of pages of information and a single 8-K report.[33] Given the dearth of allegations supporting a "strong inference" of scienter against him, Gomez's motion to dismiss is granted.

[33] Unlike Gomez, defendant Coleman, who succeeded Gomez as CFO, made specific statements about Byte operations, by attributing the increased "conversion rate" to an improved "quality of the funnel" for patients. See, e.g., AC ¶ 304. Defendant Frank, who directly supervised the Byte business segment, likewise stated that "Byte business has changed its marketing strategy to focus on specific target demographics, which has resulted in more than 20% higher customer conversion rates year-to-date versus last year." Id. ¶ 311.

However, the allegations of individual scienter against the remaining Individual Defendants are sufficient. Casey, Campion, Coleman, Frank, Gunsagar, and Brackett each held themselves out as knowledgeable about relevant Byte operations on earnings calls and/or attended meetings at which patient injuries were discussed. AC ¶¶ 131-33, 215. Frank, Dentsply's Chief Business Officer, Gunsagar, Byte's CEO, and Brackett, Senior Vice President of Orthodontic Aligner Solutions and Customer Experience, held operational roles which were even closer to Byte's customer screening, doctor oversight practices, and injury tracking than Casey, Campion, Gomez, or Coleman. Id. ¶¶ 37-39, 220-21. Gunsagar and Brackett "personally reviewed patient complaints of serious injury," and all defendants had access to information through Trackwise and/or Snowflake showing thousands of patient injuries that had not been reported to the FDA. Id. ¶¶ 215, 221. Lastly, and although it is not in and of itself sufficient, Campion, Coleman, and Frank also had clear financial incentives to conceal the alleged fraud through cash bonuses tied to "organic sales." Id. ¶¶ 242-47.

Importantly, Frank[34], Coleman[35], and Brackett[36] departed Dentsply in July, August, and September 2024, respectively, just as Dentsply's systemic underreporting of injuries was becoming evident. AC ¶ 232. Although defendants argue that plaintiffs "d[o] not link their departures" to the FDA reporting crisis, Mot. at 23 (citing In re BISYS Sec. Litig., 397 F. Supp. 2d at 447) (executive departures alone do not support scienter without a factual "link" to the fraud), the mass exodus of so many executives at the same time significantly bolsters the inference of scienter. On this issue, the Court need look no further than the recent securities fraud case against Dentsply related to "channel stuffing." In that case, Judge Subramanian explained that executive departures supported scienter because (i) "the timeline itself is suggestive: The internal investigation began in March 2022. Bruno was replaced that month, Gomez resigned in April, and Casey was fired in April" and (ii) "there were too many departures to say that they were coincidental with a straight face." Dentsply Sirona Inc., 732 F. Supp. 3d at 321-22. Here, defendants Frank,

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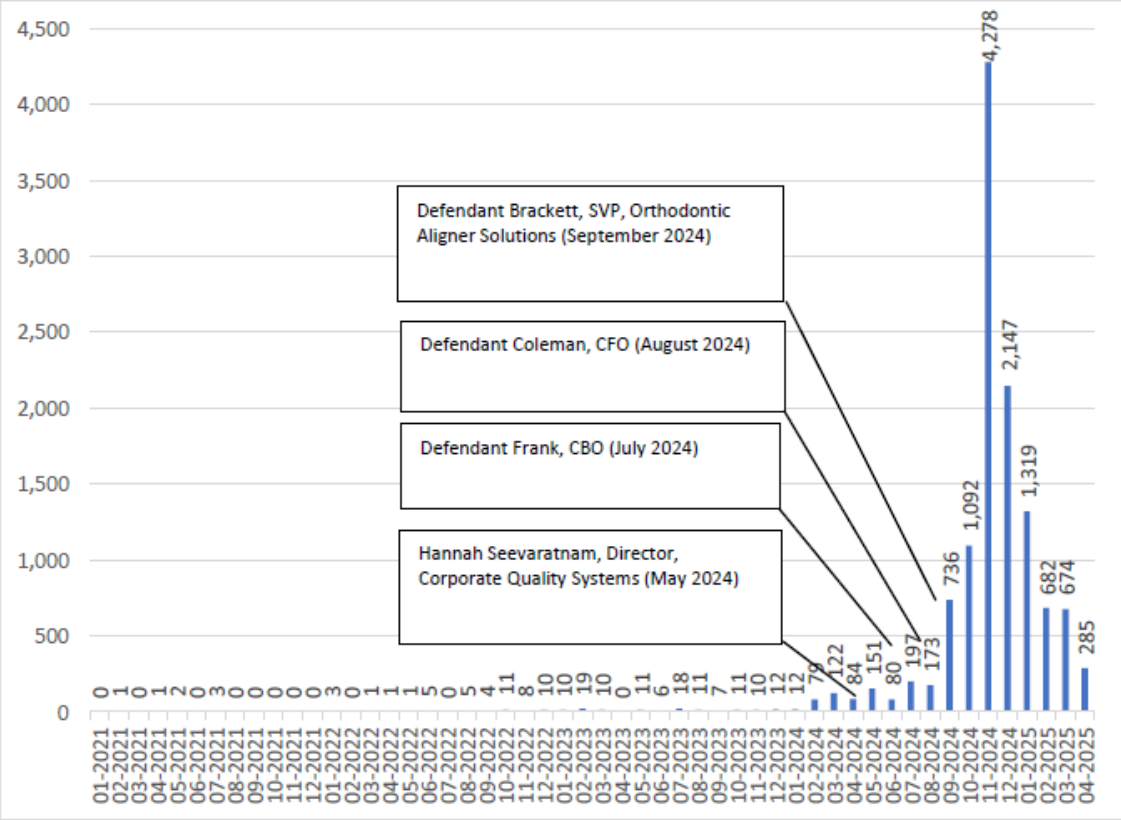
[34] Frank's position was eliminated on the board of directors, and while Dentsply "claimed that his elimination was part of a 'restructuring,' . . . Frank's was the only officer's position eliminated." AC ¶ 233.

[35] Coleman "resigned" his position as Dentsply's CFO on August 15, 2025, but that resignation did not become "effective" until November 7, 2025, the day "Dentsply wrote-down goodwill for Byte." AC ¶ 234.

[36] Brackett either resigned or was fired -- it is unclear which -- "without explanation or announcement," on or before September 3, 2024. AC ¶ 235.

Coleman, and Brackett, as well as non-defendant Hannah Seeveratnam, Dentsply's "Director, Corporate Quality Systems,"[37] departed Byte within a four-month period from May to September 2024, just as revelations about patient injuries and underreporting were breaking at the Company:

Seevaratnam, Frank, Coleman, and Brackett's Departures as Compared to Dentsply's Serious Injury Reports to FDA per Month



AC ¶ 232; see also id. ¶¶ 131, 144-45, 183-89. For this reason, and for the other reasons stated earlier, a "strong inference" of

[37] Seeveratnam's role as a quality executive included responsibility for FDA reporting. AC ¶¶ 132, 232.

scienter has been established for all the Individual Defendants except Gomez, who is dismissed.

III. Scheme Liability

Plaintiffs also bring a "scheme liability" claim under Rules 10b-5(a) and (c), which prohibit the use of "any device, scheme, or artifice to defraud" or "engag[ing] in any act, practice, or course of business which operates . . . as a fraud or deceit upon any person." 17 C.F.R. § 240.10b-5(a), (c); see AC ¶¶ 387-397. "Scheme liability under subsections (a) and (c) of Rule 10b-5 hinges on the performance of an inherently deceptive act that is distinct from an alleged misstatement." In re Smith Barney Transfer Agent Litig., 884 F. Supp. 2d 152, 161 (S.D.N.Y. 2012) (citation omitted). "To state a claim under Rule 10b-5(a) or (c), the plaintiff must allege that the defendant (1) committed a deceptive or manipulative act, (2) with scienter, that (3) the act affected the market for securities or was otherwise in connection with their purchase or sale, and that (4) defendants' actions caused the plaintiffs' injuries." In re ForceField Energy Inc. Sec. Litig., 15 Civ. 3020 (NRB), 2017 WL 1319802, at *7 (S.D.N.Y. Mar. 29, 2017). Rule 9(b) requires plaintiff to "state with particularity what deceptive or manipulative acts were performed, which defendants performed them, when the acts were performed, and the effect the scheme had on investors in the securities at issue."

Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC, 164 F. Supp. 3d 568, 577 (S.D.N.Y. 2016) (citation and internal quotation marks omitted).

Plaintiffs base their scheme liability claim on allegations that Dentsply (i) deceived the FDA by failing to timely report serious injuries, (ii) lobbied against further regulation of the clear aligner industry, in part using the inaccurate MAUDE data supplied to the FDA, (iii) used NDAs to suppress information about patient injuries, and (iv) misled patients about contraindications. Opp. at 76-80.

The Joint Defendants argue that plaintiffs "try to recast their insufficient 10b-5(b) claim as a 'scheme liability' claim in the alternative." Mot. at 36. However, "it is possible for liability to arise under both subsection (b) and subsections (a) and (c) of Rule 10b-5 out of the same set of facts, where the plaintiffs allege both that the defendants made misrepresentations in violations of Rule 10b-5(b), as well as that the defendants undertook a deceptive scheme or course of conduct that went beyond the misrepresentations." In re Alstom SA Sec. Litig., 406 F.Supp.2d 433, 475 (S.D.N.Y.2005). Here, defendants' efforts to conceal thousands of injuries visible through the internal Trackwise system from the FDA constituted a fraudulent scheme. See In re Able Lab'ys Sec. Litig., 2008 WL 1967509, at *20 (D.N.J.

Mar. 24, 2008) (finding scheme liability where defendants, inter alia, "fail[ed] to report adverse drug events to the FDA throughout [their] tenure[s] at the Company"). Concealing facts from regulators is "something more" than merely a misstatement or omission. Id. at *21; see also U.S. S.E.C. v. Brown, 740 F. Supp. 2d 148, 172 (D.D.C. 2010) (holding that the "failure to file the reports required" by statute supports a "claim under Rule 10b-5(a) and (c) for scheme liability"). Similarly, while the Court would be reluctant to view the use of NDAs, lobbying, or the provision of inaccurate information to patients as "schemes" in isolation, these measures, combined with the withholding of patient injury reports from the FDA, helped keep regulators, investors, and patients in the dark. See AC ¶¶ 173-79, 153-55.

As with the Section 10(b) and Rule 10b-5(b) claim, Gomez is not liable for the 10b-5(a) and (c) claims because plaintiffs have failed to adequately plead scienter as to him. See supra pp. 56-58; see also Gomez Opp. at 17-18. Defendant Casey also argues that defendants do not plead scienter as to his conduct, Casey Mot. at 15-16, but his arguments fail for the reasons stated earlier. See supra pp. 58-59. Not only did Casey have access to patient injury data through Trackwise, and responsibility to report such data, but he was also a participant in quarterly meetings regarding patient injuries and safety and counted

Dentsply's safety and quality executives as his direct reports. AC ¶¶ 131-33. The remaining individual defendants similarly had either firsthand knowledge of serious injuries, access to patient injury reports, responsibility for reporting serious injuries, or attended meetings at which patient injuries were discussed. See supra Background Section III, Discussion Section II.

IV. Control Person Liability

Finally, we turn to plaintiffs' claim of "control person liability" under Section 20(a) of the Exchange Act. To establish control person liability, plaintiffs must allege "(1) a primary violation by the controlled person; (2) control of the primary violator by the defendant; and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." ATSI Commc'ns, Inc., 493 F.3d at 108 (citation omitted).

Casey and the Joint Defendants argue that (i) "[p]laintiffs have failed to . . . allege a primary violation of Section 10(b)" and (ii) plaintiffs have failed to plead "culpable participation" as to the individual defendants. See Mot. at 37; Casey Mot. at 16. First, there is no doubt that a primary violation of Section 10(b) has been established. See supra Discussion Sections I, II. Second, "culpable participation" has been established for Casey, Campion, Coleman, Gunsagar, Brackett, and Frank because plaintiffs

have pled a "strong inference" of scienter as to each of them. See supra Discussion Section II.b. (finding individual scienter as to each Individual Defendant except Gomez); see In re Alstom SA, 406 F. Supp. 2d at 498 ("[F]or the reasons discussed in the analysis of scienter under Section 10(b), Plaintiffs have sufficiently pled culpable participation."). However, the Section 20(a) claim against Gomez is dismissed because plaintiffs have failed to establish a "strong inference" that he acted with scienter. See supra pp. 56-58.

CONCLUSION[38]

For the foregoing reasons, defendants' motion to dismiss is granted in part and denied in part. Defendant Gomez's motion to dismiss is granted. ECF No. 73. The Court also dismisses certain insufficiently pled alleged misstatements or omissions from the case.[39] Otherwise, the Joint Defendants' and Casey's motions to dismiss are denied. ECF Nos. 69, 76. Plaintiffs have sufficiently pled that the remaining defendants made false or misleading statements, with scienter, regarding (i) doctor-directed and overseen care, (ii) Byte's screening processes and "conversion rate," (iii) FDA reporting, and (iv) "organic" growth. Scheme

[38] The Court understands that the parties requested oral argument. However, given that our holding is based on clear legal doctrine, the Court determined that oral argument would not be productive.

[39] As explained, supra, the following alleged misstatements and omissions are dismissed: AC ¶¶ 287, 355, 356, 357.

liability and control person liability have also been sufficiently pled as to the remaining defendants. The Clerk of Court is respectfully directed to terminate the motions pending at ECF Nos. 69, 73, and 76.

SO ORDERED.

Dated: January 16, 2026
New York, New York

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE